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Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 413, 414, 488, and 494

[CMS–3818–F]

RIN 0938–AG82

Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This rule finalizes the February 4, 2005 proposed rule entitled ''Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities.'' It establishes new conditions for coverage that dialysis facilities must meet to be certified under the Medicare program. This final rule focuses on the patient and the results of care provided to the patient, establishes performance expectations for facilities, encourages patients to participate in their plan of care and treatment, eliminates many procedural requirements from the previous conditions for coverage, preserves strong process measures when necessary to promote meaningful patient safety, well-being, and continuous quality improvement. This final rule reflects the advances in dialysis technology and standard care practices since the requirements were last revised in their entirety in 1976.

DATES: The provisions of this final rule are effective October 14, 2008. Compliance with § 494.30(a)(1)(i) and § 494.60(e)(1) is not required until February 9, 2009. In addition, the compliance with § 494.180(h) is effective on February 1, 2009. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 14, 2008.

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SUPPLEMENTARY INFORMATION:

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Acronym List

AAMI Association for the Advancement of Medical Instrumentation
ACLS Advanced Cardiac Life Support
ADA American Dietetic Association
AED Automated external defibrillator
AIA American Institute of Architects
AHA American Heart Association
ALT Alanine Aminotransferase
APA Administrative Procedures Act
ANSI American National Standards Institute
BMI Body mass index
BONENT Board of Nephrology Nursing Examiners Nursing and Technology
BSW Bachelor's degree social worker
CADE Commission on Accreditation for Dietetics Education
CAHPS Consumer Assessment of Health Plans Survey
CCHT Certified Clinical Hemodialysis Technician
CDC Centers for Disease Control and Prevention
CEO Chief executive officer
CLIA Clinical Laboratory Improvement Amendments
CMS Centers for Medicare and Medicaid Services
CNSW Council of Nephrology Social Workers
CPG Clinical practice guidelines
CPM Clinical performance measures
CRAFT CROWN Responsiveness and Feedback Tree
CROWNWeb Consolidated Renal Operations in a Web-enabled Network
DFC Dialysis Facility Compare
DHHS Department of Health and Human Services
DOPPS Dialysis Outcomes and Practice Patterns Study
DOQI Disease Outcomes Quality Initiative
DTR Dietetic Technician, Registered
EDI Electronic Data Interchange
EMS Emergency medical system
ESRD End-Stage renal disease
FDA Food and Drug Administration
HBsAg Hepatitis B surface antigen
HIPAA Health Insurance Portability and Accountability Act 1996
HBV Hepatitis B virus
HCV Hepatitis C virus
HICPAC Healthcare Infection Control Practices Advisory Committee
HMO Health Maintenance Organization
ICC International Code Council
ICH In-center hemodialysis
IOM Institute of Medicine
KCP Kidney Care Partners
KDOQI Kidney Disease Outcomes Quality Initiative
K/DOQI Kidney Disease Outcomes Quality Initiative
LAL Amoebocyte lysate
LDO Large dialysis organization
LPN Licensed practical nurse
LVN Licensed vocational nurse
LSC Life Safety Code
MedPAC Medicare Payment Advisory Commission
MNT Medical nutrition therapy
MPD Mission and Priority Document
MSW Master's degree social worker
NCD National Coverage Determination
NF Nursing Facility
NKF National Kidney Foundation
NKF–KDOQI National Kidney Foundation's Kidney Disease Outcomes Quality Initiative
NNCC Nephrology Nursing Certification Commission
NNCO National Nephrology Certification Organization
NQF National Quality Forum
NTTAA National Technology Transfer and Advancement Act of 1995
OIG Office of the Inspector General
PA Physician assistant

PCT Patient care technician
QAPI Quality assessment and performance improvement
QIS Quality Infrastructure Report
RD Registered dietitian
RN Registered nurse
REMIS Renal Management Information System
RO Reverse osmosis
RPA Renal Physicians Association
SGA Subjective global assessment
SHEA Society for Healthcare Epidemiology of America
SNF Skilled nursing facility
SOW Scope of work
STIC Safe and Timely Immunization Coalition
TEP Technical Expert Panel
VISION Vital Information System to Improve Outcomes in Nephrology

I. Background

A. Introduction

End-Stage Renal Disease (ESRD) is a kidney impairment that is irreversible and permanent and requires either a regular course of dialysis or kidney transplantation to maintain life. Dialysis is the process of cleaning the blood and removing excess fluid artificially with special equipment when the kidneys have failed. Our existing ESRD services conditions for coverage were originally adopted in 1976 (41 FR 22502). In our existing requirements for dialysis facilities at 42 CFR part 405, subpart U, we emphasize the policies and procedures that must be in place to support good patient care, and we focus on a facility's capacity to furnish quality care. To determine if a facility meets ESRD conditions for coverage, the State survey agency performs an on-site survey of the facility. If a survey indicates that a facility is in compliance with the conditions, and all other Federal requirements are met, we then certify the facility as qualifying for Medicare payment. Medicare payment for outpatient maintenance dialysis is limited to facilities meeting these conditions. We have made several changes to our ESRD requirements since they were first adopted in 1976. However, they have not been comprehensively revised since that time.

On February 4, 2005, we published in the **Federal Register** a proposed rule entitled ''Conditions for Coverage for End-Stage Renal Disease Facilities'' (70 FR 6183). In that rule, we proposed revisions to the requirements that ESRD dialysis facilities must meet in order to be certified under the Medicare program.

Our decision to propose major changes to the existing conditions was based on several considerations. Revising the ESRD requirements is part of our effort to modernize regulations and improve the availability of quality-of-care information; to promote transparency; and to move toward a patient outcome-based system that focuses on quality assessment and performance improvement. We believe that revising the conditions for coverage would encourage improvement in outcomes of care for beneficiaries. We wish to incorporate the most recent medical and scientific guidelines and recommendations for dialysis facilities from the Centers for Disease Control and Prevention (CDC), the Association for the Advancement of Medical Instrumentation (AAMI), and recognize current practice guidelines and professional standards of practice such as the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (NKF–K/DOQI) clinical practice guidelines (CPGs).

B. Legislative History

Section 299I of the Social Security Amendments of 1972 (Pub. L. 92–603) originally extended Medicare coverage to insured individuals, their spouses, and their dependent children with ESRD who require dialysis or transplantation. The ESRD program became effective July 1, 1973, and initially operated under interim regulations published in the **Federal Register** on June 29, 1973 (38 FR 17210). In the July 1, 1975 **Federal Register** (40 FR 27782), we published a proposed rule that revised sections of the ESRD requirements. On June 3, 1976 the final rule was published in the **Federal Register** (41 FR 22501). Subsequently, the ESRD Amendments of 1978 (Pub. L. 95–292), amended title XVIII of the Social Security Act (the Act) by adding section 1881. Sections 1881(b)(1) and 1881(f)(7) of the Act further authorize the Secretary to prescribe health and safety requirements (known as conditions for coverage) that a facility providing dialysis and transplantation services to dialysis patients must meet to qualify for Medicare payment. In addition, section 1881(c) of the Act establishes ESRD Network areas and Network organizations to assure that dialysis patients are provided appropriate care.

We know, based on comments, that many in the community support the overall shift in the ESRD conditions for coverage from an emphasis on process-oriented requirements to a more patient-centered, outcome-oriented approach. Further, we believe that virtually all members of the community support a quality assessment and performance improvement requirement and the development of a comprehensive data set that will contain information including the characteristics of ESRD facilities, their patient populations, as well as outcome measures of patient care.

The fundamental principles that guided us during this collaborative effort to develop new conditions were as follows:

- Ensure that patients' rights and physical safety are protected;
- Stress continuous quality assessment and performance improvement, incorporating, to the greatest extent possible, outcome-oriented, data-driven measures;
- Facilitate flexibility in how dialysis facilities meet our performance requirements;
- Eliminate unnecessary administrative policies. Process-oriented standards are only included where we believe they are essential to protect patient health and safety;
- Focus on the continuous, interdisciplinary, integrated care system that a dialysis patient experiences, centered around patient assessment, care planning, service delivery, and quality assessment and performance improvement; and
- Stress patient satisfaction and ongoing patient involvement in the development of the care plan and treatment.
- Finally, in order for the ESRD facility conditions for coverage to move from a process and structure orientation toward a more patient-centered, outcome-oriented approach, individual patient and facility-specific outcome measures must be identified and evaluated, or in the absence of existing measures, they must be developed and validated with community input to ensure they are clinically meaningful and reflect current scientific knowledge.

C. Existing ESRD Regulation

The requirements from section 1881(b), (c), and (f)(7) of the Act are implemented in regulations at 42 CFR part 405, subpart U, ''Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services.''

The existing regulations describe the health and safety requirements that dialysis facilities must meet to furnish care to Medicare beneficiaries. The regulations in part 405, subpart U also include the provision that dialysis facilities be organized into Network areas and describe the role that Networks play in the ESRD program. Networks are defined at § 405.2110 as ''CMS designated ESRD Networks in which the approved ESRD facilities collectively provide the necessary care for ESRD patients.''

The purpose of the existing conditions for coverage (also known as conditions) is to protect dialysis patients' health and safety and to ensure that quality care is furnished to all patients in Medicare-approved dialysis facilities.

The ESRD conditions for coverage (health and safety provisions for dialysis facilities) will be moved from existing 42 CFR part 405, subpart U, to a new 42 CFR part 494, where they will follow regulations establishing standards for other Medicare providers, such as the conditions of participation for hospitals (42 CFR part 482), long-term care facilities (42 CFR part 483), and home health agencies (42 CFR part 484). The termination of Medicare coverage and alternative sanctions conditions at § 405.2180 through § 405.2184 will be recodified at § 488.604 through § 488.610. Since many of the existing ESRD conditions will be revised, consolidated with other conditions, or deleted, we are renumbering and reorganizing the requirements.

D. The Establishment of Central Requirements

Our 2005 proposed rule proposed new conditions for coverage for ESRD facilities that revise or eliminate many of the existing requirements and establish critical central requirements. The central requirements of this rule were grouped into three broad categories: (1) Patient safety; (2) patient care; and (3) administration. Subpart A contained general provisions, for example, statutory authority, definitions, and requirements for compliance with Federal, State and local laws and regulations. Subpart B (Patient Safety), and subpart C (Patient Care) of the proposed conditions for coverage focused on the actual care delivered to the patients, the performance of the dialysis facility, and the impact of the treatment furnished by the dialysis facility on the health status of its patients. Subpart D contained personnel, ESRD Network, medical records and governance requirements.

In subpart B (Patient Safety), we proposed to retain and strengthen some process-oriented patient safety provisions that we believe remain highly predictive of ensuring desired outcomes and preventing harmful outcomes. Accordingly, the proposed patient safety requirements incorporated current CDC infection control procedures, retained and updated our incorporation by reference of the AAMI standards and guidelines for water quality and dialysate, hemodialyzer reuse practices, and incorporated by reference applicable current Life Safety Code (LSC) provisions.

Subpart C (Patient Care) included provisions: (1) Emphasizing a dialysis facility's fundamental responsibility to respect and promote the rights of each patient (patient rights); (2) requiring a facility to perform a comprehensive assessment to determine appropriate treatments and achieve desired health outcomes (Patient Assessment); (3) requiring an interdisciplinary team approach to providing dialysis services to patients; and specifying the process by which the interdisciplinary team would achieve effective patient health outcomes (Patient Plan of Care); (4) requiring a quality assessment and performance improvement program which would charge each dialysis facility with carrying out a program of its own design to continually improve quality outcomes and patient satisfaction; and (5) consolidating various aspects of home dialysis care into a single condition (Care at home).

Subpart D (Administration) covered the operation of the dialysis facility in a patient outcome-oriented environment, including: (1) Minimum personnel qualifications; (2) the role of the medical director; (3) the facility's relationship with its servicing ESRD Network; (4) medical recordkeeping; and (5) minimum operating responsibilities of the facility, including data collection and reporting requirements (Governance).

On August 22, 2006, President Bush signed Executive Order 13410, entitled ''Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs' (71 FR 51089, August 28, 2006). In order to empower Americans to find better health care value and better health care, they should know their health care options in advance. Patients need access to information regarding the quality of doctors, hospitals, dialysis facilities and other providers in their area, as well as the costs of various medical procedures. The August 2006 executive order directs agencies to increase transparency in pricing by sharing pricing information with patients; to increase transparency in quality by sharing information with patients on the quality of services provided by doctors, hospitals, ESRD facilities, and other health care providers; to encourage the adoption of health information technology systems that meet recognized interoperability standards; and to provide patients with options that promote quality and efficiency in health care, by developing and identifying approaches that facilitate high quality and efficient care. Building on efforts of quality alliances that include a broad range of healthcare stakeholders, we will work collaboratively to improve quality and cost information. Patients will be able to access this information from a variety of potential sources, including insurance companies, employers, and Medicare sponsored Web sites. In order to help dialysis patients make more informed health care decisions and to increase transparency, this final rule promotes a patient-centered approach and focuses on disclosing relevant information regarding care to patients.

We believe that transparency will also be improved by the implementation of an electronic Web-based data collection system, Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), which is designed to collect clinical performance measures (CPMs) data from dialysis facilities. CPM data are used to monitor the performance of Medicare-certified dialysis facilities on a national and local level. These data are also used to provide information to individuals who have or may develop ESRD and their caregivers to assist them in making health care decisions; to allow the identification of opportunities for quality improvement at a national, regional, or dialysis facility-level; and to calculate case-mix adjustments and the potential future use of value based purchasing.

Dialysis Facility Compare (DFC) is an online tool at *http://www.medicare.gov* available for dialysis patients and their caregivers, which serves to enhance public accountability in healthcare by increasing transparency regarding the quality of dialysis facility care. DFC allows patients and caregivers to find and compare information about the services and quality of care provided at dialysis facilities in any State. Important information and resources regarding chronic kidney disease is also available on the DFC Web site.

II. Summary of the Proposed Provisions and Response to Comments on the February 4, 2005 Proposed Rule

The comment period for the February 4, 2005 proposed rule was 90 days, and closed on May 5, 2005. We received over 3,000 public comments, but many were form letters, so that the total number of discrete comments was approximately 315. Interested parties that commented included the American Association of Kidney Patients, the American Kidney Fund, the American Nephrology Nurses Association, the American Society of Nephrology, the American Healthcare Association, the Association of Dialysis Advocates, the

Association for the Advancement of Medical Instrumentation, the American Society of Pediatric Nephrology, the American Dietetic Association, DaVita, Inc., Dialysis Centers Inc., Fresenius Medical Care North America, Gambro Healthcare, Kidney Care Partners, Life Options Rehabilitation Advisory Council, the National Kidney Foundation, the National Renal Administrator's Association, the National Association of Nephrology Technicians, the Renal Care Group, the Renal Physicians Association, the Renal Support Network, Medical Education Institute, Inc., state survey agencies, ESRD Networks and the Forum of ESRD Networks, healthcare professionals, administrators, academics, dialysis patients, pharmaceutical and dialysis product companies, and hospital-based and non-hospital-based dialysis providers. Many commenters applauded the long overdue modernization of the ESRD conditions for coverage, even though they may have disagreed with a specific requirement or concept. Below we provide a brief summary of each proposed provision, a summary of the public comments we received, and our responses to the comments.

We received several comments on issues outside of the scope of this final rule, which we will not address. Please note, that in this final rule we have revised the title of subpart U from ''Conditions for Coverage for Suppliers of End-Stage Renal Disease'' to read ''Requirements for End-Stage Renal Disease Facilities.'' We are changing this final rule because the ''Hospital Conditions of Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants'', published on March 30, 2007 (72 FR 15198) updated and recodified the kidney transplant center conditions for coverage and the remaining provisions only apply to the ESRD Networks.

A. Part 414—Payment for Part B Medical and Other Health Services; Payment for Home Dialysis Equipment, Supplies, and Support Services (Proposed § 414.330)

We proposed a new § 414.330(a)(2)(iii)(C) that would require the patient's home dialysis medical equipment supplier to report to the facility, every 30 days, all services and items furnished to the beneficiary, so that the information could be documented in the patient's medical record.

Comment: Two commenters supported the proposed requirement for a 30-day reporting timeframe for durable medical equipment suppliers who provide support services to home dialysis patients. Several other commenters suggested that the 30-day timeframe was inappropriate and restrictive and recommended we allow 45 days in the final rule.

Response: We agree with both sets of comments because we believe that all information showing what supplies and services were provided to the patient and when each was provided should be reported to the ESRD facility on a regular basis. However, we agree with the second group of commenters that the 30-day timeframe is restrictive. Therefore, to allow greater flexibility, we have modified the final rule at § 414.330(a)(2)(iii)(C) to allow durable medical equipment suppliers to report to the ESRD facility providing support services at least once every 45 days.

B. Part 488—Survey, Certification, and Enforcement Procedures; Special Procedures for Approving End-Stage Renal Disease Facilities (Proposed § 488.60)

We proposed to retain the procedures for approving ESRD facilities as specified at § 488.60. We received one public comment pertaining to the procedures for approving ESRD facilities. The comment and response are found at the end of this section. We have recodified § 405.2180, § 405.2181, § 405.2182, and § 405.2184 as § 488.604, § 488.606, § 488.608, and § 488.610, respectively. These provisions were relocated without any modifications. Comments pertaining to hemodialyzer reuse sanctions are addressed in the § 494.50, ''Reuse of hemodilayzers and bloodlines'' discussion, later in this preamble.

Comment: One commenter expressed concern regarding the certification process for ESRD facilities. The commenter remarked that facilities applying for initial approval may not have all of the data required by the conditions for coverage in accordance with § 488.60(a).

Response: Although we understand the commenter's concern that a new provider may not have all of the required data available, data are important for use in improving quality outcomes and play an important part in the management and oversight of the ESRD facilities. Therefore, we are retaining the provisions of § 488.60(a) as proposed. In addition, the absence of data would not necessarily result in the denial of certification. If an ESRD facility is unable to supply all of the data required in § 488.60(a), the facility could be cited at a standard deficiency level, thus emphasizing the importance of the data, but not precluding the ESRD facility from receiving approval to operate in the Medicare program.

C. Part 494—Conditions for Coverage for End-Stage Renal Disease Facilities

1. Subpart A (General Provisions)

a. Basis and Scope (Proposed § 494.1)

We proposed a new organizational format for the conditions for coverage, which permitted the elimination of almost all of § 405.2100, Scope of subpart. This section consists largely of a description of the contents of the existing ESRD conditions for coverage. We proposed at § 494.1 to identify the statutory authority for the revised regulations, and to state that provisions of part 494 would serve as the basis for survey activities for determining whether a dialysis facility met the conditions for coverage under the Medicare program. We received no comments on this section.

b. Definitions (Proposed § 494.10)

We proposed to recodify § 405.2102 as § 494.10, with an abbreviated set of definitions. While § 405.2102 defined 32 terms, we proposed to define only 7 terms at § 494.10. We proposed to eliminate several terms that were self-evident and others that would not be utilized in these revised conditions. In addition, we did not believe it would be appropriate to have substantive requirements contained within definitions, so we proposed to move definitions that contained qualification requirements, such as the term ''interdisciplinary team,'' to the appropriate conditions in the final rule.

Comment: A few commenters suggested revisions to the proposed definition for ''dialysis facility.'' One commenter recommended we adopt the phrase ''chronic kidney dialysis facility'' and two other commenters suggested the addition of ''self-care dialysis'' to the current list of services provided by the facility.

Response: Adding the word ''chronic,'' we believe, would add no value to the term ''dialysis facility'' since kidney disease requiring outpatient dialysis is chronic by nature. The proposed definition for ''dialysis facility'' does recognize self-care dialysis. Self-care dialysis is a modality described in section 1881 of the Act. We believe the proposed definition of ''dialysis facility'' is sufficient. Therefore, we adopt this definition as proposed.

Comment: Two commenters suggested adding language to clarify that a facility that taught a patient how to self-cannulate would not need to obtain

certification as a self-dialysis unit exclusively because of such instruction.

Response: We agree with the commenters that any dialysis facility that is Medicare-certified to provide outpatient dialysis services may include instruction in self-cannulation in its dialysis program. We do not require any additional certifications, nor is a separate ''self-dialysis'' certification category available. Dialysis facilities receive Medicare certification to provide in-center dialysis or home dialysis training and support services, or both. We are not adding a regulatory statement regarding the absence of a self-dialysis certification category to this final rule.

Comment: One commenter requested additional clarification regarding what would constitute ''discharge'' (for example, ''30 days after departure from a facility for any reason'').

Response: Our intent was to describe the cessation or end of patient care services for patients who either voluntarily leave the facility or for patients who are discharged for reasons listed at § 494.180(f). To address the commenter's concern, we have added clarifying language at § 494.10 to read, ''Discharge means the termination of patient care services by a dialysis facility or the patient voluntarily terminating dialysis when he or she no longer wants to be dialyzed by that facility.''

Comment: We requested comments regarding whether to reference nursing facilities (NFs) and skilled nursing facilities (SNFs) in the definition for ''home dialysis.'' We received many comments regarding the definition of ''home dialysis.'' Some commenters questioned the definition of ''home,'' while others commented that nursing homes and other institutional settings were appropriate for home dialysis. Yet others stated that nursing homes and other institutional settings were inappropriate for home dialysis. One commenter expressed concern regarding permanent versus temporary residence status within a nursing facility. One commenter suggested we adopt a new term, ''institutional home dialysis,'' to describe patients in a nursing home setting. Other commenters suggested a separate definition for dialysis provided in a nursing home setting that would be distinct from ''home dialysis.''

Many commenters noted the nursing home setting is different from the typical dialysis facility setting, and that the needs of the NF/SNF patient population are unique. One commenter proposed the term ''staff assisted nursing home dialysis'' be used. Other topics of concern included training course specifications, recommendations about peritoneal dialysis and hemodialysis modalities, and the burden associated with including NFs and SNFs in the definition.

Some commenters believed that neither short nor long-term stays in NFs/SNFs should be considered a patient's home for purposes of home dialysis, while others took the opposite view. Other commenters responded that only a long-term stay in a NF/SNF should be considered a patient's home for purposes of home dialysis. Major dialysis associations and a major nursing home association urged Centers for Medicare and Medicaid Services (CMS) not to classify NF/SNF as the patient's ''home'' in this final rule, but to convene an expert panel to study this complex issue and then address it in a separate rule at a later date.

Response: We understand the concerns of commenters. Currently a SNF may be considered a patient's home for self-dialysis, as noted in the Medicare Claims Processing Manual, which can be found at *http://www.cms.hhs.gov/manuals/downloads/clm104c20.pdf* and as noted in the Program Integrity Manual, Chapter 5 at *http://www.cms.hhs.gov/manuals/downloads/pim83c05.pdf*.

We recognize that the provision of hemodialysis to nursing home patients presents unique challenges, given this frail population. We note that there was no consensus within either the renal community or the medical community at large as to the inclusion of SNFs or NFs in the definition of ''home dialysis.'' A more detailed discussion of this issue can be found later in this preamble under the ''Care at home'' condition (§ 494.100). Given the variety of differing comments, we believe that a regulation regarding NF/SNF dialysis would be premature. Therefore, we will consider addressing this issue at a later date, and the current guidance for dialysis in a nursing home environment will remain in effect at this time.

Comment: Three commenters suggested that the definition for ''interdisciplinary team'' use the same language as that of § 494.80, and that the definitions be cross-referenced throughout the text.

Response: The composition of the interdisciplinary team is a minimum requirement of this final rule. We are not including requirements in the definition section. We are defining the ''interdisciplinary team'' in the ''Patient assessment'' condition opening paragraph at § 494.80. We have also added the requirement to the ''Patient plan of care'' condition at § 494.90, to include the same language describing the composition of the team. The definition for ''interdisciplinary team'' appearing under § 494.10 in the proposed rule has been removed from this final rule.

Comment: We received several comments regarding the definition of ''self-dialysis.'' Two commenters suggested changing the definition from ''dialysis performed with little or no professional assistance'' to ''dialysis performed with limited or no professional assistance * * *.'' Some commenters stated the definition should not reference the training requirement at § 494.100(a) since such requirement would not apply to all self-dialysis, and that many patients would perform some level of self-care in the facility. One commenter recommended that we issue interpretive guidelines to address the issue of patients that would perform self-care dialysis in a facility. Another commenter suggested dropping ''self-dialysis'' terminology from the definition section of this final rule.

Response: ''Self-dialysis'' is addressed in section 1881 of the Act and the Secretary has the discretion to define ''self-dialysis services'' in regulations. We are retaining the proposed language, which contains the term ''little'' because we believe ''limited'' may imply the necessity of a potentially higher degree of professional assistance for self-dialysis patients than envisioned by the statute. Interpretive guidelines will be developed to instruct the surveyors how to review facilities for compliance with the requirement.

Comment: Several commenters requested clarifications of terminology and additional definitions in the final rule such as: New patient; first dialysis; direct supervision; and grievance.

Response: The terms ''first dialysis'' and ''new patient'' are clarified in the section in which the terms are used. For example, ''new patient'' is now clarified in the ''Patient assessment'' condition at § 494.80(b). The term ''direct supervision'' has been deleted from the final rule, as explained in the preamble discussion for ''Personnel qualifications'' at § 494.140(e)(3). ''Grievance'' is discussed in the preamble for ''Patients' rights'' at § 494.70.

Comment: A renal association recommended that we define the term ''standards'' in the final rule since we used that term in the preamble of the proposed rule. The commenter noted that the use of the term ''standards'' is significant and should be explicitly defined to ensure consistency throughout the regulation. The commenter also noted that each of the NKF's clinical practice guidelines

contains a disclaimer stating that guideline is ''not intended to define a standard of care, and should not be construed as one.''

Response: The term ''standards'' appears throughout the regulation, as it is used to identify levels of requirements within each condition for coverage. Historically, our conditions of participation and conditions for coverage are written in hierarchical form of conditions, with standards and elements (or factors) contained within the conditions. For the most part they are written as individual, surveyable requirements. Merriam-Webster's Collegiate Dictionary defines ''standards'' as ''something established by authority, custom, or general consent as a model or example.'' This definition matches how the term ''standards'' is used in this final rule. When using the term ''standards'' as applied to care of patients, we expect that professionals would rely upon principles and practices of care that are, for example, widely used and supported by professional organizations, academic institutions, and recognized standard-setting organizations. We recognize that professionals may vary in their use of particular ''standards.'' We assume the commenter is concerned about the use of the terms ''standards'' as used in the preamble discussion of facility-wide standards to be used for enforcement. Any facility-level standards for Medicare participation developed subsequent to publication of this final rule, will be developed in accordance with the National Technology Transfer and Advancement Act of 1995 (NTTAA) process adopted by the Secretary, as discussed in the ''Governance'' condition at § 494.180.

c. Compliance With Federal, State, and Local Laws and Regulations (Proposed § 494.20)

We proposed a slightly broader version of § 405.2135 in our February 2005 proposed rule. While § 405.2135 specifies applicable laws and regulations pertaining to licensure, fire safety, equipment, and other relevant health and safety requirements with which a facility had to comply, we proposed that, additionally, facilities specifically comply with State and local building codes, and any laws regulating drugs and medical device usage.

Comment: Several commenters suggested deleting the reference to ''drugs'' at proposed § 494.20. Commenters are concerned that this reference to drugs would restrict physicians' use of Medicare Part B covered drugs for ''off label'' use.

Response: We agree with the commenters. The reference to ''drugs'' has been removed from § 494.20 of the regulation text. Medicare contractors may make reasonable and necessary determinations regarding off-label uses of drugs pursuant to instructions published in program manuals.

Additionally, we removed the phrase ''staff licensure and other personnel staff qualifications'' from § 494.20, as this requirement may be found in ''Personnel qualifications'' at § 494.140. We removed the phrase ''fire safety, equipment, building codes'' from § 494.20, as these issues are addressed in the ''Physical environment'' condition at § 494.60. In addition, we removed the phrase ''medical device usage'' from § 494.20, as it is covered under the condition for ''Water and dialysate quality'' at § 494.40, the condition for ''Reuse of hemodialyzers and bloodlines'' at § 494.50, the ''Physical environment'' condition at § 494.60(b), and in the ''Care at home'' condition at § 494.100.

Comment: A commenter stated that water treatment systems are ''medical devices'' and fall under Food and Drug Administration (FDA) regulations. The commenter stated that the proposed rule preamble suggests that water systems would have to meet FDA guidance document requirements even if installed before May 1997. The commenter is concerned that replacement of water systems with ''510(k) cleared'' systems would incur needless expense.

Response: As explained above, we have removed the words ''equipment'' and ''medical device usage'' from § 494.20 and do not single out these categories of law. Facilities are expected to comply with all Federal, State and local laws regarding health and safety. Under current FDA regulations, all water treatment systems installed after May 30, 1997 must meet review requirements under section 510(k) of the Food, Drug, and Cosmetic Act (21 U.S.C. sec. 360(k)) as described in *Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis (http://www.fda.gov/cdrh/ode/hemodial.pdf).* This document is intended to provide guidance in the preparation of a regulatory submission and reflects the current FDA review guidance for water purification components and systems for hemodialysis. Water purification systems installed before May 30, 1997 are not affected by this guidance; however, all systems installed after this date must meet FDA requirements. Regardless of when a water purification system was installed, the system must yield water and dialysate that meets AAMI standards and must be monitored and maintained in accordance with the AAMI RD52 guidelines, which are incorporated by reference in this final rule at § 494.40.

Comment: A number of commenters recommended we include a reference to the Americans with Disabilities Act of 1990 (Disabilities Act) within this condition. The rationale is that patients must be accommodated for mobility, hearing, vision, or other disabilities or language barriers.

Response: A specific reference to the Disabilities Act is not necessary since ESRD facilities must comply with all applicable Federal, State, and local laws, including the Disabilities Act. The Department of Justice, Civil Rights Division, is charged with oversight and enforcement of the Disabilities Act. We would also continue to support the enforcement of the Disabilities Act provisions through the survey process under § 494.20.

2. Subpart B—Patient Safety

a. Infection Control (Proposed § 494.30)

We proposed a separate condition for coverage for infection control requirements, to update the provisions currently found at § 405.2140(b) and § 405.2140(c). We proposed incorporating by reference ''Recommended Infection Control Practices for Hemodialysis Units at A Glance'' precautions found in the CDC publication ''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients'' (DHHS/CDC, pages 20–21), with the exception of the screening recommendations for hepatitis C. We proposed that dialysis facilities implement appropriate procedures for patient isolation; for the handling, storage, and disposal of waste; and the disinfection of surfaces, devices, and equipment. We proposed the appointment of an infection control officer registered nurse (RN) to ensure oversight of the facility's infection control program, maintenance of current infection control information, reporting of infection control issues to the facility chief executive officer (CEO) or administrator and the facility improvement committee, and the development of facility infection control improvement recommendations. We also proposed monitoring and reporting standards that would require the facility to analyze and document the incidence of infection to identify trends, establish baselines, take action to reduce future infection control incidents, and report incidences of communicable diseases as

required by Federal, State, and local regulations.

Comment: We received numerous comments on § 494.30 ''Infection control'' condition. Many commenters agreed with the inclusion of the CDC infection control precautions for hemodialysis settings. Some commenters recommended that we incorporate in the final rule the entire CDC (RR05) document entitled, ''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients'' (published on April 27, 2001), rather than only the ''At A Glance'' section.

A number of commenters referenced particular infection control precautions included in the ''At A Glance'' section and requested clarification or raised issues related to the cost or logistics of implementing the specific precaution in a hemodialysis facility. The precautions referred to in these comments include: use of disposable items, use of cloth-covered blood pressure cuffs, use of leak-proof containers for used hemodialyzers, specifications for medication carts, carrying supplies or medications in the pockets of staff, and isolation room requirements. Some commenters stated that there was no need for every new dialysis unit to have an isolation room. Two commenters supported having separate staff to care for hepatitis B-positive patients, but other commenters stated the cost of separate staff for this would be prohibitive.

Response: We appreciate the support for inclusion of the CDC hemodialysis infection control precautions in this final rule. Based on the comments, it is apparent that clarifications are needed for the ''At A Glance'' guidelines, which are an abbreviated version of the CDC RR05 ''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients.'' The majority of comments concerning specific precautions are addressed in the CDC narrative section entitled ''Recommendations'' on pages 18 through 28 of ''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients.'' In order to better clarify the requirements of the infection control precautions, we are expanding our RR05 incorporation by reference to include the entire ''Recommendations'' narrative section of the document (pages 18–28) in the final rule, with one exception (hepatitis C screening), as discussed below. The introduction and background sections of the RR05 document (pages 1–17) provide the evidentiary basis for the recommended precautions. The entire CDC RR05 document provides rich background information and rationale for the recommended practices; we encourage facilities to use the entire document as a resource.

The RR05 CDC infection control precautions state that items taken into the dialysis station should be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient. Items that cannot be cleaned and disinfected (for example, adhesive tape, cloth-covered blood pressure cuffs) should be dedicated for use only on a single patient. Blood pressure cuff covers may be more cost-effective and may be used for blood pressure cuffs that cannot be decontaminated easily between patients. In contrast, rolls of tape cannot be decontaminated and can serve as a source of contamination for both facility personnel and patients. Tape rolls must be dedicated to a single patient, or disposed of after patient use.

Hemodialyzers carried to the reuse area should always be in a leak-proof container. We wish to prevent a blood-contaminated item from potentially contaminating the treatment (and clean) areas as it is carried from a patient's station. A container could be a plastic bag. We believe that the practice of carrying a contaminated hemodialyzer to the reuse room without the use of a leakproof container does not adequately prevent contamination.

Although one commenter stated that banning a medication cart and taping medication to the hemodialysis machine would ''waste'' RN time, the CDC has made clear that patient safety is best protected and risk of cross-contamination reduced when medications are prepared and distributed from a centralized clean area dedicated to that purpose. Another commenter argued that staff should have immediate access to gloves for times when a patient suddenly starts to bleed, and that staff members should be allowed to carry extra gloves in their pockets. The CDC precautions do not allow this practice. Instead, the facility should have gloves strategically placed so that staff has adequate access to them for both routine and emergency use.

Regarding the treatment of hepatitis B-positive patients, many commenters provided alternative isolation room recommendations and requested clarification of the isolation room requirement for new units as well as for existing units. The ''At A Glance'' page states (under ''Management of HBsAg-Positive Patients'') that the dialysis facility should dialyze hepatitis B surface antigen (HBsAg) positive patients in a separate room using separate machines, equipment, instruments, and supplies; and that staff members caring for HBsAg-positive patients should not care for hepatitis B virus (HBV) susceptible patients at the same time (for example, during the same shift or during patient change-over). CDC language from page 27 of the CDC RR05 document states, ''For existing units in which a separate room is not possible, HBsAg-positive patients should be separated from HBV-susceptible patients in an area removed from the mainstream of activity and should undergo dialysis on dedicated machines. If a machine that has been used on an HBsAg-positive patient is needed for an HBV-susceptible patient, internal pathways of the machine can be disinfected using conventional protocols and external surfaces cleaned using soap and water or a detergent germicide.'' Therefore, we are incorporating this section by reference into the ''Infection control'' condition at § 494.30, as it is found in the ''Recommendations'' narrative section of the CDC ''At A Glance'' infection control precautions. However, we are allowing dialysis facilities extra time to come into compliance with the provision requiring a separate isolation room (recommendation found on pages 27 and 28 under the ''HBV-Infected Patient'' section header of RR05), since in some cases the provision would require that a facility retrofit its building, which would necessitate project development, architectural design, contractor bids, building permits, and time to complete the job. Therefore, we are allowing dialysis facilities 300 days after the publication of this final rule in the **Federal Register** to comply with the requirements of this provision. In addition, any HBsAg-positive patient in an existing dialysis facility should be separated from hepatitis B-susceptible patients either by a buffer zone of hepatitis B-immune patients or by a demarcated physical space at least equal to the width of one dialysis station. Separate dedicated supplies and equipment must be used to provide care to the HBsAg-positive patient. Note that ''separate equipment'' includes glucometers. Use of an ''end of row'' hemodialysis station can facilitate the separation of the area from the mainstream of the dialysis facility's activities and decreases the number of adjacent dialysis stations. If this space is needed for both HBsAg-positive as well as HBsAg-negative patients on other shifts, the space may be disinfected using conventional protocols and used for both types of patients at different

times. If a facility does not have any HBsAg-positive patients, this space may be used by non-HBsAg-positive patients on a normal basis. Every facility must have the capacity to separate HBsAg-positive patients in the facility.

In response to comments that not every new unit should be required to have an isolation room due to the low incidence of hepatitis B in hemodialysis patients, we have added a waiver provision at § 494.30(a)(1)(ii) that states, ''When dialysis isolation rooms as required by (a)(1)(i) are available locally that sufficiently serve the needs of patients in the geographic area, a new dialysis facility may request a waiver of such requirement. Such waivers are at the discretion of and subject to such additional qualifications as may be deemed necessary by the Secretary.''

The CDC infection control precautions specifically call for separate staff to care for hepatitis B-positive patients to prevent infection of susceptible dialysis patients. According to the CDC, using separate staff is a very effective method to reduce the spread of HBV. One staff person may care for a HBsAg-positive patient and immune patients at the same time, but may not simultaneously care for hepatitis B-susceptible patients. Section 494.30 requires dialysis facilities to implement this infection control precaution.

Comment: Two commenters pointed out that the RR05 ''At A Glance'' section uses the word ''should'' and seems to allow less than full compliance with the infection control precautions.

Response: We recognize that the RR05 CDC document uses the word ''should'' when describing implementation of the infection control precautions, for example, ''clean areas should be clearly designated for the preparation, handling and storage of medications * * *'' The CDC document is written as guidelines and therefore guideline language is used. For purposes of these Conditions for Coverage, the CDC infection control precautions, which are incorporated by reference, are mandatory and must be adhered to and demonstrated within the dialysis facility. The regulation states, ''the facility must demonstrate that it follows standard infection control precautions' by implementing the CDC hemodialysis infection control practices found in the RR05 document. The guidelines incorporated by reference will be deemed mandatory in the survey process.

Comment: One commenter asked whether a reverse isolation negative pressure room would be required.

Response: The RR05 CDC recommended infection control practices incorporated by reference address the unique needs of a hemodialysis unit and include contact precautions. When airborne pathogens are discovered within the dialysis unit, the CDC infection control recommendations regarding airborne pathogens should be consulted and the proper measures taken to protect patients and staff from exposure. This could mean that the affected patient is transferred to a setting that provides the necessary isolation precautions for the pathogen. The facility may want to have an agreement with a hospital if the facility discerns that this is necessary; however, we are not incorporating this provision into the Medicare ESRD conditions for coverage.

Comment: One commenter asked whether staff cover gowns are required.

Response: Staff scrubs or uniforms are sufficient attire within the dialysis unit, except for times when one might expect to be exposed to a blood spattering. Cover gowns primarily serve to protect a staff member from exposure to blood within the dialysis unit. This is addressed on page 22 of RR05 CDC document.

Comment: We received more than a dozen comments regarding the CDC RR05 recommendation for hepatitis C screening of dialysis patients. Most of the comments supported the CDC recommendation and several suggested that Medicare pay for hepatitis C screenings. Commenters stated that hepatitis C is an important pathogen for dialysis patients, screening would allow for early detection, and would alert the facility to significant breaks in use of infection control precautions. Some commenters did not support hepatitis C screening by the dialysis facility, and one noted that a positive diagnosis would not change treatment or patient care within the dialysis facility.

Response: In the proposed rule, we specified an exemption for hepatitis C screening, since Medicare only covers diagnostic hepatitis C testing when indicated, and does not cover general screening for hepatitis C. A patient with a hepatitis C positive test is treated in the dialysis facility with the same protocols as a patient who is not positive for hepatitis C. However, transmission of hepatitis C serves as a marker to evaluate the adequacy of infection control practices within a dialysis facility. Medicare generally covers preventive care and screenings if stipulated in law, including diagnostic testing. We will continue to omit from our incorporation by reference the CDC RR05 sections that specify hepatitis C screening.

On December 14, 2005, we published a coverage decision memo (CAG–00304N) that allows Medicare coverage of hepatitis panel testing when there is an elevation of liver enzyme levels. The memo title is ''Decision Memo for Addition of ICD–9–CM code 790.4, Nonspecific Elevation of Levels of Transaminase or Lactic Acid Dehydrogenase, as a Covered Indication for the Hepatitis Panel/Acute Hepatitis Panel National Coverage Determination'' and may be found at *http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=173.* Elevated liver enzymes, with or without other signs or symptoms of hepatitis, is a covered indication for the hepatitis panel. Most hemodialysis patients with newly acquired Hepatitis C virus (HCV) infection have elevated serum transaminase levels. Elevations in serum transaminase levels often precede anti-HCV seroconversion. Monthly serum ALT (a transaminase) determination is included in the composite payment to renal dialysis facilities. Consequently, if a beneficiary has an elevated ALT, the provider may order a diagnostic hepatitis panel, which includes a hepatitis C antibody test as part of the panel. The hepatitis panel National Coverage Determination (NCD) does not require the physician to order all of its constituent component tests. Thus, a provider may order a hepatitis C antibody test when the beneficiary's serum ALT, ordered and covered for monthly testing in the composite rate, is elevated.

Comment: A few commenters referred to the CDC guidelines regarding injectable medications and disagreed with the established protocol that allows re-entry of single-use medication vials.

Response: The April 27, 2001/50 (RR05); 1–43 CDC infection control guidelines, ''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients'' (*http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5005a1.htm*) state: ''Intravenous medication vials labeled for single use, including erythropoietin, should not be punctured more than once (196,197). Once a needle has entered a vial labeled for single use, the sterility of the product can no longer be guaranteed. Residual medication from two or more vials should not be pooled into a single vial.''

We have retained the intent of this policy and the proposed requirement at § 494.30(b)(2), regarding current infection control information including the most current CDC guidelines for the proper techniques in the use of vials and ampules containing medication. However, we have modified the wording slightly because we have

removed the proposed infection control officer requirement, as discussed below.

Under the ''Oversight'' standard at § 494.30(b)(2) we are requiring the clinical staff to ''demonstrate compliance with current aseptic technique when dispensing and administering intravenous medications from vials and ampules.''

Comment: Several comments were submitted in response to our solicitation as to whether we should incorporate by reference the Healthcare Infection Control Practices Advisory Committee's (HICPAC) ''Hand Hygiene in Healthcare Settings'' guidelines and the ''Guideline for Preventing Intravascular Device-Related Infections.'' Comments were evenly divided regarding incorporation of the hand hygiene guidelines. Two of the commenters stated there is no consensus between HICPAC hand hygiene guidelines and guidelines developed by Society for Healthcare Epidemiology of America (SHEA) regarding standards of care for preventing nosocomial transmission of staph aureus and enterococcus. While one commenter did not support incorporation of the intravascular device guidelines, there was some support for their inclusion, notably from the American Nephrology Nurses Association.

Response: We would expect that dialysis facilities demonstrate adherence to professional standards of practice for infection control, which include adherence to hand hygiene guidelines. This expectation is included in the stem statement of the infection control condition: ''The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.'' The expectation of acceptable hand hygiene extends to all healthcare providers. We will not specifically incorporate by reference the HICPAC hand hygiene standards, but we do expect compliance to the hand hygiene professional standards of practice.

We do not agree that the guidelines developed by SHEA regarding standards of care for preventing nosocomial transmission of staph aureus and enterococcus conflict with the HICPAC hand hygiene standards. We note that the SHEA guidelines are not specific to dialysis facilities where contact precautions are recommended, but address infection control issues in the hospital setting. The SHEA guidelines reflect the general lack of adherence by health care workers to hand hygiene standards and recommend additional measures, such as surveillance cultures, to prevent and monitor cross-contamination. Facilities have the flexibility to use appropriate resources to assist in the development and implementation of their hand hygiene infection control and prevention program.

Catheter infections continue to be a concern in hemodialysis facilities and lead to hospitalizations. HICPAC states in its ''Guidelines for the Prevention of Intravascular Catheter-Related Infections'' RR–10 document (*http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5110a1.htm*) (page 11), that the use of catheters for hemodialysis is the most common factor contributing to bacteremia in dialysis patients and the relative risk for bacteremia in patients with dialysis catheters is sevenfold the risk for patients with primary arteriovenous fistulas. In § 494.30(a)(2) we are incorporating by reference the pertinent hemodialysis catheter use sections (pages 13–14, and 17–18) of RR–10, 2002, ''Guidelines for the Prevention of Intravascular Catheter-Related Infections.'' These guidelines describe appropriate health-care worker education and training, surveillance, hand hygiene (I–III, page 16), aseptic technique (IV, page 16), hemodialysis catheter exit site care (section III–V, page 21), and catheter-site dressing regimens (section VI, C, page 22), and are the nursing standard of practice for catheter care. We expect that incorporation of these guidelines will increase staff awareness of the protections needed for hemodialysis patients with catheters and lead to reduced catheter infections.

Comment: Few commenters responded to our solicitation for comment regarding whether we should incorporate by reference the American Institute of Architects (AIA) Guidelines for Design and Construction of Hospitals and Health Care Facilities, which outline building requirements pertinent to dialysis facilities. Comments were split between supporting and rejecting AIA guidelines, and incorporation by reference if adopting the guidelines.

Response: We have not incorporated the AIA building standards in our final rule. However, facilities must comply with all State and local building codes/requirements.

Comment: Several commenters addressed our proposed infection control officer requirement at § 494.30(b)(2). Some supported having an RN assume the role of the infection control officer. Others believed that a staff member other than an RN should assume the role. Some commenters stated this role was not the best use of RN time, and a few cited cost concerns. Several commenters stated that oversight of infection control should be performed by the medical director or that the medical director should be notified of infection control issues at proposed § 494.30(b)(2)(ii) instead of our proposed notification of the chief executive officer or administrator and the quality improvement committee.

Response: We understand that dialysis facilities may face a shortage of RNs and that in many facilities RNs must be used to perform duties that only an RN can perform. While comments supported infection control to protect patient safety, several alternatives to an RN infection control officer were suggested. In response to comments and in order to increase facility flexibility in assigning staff roles, we have removed the infection control officer requirement from § 494.30(b)(2), and added infection control to the quality assessment and performance improvement (QAPI) condition at § 494.110(a)(2)(ix) as a required topic. This change requires that infection control be addressed within the action-oriented, data-driven QAPI program, which is under the direction of the medical director and requires RN and interdisciplinary team participation.

In response to comments we have also modified the proposed requirement at § 494.30(b)(2)(ii) (now § 494.30(b)(3)), to require that clinical staff report infection control issues to the dialysis facility's medical director and the quality improvement committee instead of the chief executive officer or administrator. The medical director has a critical role in addressing infection control issues in the dialysis facility and § 494.150(c)(2)(i) now requires the medical director to ensure that staff adhere to infection control policies and procedures.

Comment: We received a few comments regarding the role of the patient and patient perceptions of infection control practices in dialysis facilities. One patient stated that patients should be fully informed about infection control so they can protect themselves and be aware of staff infection control violations. Another patient's observation was that facility staff has no training regarding infection control and no one seems to worry about its ramifications.

Response: We agree that the dialysis patient has a role in assisting the staff in preventing the spread of infection. It is appropriate for the patient to be educated regarding infection control. We have added ''infection prevention and personal care'' to the Patient Education standard under § 494.90(d) in

the ''Patient plan of care'' condition. The facility should provide information to dialysis patients on topics including current infection control precautions, the facility's infection control practices, and the role of the patient in preventing the spread of infection. As explained above, we have strengthened infection control by making it a condition for coverage and expect that dialysis staff will comply with the hemodialysis infection control precautions developed by the CDC and required by this rule.

Comment: One commenter asked whether State surveyors could enforce local regulations and laws pertaining to disposal of hazardous wastes.

Response: Surveyors make referrals regarding unlawful disposal of hazardous wastes to the appropriate local authorities. If there is a problem, it can be cited by the surveyor under § 494.20, ''Compliance with Federal, State, and local laws and regulations,'' when local authorities confirm infringement.

Comment: It was suggested that the final rule require more surveillance, include septicemia and infection data elements, include an added CPM or standard for infection control, and require mandatory reporting of such data on the DFC Web site.

Response: As stated above, the facility must address infection control within the action-oriented, data-driven QAPI program. Surveillance and use of infection data will be necessary components of QAPI. We will consider the ''reporting'' as appropriate when developing new CPMs and adding new measures to the DFC Web site. We are not requiring new performance measures that have not been fully developed in this regulation.

b. Water and Dialysate Quality (Proposed § 494.40)

We proposed a separate condition for coverage to update the water purity requirements that were incorporated by reference into part 405, subpart U (§ 405.2140(a)(5)) in 1995. AAMI has since rescinded the document from which the sections were incorporated (ANSI/AAMI RD5:1992, Hemodialysis Systems, second edition) and published updated AAMI guidelines in 2001. We proposed to incorporate sections from the new AAMI document, ''Water Treatment Equipment for Hemodialysis Applications'' (ANSI/AAMI RD62:2001), to update the bacterial and chemical concentrations allowed in water used in hemodialysis. The new AAMI guidelines established action levels for contaminants in addition to merely identifying unsafe contaminant levels. At ''action levels,'' the facility must implement corrective actions to prevent contaminants from reaching unsafe levels. We also proposed water treatment equipment requirements and water testing frequency and sample sites that are consistent with the new AAMI document, ''Dialysate for Hemodialysis'' (ANSI/AAMI RD52:2004). We proposed chlorine and chloramine testing frequency, thresholds, and actions for unacceptable high levels to prevent the occurrence of hemolytic anemia in patients. We proposed corrective action plan and adverse event standards to further protect patient safety. We additionally proposed that facilities use bicarbonate dialysate, which has the potential for high levels of bacterial contamination, within the timeframe specified by the manufacturer.

Comment: We received many comments regarding § 494.40 ''Water quality'' condition. The comments were unanimous in supporting incorporation of AAMI water quality guidelines. Several of the comments recommended that the more recent 2004 ANSI/AAMI RD52 ''Dialysate for hemodialysis'' guidelines, written for water treatment system users, be incorporated by reference, rather than the 2001 ANSI/AAMI RD62 ''Water treatment equipment for hemodialysis applications,'' which are addressed primarily to the manufacturers of equipment. A commenter associated with the AAMI Renal Disease and Detoxification Committee stated that the 2001 ANSI/AAMI RD62 guidelines are slated to be revised in the near future.

Response: We agree with the commenters that ANSI/AAMI RD52:2004 ''Dialysate for hemodialysis'' is the more appropriate set of guidelines to incorporate by reference into these conditions for coverage. In fact, the RD52 guidelines addressing water purity monitoring and equipment parameters are similar to the requirements we proposed at § 494.40(a), § 494.40(b), and parts of § 494.40(c). Therefore, we are incorporating the AAMI guidelines (ANSI/AAMI RD 52:2004) by reference at § 494.40(a). These RD52 guidelines are compatible with the RD62 guidelines that we proposed to incorporate by reference, and are the standard of practice in dialysis facilities. We have removed the redundant sections of proposed § 494.40(a) through § 494.40(c) from the regulation, since the ANSI/AAMI RD52:2004 incorporation by reference addresses this issue. We are also renaming this condition ''Water and dialysate quality'' to more closely reflect the requirements of this condition.

Comment: One commenter recommended that we define ''established pattern'' (as related to collecting cultures for new water systems) (proposed § 494.40(a)(2)(i)(B)), as being on a weekly basis until an established pattern can be demonstrated.

Response: We agree. This issue is addressed in ANSI/AAMI RD52 (section 6.1—page 19; table 4), which, as discussed above, we are incorporating by reference. This section states that cultures should be drawn ''weekly until a pattern of consistent compliance with limits can be demonstrated.'' We have removed proposed § 494.40(a)(2)(i)(B).

Comment: One commenter stated that § 494.40(a)(2)(ii)(C) and (D) are redundant since the ''seasonal variations in source water'' specified as a trigger for chemical analysis at (C) will cause the reverse osmosis (RO) rejection rate to fall below 90 percent, the trigger listed at (D). A second commenter stated that RO is monitored by both rejection rate and dissolved solids or resistivity, and all of these types of monitoring should be indicated as acceptable.

Response: RO monitoring is addressed by ANSI/AAMI RD52 section 5.2.7 (page 10) and section 6.1 (pages 18–19), which we are incorporating by reference. As explained above, we have removed the redundant language from § 494.40(a)(2)(ii)(C) and § 494.40(a)(2)(ii)(D). Facilities also must follow the manufacturers' instructions for feed water treatment and monitoring. In the absence of manufacturer's recommendations, the AAMI guidelines require facilities to monitor product water conductivity, total dissolved solids or resistivity, and calculated rejection at a frequency and using thresholds provided by the manufacturer.

Comments: Many commenters made recommendations or requested clarification regarding carbon tank requirements at proposed § 494.40(c)(1). Many commenters supported a two carbon tank requirement, and some opposed it. A few commenters agreed with the 10-minute empty bed contact time, while one commenter said that the ''adequate'' empty bed contact time standard was too subjective. One commenter recommended that we clarify that the second carbon tank is in series with the first, and that we require the first tank to be replaced if test results are above the specified permissible levels. A few commenters pointed out that high chloramine levels may be mitigated with the use of ascorbic acid.

Response: Section 5.2.1 of the ''Dialysate for hemodialysis'' ANSI/

AAMI RD:52 guidelines specify, ''Whether a device is included in a particular water purification system will be dictated by local conditions.'' Since comments overwhelmingly supported two carbon tanks in series due to patient safety concerns and the fact that carbon tanks also remove organic contaminants from water, we will require at least two carbon tanks or equivalent components at § 494.40(b)(1) of our final rule (proposed § 494.40(c)(1)). Section 5.2.5 of ANSI/AAMI RD52 clarifies that two carbon tanks must be placed in series and that the carbon bed must be replaced in the first tank when depleted. We have added the phrase ''in series'' to our carbon tank requirement at § 494.40(b)(1), as suggested by the commenter. This RD52 section also clarifies that empty bed contact time must be at least 5 minutes in each bed. The empty bed contact time is an indicator of how much water contact with the particles in the carbon bed occurs so that there is adequate binding and removal of impurities.

AAMI does refer to use of ascorbic acid to correct chloramine/chlorine levels in RD62 (section A.4.3.9), though only in reference to portable water treatment systems. In RD52 (section 5.2.5 and appendix section A.5.2.5), AAMI also acknowledges the supplementation of carbon adsorption with other methods of chloramine removal.

In response to comments regarding an alternate means of correcting chloramine/chlorine breakthrough that would permit the continuation of hemodialysis, we have added a provision to the final rule at § 494.40(b)(2)(ii)(A) to allow immediate corrective action, and confirm through testing that the corrective action has been effective. We will not limit the means by which chloramines/chlorine levels are brought back into compliance at § 494.40(b)(2)(ii)(A). This regulation allows for use of other proven methods to remove chloramines including ascorbic acid and new technologies that may be developed. When using alternate methods to remove chloramines/chlorine, the facility must perform the required testing to ensure the successful removal of harmful chloramine/chlorine. After measures have been taken to resolve the immediate problem of chloramine/chlorine breakthrough, the facility must implement actions to maintain long-term compliance with acceptable chloramines/chlorine levels. We have added a provision at § 494.40(b)(2)(ii)(D), which requires facility action to ensure ongoing compliance. This provision reads, ''The facility must * * * Take corrective action to ensure ongoing compliance with acceptable chlorine and chloramine levels as described in paragraph (b)(2)(i) of this section.''

Comment: Many comments addressed our proposed requirement for chlorine/chloramine testing (proposed § 494.40(c)(2)) before each patient shift or every 4 hours, whichever was shorter. The majority of comments favored chlorine/chloramine testing only before every shift and not every 4 hours. One commenter recommended we change the 4 hours to 6 hours and retain the requirement, while another suggested we delete the phrase ''whichever is shorter.'' A few commenters agreed with the testing frequency of every 4 hours.

Response: According to ANSI/AAMI RD52, section 6.2.5 (page 20), testing should be done at the beginning of the day and again before each shift, and if there are no set shifts, then every 4 hours. We refer to this section, which has been incorporated by reference, at § 494.40(b)(2)(i), and we believe it provides sufficient clarification. We have deleted the proposed requirement at § 494.40(c)(2).

Comment: One commenter stated the regulation should include maximum carbon tank limits on usage time, flow, volume, and that testing for iodine should be required.

Response: The AAMI guidelines call for chlorine/chloramine testing every shift to monitor carbon tank performance. We are not aware of any evidence suggesting that these precautions are insufficient. We believe the commenter is suggesting that a minimum iodine number for the carbon should be required. Section 5.2.5 of the AAMI RD52 document states that ''When granular activated carbon is used as the medium, it shall have a minimum iodine number of 900.''

Comment: A few commenters stated that chlorine/chloramine testing requirements should also allow the testing for total chlorine with a limit of 0.10 mg/L.

Response: This suggestion corresponds with ANSI/AAMI RD52 section 6.1; table 4 (page 8) which allows total chlorine levels of less than 0.1 mg/L. This section is now incorporated by reference. We have modified proposed § 494.40(c)(2)(i), now § 494.40(b)(2)(i) to allow total chlorine testing with acceptable levels of less than 0.1 mg/L as an alternative to testing free chlorine and chloramine levels.

Comment: One commenter stated that chlorine/chloramine requirements at proposed § 494.40(c)(2)(ii) do not account for facilities with a holding tank, and we should allow water in the holding tank to be used if testing shows this water contains total chlorine < 0.1 mg/L.

Response: Water in the holding tanks may be used during failure of carbon tanks only if testing indicates the holding tank water meets AAMI chlorine/chloramines standards of < 0.1 mg/L total chlorine OR < 0.50 mg/L free chlorine AND < 0.1 mg/L chloramines and no additional water is allowed to enter the tank. Revised § 494.40(b)(2)(ii)(B) (proposed (c)(2)(ii)) allows use of purified water in the holding tank when it meets the AAMI standards at § 494.40(b)(2)(i).

Comment: One commenter recommended that endotoxin levels be measured in addition to blood and dialysis cultures when there is an adverse event (proposed at § 494.40(e)(1)), since cultures may be negative even with high endotoxin levels.

Response: We agree with the commenter that measurement of dialysate endotoxin levels should be performed along with dialysate cultures when a suspected adverse event occurs. We note that the AAMI guidelines call for dialysate bacterial cultures to be accompanied by endotoxin level testing. The AAMI guidelines state that endotoxin testing, if performed in the dialysis facility, can give results in about 1 hour, eliminating the long delay between sampling and obtaining a result (ANSI/AAMI RD52:2004, section A.1.4). We have added endotoxin testing to the blood and dialysate culture requirement at § 494.40(d)(1) (proposed § 494.40(e)(1).

Comment: Two commenters requested that we clarify the language of proposed § 494.40(e) ''Adverse events'' (now § 494.40(d)), regarding the active surveillance of patient reactions during and following dialysis. One commenter suggested that the word ''following'' be defined to mean ''after post-dialysis assessment with subsequent discharge by nurse or caregiver.''

Response: We appreciate the comment; however, we believe that the suggested definition is too narrow, since not every adverse advent will be limited to the time period the patient is physically in the dialysis unit. ''Following dialysis'' runs from the moment when the treatment session ends through the time the patient leaves the unit and beyond. In addition, when the patient calls and/or when the patient returns for the next dialysis session, if there are symptoms that are correlated with a water purity adverse event, then cultures and endotoxin testing must be performed.

Comment: Many comments reflected concern regarding the proposed requirement at § 494.40(f) that mixed bicarbonate concentrate be used within the timeframe specified by the manufacturer of the concentrate, and the accompanying preamble statement that fresh bicarbonate must not be mixed with other batches of fresh bicarbonate. Several commenters stated that mixing batches of bicarbonate concentrate may be unavoidable due to mixing processes and the use of holding tanks. Two commenters agreed with limiting use of bicarbonate to the time limit given by the manufacturer, while others stated that it was only necessary to use bicarbonate the same day it was mixed. Some commenters stated that bicarbonate is the most vulnerable part of dialysis solutions.

Response: AAMI addresses procedures for bicarbonate concentrate in ANSI/AAMI RD52, section 7.1 (page 24), stating, ''Storage times for bicarbonate concentrate should be minimized, as well as the mixing of fresh bicarbonate concentrate with unused portions of concentrate from a previous batch.'' Section 5.4.4.3 (page 15), also states, ''Once mixed, bicarbonate concentrate should be used within the time period recommended by the manufacturer of the concentrate. The concentrate shall be shown to routinely produce dialysate meeting the recommendations of 4.3.2.1.'' ANSI/AAMI RD52 stipulates the use of bicarbonate concentrate within the time period recommended by the manufacturer and does not expressly prohibit the mixing of bicarbonate concentrate. If the first batch of bicarbonate concentrate has not yet expired, it could be mixed with a second batch, provided the first batch had not expired in accordance with the manufacturer's time limitations before it was used. We have removed the proposed water and dialysate quality standard at § 494.40(f), regarding unused bicarbonate, since we are instead incorporating ANSI/AAMI RD52 by reference.

Comment: We received many comments regarding whether we should include requirements related to ultrapure dialysate. Although two commenters (including a large patient organization) supported ultrapure dialysate requirements, a number of commenters opposed such requirements, citing a lack of evidence that supported the use of ultrapure dialysate. One commenter stated that in light of new findings showing that ultrapure dialysis could be beneficial to hemodialysis patients, ultrapure dialysate should be strongly encouraged. Another commenter, who was a national expert in the area of dialysis water treatment systems, suggested that we require that all new water systems installed after publication of the final rule be capable of delivering ultrapure dialysate. This would allow facilities to provide ultrapure dialysate in the future should an evidentiary basis be solidified. A few comments suggested that if we require ultrapure dialysate, Medicare should provide corresponding reimbursement.

Response: We appreciate the comments; however, we are not requiring dialysis facilities to provide ultrapure dialysate in this final rule. Current information shows promise of ultrapure dialysate, but we believe that sufficient evidence is lacking. We will revisit this issue in the future when more evidence is available, recognizing that dialysis patients are in favor of a lower permissible level of bacterial contamination in the dialysate. If additional evidence supports the use of ultrapure dialysate, we may undertake the necessary rulemaking to incorporate the requirement at a later date. Facilities choosing to provide ultrapure dialysate must meet section 4.3.2.2 of the ANSI/AAMI RD52 guidelines.

Comment: Some commenters suggested that we avoid codifying dates and values in the regulations, as these may change before the regulation changes.

Response: We believe that the avoidance of values and use of general language for Medicare patient safety requirements may create confusion and allow less than full compliance with these conditions for coverage. There are currently clear thresholds and standards for dialysis water purity, which we have included. Where necessary, we will consider updating specific dates and values via future rulemaking, as appropriate.

Comment: Two commenters pointed out that the AAMI guidelines for bacteria and bacterial toxin sample sites were misquoted in the proposed rule preamble bullets (70 FR 6195) as follows:

- Outlet of the water storage tanks if used
- Concentrate or from the bicarbonate concentrate mixing tank.

Response: The commenters are correct. The bullets above do not accurately reflect the guidelines. However, the language will not appear in this final rule since the issue is covered in ANSI/AAMI RD52; section 7.2.1 (page 25), incorporated by reference at § 494.40(a) in this final rule, which addresses collection sites for water/dialysate samples.

Comment: One commenter stated that the final rule should require a water quality technician who would be independent from the primary caregivers.

Response: Provisions regarding the water treatment system technicians are found at § 494.140(f); water treatment system technicians must complete a training program that has been approved by the medical director and governing body. Section 9 of AAMI RD52 calls for a training program that includes ''quality testing, the risks and hazards of improperly prepared concentrate, and bacterial issues.'' Section 9 also states, ''Operators should be trained in the use of the equipment by the manufacturer or should be trained using materials provided by the manufacturer. The training should be specific to the functions performed (that is, mixing, disinfection, maintenance, and repairs). Periodic audits of the operators' compliance with procedures should be performed. The user should establish an ongoing training program designed to maintain the operator's knowledge and skills.'' The dialysis facility has flexibility with staff assignments and the water quality technician may or may not be independent of the primary caregivers. As noted, we are incorporating these provisions by reference.

Comment: One commenter objected to the RO/deionization component requirement at § 494.40(b), which it believed could preclude use of new/improved technologies.

Response: We have removed this language from § 494.40(b). At § 494.40(a), we have incorporated by reference ANSI/AAMI RD52, which states in section 5, ''Equipment'' (page 8):

> Since feed water quality and product water requirements may vary from facility to facility, not all of the components described in the following clauses will be necessary in every purification and distribution system. Components must be included, which would allow product water and dialysate to meet the AAMI standards specified at 4.1.2, 4.2.1, and 4.3.2.1.

Comment: One commenter objected to the requirement to assay cultures within 24 hours since this may not be realistic on weekends. The commenter suggested allowing a 48-hour time period for cultures.

Response: The proposed rule did not prescribe culture assay timelines. However, the ANSI/AAMI RD52 guidelines at section 7.2.3 state that samples that cannot be cultured within 1–2 hours can be refrigerated for up to 24 hours. Samples that are held longer than 24 hours do not accurately measure

the degree of contamination against the established AAMI standards. We have incorporated ANSI/AAMI RD52 standards into this final rule by reference at § 494.40(a).

Comment: One comment stated that facilities should be able to substitute a reuse water sample from the site where the dialyzer connects to the reuse system for a sample taken from the entrance to the reprocessing equipment (described at 70 FR 6195).

Response: AAMI specifies collection of water samples from the outlets supplying the reuse equipment (ANSI/AAMI RD52 section 6.3.3, page 22). We will adhere to this AAMI guideline. We have incorporated ANSI/AAMI RD52 by reference at § 494.40(a) in this final rule.

Comment: One commenter suggested the requirement for a water sample at the outlet of the water storage tank be deleted, since this is only necessary initially and when trouble-shooting.

Response: The commenter refers to proposed rule preamble language (70 FR 6195) describing RD52 sample sites and is correct in observing that samples are taken from the outlet of the water storage only initially and when troubleshooting. This matter is addressed in section 7.2.1 of AAMI RD52, which we are incorporating into this final rule by reference.

Comment: One commenter stated that when referring to water samples from the distribution ''loop'' we should change our wording, as a ''loop'' has no ''beginning'' or ''end''.

Response: We refer the commenter to AAMI RD52 section 6.3.3 (page 22), which states that samples should be taken from the first and last outlets of the water distribution loop and the outlets supplying the reuse equipment and bicarbonate mixing tanks. We have incorporated ANSI/AAMI RD52 by reference at § 494.40(a) into this final rule. We believe that the AAMI language is generally understood.

Comment: We received comments regarding the quality of home hemodialysis water, recommending that there be separate water purity standards for home dialysis systems due to the availability of new technology and the cost burden associated with the proposed water quality requirements.

Response: We acknowledge that the AAMI RD52 water and dialysate purity guidelines were not intended by AAMI for home dialysis or portable systems. However, in the absence of water purity guidelines for home hemodialysis, we believe that the AAMI RD52 water and dialysate purity guidelines offer the best protection for use in preconfigured systems.

Therefore, the dialysis facility must monitor the quality of water and dialysate used by home hemodialysis patients, and conduct an onsite evaluation and testing of the water and dialysate system. The water and dialysate monitoring must be in accordance with the system's manufacturer instructions at § 494.100(c)(1)(v)(A), and the system's FDA approved labeling for preconfigured systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate. The facility must meet testing and other requirements of AAMI RD52:2004 for water and dialysate. In addition, bacteriological and endotoxin testing must be performed at least quarterly, or on a more frequent basis, as needed, to ensure that the water and dialysate are within AAMI standards at § 494.100(c)(1)(v)(B).

In cases where these new preconfigured hemodialysis machines are used in a dialysis facility, the home dialysis requirements do not apply. Therefore, we have added the following language at § 494.40(e) to address in-center use of these machines: ''When using a preconfigured, FDA-approved hemodialysis system designed, tested, and validated to yield AAMI-quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate, the system's FDA-approved labeling must be adhered to for machine use and monitoring of the water and dialysate quality. The facility must meet AAMI RD52:2004 requirements for water and dialysate. However, the facility must perform bacteriological and endotoxin testing on a quarterly or more frequent basis, as needed, to ensure that the water and dialysate are within AAMI limits.''

Comment: One commenter recommended that we require facilities to use only certified labs for analysis of bacteria growth and limulus amoebocyte lysate (LAL) testing.

Response: We are aware that many facilities do their own water and dialysate cultures and endotoxin testing on-site. The AAMI RD52 guidelines address the monitoring of water and dialysate systems for bacteria and endotoxin levels. Section 7.2.3 states that ''Dip samplers may be used for bacterial surveillance. However, they should be used only in conjunction with a quality assurance program designed to ensure their appropriate use.'' Section 7.2.4 addresses in-house testing for endotoxin levels. We have not modified the requirements as the RD52 document provides guidance regarding cultures and endotoxin testing.

c. Reuse of Hemodialyzers and Bloodlines (Proposed § 494.50)

We proposed to update our condition for coverage at § 405.2150, ''Reuse of hemodialyzers and other dialysis supplies'', by replacing it with a new condition for coverage at § 494.50. The ANSI/AAMI ''Reuse of Hemodialyzers'' guidelines (ANSI/AAMI RD47: 1993, second edition), incorporated by reference in 1995, were revised in 2002 and amended in 2003. We proposed incorporation by reference of the third edition of ''Reuse of Hemodialyzers'' (ANSI/AAMI RD47: 2002/A1: 2003). We proposed that only hemodialyzers and bloodlines labeled for reuse could be reprocessed and that reprocessing would have to meet the AAMI guidelines and adhere to the manufacturer's recommendations, unless an alternate method, documented to be safe and effective, was employed. The prohibition on reuse of hemodialyzers for hepatitis B patients was retained in the proposed rule, to protect staff from exposure to the hepatitis B virus. The requirement that the facility use only one germicide for each reprocessed hemodialyzer was retained in the proposed rule, to ensure integrity of the dialyzer membrane; we added a clarification that bleach would not be considered a germicide in this context. We proposed monitoring, evaluation, and reporting requirements to ensure surveillance for adverse patient reactions to reuse, and proposed that the facility suspend reuse when a problem was suspected or discovered. We also proposed that when required by law, adverse outcomes would have to be reported to the FDA and other Federal, State, or local government agencies.

We received more than two dozen comments on the Reuse condition. The comments support inclusion of the updated 2002/2003 AAMI ''Reuse of hemodialyzers'' guidelines.

Comment: Several commenters addressed the first provision of this condition, which states, ''The dialysis facility that reuses hemodialyzers or bloodlines must meet the requirements of this section. Failure to meet any of these requirements constitutes grounds for denial of payment for the dialysis treatment affected and termination from participation in the Medicare program.'' Some of the commenters suggested deletion of this statement, while others suggested stronger penalties. One commenter stated this statement merely repeated proposed § 488.604, while another suggested the penalty was too drastic.

Response: The language regarding penalties for failure to meet the reuse

requirements is consistent with section 1881(f)(7) of the Act, which directly addresses dialyzer filter reuse. However, denial of payment for discrete instances of reuse non-compliance, authorized by section 1881(f)(7)(C) of the Act, has not been implemented, due to administrative difficulties associated with identifying which particular treatments would be associated with any specific denial of payment when there is a reuse problem. Currently, when a compliance problem is identified, the surveyor cites the facility and the facility must develop and implement a corrective action plan. If the facility does not make the necessary corrections then the facility is put on a termination track. This process has been effective in protecting patient health and safety when hemodialyzers are reused and will continue under this final rule. Therefore, we have removed the undesignated paragraph ''Failure to meet any of these requirements constitutes grounds for denial of payment for the dialysis treatment affected and termination from participation in the Medicare program'' from § 494.50.

We believe dialysis facility termination for reuse deficiencies and non-compliance fulfills the statutory requirement at section 1881(f)(7)(C) of the Act, that CMS deny payment for hemodialyzer reuse non-compliance. Under the current process, when a reuse problem is confirmed by a surveyor, we require immediate corrective action, which protects patient safety. If the reuse problem presented immediate jeopardy to patient safety, we would shut down the reuse program immediately until the facility could demonstrate that the problem had been corrected. CMS also has the authority to withhold payment from a facility when it has determined that there have been specific violations of this provision. If the facility were to continue to compromise patient safety, we would put the facility on a termination track. We believe that termination procedures provide more incentive to return to compliance than the denial of payment alternative sanction.

Comment: One commenter asked how the proposed rule ensures patient consent for dialyzer reuse.

Response: Our requirement for patient consent for dialysis reuse is located at § 494.70(a)(9), which states the patient has the right to be informed of facility policies regarding the reuse of dialysis supplies, including hemodialyzers. Patients may want to discuss this aspect of their medical treatment with their physician.

Comment: An organization representing kidney disease patients expressed concern regarding the large number of times a hemodialyzer is reused (up to 30 times), and requested that CMS convene a technical expert panel to examine all facets of reuse and make recommendations to improve current practice.

Response: We have added incorporation by reference the AAMI reuse guidelines, ANSI/AAMI RD47:2002 & RD47:2002/A1:2003 ''Reuse of hemodialyzers'' to this final rule at § 494.50(b)(1). The AAMI guidelines, which represent the consensus of technical experts, include dialyzer performance measurements (that is, total cell volume) that must be met in order for a dialyzer to be reused. Currently these parameters do not include a maximum number of allowable reuses. We may consider updates to this final rule through separate rulemaking when AAMI updates its reuse guidelines.

Comment: A few commenters disagreed with some of the AAMI hemodialyzer reuse guidelines. One commenter recommended that we require immediate disinfection of dialyzers and not allow the refrigeration of dialyzers; another commenter suggested that we ban the reuse of bloodlines, since AAMI is withdrawing the bloodline reuse guidelines. A third commenter recommended that dialyzer heat disinfection be prohibited.

Response: We defer to the AAMI guidelines on each of these reuse issues. Section 11 of the AAMI reuse guidelines, ANSI/AAMI RD47:2002 & RD47:2002/A1:2003 ''Reuse of hemodialyzers,'' incorporated into this final rule by reference, describes the approved processes for cleaning and disinfecting dialyzers, including heat disinfection. The guidelines also permit refrigeration of hemodialyzers that cannot be reprocessed within 2 hours, in order to inhibit bacterial growth. The AAMI guidelines allow disinfection procedures that have been shown to accomplish at least high-level disinfection when tested in dialyzers artificially contaminated with the relevant types of microorganisms. The guidelines also state that the disinfection process shall not adversely affect the integrity of the dialyzer. To date, AAMI has not rescinded the bloodline reuse guidelines and this final rule requires facilities that reuse bloodlines to follow them.

Comment: Two commenters recommended a further clarification of the requirement we proposed at § 494.50(b)(3), which stated that facilities will ''Not expose hemodialyzers to more than one chemical germicide, other than bleach, during the life of the dialyzer.'' One suggestion was to insert a clarifying parenthetical phrase so that this requirement would read, ''Not expose hemodialyzers to more than one chemical germicide, other than bleach (used as a cleaner in this application), during the life of the dialyzer.'' This commenter suggested that without adding this phrase the statement would be misleading, as it implied that bleach could be used as a disinfectant, which could damage the dialyzer if used long-term in such a manner.

Response: We agree with the commenter. We have revised § 494.50(b)(3) to clarify that bleach is considered a ''cleaner'' and not a disinfectant in this context.

Comment: We received a few comments regarding § 494.50(c), ''Monitoring, evaluation, and reporting requirements for the reuse of hemodialyzers and bloodlines.'' Some commenters recommended clarifying the phrase ''cluster of adverse patient reactions'' and two commenters supported a requirement that a blood test be done whenever a febrile reaction occurs, not just when there is a cluster. Another commenter cited a 1987 study published in the Journal of the American Medical Association that established a direct relationship between endotoxin levels and febrile reactions caused by poor reuse reprocessing techniques and recommended that endotoxins be measured in addition to blood and dialysis cultures since cultures may be negative with high endotoxin levels.

Response: ''A cluster of adverse patient reactions'' means a set of undesirable events affecting the health of dialysis patients that could be clinically related to dialyzer reuse practices. In such cases, the physician responsible for the hemodialyzer reprocessing program must act in accordance with the AAMI guidelines found at ANSI/AAMI RD47:2002 & RD47:2002/A1:2003. If a single patient has a suspected adverse reaction, the physician should evaluate the incident and order testing as appropriate in his or her clinical judgment.

The requirements of section 494.50(c) (regarding obtaining blood and dialysate cultures and evaluation of dialyzer reprocessing and water purification systems) would apply if a group of patients (that is, a cluster) was suspected of having adverse reuse reactions. We agree with the commenter that facility personnel should perform dialysate endotoxin level tests along with dialysate cultures when a

suspected adverse event occurs; this is consistent with our requirement in the ''Adverse events'' standard in the ''Water and dialysate quality'' condition at § 494.40. Therefore we have added endotoxin testing requirements at § 494.40(d)(1) and § 494.50(c)(2)(i).

A dialysis facility that uses outside hemodialyzer reprocessing services is responsible for fully protecting patient health and safety and ensuring compliance with these conditions for coverage and AAMI reuse guidelines as well as carrying out appropriate testing and evaluation of reuse processing and water purification systems when a cluster of adverse events occurs.

d. Physical Environment (Proposed § 494.60)

We proposed to update the § 405.2140 ''Physical environment'' requirements, which address facility building safety, equipment maintenance, the patient care environment, emergency preparedness, and fire safety, at new § 494.60. The proposed rule was consistent with part 405, subpart U provisions in requiring that a facility be constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable environment. The proposed rule further addressed patient comfort by requiring that the facility temperature be comfortable for the majority of its patients or that reasonable accommodations be offered. We proposed that the dialysis facility implement processes and procedures to manage medical and nonmedical emergencies (including fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters) that are likely to threaten the health or safety of the patients, the staff, or the public. The proposed rule would require emergency preparedness training for staff and patients, and would specify the emergency equipment that would have to be available in the dialysis facility (including oxygen, airways, suction, defibrillator, artificial resuscitator, and emergency drugs). The proposed fire safety requirements called for facility compliance with applicable provisions of the 2000 edition of the LSC of the National Fire Protection Association. The LSC waiver provisions were included in the proposed rule for those instances when, in the view of CMS, LSC compliance would result in unreasonable hardship and patient health and safety would not be adversely affected; or when a State had fire and safety codes that adequately protected dialysis patients. For a detailed discussion of our proposed physical environment provisions at § 494.60, see the February 4, 2005 proposed rule (70 FR at 6197).

Comment: Under the ''Equipment maintenance'' standard at § 494.60(b), one commenter suggested that equipment be maintained according to a regular maintenance schedule rather than the manufacturer's recommendations. The commenter was concerned that the manufacturer might overstate the amount of maintenance required.

Response: Our intent was to ensure that all dialysis facility equipment was adequately maintained and working properly. We proposed that ''The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) is maintained and operated in accordance with the manufacturer's recommendations.'' It is expected that routine maintenance be performed so that the risk of equipment malfunction is small. The facility will need to use the manufacturer's recommendations as a reference and guide. We have retained § 494.60(b) as proposed.

Comment: While the majority of commenters support our proposed requirement at § 494.60(c)(2) (that the facility maintain a room temperature that would be comfortable for patients, and make reasonable accommodations for the patients who might not be comfortable at the temperature that is comfortable for the majority), several commenters disagreed with this requirement. Some thought the proposal was too prescriptive, ignored the needs of staff (who are required to wear protective clothing), and allowed patients to dictate staff working conditions. Commenters noted that facilities already strive to keep patients comfortable, and stated that patients should be educated as to why body temperature drops during dialysis.

Response: Room temperature is a source of frequent tension in a hemodialysis facility. Generally, the sedentary patients undergoing treatment prefer a warmer room temperature, while staff who are engaged in activity and wearing protective coverings prefer a cooler room temperature. The proposed requirement would have tilted the room temperature in favor of the patients without consideration of the needs of the staff. In response to comments, we have modified the requirement to acknowledge the room temperature needs of staff. The intent of the new requirement is to have facilities arrive at a middle ground so that the room temperature is at least marginally acceptable to both patients and staff. Patients who continue to feel cold could use coverings or blankets. Regardless of the room temperature, patients should not be deprived of the ability to use covers or blankets. The dialysis facility may allow patients to bring their own blanket or may opt to provide a cover. In either case, adequate infection control precautions must be taken considering the risk of blood spatter. Additionally, the access sites and line connections should remain uncovered to allow staff to visually monitor these areas to ensure patient safety. In response to comments, we have revised § 494.60(c)(2)(i) by removing the phrase ''that is comfortable for the majority of its patients'' and inserted the word ''comfortable'' earlier in the sentence. Section § 494.60(c)(2)(i) and § 494.60(c)(2)(ii) now requires a facility to maintain a comfortable temperature within the facility; and make reasonable accommodations for the patients who are not comfortable at this temperature.

Comment: Many commenters recommended that we add privacy requirements to allow facility staff to conduct confidential interviews with patients, and to ensure that facilities utilized physical barriers whenever body exposure necessitated usual privacy. Commenters who supported a confidential area for patient interviews cited the April 14, 2003 Health Insurance Portability and Accountability Act (HIPAA) fact sheet (*http://www.hhs.gov/news/facts/privacy.html*) which outlines patient information privacy protections, including the patient's right to request confidential communications.

Response: HIPAA requirements protecting patient privacy apply to dialysis facilities. Two provisions of the proposed rule would support the patient's right to privacy. Proposed paragraph § 494.70(a)(3) stated that the patient would have the right to privacy and confidentiality in all aspects of treatment. Likewise, proposed § 494.70(a)(4), stated that the patient would have the right to privacy and confidentiality in personal medical records. Our preamble discussion of this requirement in the proposed rule (70 FR 6201) clearly stated our belief that any staff discussion with dialysis patients regarding treatment, the patient care plan, and medical conditions should be held in private and kept confidential, using reasonable precautions. We also pointed out that in situations when there was patient body exposure, the staff would be instructed to provide temporary screens, curtains, or blankets to protect patient privacy. To respond to these comments and to further

strengthen the patient's right to physical privacy, we have added a new provision at § 494.60(c)(3), stating that ''The dialysis facility must make accommodations to provide for patient privacy when patients are examined or treated and body exposure is required.'' This provision also protects those patients who do not wish to intrude on another patient's privacy.

Comment: Several commenters objected to the deletion of the centralized nursing monitoring station requirement in the proposed rule, formerly at § 405.2140(b)(3), as they believe a monitoring station is needed to support adequate surveillance of patients receiving dialysis. One commenter suggested that patient call buttons be required. Another commenter suggested retaining the concept of the nursing station requirement by adding the language, ''Patients should be in view of staff at all times during treatment to ensure patient safety.''

Response: We had proposed deleting the centralized nursing station requirement in order to increase facility flexibility in designing the clinical area. Patients undergoing hemodialysis require surveillance and continuous monitoring. Without vigilant monitoring it is possible for a dialysis needle to become dislodged, which could result in patient death from blood loss in just minutes. The suggested call button would place responsibility on the patient to alert staff to a problem; however, we expect continual monitoring of the patient, which would make a call button unwarranted. We are not restoring the requirement for a ''nursing station'' to allow maximum facility flexibility, but will require staff surveillance of in-center hemodialysis patients during treatment. Therefore, we have added a new provision at § 494.60(c)(4), ''Patients must be in view of staff during hemodialysis treatment to ensure patient safety (video surveillance will not meet this requirement).''

Comment: We received several comments regarding ''Emergency preparedness'' at § 494.60(d). Two commenters objected to having specific types of emergencies ''spelled out'' in regulation while another commenter recommended that bioterrorism be added to the list of emergencies for which facilities would be required to be prepared.

Response: In the proposed rule, the list of emergencies at § 494.60(d) for which dialysis facilities must be prepared ''include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.'' This list clarifies for facilities what types of emergencies must be addressed in the emergency plans. Facilities may prepare for many types of emergencies, including bioterrorism, which are identified as a risk after the performance of a facility risk assessment. We are retaining the proposed list of emergencies in this final rule.

Comment: Some commenters concurred with the standard as proposed. Two commenters advocated for a back-up generator requirement. Others requested clarification of proposed requirement for periodic training of staff and patients.

Response: The proposed emergency preparedness standard was designed to allow dialysis facilities maximum flexibility in meeting our requirements, which could include a back-up generator or other means of supplying needed power to the facility.

As for training, our final staff training requirements (§ 494.60(d)(1)) state that the dialysis facility must ''provide appropriate training and orientation in emergency preparedness to the staff. Staff training must be provided and evaluated at least annually * * *.'' The regulation goes on to specify what topics must be included in the training and the patients' instruction. The frequency of this training must be sufficient so that staff and patients are able to implement emergency procedures at any time. We are adopting § 494.60(d) introductory text and § 494.60(d)(1) introductory text as proposed. We believe this addresses the commenter's concern.

Comment: After the tragic hurricane events of 2005 (Hurricanes Katrina, Rita, and Wilma) we received some additional comments and recommendations from the national ESRD disaster response workgroup related to natural disaster preparedness, as these experiences led to new ''lessons learned.'' One recommendation was to add a requirement that would enable patients to contact their dialysis facility during a disaster, such as requiring each facility to provide an emergency toll-free phone number where patients could obtain critical medical information. A second recommendation was to include evacuation procedures in the disaster plan. A third recommendation was to require not only a plan, but also to require facilities to have a procedure in place to obtain back-up utilities, including agreements with utility companies for water and energy. A fourth suggestion was to require dialysis facilities to contact local disaster management officials at least annually, to ensure that local disaster aid agencies were aware of the dialysis facility's patients' needs in the event of an emergency.

Response: The final emergency preparedness standard includes requirements for the emergency preparedness of staff and patients and addresses instructions that are provided to dialysis patients. We have revised § 494.60(d)(1)(i)(B) to require that staff inform patients of where to go during an emergency, including evacuation instructions for emergencies in which geographic area of the dialysis facility must be evacuated.

We believe it is reasonable for dialysis facilities to provide an alternate phone number if the phone is not being answered, and/or the facility is not functioning during a disaster. We have added this requirement at § 494.60 (d)(1)(i)(C). This additional requirement reads, ''This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions) * * *.''

A disaster plan must include procedures and processes for use in the event of power or water source loss, or a disaster that would make the dialysis facility inoperable. We believe that it is reasonable for a dialysis facility to establish at least annual contact with its local disaster management agency to ensure that the agency is aware of the dialysis facility's needs in the event of an emergency. This pre-emptive contact could facilitate the meeting of dialysis patient needs during a disaster. We have added a new provision, codified at § 494.60(d)(4)(iii), requiring the dialysis facility to, ''Contact its local disaster management agency at least annually to ensure that such agency is aware of dialysis facility needs in the event of an emergency.''

We did not modify the final rule in response to the disaster response workgroup's recommendation that we require facilities to have a procedure in place to obtain back-up utilities, including agreements with utility companies for water and energy. This final rules requires that dialysis facilities develop an emergency plan that addresses emergency situations that may occur. These emergencies include power failure and water supply problems. The dialysis facility has flexibility in designing an emergency plan for these types of emergencies. The plan may include agreements with utility companies or alternative

interventions. We will not prescribe the methods that must be employed in responding to the various types of emergencies. The emergency plan must provide sufficient guidance to staff in preparing for emergencies and carrying out the plan.

Comment: A few comments were specific to proposed § 494.60(d)(1)(iii), requiring the facility to ensure that nursing staff are properly trained in the use of emergency equipment and emergency drugs. Two commenters objected to such nurse training, because it ''placed an emergency room-type burden on them.'' Other commenters suggested that the relevant emergency drugs be specified, and that suction devices be specifically excluded from the definition of ''emergency equipment.''

Response: We believe it is reasonable for dialysis facility nurses to be trained and prepared to handle emergencies that are likely to occur within the dialysis facility, and to require the facility to have equipment available for treating these emergencies. Suction machines are necessary medical devices used to clear a patient's airway of secretions or vomit. In the absence of these medical devices, it is possible that the patient's airway could not be cleared. Therefore, we are not deleting this requirement. The specific emergency drugs that are to be available should be determined by the medical director and described in the facility's policies and procedures. We are making no changes based on these comments.

Comment: We received many comments regarding the proposed defibrillator requirement at § 494.60(d)(3). The vast majority of commenters support inclusion of a defibrillator requirement, but recommended that an automated external defibrillator (AED) be an acceptable option. Commenters stated that AEDs were preferable because they are easy to use, more affordable, and do not require the extensive Advanced Cardiac Life Support (ACLS) training and certification that a non-automated defibrillator would require. Commenters did not support a defibrillator exception for small rural dialysis facilities, stating that these more remote facilities do not have nearby emergency medical services (EMS) and have a greater need for an in-house AED. A few commenters objected to the defibrillator requirement because they saw this as an unfunded mandate. One commenter said defibrillators should only be required if Medicare funds them, while another dissenting commenter said the need for a defibrillator should be based on the facility's proximity to EMS. The American Heart Association (AHA) commented on this issue and strongly supported a defibrillator requirement and AEDs in dialysis units, and suggested that AED training be combined with cardiopulmonary resuscitation training. The AHA pointed out that defibrillators have been shown to save lives in a variety of settings including office buildings, airplanes, and stadiums, where survival rates without AEDs are otherwise 1 percent. The AHA also noted that cardiac disease accounts for 43 percent of deaths in ESRD patients (United States Renal Data System 2003 Annual Data Report). The AHA recommended no exemptions for small, rural units but suggested a 1-year phase-in period for these types of dialysis facilities.

Response: We received substantial support from commenters for requiring a defibrillator, specifically an AED. In response to comments, we will require a defibrillator or an automated external defibrillator in our ''Emergency equipment'' standard at § 494.60(d)(3). However, we are not allowing a ''1-year phase-in period'' for small, rural units as suggested by one commenter. This is because we believe that a small, rural unit is likely to be further from emergency services and/or ambulance services, and as such, we believe that having a defibrillator or AED on hand would greatly increase the chance of survival for a dialysis patient in the event of a cardiac arrest. We believe that facilities will have sufficient time to purchase a defibrillator or AED and to train staff, since this regulation is effective 180 days after publication in the **Federal Register**.

Comment: We received many comments on proposed § 494.60(e) ''Fire safety.'' Several commenters concurred with the standard as proposed. We received many comments objecting to the proposed LSC provisions that require sprinklers and central monitoring systems in dialysis facilities. The commenters felt that LSC provisions should apply only to new facilities that are built after the effective date of the final rule. Several commenters felt that requiring the installation of sprinkler and a central monitoring system would be costly and burdensome. Some stated this could impose excessive burdens on leased dialysis facilities, building landlords, multi-story buildings and multi-tenant buildings, where sprinkler systems would need to be installed in a general retrofit for the entire structure. Commenters stated that since existing dialysis facilities occupied buildings that met the building codes in effect at the time of construction, they should be grandfathered for the 2000 LSC requirements, as long as State codes were met.

Response: The proposed LSC requirements provide significantly greater protection to dialysis patients than the fire protection provisions of part 405, subpart U at § 405.2140(a) and § 405.2140(c). Commenters objected most strongly to the LSC requirement for a sprinkler system in certain existing buildings. The 2000 LSC only requires buildings with certain structural configurations to have sprinkler systems. Specifically, 2000 LSC requires that only Type II (000) and ordinary constructed Type III (200) buildings, and Type V (000) buildings of two or more stories must be protected throughout by an approved, supervised automatic sprinkler system (2000 LSC section 21.1.6.3). We acknowledged in the proposed rule preamble that for some existing dialysis facilities it could be overly burdensome to comply with certain LSC requirements, and provided the sprinkler requirement as an example (70 FR 6200). We indicated that this could be a situation where a waiver might be warranted. However, the January 10, 2003 final rule, ''Fire Safety Requirements for Certain Health Care Facilities,'' allowed the grandfathering of existing facilities for the sprinkler systems requirement (as long as the facility was not undergoing renovations), without the imposition of a waiver process (68 FR 1375). Likewise, we will only apply the sprinkler provisions called for in the 2000 LSC to new dialysis facilities and existing facilities that are undergoing extensive renovations. Therefore, in new § 494.60(e)(2), we are exempting dialysis facilities in operation on the effective date of this rule and utilizing facilities built before January 1, 2008 from installing sprinkler systems if State law so permits. However, no dialysis facility may open and/or move to a location without a sprinkler system after the effective date of this rule. All other 2000 LSC provisions found in chapters 20 and 21 (New and Existing Ambulatory Health Care Occupancies) will be applied to dialysis facilities, including the provisions regarding automatic notification-equipped fire detection and alarm systems. However, in recognition of the possible extra expense and time required to review current building leases and fire codes, and if necessary, to make changes in the building structure, we are allowing dialysis facilities 300 days after the publication of this final rule in the **Federal Register** to comply with the requirements found at § 494.60(e)(1).

The stipulation at § 494.60(e)(4) regarding the waiver process for other provisions of the LSC has been retained in this final rule. A dialysis facility may apply for a waiver after receiving a notice of deficiency resulting from a survey by the State agency. The State agency will review the request and may seek guidance from the State fire marshal to make recommendations to the appropriate CMS Regional office. Our regional office will review the request and all associated documentation and make a final decision on the waiver.

Comment: Several commenters asked why ESRD facilities would have to meet State and local fire codes along with Federal fire safety standards. Many commenters requested waivers or extensions of the implementation date and stated that if presented with an option, they would prefer to follow State and local fire codes in lieu of the Federal standards.

Response: This final rule provides for a statewide waiver of any provision of the LSC (see § 494.60(e)(3) through § 494.60(e)(4)) that would not adversely affect patient health and safety, if endorsed by State survey authorities and approved by CMS. Any statewide waiver granted would apply to both new and existing facilities in the state. Individual waivers can be requested by both new and existing facilities. In States receiving a CMS-approved LSC waiver, dialysis facilities will only need to meet State fire safety provisions. Additionally, we have removed our proposed language at § 494.60(e)(2), which proposed that Chapter 5 of the 2000 edition of the LSC would not apply to a dialysis facility. Use of Chapter 5 of the LSC allows a dialysis facility a performance-based option for meeting the LSC occupant protection, structural integrity, and systems effectiveness goals and objectives. This change allows the design of a LSC-compliant dialysis facility building using a performance-based template that employs a computer-based methodology. This requirement is consistent with our LSC provisions for other provider-types and increases flexibility for dialysis facilities.

Comment: One commenter suggested that an emergency evacuation chair should be required for dialysis facilities in multi-level buildings.

Response: We appreciate the comment; however, we do not agree that an emergency evacuation chair should be required. We believe that LSC protections at § 494.60(e)(1) will provide an adequate level of safety. Dialysis facilities should develop a disaster preparedness plan as required at § 494.60(d) that includes evacuation procedures. Facilities may choose to have an emergency evacuation chair if necessary.

Comment: Many commenters objected to removing patients from dialysis equipment and evacuating them in order to comply with the fire drill requirement. It was felt that this exercise was unreasonable and medically unsafe. Many commenters preferred annual fire drills instead of quarterly fire drills.

Response: We agree with the commenters regarding removal of patients during fire drills. As we indicated in the preamble of the proposed ESRD conditions for coverage (70 FR 6200), we are not going to require that patients be physically removed during a fire drill. Fire drills may be conducted using simulated patients or empty wheelchairs. According to the LSC 2000, quarterly fire drills are not required. Instead, section 4.7.2 of the LSC—Drill Frequency states, ''Emergency egress and relocation drills, where required by chapters 11 through 42 or the authority having jurisdiction, shall be held with sufficient frequency to familiarize occupants with the drill procedure and to establish conduct of the drill as a matter of routine.''

3. Subpart C—Patient Care

a. Patients' Rights (Proposed § 494.70)

We proposed to update the existing condition for coverage at § 405.2138, ''Patients' rights,'' by replacing it with a new condition for coverage at § 494.70. We proposed that patients or their designated representatives be informed of their rights and responsibilities when beginning treatment in the facility. The essence of the provisions in existing § 405.2138 was retained in the new condition for coverage under § 494.70(a), ''Patients' rights.'' In addition to these provisions, new § 494.70(a)(6) states that patients must be informed about their right to have advance directives. Patients must also be informed of all modality choices, including home hemodialysis. The provision that patients must be informed of facility policies regarding patient care, including, but not limited to, isolation of patients, was proposed at § 494.70(a)(7). We also proposed changes to the existing grievance mechanism requirements at § 405.2138(e). The proposed rule would require facilities to inform patients of internal and external grievance processes, including how to contact the ESRD Network and State survey agency.

Standard (a) also proposed that patients be informed that they could file grievances personally, anonymously, or through a representative, and could do so without reprisal or denial of services. We also proposed a new standard at 494.70(b) to guarantee the patient's right to be informed regarding the facility's discharge, transfer, and discontinuation of services policies. This proposed standard also would have required facilities to provide a written notice to patients 30 days in advance of the facility terminating care, but would provide that in the case of immediate threats to the health and safety of others, an abbreviated discharge procedure could be allowed. We also proposed to require the facility to prominently display a copy of the patients' rights in the facility where patients could easily see and read it. We proposed that this posted information also include up-to-date State agency and ESRD Network telephone complaint numbers.

The Children's Health Act amended the Public Health Service Act by (among other things) adding a new section 591 (Pub. L. 106–310, section 3207; 42 U.S.C. 290ii); this section requires health care facilities to protect and promote the rights of residents to be free from restraint and seclusion imposed for purposes of discipline or convenience. The law applies to any ''public or private general hospital, nursing facility, intermediate care facility, or any other health care facility that receive support in any form from any program supported in whole or in part with funds appropriated to any Federal department or agency * * *.'' Section 591(d)(1) of the Public Health Service Act defines restraint as any mechanical or personal restriction that immobilizes or reduces the ability of an individual to move freely or a drug or medication that is used as a restraint to control behavior or restrict freedom of movement. Seclusion is defined as any behavior control technique involving locked isolation, not including a time out.

While we believe that section 591 of the Public Health Service Act applies to Medicare-participating dialysis facilities, this final rule does not address these specific restraint and seclusion provisions because these issues are being considered under a separate rulemaking. Therefore, the patient rights section does not contain any restraint or seclusion requirements at this time.

Comment: We received many public comments regarding the rights of patients. There was overall support for the condition as a whole, as well as many recommendations and suggestions.

Some commenters recommended that we mandate that facilities inform

patients of their rights at the start of care or within 30 days after the start of care. Others suggested that these rights be reviewed with the patient at least annually, or more frequently depending on patient need. One commenter suggested patient rights be reviewed during the first dialysis treatment and reviewed in detail by a social worker within the first month, while another suggested that a summary of patient rights would be sufficient. A number of commenters suggested the addition of language to mandate that facilities inform patients of facility policies, including discharge policies.

Response: Patients are entitled to be informed of their rights at the start of care, meaning within the first 3 treatments in the facility, which, we believe, will allow patients to exercise their rights and make choices regarding their care immediately. We are not prescribing the level of detail for a patient's rights review, nor which facility staff members must perform the review. The facility has flexibility in meeting the intent of this provision, so long as the facility sufficiently informs the patient so that he or she may exercise his or her rights early in dialysis care. The professionals at the dialysis facility should determine the most appropriate time for a more detailed review of patient's rights (including discharge policy information) according to individual patient's needs. Patients must also be informed of dialysis facility discharge policies as required at § 494.70(b)(1), and we expect all information would be provided at one time. We believe requiring a facility to provide patient's rights information within 3 treatments is reasonable, given that dialysis is normally performed 3 times per week for approximately 3 to 4 hours per session.

Comment: We received several comments regarding possible misinterpretations by State surveyors as to what is meant by patients being ''informed'' of facility policies.

Response: The word ''inform'' simply means to communicate knowledge. We have not dictated the mode of communication. Patient rights information may be presented to patients in writing, orally, in audiovisual form, etc. Since the means by which information is communicated to the patient is not specified, facilities and their staff have the necessary flexibility to comply within the intent of the condition. Our interpretive guidelines for surveyors will reflect the intent of the final rule.

Comment: We received several comments regarding discrimination and harassment. Some commenters specifically recommended that we add language that states patients have the right to be free from verbal, physical, sexual abuse, intimidation, and harassment.

Response: The ''Patients' rights'' condition specifies the patient's right to dignity and respect. Moreover, section 494.20 states that facilities and staff must comply with applicable Federal, State, and local laws, and these laws and protections apply to dialysis patients. Illegal acts must not be tolerated in dialysis facilities and should trigger notification of appropriate law enforcement officials. We have not expanded ''Patients' rights'' as suggested by the commenters; we believe sufficient safeguards, laws, and regulations are already in place.

Comment: Two commenters suggested additional language for the protection of patients' rights and dignity. The commenters explained that some patients are disconnected from a dialysis machine only after being made to sign a ''Leaving Against Medical Advice'' waiver of liability, for such activities as using the restroom, taking pain medications, or eating or drinking. The commenters suggested that the ''Patients' rights'' condition include protection for these patients whose rights and dignity are being violated.

Response: At § 494.70(a)(1) patients have the right to receive respect for their personal needs. The intent of this standard is that all facilities must respect patients and their individual characteristics or unique needs. For instance, facilities may want to develop policies for a variety of situations, such as patient restroom use during a dialysis session, to ensure that their patients' rights are protected. We do not expect that patient signatures on liability waivers are necessary or appropriate in most cases. When a patient needs to use the restroom, that time should not be deducted from the dialysis treatment session. Facilities should schedule patients in such a way so that patients are not forced to give up prescribed services for which Medicare provides payment. In addition, CMS considers facilities that fail to schedule patients appropriately and thus, force patients to give up prescribed services, to be a serious matter of program integrity.

Comment: Several commenters suggested that current subpart U regulatory language, requiring a facility to use translators where a significant number of patients exhibit language barriers, remain in the final rule. Two commenters suggested language be added to specify that a facility must make a clear, reasonable effort to provide information in a language the patient can understand and to document such provision in the patient's record. Two commenters suggested that facilities be required to provide information in the appropriate language and in a culturally sensitive manner. Additionally, several commenters suggested that a facility confirm that patients understand the information they receive.

Response: The intent of the proposed rule language was to provide the facility with flexibility in meeting the requirement that it provide information in a way the patient understands. If a facility needs to obtain the use of a translator service to provide information to a patient and respond to questions, then we expect the facility to obtain that service. The suggestion to add language that requires information to be provided in a culturally sensitive manner, as well as in the appropriate language, would be redundant, since this is required as part of § 494.70(a)(2). The information required to be provided under § 494.70 would include all the information patients need to understand their rights and participate in their care if they choose (see § 494.70(a)(5)).

Comment: One commenter suggested that specific language be added to state that a social worker should have the ability to assess a patient's psychological needs in a private environment.

Response: The intention of § 494.70(a)(3) and § 494.70(a)(4) is that all facilities must respect privacy and confidentiality for all patients; therefore social worker-patient interactions that require privacy should be conducted in private.

Comment: A number of commenters stated that patient participation can optimize care. One commenter suggested language to specify that patients and their family members participate in their care and training. Several other commenters suggested we state that patients have some obligation to take part in, and be accountable for their care, and that patients must be fully aware of and engaged in their course of treatment.

Response: The ''Patients' rights'' condition requires that patients or their representatives be informed about patient rights and responsibilities. Section 494.70(a)(5) states that patients have the right to participate in all aspects of care. It may be desirable that patients participate fully in their care; however, neither CMS nor a facility can demand full patient participation. Additionally, we cannot mandate the involvement of patient representatives in the care of patients. We do require that patients have the opportunity to

participate in their care. Patients have the right to accept or decline to participate.

Comment: Two commenters suggested that we add language to specify that a patient has the right to attend care planning meetings and that a patient also has the right to request a care conference that would include his or her care team members. One commenter stated that there was no regulatory language that provides that a patient has the right to be involved in care planning, and that the language only required the patient to be informed of care planning.

Response: Patients have the right to be involved in their care planning as part of the interdisciplinary team, which is defined at § 494.80 and § 494.90. Because patients have the right to be part of the interdisciplinary team, they have the opportunity to participate in all aspects of care, which includes, but is not limited to, care planning. The language in the final rule allows for flexibility in the way a facility demonstrates that a patient has had sufficient opportunity to participate as part of the team. Care plan meetings or conference calls that allow the patient to call in from home would allow the patient to participate. The dialysis facility must encourage patient participation in care planning.

Comment: Some commenters, including patients, suggested language be added to state that a patient has the right to refuse cannulation by specific nurses or patient care technicians (PCTs) if problems cannulating his or her access site have occurred with that staff member. Some patients have experienced situations causing them fear and/or discomfort due to cannulation by specific members of a facility's staff.

Response: Patients have the right to be informed of the right to refuse treatment, as required at § 494.70(a)(5). However, this final regulation includes new minimum qualifications for PCTs, who frequently cannulate patients during in-center hemodialysis sessions. Dialysis facilities will now be required to employ trained and certified patient care technicians. We have added ''proper cannulation techniques'' as part of the technician training program at § 494.140(e)(3)(iii). We would anticipate patients having less difficulty with cannulation due to the more stringent technician training requirements required for certification. Additionally, ''Fistula First'' is a nationwide initiative that promotes the adoption of recommended ''best practices,'' including cannulation methods, in dialysis facilities. Facilities are encouraged to implement these practices, including increased self-cannulation. The initiative encourages self-cannulation with the appropriate course of training, as part of an emphasis on broader patient involvement in care.

Comment: A number of comments reinforced the importance of advance directives. Many comments support the inclusion of providing advance directives information in the ''Patients' rights'' condition. A few comments requested that the proposed advance directives language be strengthened by adding discussion of ''end of life'' options. Another commenter suggested the intent of the regulation text could be clarified further by adding language to require that facilities provide an advance directive planning process. One commenter remarked that patients should not be required to have an advance directive on file. Additionally, a few comments suggested that patients be educated about advance directives rather than just informed.

Response: The large number of supportive comments regarding advance directives is appreciated. We believe that it is important to include this language in the final regulation for several reasons, not the least of which is that while ESRD treatment has prolonged life, the typical patient receiving dialysis treatment is often afflicted with multiple co-morbidities. We are not mandating that facilities discuss ''end of life'' options, requiring units to provide advance directives planning assistance, or requiring patients to complete advance directive documents. We are requiring in the final rule at § 494.70(a)(6) that facilities inform patients of their right to have advance directives and inform patients of the facility's policies regarding advance directives. While the actions suggested by commenters might assist in the planning process, we believe requirements such as these would extend beyond the scope of a facility's expertise and responsibility, as well as beyond the scope and intent of these regulations. Patients requiring assistance in advance directive preparation should look to the facilities' social workers for guidance, as social work professionals are trained to use their clinical judgment to evaluate, provide information and make referrals if necessary.

Comment: Several commenters suggested that we strengthen and clarify the advance directives language by adding specific requirements to the regulation text. One commenter suggested that patients be required to identify a preferred surrogate decision-maker, complete an advance directive and durable power of attorney, as well as indicate the amount of leeway for their chosen surrogates. Another commenter suggested that the social worker be required to inform, encourage, and assist in completion of advance directives.

Response: We appreciate the comments; however, we will not require specific professionals to be responsible for encouraging patients to complete advance directives. The dialysis facility staff must assess individual patient needs, and determine if there is a need for further clarification or discussion. They may suggest referral to a resource, lawyer, or other appropriate professionals if indicated. Some patients may desire to execute very detailed directions and advance directives while other patients may not. We are not specifying patient advance directive execution requirements in this final rule.

Comment: Many commenters suggested that we require a facility to honor an advance directive, including ''do-not-resuscitate'' orders. Two commenters suggested that the rule state that, if a facility could not honor the wishes of an advance directive, the facility would have to notify the patient and transfer patient to a facility that was able to honor those wishes.

Response: The ''Patients' rights'' section of the proposed rule would allow patients the right to be informed of their ability to execute an advance directive. In response to comments, we have added a provision stating that patients have the right to be informed of the facility's policy regarding advance directives. The advance directive language at § 494.70(a)(5) in the proposed rule has been revised and relocated. We have redesignated proposed § 494.70(a)(6) through § 494.70(a)(16) as § 494.70(a)(7) through § 494.70(a)(17) and have added a new § 494.70(a)(6) to require facilities to ensure that a patient is informed about his or her right to execute advance directives and the facility's policy regarding advance directives. We have also added language to the ''Medical records'' condition at § 494.170(b)(2) to require that facilities document in the patient's medical record whether or not an advance directive has been executed by the patient. The facility should address advance directives in their policies and procedures, which must be available to patients as required in the ''Patients' rights'' condition. We expect facilities to make patients aware of their policies regarding honoring properly executed advance directives. If a facility does not honor advance directives, we

expect it to make the patient aware of that policy. In addition, we believe that the facility should develop a protocol for patient transfer, if a facility does not intend to honor advance directives. Some patients will opt to be treated in a facility that will honor their advance directives.

Comment: One commenter suggested there is a need for national guidelines for advance directives specific to dialysis services.

Response: Advance directive guidelines developed by national organizations, such as the Renal Physicians Association (RPA) and the National Kidney Foundation (NKF) already exist. Although we will not require adherence to RPA and NKF advance directive guidelines, we encourage facilities to use these valuable resources.

Comment: Many commenters concurred that information on all modalities should be presented to all patients. One commenter remarked that family members should also be presented with information on all modalities. Another suggested we require facilities to inform patients about all modalities at least annually.

Response: The ''Patients' rights'' condition at § 494.70(a)(7) requires that the patient or his or her representative be informed of patient rights, including information about treatment modalities and settings. Patients must decide what is in their best interest and they should have the flexibility to include family members in their decisions regarding dialysis modalities as they see fit. Patients are periodically reassessed, as required under the condition for patient assessment at § 494.80(d). The patient's suitability for various dialysis modalities and/or transplantation are assessed by the interdisciplinary team, which may include the patient if desired, and reviewed with the patient each year. Consequently, we believe it would be redundant to add the suggested language under the ''Patients' rights'' condition, since the requirement already exists elsewhere.

Comment: One commenter suggested that modality options be broader to allow for new modalities, and that the facility offer an option for ''no treatment.''

Response: Individual patients always have the choice to not seek treatment. As indicated at proposed § 494.70(a)(5), patients have the right to refuse treatment. If an individual is a patient of an ESRD facility, then he or she has likely made the decision to treat his or her illness. However, the patient's medical condition may change in later months or years and there could be a time when the patient decides that dialysis treatment is no longer appropriate. Therefore, in response to this comment, we have modified our requirement so that a patient must be informed of the right to discontinue as well as refuse treatment.

Comment: One commenter suggested that the modality discussion include the offer of transplant information and home dialysis education.

Response: Transplant information and home dialysis education are addressed under the condition ''Patient plan of care.'' The standard for patient education and training at § 494.90(d) mandates that the plan of care include education and training in aspects of the dialysis experience, dialysis management and transplantation, among other things. Since transplant education for patients is captured as a standard level requirement, it would be redundant to include the language in the ''Patients' rights'' section.

Comment: One commenter suggested that all facilities be required to offer home dialysis.

Response: While it may be ideal for every dialysis facility to offer home dialysis, dialysis facilities have the flexibility to choose which modalities to offer. However, patients must be informed of all possible dialysis modalities, and where those modalities are offered. We have revised § 494.70(a)(7) to specify that facilities must provide resource information about those modalities not offered in their specific facilities. In addition, facilities must provide information about alternative scheduling options for working patients within and outside their own facility.

Comment: Many commenters suggested that facilities be required to provide information on where all modalities may be obtained, including home dialysis options. Some recommended that the regulation specify that alternate dialysis locations be located within 120 miles of the facility.

Response: As noted above, patients have the right to receive resource information for modalities not offered in their facilities. The facility may wish to create a resource information packet or provide patients with an existing list from Medicare's DFC Web site. This resource information may include giving the patient a handout, or the DFC Web site information. Doing any of these things would meet the requirement to provide the patient with resource information on where they may obtain alternate care options. Requiring a facility to identify dialysis options within a certain geographical limit would be a burden without benefit, as the suggested 120 mile radius would likely be too far for many patients. Those patients living in rural areas might be more accustomed to traveling longer distances for services than those residing in more urban areas and as such, we expect rural dialysis facilities would consider this and make referrals as appropriate.

Comment: A few commenters suggested that language be added to state that a patient has the right to perform self-care after being trained. Additionally, a number of comments suggested that we add specific language to include self-cannulation and self-care to the list of modalities at § 494.70(a)(7).

Response: Some of the comments received on this issue were vague, but we assume they generally refer to self-cannulation as an example of self-care that may be performed by the patient in the dialysis facility following training. Patients currently are allowed to self-cannulate upon receiving the proper training and demonstrating competency. The patient's right to participate in aspects of his or her care is addressed at § 494.70(a)(5), and as written, is flexible enough to include self-cannulation as well as other forms of in-center self-care and home dialysis.

Comment: Several commenters requested that language be added to require dialysis facilities to inform patients about their right to schedule treatments that can accommodate work and/or school schedules. Others suggested that we add language at proposed § 494.70(a)(7) to specify that patients have a right to have access to a work-friendly dialysis modality or schedule that accommodates work and/or school, and if a schedule cannot be accommodated within that facility, the facility must refer the patients to another facility that can meet the patients' needs. Additionally, another commenter remarked that CMS should not drop the existing requirement that a facility accommodate patients who work.

Response: We believe that facilities should inform patients about different modalities, and where to obtain them. This allows patients to make a choice about what type of dialysis treatment is most convenient for them. Working patients do have the option of home dialysis, which may be more attractive because of the more flexible treatment schedule. Facilities generally are willing to work with patients who have other medical appointments that may affect their dialysis schedule. Facilities with a full patient census may have limited ability to change the dialysis schedule but will try to switch dialysis session

appointments when other patients are agreeable. Dialysis patients who work or attend school should be encouraged to continue doing so and dialysis facilities should recommend the most appropriate modality and setting for dialysis. While we are not requiring a facility to provide every modality or schedule to accommodate patients' unique schedules, we are now requiring that facilities inform the patient where such accommodations may be obtained. We have added new language at § 494.70(a)(7), giving the patient the right to receive resource information about dialysis modalities not offered by that facility, including alternative scheduling options for working patients. Accommodations for working patients may include, for example, home hemodialysis, peritoneal dialysis, or extended facility hours.

Comment: One commenter objected to the proposal that facilities be required to fully inform all patients about isolation, stating that the regulation should ensure that patients have access to policies but not require all policies be provided to all patients.

Response: This requirement is not a new mandate, but has been retained from part 405, subpart U, the ESRD Conditions for Coverage. Open communication between the facility staff and the patient, as well as patient access to information, are both important for enhancing the patient's participation in his or her care; this requirement will remain in the final rule.

Comment: Two commenters recommended that the facility inform the patient about the health and safety risks involved in reusing dialyzers, provide accurate reuse data, provide the patient with treatment options other than reuse, and notify the patient that reuse is a patient choice. Another commenter stated that patients should have the right to decline reuse and receive single use dialyzers in a facility. One commenter questioned whether there should be a reuse consent form, while another asked how patient choice would be protected.

Response: Reuse is a safe practice when performed correctly. Reuse language at proposed § 494.50 was retained from existing regulation and now requires ESRD facilities reusing hemodialyzers to meet the new guidelines and standards adopted by AAMI. Additionally, section 1881(f)(7) of the Act directly addresses dialyzer reuse. Reuse is a care decision that is to be made between the patient and his or her physician. Patients also have the option to seek treatment in a facility that exclusively uses new dialyzers.

Comment: One commenter suggested deletion of the requirement that facilities inform patients of their own medical status. Another suggested that we add broader language in the regulation text, which would allow physicians, nephrologists, nurse practitioners or physician assistants to provide patients with their own medical information.

Response: Providing the patient with his or her medical information is an existing requirement and is found at § 405.2138(a)(3). The commenter provided no rationale for the deletion of this standard language and thus, the language has been retained. We have added the nurse practitioner, clinical nurse specialist and/or physician's assistant treating the patient for ESRD to the list of authorized personnel at § 494.70(a)(10), which now states that patients have the right to be informed by the physician, nurse practitioner, clinical nurse specialist, or physician's assistant treating the patient for ESRD of his or her own medical status as documented in his or her medical record, unless the medical record contains a documented contraindication. Individual facilities may determine policies and procedures, in accordance with the State Boards of Practice, regarding the practice of advance practice nurses and PAs in the facility.

Comment: A commenter objected to the requirement that facilities fully inform patients about charges not covered by Medicare. Another commenter suggested that trained and informed staff should explain non-covered charges.

Response: The intent of the existing subpart U language at § 405.2138(a)(2) was carried over into the proposed language at § 494.70(a)(10), now redesignated as § 494.70(a)(11) in this final rule, which requires facilities to tell patients what services are available in the facility, and inform them of charges for services not covered under Medicare. Additionally, if a facility plans to bill a patient for items and/or services which are usually covered by Medicare, but which may not be considered reasonable and necessary for a particular situation (according to section 1862 of the Act), an advanced beneficiary notice must be given pursuant to section 1879 of the Act.

Comment: A few commenters suggested that regulatory language require that patients be given access to social work and psychological services, psychosocial counseling, and nutritional counseling. Some commenters suggested that language be added to the ''Patients' rights'' condition that specifies that patients would have access to, and receive counseling from, a qualified social worker and a dietitian. Some commenters recommended that patients have the right to receive a referral for mental health services, physical or occupational therapy and/or vocational rehabilitation, as needed. Another commenter suggested the addition of language that would stipulate that patients would have the right to receive necessary services, as authorized by their insurance plan.

Response: The ''Patient assessment'' and the ''Patient plan of care'' conditions for coverage (§ 494.80 and § 494.90, respectively), require input by an interdisciplinary team. This team of professionals includes, at minimum, a registered nurse, physician, social worker and dietitian. The team is responsible for properly assessing and treating the patient, which would include identifying additional treatment needs, such as psychosocial counseling, etc. Therefore, we believe that expanding the language at § 494.70(a)(12) to include social work and psychological services, psychosocial counseling and nutritional counseling, as suggested by these public comments, would be redundant under the final rule. Under the final rule, following the comprehensive assessment required at § 494.80, a plan of care for each patient must be implemented, which must include care and services deemed necessary by the interdisciplinary team. The requirements for the provision of services under the ''Plan of care'' condition at § 494.90, do include nutritional and social services, such as psychosocial and nutritional counseling. Furthermore, the ''Patients' rights'' condition at § 494.70(a)(11) requires facilities to inform patients of their right to be informed of services available in the facility and the charges for services not covered under Medicare. At § 494.70(a)(12), patients have the right to receive the necessary services outlined in the patient plan of care. Therefore, we believe the concerns of commenters are adequately addressed at § 494.70, § 494.80 and § 494.90.

Comment: Some commenters suggested adding language to specify that facilities must inform patients of their responsibilities, including punctuality, following dietary/fluid restrictions, following treatment regimens, exhibiting appropriate personal behavior, informing the team of scheduling problems, and issues in filling prescriptions. Other commenters stated that facilities should inform patients that the patients have a responsibility to listen and ask

questions when they do not fully understand their rights or responsibilities. Another commenter stated that CMS should clarify patient responsibilities in the standard for patient rights.

Response: Patient responsibilities are addressed at § 494.70(a)(13). We have retained the existing requirement found at § 405.2138(a)(1), which states that patients must be informed of the rules and expectations of the facility regarding patient conduct and responsibilities. The proposed language has been retained in the final rule. It is essential to recognize that positive patient behavior may be encouraged but cannot be regulated.

Comment: One commenter suggested that we add regulatory language to clarify that there needs to be a balance between providers' duties and patient rights.

Response: Proposed section 494.70(a)(12), now § 494.70(a)(13) of this final rule, requires that the dialysis facility inform patients of their rights, including rules and expectations regarding patient conduct and responsibilities. Moreover, facilities must protect and provide for the exercise of patient rights. Informing patients of their responsibilities promotes and supports patient involvement in their care. We will not attempt to address unique individual situations in this regulation, but we expect that while facility staff informs patients of their rights and responsibilities, we also expect patients to try to adhere to facility rules and guidance from facility staff, which would help patients maintain optimal health while receiving facility services.

Comment: We received many comments in support of more patient-protection requirements regarding facility internal grievance processes. Commenters supported the proposed requirement for facilities to post information on how to file a grievance. Some commenters specifically supported requiring the posting of Network and State Agency phone numbers and/or mailing addresses.

Response: We agree that it would be in the best interest of patients that Network and State Agency mailing addresses and phone numbers be posted. Posting the additional patient rights information will not be a significant burden upon facilities. We have revised § 494.70(c) to include ''mailing addresses.''

Comment: One commenter suggested that CMS establish a separate definition of ''grievance.'' Another remarked that the term ''grievance'' should always be used carefully and with full understanding of its seriousness. One commenter suggested that facilities be required to review the grievance process with patients on a regular basis. One commenter suggested adding language requiring a facility to ''attempt to resolve'' grievances.

Response: We appreciate the comment, as well as the suggestions regarding the grievance procedure. We believe the term ''grievance'' is a commonly understood term and we did not receive substantial public comment indicating this to be a particularly difficult concept to understand within the renal community. We disagree with the commenter and have not added a definition for the term ''grievance'' in the ''Patients' rights'' condition at § 494.70. Whether patients use the term ''complaint'' or ''grievance,'' they have the right to be informed of and use established internal and external grievance procedures. The proposed language was added to inform patients about external mechanisms for filing a grievance and how to contact the ESRD Network and State survey agency; the language strengthens the existing requirements. We believe that it is imperative that all patients be made aware of every grievance option available to them. Mandating regular review of patient rights information with patients, we believe, would be an unnecessary burden since patient rights information must be prominently displayed within the dialysis facility, as required at § 494.70(c), and is thus available for review at any time. We expect that the internal facility grievance procedures would aim to resolve patient grievances. The provision at § 494.180(e) requires facility-level internal grievance processes.

Comment: One commenter sought clarification of the phrase ''appropriateness of discharge.'' Another commenter suggested that the final rule clarify what we meant by stating that we would ''hold the facility responsible'' for ensuring that patients were notified about their rights.

Response: The phrase ''appropriateness of discharge'' did not appear in the proposed rule text; however, clarification may be found in the ''Governance'' condition at § 494.180, which does address the discharge procedure. This section specifies the acceptable circumstances for an involuntary discharge or transfer of a patient, as well as the required actions that must be completed by the interdisciplinary team prior to ceasing treatment within the facility. Regarding our intentions regarding the facility's involuntary discharge responsibilities at § 494.180(f), facilities are required to inform patients of their rights and protect patients' rights; in the event a facility fails to do so, the facility will be cited as being out of compliance during a survey. In addition to the provision at § 494.180(f), patients also have the ''right to be informed of the facility's policies for transfer, routine or involuntary discharge, and discontinuation of services to patients'' at § 494.70(b).

Comment: Some commenters recommended the addition of language that would require facilities to provide information on topical analgesics for needle pain.

Response: Facilities have the flexibility to inform patients about topical analgesics. We do not believe this should be a regulatory requirement. We are not adopting this recommendation.

Comment: A commenter remarked on the issue of disruptive and challenging dialysis patients and indicated that there is existing case law regarding this topic, illustrating the inability of the law to assist the abandoned patient who manifests extreme non-compliance. The commenter specifically cited *Payton* v. *Weaver,* 131 Cal. App. 3d 38, 182 Cal. Rptr. 225 (1982), and *Brown* v. *Bower,* No. J86–0759(B) (S.D. Miss., Dec. 21, 1987). Another commenter suggested the addition of language to specify that patients have a right to receive counseling and support from the team in order to resolve behavioral issues and be informed of appropriate/inappropriate behaviors, prior to being discharged from a dialysis facility. There were a large number of comments regarding discharge policies within the dialysis facility. Some comments supported a 30-day notice for involuntary discharge. Several other comments supported the proposed involuntary discharge guidelines regarding an immediate threat. Many commenters suggested the addition of language to specify that patients could not be involuntarily discharged for noncompliant behaviors/non-adherence to medical regimens. A few comments supported the waiver of discharge policies and procedures in the face of an ''immediate threat.''

Response: We appreciate the comments regarding involuntary discharge. While we appreciate the comment regarding *Payton* v. *Weaver* and *Brown* v. *Bower,* the cases cited do not appear to be applicable to this rulemaking. Patients are to be reassessed by the interdisciplinary team, including a Master's degree social worker (MSW) at least monthly when a patient exhibits significant changes in psychosocial

needs (as required at § 494.80(d)(2)(iii)), manifested by, for example, issues such as disruptive behavior, that could result in discharge. In § 494.180(f), we are requiring facilities to have discharge policies and to manage involuntary discharge issues according to facility protocols. Language at § 494.180(f)(4)(i) through § 494.180(f)(4)(v) responds to the ''disruptive'' or ''challenging'' patient issue. We have also added language to § 494.70(b)(1) in response to comments, to clarify that patients must be informed of routine as well as involuntary discharge policies. As stated in the proposed rule preamble, we do not expect that a patient should be involuntarily discharged from a dialysis facility merely for failure to follow the instructions of a facility staff member. However, we recognize it may be necessary to discharge a disruptive patient in order to protect the rights and safety of other patients and staff in the facility. If, for instance, a patient physically harms or threatens other patients and/or staff, brings weapons or illegal drugs into a facility, or verbally abuses and disrupts the facility to a degree that the facility is unable to operate effectively, then the 30-day discharge notice policy could be abbreviated pursuant to § 494.180(f)(5). This issue is further discussed later in this preamble under the ''Governance'' condition.

Comment: One commenter noted that some facilities already have policies in place regarding discharge and transfer policies as well as policies regarding patient conduct, and questioned whether federal requirements were needed.

Response: We are aware that some facilities already have policies in place regarding discharge and transfer of patients. Many of these facilities have established protocols regarding how staff must deal with patient conduct. It is not our intent to create more prescriptive requirements in this area, but to ensure that all dialysis facilities review any established documentation and policies to make certain they meet the minimum discharge and transfer requirements set forth at § 494.180(f).

Comment: Two commenters recommended that we delete the phrase ''reducing or terminating ongoing care.'' The concern was that the phrase was too indefinite.

Response: We agree that the wording in the proposed rule was unclear. Therefore we have modified § 494.70(b)(2) to require that patients receive written notice 30 days in advance of an involuntary discharge following the procedures described in § 494.180(f)(4)(i).

Comment: One commenter recommended that we require posted patient rights to be written in English at a 7th to 9th grade level and translated into a patient's native language if possible. Many other comments suggested that we require facilities to have an ''alternate method'' to inform patients who cannot read posted information.

Response: The concerns raised in these comments have already been addressed at § 494.70(a)(2). The ''Patients' rights'' condition requires that all patients receive information in a way they can understand. Facilities have the flexibility to provide information to patients in the most appropriate manner based upon patient needs. The qualified professionals at the facility are capable of evaluating an individual patient's level of understanding and making a determination regarding the needs of that patient. We have retained the proposed language.

Comment: One commenter suggested that the criteria for transplantation be posted at the dialysis facility along with a copy of the patient rights, which we proposed at 494.70(c).

Response: Dialysis facilities have the flexibility to post transplant criteria within the facility. At § 494.70(a)(7), it is required that patients be informed about transplantation as a modality. Additionally, the ''Plan of care'' condition at § 494.90(d) of this final rule requires that patients and caregivers be provided with education and training on several topics, including transplantation. These requirements will provide patients and their caregivers with increased awareness of transplantation.

Comment: A commenter suggested that we add language that would specifically state that patients have the right to know the identity of their facility caregivers and the nature of their credentials. Another commenter suggested that facility staff be required to wear nametags.

Response: The issue of staff nametags should be addressed in facility-level policies and procedures. While it is desirable for staff to wear nametags, we would like to allow flexibility within this health and safety regulation. We would expect that facility staff introduce themselves; however, we do not believe that it is necessary or appropriate to add this prescriptive requirement to this final rule.

Comment: One commenter recommended that CMS use an ombudsman to build relationships with ESRD patients and their families.

Response: Section 923 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (Pub.L. 108–173)(MMA), mandated the creation of the Medicare Beneficiary Ombudsman in section 1808(c) of the Act, to ensure that people with Medicare get the information and help they need to understand their Medicare options and to apply their rights and protections. A Medicare Beneficiary Ombudsman Open Door Forum has been established to provide an opportunity for beneficiaries, their caregivers and advocates, to publicly interact with the Medicare Beneficiary Ombudsman to discuss issues and concerns regarding ways to improve the systems and processes within the Medicare program. Information on the Office of the Medicare Ombudsman may be found at *http://www.cms.hhs.gov/center/ombudsman.asp*.

Comment: One commenter suggested that the language in the final rule include some mention of senile dementia and how it relates to consent forms.

Response: Dialysis facilities employ professionals who must assess whether a patient is competent to make medical decisions and assess patients' mental capacities in general. This issue is present across provider settings and we do not believe it is appropriate to implement a new provision of this nature within these conditions for coverage. Facilities may wish to address such issues and concerns in their own policies.

b. Patient Assessment (Proposed § 494.80)

We proposed to add a ''Patient assessment'' condition for coverage at § 494.80 that would make the ESRD facility, through the patient's interdisciplinary team, responsible for providing each patient with an individualized and comprehensive assessment of his or her needs. This condition would define the interdisciplinary team to include, at minimum, the patient (or patient designee), a registered nurse, a physician, a qualified social worker, and a registered dietitian. The proposed rule would expand the existing requirements to specify the criteria that a facility must include in a comprehensive patient assessment. We believe that these criteria would be necessary in order to develop a specialized care plan that is based upon the nature of the patient's illness, the treatment prescribed, and patient needs. The frequency of patient assessment was also addressed in the proposed rule. We proposed that the facility conduct an initial

comprehensive assessment within 20 calendar days of the first treatment and that the facility conduct a follow up comprehensive assessment within 3 months after the completion of the initial assessment. We also proposed that the facility assess the adequacy of the treatment prescription at least monthly for hemodialysis and at least every 4 months for peritoneal dialysis. Finally, we proposed patient reassessment timeframes for both stable and unstable patients. We proposed that the facility perform comprehensive assessments at least annually when the patient is stable; if unstable, the facility must reassess monthly. In addition, the proposed rule also added criteria to specify which patients would be considered to be unstable.

We received more than 100 comments regarding the ''Patient assessment'' condition at § 494.80. Many commenters supported the condition as proposed, while others supported the condition with minor revisions.

Comment: A few commenters recommended we subsume standards (b), (c) and (d) of proposed § 494.80 ''Patient assessment'' condition into the ''Patient plan of care'' condition at § 494.90 and delete the assessment criteria at § 494.80(a). Some commenters opposed the assessment criteria at standard (a), stating that it was unnecessary to require assessment criteria because assessments using such criteria are already being performed in their facilities.

Response: We appreciate the support for § 494.80 ''Patient assessment.'' We purposely linked the ''Patient assessment'' and ''Patient plan of care'' requirements, as evidenced by the inclusion of both under subpart C ''Patient care.'' The ''Patient assessment'' condition provides a set of criteria for the evaluation of all ESRD patients. The condition promotes an interdisciplinary approach to evaluating and treating patients in order to achieve better outcomes. Measuring patient outcomes of care is our goal, and outcome measures are inherently linked to patient assessment tools. It is possible that these dialysis patient assessment criteria will lead to the development of a standardized assessment tool, which we hope that facilities would use in the future to meet QAPI requirements. We expect that quality-oriented facilities already are performing comprehensive patient assessments that meet these new conditions.

We are retaining the proposed condition for coverage in the final rule. A large number of commenters agreed that a comprehensive patient assessment for each patient is critical to developing an appropriate plan of care. The assessment criteria required at § 494.80(a) are necessary to ensure consistent assessments for all patients, ensuring that all important assessment areas are addressed for every patient. The comprehensive assessment is the tool used to develop a plan of care based upon patient needs. In addition, the comprehensive assessment criteria promote less fragmented care and will assist the facility's QAPI program as a clinical data source.

Comment: Two commenters suggested CMS mandate that a physician or an RN conduct the patient assessment. Other commenters suggested the final rule allow nurse practitioners and physician's assistants to conduct the physician portion of the assessment.

Response: The interdisciplinary team must include a physician and a registered nurse, and these individuals are responsible, along with other team members identified at § 494.80, for providing each patient with an individualized and comprehensive assessment. This final rule retains the proposed requirement at § 494.80 regarding the composition of the interdisciplinary team. We expect every patient to be assessed by the interdisciplinary team physician or ''physician extender'' (that is, a nurse practitioner, clinical nurse specialist, or a physician assistant (PA)), if a state practice act allows such physician extenders to conduct the physician portion of the patient assessment. Although a physician extender may conduct an assessment in some states, the physician providing ESRD care must participate in the assessment by reviewing and approving the assessment.

Comment: A few commenters recommended the addition of the term ''qualified,'' when referring to the social worker, and the term ''registered,'' when referring to the dietitian, who are members of the interdisciplinary team as required in the first paragraph at § 494.80.

Response: The dietitian and social worker specified under the ''Patient assessment'' and ''Patient plan of care'' conditions must possess the professional qualifications set forth at § 494.140(c) and § 494.140(d), respectively. We do not agree with the commenters that further clarification is necessary regarding the qualifications of the interdisciplinary team members. However, to further clarify the dietitian and social worker duties required in the ''Patient assessment'' condition, we have modified § 494.80(a)(6) to require that the assessment include evaluation of nutritional status by a dietitian, and modified § 494.80(a)(7) to require the assessment to include evaluation of psychosocial needs by a social worker.

Comment: Two commenters suggested that we specify in the final rule that the interdisciplinary team's nephrologist must be the facility medical director or treating nephrologist. The commenters were concerned that the proposed phrase at § 494.80, which would require ''a nephrologist or the physician treating the patient for ESRD'' to be a member of the interdisciplinary team was unclear. Commenters suggested that this phrase could mean that any nephrologist, not necessarily a nephrologist treating the patient, could participate on the interdisciplinary team.

Response: Because the public may interpret the proposed language to mean that any nephrologist may participate on the interdisciplinary team, as opposed to the patient's treating nephrologist, we have modified the introductory paragraph at § 494.80 to include ''the physician treating the patient'' and removed our reference to the nephrologists, since the term ''physician'' includes nephrologists.

Comment: A few commenters suggested clarification regarding the patient participation on the interdisciplinary team. The suggested modification was ''the patient or the patient's designee (if the patient chooses)'' in order to clarify that the patient not only has the choice to participate, but also has the choice to have a designee participate as part of the interdisciplinary team. Another commenter suggested that facilities be required to document patient participation and the reasons patients do not participate on the interdisciplinary team.

Response: Patients have the right to be informed about and participate, if desired, in all aspects of care, as required in the ''Patients' Rights'' condition at § 494.70(a)(5). The ''Patient assessment'' condition at § 494.80 states that the interdisciplinary team includes the patient or a patient designee if chosen by the patient. Patients must have the option to participate in the facility's interdisciplinary team. Conversely, the patient has the right not to participate or to designate another individual to participate on his or her behalf on the interdisciplinary team. Although patient participation on the interdisciplinary team is important and should be encouraged, we do not want to mandate patient participation. We have modified the provision at § 494.80, which proposed to require that the facility provide every patient the opportunity to participate with the

interdisciplinary team. The modified language in the first paragraph of § 494.80 clarifies that the patient may choose whether he or she wants to identify a designee to participate in the interdisciplinary team.

We note that the facility must demonstrate that the patient has been provided the opportunity to participate in the interdisciplinary team. The facility may develop policies and procedures regarding standard documentation of patient participation and may document the reasons for patient non-participation. If, for instance, a facility has a low level of patient participation in the interdisciplinary team, the facility may choose to document and monitor reasons for patient non-participation as part of a quality assessment and performance improvement plan.

Comment: We received two comments that suggested that the final rule specify that individual assessments be conducted by all members of the interdisciplinary team. Additionally, the commenters requested that the final rule clarify that face-to-face meetings between the patient and the interdisciplinary team would be required. Another commenter recommended that we eliminate team assessment altogether and only require use of individual assessments by each discipline.

Response: The entire interdisciplinary team is responsible for ensuring that each patient is individually assessed and his or her needs identified, as required at § 494.80. We agree that in order to conduct a clinical assessment, the patient must have face-to-face contact with the other interdisciplinary team members. We expect all professional members of the interdisciplinary team to complete the portions of the comprehensive patient assessment that are within their respective scopes of practice. It is not necessary for each professional team member to individually complete the entire comprehensive assessment and thereby duplicate efforts. Professional interdisciplinary team members might choose to conduct one-on-one interviews with patients to complete the assessments. The team may also opt to set up team meetings, which would include the patient, in order to collect the appropriate assessment information. We expect facilities to determine the best way to manage this process, and create policies and procedures to accurately and effectively collect patient assessment information. The assessment information is used to develop the patient's treatment plan and expectations for care, and thus it is critical for the members of the interdisciplinary team to participate.

Comment: One commenter recommended that the final rule be modified to include advance directive planning as part of the patient assessment at § 494.80(a).

Response: Patients are entitled to be informed about their right to have an advance directive, as required at § 494.70(a)(6). Additionally, if a patient has an advance directive, this information must be recorded in his or her medical record, as required at § 494.170(b)(2). In some cases, it may be appropriate for a patient to be assessed for advance directives and facilities should use their professional judgment to evaluate and determine if such an assessment is appropriate. We are not requiring advance directive planning as part of the patient assessment, but are allowing facilities the flexibility to include it in the patient assessment when deemed appropriate.

Comment: We received a comment recommending that language be added to the final rule to ''allow the Secretary to modify or update these 'elements' with new technology and knowledge.''

Response: We believe the commenter is referring to the assessment criteria found at § 494.80(a), and we also believe the commenter would like to see language that allows for updates without rulemaking. We have not modified this final rule to allow for automatic updates for assessment criteria because the Administrative Procedure Act (APA) requires rulemaking with public notice and comment if and when new regulatory requirements are proposed.

Comment: One commenter suggested the final rule at § 494.80(a)(1) be modified specifically to include chest auscultation, visual observance, gastrointestinal evaluation, access site evaluation, and patient symptoms between treatments as part of the evaluation of current health status and medical condition.

Response: Professional standards of practice require clinicians to perform appropriate clinical assessments and use their clinical judgment when caring for patients. The expectation is that these standards of practice will be employed by all clinicians. We have retained the proposed language at § 494.80(a)(1). Evaluation of current health status and medical condition, including co-morbid conditions, would include the techniques, specific evaluations and symptoms recommended by the commenter.

Comment: A few commenters recommended that the final rule include an assessment criterion for cardiovascular disease.

Response: Dialysis patients are at risk for cardiovascular disease, which is affected not only by individual risk factors, but also by renal bone disease, blood pressure and fluid management. These patients may have a number of co-morbid conditions and this final rule requires the interdisciplinary team to assess the patient's medical history, including any co-morbid conditions (§ 494.80(a)(1)). Since cardiovascular disease is a co-morbid condition we expect it would be assessed as appropriate for individual patients in order to comply with § 494.80(a)(1).

Comment: It was recommended by one commenter that ''intradialytic symptom frequency, causes, prevention, and tracking symptoms'' be added to this condition as new assessment criteria. Another commenter suggested that dialysis adequacy be specifically referenced in the assessment criteria.

Response: Patients must be assessed for the appropriateness of the dialysis prescription, blood pressure and fluid management at § 494.80(a)(2), which encompasses intradialytic symptoms and issues, such as cramping, as well as dialysis adequacy.

Comment: Many commenters suggested minor edits to the ''Patient assessment'' condition, but concurred with the condition as a whole and agreed with our belief that systematic patient assessment is essential to improving quality of care and patient outcomes. We received a comment from the Safe and Timely Immunization Coalition (STIC), which is facilitated by the Southeastern Kidney Council, Inc. (ESRD Network 6). This comment presented the benefits of immunization including prevention of illness and hospitalizations. The commenter stated that immunization is one of the most cost effective strategies to prevent unnecessary hospitalizations and deaths, and that immunization is currently a Government Performance and Results Act of 1993 (Pub. L. 103–62 (1993)) and Healthy People 2010 goal. According to the commenter, the current rates of immunizations for influenza, pneumococcal and hepatitis B immunizations nationwide are lower than 50 percent. STIC recommended adding influenza, pneumococcal, and hepatitis requirements to this final rule. The suggested requirements are consistent with the immunization requirements for long-term care facilities. The recommended provisions address: (1) The offering of influenza, pneumococcal and hepatitis B immunizations to the patient (or legal representative) at appropriate times and

frequencies; (2) a process for patient immunization refusal; and (3) documentation parameters.

Response: We agree with commenters that the systematic approach to patient assessment is essential for improving quality of care and patient outcomes.

We appreciate the work of STIC and their recommendations for specific immunization requirements. In order to promote the immunization initiative and the ongoing cooperative effort between CMS and the dialysis industry to screen patients for their immunization needs, we have modified the final rule at § 494.80(a)(3) to include immunization history as part of the assessment criteria. We believe it is reasonable for facilities to include immunization history as part of the comprehensive assessment at least annually so that immunization needs may be identified. However, we have not added the extensive provisions recommended by the commenter. If we determine that further immunization requirements are warranted, we will undertake rulemaking at a future date and provide the public the opportunity to comment on any new proposed provisions.

Comment: One commenter recommended that erythropoietin not be specifically referenced in the ''Patient assessment'' condition in the final rule, so as not to limit the use of other erythropoiesis-stimulating drugs.

Response: We agree with the commenter and in order to allow flexibility for other medications that stimulate erythropoietin, as well as new developments in the future, we have modified the final rule to eliminate specific references to erythropoietin, and instead will use the term erythropoiesis-stimulating agent(s).'' The new language at § 494.80(a)(4) reads: ''including administration of erythropoiesis-stimulating agent(s).''

Comment: We received several comments suggesting that bone disease be retained and added to the assessment criteria in the final rule.

Response: The proposed rule included bone disease as part of the assessment criteria. The final rule will retain the language at § 494.80(a)(5), which reads: ''Evaluation of factors associated with renal bone disease.''

Comment: We received several comments regarding the evaluation of nutritional status, which is required as part of the comprehensive patient assessment. Two commenters suggested we modify the final rule to add more specificity regarding nutritional status, suggesting the use of K/DOQI guidelines, to insure uniformity in assessment. One commenter suggested that serum albumin not be used as a sole indicator and another commenter suggested specific nutritional parameters for growth assessment for pediatric patients be added to the final rule.

Response: The K/DOQI guidelines are clinical practice guidelines developed by the NKF via a technical expert workgroup and consensus process (*http://www.kidney.org/PROFESSIONALS/kdoqi/guidelines.cfm*). In order to allow for flexibility and professional clinical judgment we are not adding specific criteria to the evaluation of nutritional status requirement in this final rule at § 494.80(a)(6). We discuss ''nutrition'' and nutritional indicators under the ''Patient plan of care'' (§ 494.90(a)(2)) condition discussion in the preamble below.

Comment: We received many comments suggesting revisions to the final rule regarding the evaluation of psychosocial needs. Many commenters recommended the addition of a standardized survey tool to be used in assessing the psychosocial status of dialysis patients, namely the SF–36 or another instrument advocated by National Kidney Foundation Life Options subgroup. One commenter suggested the final rule be modified so that § 494.80(a)(7) would specifically require ''evaluation of psychosocial needs, functioning and well-being using the SF–36 or other standardized survey.'' Two commenters suggested the final rule specify a list of psychosocial needs to be assessed, such as mood changes and coping with chronic illness. We received suggestions regarding additional forms that could be used for assessing psychosocial status. One commenter suggested that ''depression'' be added as a separate assessment criterion.

Response: In response to concern regarding the psychosocial status of dialysis patients, we have modified the ''Patient assessment'' condition and strengthened the ''Patient plan of care'' condition. At § 494.80(a)(7) we have added the phrase ''by a social worker'' to ensure that patients are being assessed by an MSW, as defined at § 494.140(d). Additionally, we are requiring at § 494.90(a)(6) that a standardized tool, chosen by the MSW, be used to monitor patient status, and that counseling be provided and referrals be made as appropriate. There is further discussion of the standardized tool under the ''Patient plan of care'' discussion below.

Comment: One commenter suggested that all patients be encouraged to first consider home dialysis options when evaluating modality and setting.

Response: We have emphasized increasing patient awareness of home dialysis options in this final rule. In § 494.70 we require that the patient has the right to be informed about all treatment modalities and settings, including home dialysis. We expect facilities to encourage patients to consider home dialysis if it is a suitable choice. In addition, we encourage the use of home dialysis under the ''Patient plan of care'' condition at § 494.90(a)(7)(i).

Comment: A commenter suggested the comprehensive assessment include an evaluation of self-care activities the patient performs. Another commenter remarked that the evaluation of a patient's potential for self-cannulation should be part of the assessment, and that documentation in the patient record should be required if the patient chooses not to participate. One commenter made a general observation that patients are not treated as adults in the facility.

Response: All patients are to be encouraged to participate in their own care, as ability and interest allows. Some patients may be able to self-cannulate, while others may not. Some may be able to weigh themselves or they may be charged with holding their access site to stop bleeding after completion of a course of dialysis. Regardless of the patient's level of participation, an evaluation of self-care activities is encompassed within the comprehensive assessment requirement at § 494.80(a)(9), which requires ''Evaluation of the patient's abilities, interests, preferences, and goals, including the desired level of participation in the dialysis care process; the preferred modality (hemodialysis or peritoneal dialysis) and setting (for example, home dialysis), and the patient expectations for care outcomes.''

Comment: We received many comments regarding the responsibility and basis for transplantation referral of dialysis patients. Some commenters remarked that ESRD facilities should not be responsible for referring patients for transplantation. Commenters explained that often dialysis units must cooperate with multiple transplantation centers that may have varied criteria and some transplantation centers do not have any criteria available on which a dialysis facility could base a referral. Another commenter suggested that referral for transplantation is the nephrologist's and patient's responsibility.

Response: The part 405, subpart U ESRD conditions for coverage required facilities to evaluate patients for transplantation referral as part of the long-term care program planning process. This final rule does not require transplantation referral as an activity separate from the short-term care plan, but rather, it is now encompassed within the plan of care. Referrals will continue to be a facility-level responsibility. We recognize the role of the physician as the leader of the interdisciplinary team; however, these regulations apply to the facility, and the interdisciplinary team is responsible for patient referral for transplant.

It is important for dialysis facilities and transplantation centers to make a concerted effort to communicate and cooperate. Two-way communication is required not only in this final rule, but also within the recently published Medicare Transplant Center conditions of participation. The March 30, 2007 transplant center final rule (''Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants'' (72 FR 15276)) requires kidney transplant centers to make transplant referral criteria available to any requesting dialysis center (see § 482.90(a)(4)). The purpose of using transplant center criteria is to remove and reduce the chances of referral bias and transplant referral disparities.

Comment: One commenter suggested that the final rule require a written agreement between transplant centers and dialysis facilities and that such agreement contain the transplant center criteria for patient referral.

Response: If a dialysis facility finds it useful to have a written agreement with the transplant center regarding communication and responsibilities of each entity, as well as transplant criteria, the dialysis facility has the flexibility to do so, but we do not believe we have sufficient cause to require such an agreement of all facilities.

Comment: We received many comments regarding the proposed requirement that the assessment include an evaluation of patient physical activity level and rehabilitation status (§ 494.80(a)(12) and § 494.80(a)(13)). Some commenters agreed with the proposed assessment criteria here, while others suggested modifications to the final rule. Commenters remarked that the interdisciplinary team members are not qualified or trained to assess a patient's physical activity level or rehabilitation status. One commenter suggested we modify the final rule to specify evaluation of developmental progress and educational needs as part of the rehabilitative assessment for pediatric patients.

Response: We agree with commenters that the proposed language at § 494.80(a)(13), which would require the facility to evaluate the vocational and physical rehabilitation status and potential of patients, is beyond the scope of a facility's responsibilities. The professionals who are part of the interdisciplinary team do not have complete knowledge and training necessary to accurately and fully assess physical activity level or physical rehabilitation status and potential. Therefore, we have modified the final rule at § 494.80(a)(13) to require the interdisciplinary team to evaluate the patient for referral to vocational and physical rehabilitation services. Facilities are expected to evaluate whether the patient should be referred for services as appropriate, not perform a complete physical therapy or rehabilitation assessment in the facility. Evaluation and referral of developmental progress and educational needs may be appropriate for some patients; however, the final rule will not be modified to require that these needs be evaluated for all patients. If, during the assessment process, either of these issues is identified by the interdisciplinary team, we expect the patient will be referred to the appropriate professional for further evaluation.

Comment: One commenter suggested that the final rule require the assessment elements laid out at § 494.80(a)(11) through § 494.80(a)(13) (support systems, physical activity level, and rehabilitation services) be completed by a social worker using a standardized assessment instrument that measures physical, social, and emotional status.

Response: Facilities have the flexibility to designate staff with the appropriate expertise to complete the comprehensive assessment. The social worker may possess the greatest expertise related to these areas; however, another team member might perform the physical activity level assessment. At § 494.80(a)(7), a social worker is required to assess the psychosocial needs of patients, and § 494.90(a)(6) of the final rule requires the plan of care to address psychosocial status using a standardized mental and physical assessment tool, chosen by the qualified social worker. As discussed previously, we are not requiring facilities to use any specific assessment tool.

Comment: A few commenters sought clarification on the meaning of the phrase ''new patient'' at proposed § 494.80(b), ''Frequency of assessment for new patients.'' The commenters asked whether ''new patient'' meant a patient new to dialysis or a patient new to a particular dialysis unit. Another commenter asked if ''new patient'' referred to a patient receiving his or her first treatment in an outpatient dialysis unit.

Response: In order to clarify the meaning of ''new patient,'' we have modified the title of § 494.80(b), so that it now reads: ''Frequency of assessment for patients admitted to the dialysis facility.'' We intend for all dialysis patients new to any particular outpatient dialysis facility be categorized as ''new patients'' and have a comprehensive assessment within the specified 30-day timeframe even if they are transferring from another dialysis facility. This means a comprehensive assessment must be done on all transfer patients, as well as those new to dialysis, within the first 30 days.

Comment: We received more than 50 comments regarding the frequency of assessment and the timeframe for completion of patient assessments. A few commenters agreed with the proposed timeframe for completing the patient assessment; however, the majority of commenters were concerned that the 20-day proposed timeframe did not allow enough time to complete a thorough comprehensive assessment. Many commenters stated that completion of the patient assessment within 20 days would be ideal but is impractical for staff that often cover multiple units and/or cover large geographical areas; such a requirement would be particularly impractical in rural areas. Commenters also stated that the proposed timeframe is unrealistic for MSWs carrying large patient caseloads. Other commenters suggested 20 days would not be enough time for all team members to participate, specifically those who work in part-time positions. Other commenters were concerned that the 20-day timeframe was inadequate for complete evaluation of all assessment criteria, including nutritional status, physical activity level or vocational or physical rehabilitation status. Commenters offered many suggestions regarding the deadline to complete the assessment. Some suggested alternatives that included time periods ranging from 30 to 60 days, and assessment timelines based on the number of dialysis sessions ranging from 6 to 13 sessions. Other suggestions included a split assessment with part 1 completed within 20 to 30 days or 9 sessions, and part 2 at 3 months. Commenters also suggested completing

the assessment and plan of care within 30 days, or allowing medical justification for the assessment time period to exceed 30 days.

Response: We agree with many of these commenters. A comprehensive initial assessment is the basis for an effective plan of care and for achieving desired patient outcomes. We also recognize dialysis facilities may have difficulties when conducting assessments on patients who face a wealth of challenges, including frequent hospitalizations; however, these difficulties should not outweigh the need to complete a comprehensive initial assessment within a reasonable period of time. If a patient has received dialysis for a 1-month period, or 13 hemodialysis treatments, that in-center patient has likely been physically present in the facility for at least 40 hours. We are therefore revising the deadline. We believe that, by allowing facilities 30 days or 13 hemodialysis treatments to complete the assessment (whichever is later), we are providing a reasonable timeframe for every member of the interdisciplinary team to assess the patient before developing the treatment plan. We have modified the final rule at § 494.80(b)(1) ''Patient assessment'' and at § 494.90(b)(2) ''Patient plan of care'' so that the interdisciplinary team has a timeframe of 30 days or 13 outpatient hemodialysis sessions, whichever is later, for completion of the assessment and implementation of the plan of care. Because some assessment criteria may take a longer period of time to evaluate, such as nutritional status and vocational and physical rehabilitation status, we expect that these areas would be more fully covered during the follow-up comprehensive reassessment that we are requiring for stable patients within 3 months after the completion of the initial assessment, as required at § 494.80(b)(2) and discussed below.

Comment: We received more than 50 comments on the proposed 3-month follow up comprehensive reassessment for dialysis patients. Half of the commenters supported the requirement, arguing that a follow-up assessment is necessary in order to evaluate the level of patient adherence to the treatment plan, determine whether the care plan is effective, and track the patient's overall adjustment to dialysis. One commenter supported the 3-month timeframe, stating, ''many patients are too sick and/or depressed to participate in life-altering decisions regarding their care and treatment'' during the initial assessment. Two commenters supported the 3-month reassessment but suggested that it be a ''focused'' reassessment used exclusively to determine whether changes would be needed in the plan of care.

The other half of the commenters opposed the proposed requirement, stating that the requirement was redundant, burdensome and of ''questionable value.'' Some commenters suggested that follow-up reassessments be completed after 6 months to relieve burden, especially in rural areas. Some commenters suggested the 3-month reassessment timeframe would be impractical because many new patients do not stabilize for the first 6 months of dialysis. Some commenters suggested that we modify the final rule to require a follow-up reassessment within 36 hemodialysis treatments rather than within the proposed 3-month timeframe. One commenter suggested that monthly progress notes would eliminate the need for the 3-month follow-up reassessment.

Response: We recognize that patients who are new to dialysis need time to adjust and adapt to the treatment. Initially, patients may experience anxiety while learning self-care skills, modifying their diet, changing their behavior, and perhaps dealing with access issues. The 3-month comprehensive reassessment enables the interdisciplinary team to evaluate, among other things, the patients' adherence to treatment plans; the accuracy of the patient's plan of care; and the patient's educational needs, rehabilitation needs, nutritional needs, quality of life and adjustment to the dialysis regimen. We recognize the burden this 3-month reassessment places on the interdisciplinary team. However, the burden has been significantly reduced in this final rule by eliminating the previous requirement that the team review the care plans and associated patient assessments of all *stable* patients every six months, which was previously required in part 405, subpart U. This rule does not preclude facilities from performing an assessment 6 months after the initial assessment, if they desire.

Comment: We received several comments regarding the assessment of the efficiency of the treatment prescription for hemodialysis and peritoneal dialysis. One commenter believed that proposed § 494.80(c) merely repeated § 494.90(a)(1) and recommended that the final rule combine the two.

Response: We disagree with the commenter regarding redundancy of the ''Patient assessment'' and ''Patient plan of care'' provisions. The requirement at § 494.80(c) mandates the frequency of assessment of the effectiveness of the treatment prescription for both hemodialysis patients and peritoneal dialysis patients, while § 494.90(a)(1) requires the interdisciplinary team to develop a patient plan of care to address the dose of dialysis and provide the necessary care and services to achieve and sustain the prescribed dose of dialysis. These conditions are also in keeping with our payment regulations (Medicare Claims Processing Manual, Chapter 8, 50.1) (*http://www.cms.hhs.gov/manuals/IOM/list.asp*).

Comment: One commenter suggested § 494.80(c), which addresses the frequency of dialysis adequacy monitoring, be modified to require facilities to ''monitor fluid status.'' The commenter cited a study that argued Kt/V levels did not correlate with mortality or morbidity and that better methods of measuring intravascular volume and related blood pressure changes are needed.

Response: Proposed § 494.80(a)(2) would require the interdisciplinary team to evaluate fluid management needs. We have retained this provision in this final rule. We have also added, ''manage the patient's volume status'' at § 494.90(a)(1), under the ''Patient plan of care'' condition.

Comment: One commenter proposed that a Kt/V measurement should be done every 2 months and that urea reduction rate could be used in alternate months. The commenter argued that Kt/V measurement was excessively burdensome for both patients and staff.

Response: Monthly monitoring of dialysis adequacy for hemodialysis patients is consistent with current dialysis facility practice and Medicare payment policies. We are not making any change to § 494.80(c) based on this comment.

Comment: One commenter suggested the final rule be reworded at § 494.80(d)(1) to clarify what kind of annual reassessment must be completed, as required in this condition.

Response: We appreciate the comment; however, § 494.80(d) states clearly that the reassessment must be completed in accordance with the standards specified in paragraphs 494.80(a)(1) through (a)(13). We do not believe that further clarification is needed. The proposed language has been retained in the final rule.

Comment: We received a comment that suggested the final rule require ''monthly reassessments for all stable patients using a simple tool.'' Another commenter remarked that annual assessments for stable patients are not enough and that co-morbid conditions

may necessitate assessments that are more frequent.

Response: While we are requiring stable patients to be comprehensively reassessed at least annually, we recognize that appropriate monitoring of patients may require ongoing assessments in various areas. We expect that patients would be monitored on an ongoing basis and expect progress notes would be entered in the patient's medical record as needed. The interdisciplinary team has the flexibility to use its professional judgment regarding on-going monitoring methods as appropriate for their patients, as specified in the patient plan of care.

Comment: We received many comments regarding the monthly reassessments for unstable patients. Many commenters requested we clarify what we meant by ''unstable patients'' and provide a definition for ''unstable'' in the final rule, as well as identify what the reassessment for such patients would specifically need to include. A few commenters said ''unstable'' should be clarified to state that all four criteria listed at § 494.80(d)(2)(i) through § 494.80(d)(2)(iv) must be present at once in order for the patient to be considered ''unstable.'' Another commenter suggested § 494.80(d)(2)(iv) be modified to add ''and/or'' so that presence of any one of the three criteria listed in (iv) (poor nutritional status, unmanaged anemia, and inadequate dialysis) would deem the patient ''unstable.'' A couple of commenters recommended modifying the final rule to allow each facility to provide its own definition of ''unstable'' as part of their facility policies.

A few commenters recommended that nutritional status should not be linked with anemia management or dialysis adequacy at § 494.80(d)(2)(iv). One commenter suggested nutritional status should stand alone, as should unmanaged anemia. One commenter recommended the final rule clarify ''unmanaged anemia'' and defer to the most recent KDOQI anemia clinical practice guidelines. A couple of commenters asked whether the requirement at § 494.80(d)(2)(iv) required all three criteria to be present simultaneously. Another commenter strongly recommended that the final rule clarify that all three parameters of (iv), poor nutritional status, unmanaged anemia, and inadequate dialysis be present to justify the determination that the patient was ''unstable.'' Another commenter suggested that ''poor nutrition'' should not be deemed a marker for instability, because facilities have minimal influence over poor nutritional status, which is a chronic problem.

We received many comments from social workers suggesting additional assessment criteria which would indicate that patients were ''unstable,'' and therefore, trigger the requirement for monthly reassessments. These suggestions included hemoglobin less than 11 gm/dL for more than 8 weeks, frail patients, reduced physical and mental component summary scores, physical debilitation, diminished emotional well-being, loss of employment, intradialytic symptoms, blood pressure, use of certain types of hypertensive medications, dry weight changes, chronic heart failure admissions, depression, and significant change in psychosocial needs.

Response: The comprehensive reassessment process can be seen as part of a cycle. Through the use of patient assessment, accurate and timely patient information is reflected in the plan of care. As the assessment changes, the plan of care must be revised accordingly. Once the patient is determined to be unstable, a monthly reassessment is necessary to update the plan of care appropriately. Existing regulations at part 405, subpart U required the professional care team to review the plan of care for an unstable patient at least monthly. The proposed rule aimed to add clarification and guidance as to how to classify a patient as unstable, and we specified at § 494.80(d)(2) the minimum criteria necessary to consider a patient unstable. A patient is unstable if he or she has had extended or frequent hospitalizations, or a marked deterioration in health status, or a significant change in psychosocial needs. In addition, a patient is unstable when he or she is determined by the interdisciplinary team to have poor nutritional status, unmanaged anemia, and inadequate dialysis concurrently. Unstable patients must be reassessed in accordance with § 494.80(d), which specifies use of the assessment criteria at § 494.80(a)(1) through § 494.80(a)(13). While a comprehensive reassessment for patients classified as unstable is required, it is possible that patient status may not change in all parts of the assessment. Patient status, whether changed or unchanged, should be clearly reflected in the new assessment.

This final rule allows facilities the flexibility to use their professional judgment to develop more stringent policies regarding the definition of ''unstable'' patient based on their unique patient population and patient characteristics and to insert additional assessment criteria, such as those offered by the commenters.

Comment: One commenter was concerned that facilities have previously developed their own definitions of ''unstable patient'' that ultimately classify very few patients as unstable. The commenter suggested that this trend should be discouraged.

Response: The proposed rule at § 494.80(d)(2) aimed to specifically address these concerns by establishing minimum criteria by which to identify patients considered ''unstable.'' As stated above, facilities continue to have the flexibility to develop their own policies and procedures with regards to how they define ''unstable'' patient, as long as that definition meets the minimum requirements put forth in this final rule.

Comment: One commenter remarked that it is unclear how monthly reassessments of stable patients coordinate with the ''monthly unstable care plans.'' The commenter questioned if patients would be considered ''unstable'' if care plan goals were not met.

Response: Patients are considered unstable if they meet any of the criteria listed at § 494.80(d)(2). Implementation of the initial and revised plan of care is discussed in the ''Patient plan of care'' section of the preamble below. The implementation of an updated plan of care, which results from a new patient assessment, is addressed at § 494.90(b)(2).

c. Patient Plan of Care (Proposed § 494.90)

We proposed a new condition for coverage entitled ''Patient plan of care,'' which would require the interdisciplinary team to develop and implement a written, individualized comprehensive plan of care that specified the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and would have included measurable and expected outcomes and estimated timetables to achieve these outcomes. Proposed components of the patient plan of care included dose of dialysis, nutritional status, anemia, vascular access, transplantation status, and rehabilitation status. This proposed condition for coverage called for documentation of a plan for transplantation, or, in the alternative, the patient's decision not to accept transplant referral, or documentation of the reason for the patient's nonreferral. We proposed implementation of the plan of care within 10 days of completion of the initial or updated patient assessment. We would no longer require the separate short-term and

long-term care plans required, biannually and annually, respectively, by part 405, subpart U of our rules. This proposed condition for coverage would also have required that the facility would have to adjust the plan of care if the expected outcome was not achieved. We proposed that the dialysis facility would have to ensure that all dialysis patients were seen by a physician providing the ESRD care at least monthly, that this visit was documented, and occurred periodically while the patient was receiving dialysis. Under the proposed rule, the interdisciplinary team would have been required to track the results of each kidney transplant center referral, monitor patient status, and communicate with the transplant center at least quarterly. The proposed ''Patient plan of care'' condition included a patient education and training standard, which would have required, as applicable, education and training for patients and facility members or caregivers on the aspects of the dialysis experience, dialysis management, quality of life, rehabilitation, and transplantation. Further discussion of § 494.90 provisions may be found in the proposed rule (70 FR 6205).

We received more than 100 comments regarding the ''Patient plan of care'' condition. The majority supported the proposed ''Patient plan of care'' condition.

Comment: Dozens of commenters made recommendations regarding the composition of the interdisciplinary team that would develop the plan of care. Several commenters agreed with the proposed interdisciplinary team definition and some suggested that the team definition wording at § 494.80 be carried over to § 494.90. Two commenters supported excluding the medical director from the interdisciplinary team, while others thought the medical director team role should be retained from part 405, subpart U, or changed to a team supervisory role. Commenters disagreed as to whether the home dialysis physician role on the interdisciplinary team should have been deleted in the proposed rule. One commenter stated that some patients need a physical therapist and psychiatrist on the interdisciplinary team. Another two commenters stated it would be ideal to have a vascular access coordinator on the interdisciplinary team, although this could be a cost issue. A number of commenters suggested that a pharmacist be included as a member of the interdisciplinary team.

Response: We are specifying the multidisciplinary team composition in § 494.90 of the final rule by cross-referencing the wording used at the beginning of § 494.80 (introductory text). The final rule language at § 494.80 reads as follows: ''The facility's interdisciplinary team consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian * * *.'' We do not agree there is a need to require that the medical director, the home dialysis physician or other professional staff be members of the interdisciplinary team. The medical director role has been strengthened at § 494.150 so that the medical director is responsible for the delivery of patient care and outcomes in the facility. In this role, the medical director may choose whether to be a member of the interdisciplinary team and participate in interdisciplinary team activities. The patient's right to be informed about home dialysis was strengthened both in the ''Patients'' rights' (§ 494.70(a)(7)) and ''Patient assessment'' (§ 494.80(a)(9)) conditions, so that the patient could be informed of home dialysis options whether or not a home dialysis physician was included in the multidisciplinary team.

Patients needing physical therapy or psychiatric services should be referred for these services, as we would not necessarily expect the dialysis facility to employ these professionals as staff members. Facilities may want to have a vascular access coordinator. While we encourage this, we will not mandate it, as dialysis facilities should have the flexibility to use other approaches and staff as interdisciplinary team members in ways that best meet the needs of their patient population.

We have addressed comments related to a pharmacist's role at § 494.140 ''Personnel qualifications'' discussion below. We have defined in regulation the minimum staff that must be part of the team in order to meet basic dialysis patient care needs. This regulation does not preclude the use of an expanded interdisciplinary team, and dialysis facilities always have the flexibility to add staff to the interdisciplinary team.

Comment: Many commenters agreed with the proposed modification to the provision specifying the role of the transplant surgeon in the development of the patient's plan of care. A few commenters opposed eliminating the requirement that the transplant surgeon's signature be part of the plan of care, while some of the comments supported transplant surgeon involvement via a designee.

Response: The previous ESRD conditions required a transplant surgeon to participate in the long-term care program planning process. The interpretive guidelines used by surveyors provided that a transplant surgeon designee could be used, and this designee was often a transplant nurse or the attending dialysis nephrologist. We proposed that while the transplant surgeon would not be a required member of the interdisciplinary team, the team must use criteria from the transplant center to determine whether a patient was a transplant referral candidate. The majority of comments supported this approach; therefore, we will retain the proposed requirement, which does not include the transplant surgeon. We are requiring use of transplant center criteria for assessing potential transplant candidates (§ 494.80(a)(10)), including transplantation status, as a component of the patient plan of care (§ 494.90(a)(7)(ii)), and the transplantation referral tracking standard (§ 494.90(c)).

Comment: A few commenters recommended further clarification of the term ''current evidence-based community-accepted standards'' at proposed § 494.90, and some suggested that this be defined as the K/DOQI standards. Some felt that the use of the word ''community'' could allow wide variation throughout the country as different communities embraced different standards, some of which might not be evidence-based.

Response: The first provision of the proposed ''Patient plan of care'' condition required that the plan of care ''include measurable and expected outcomes and estimated timetables to achieve these outcomes.'' The outcomes specified in the ''Patient plan of care'' condition must allow the patient to achieve ''current evidence-based community-accepted standards.'' The phrase ''community-accepted standards'' was intended to mean nationally-accepted professional standards of practice accepted by the renal community at large. ''Community'' was not intended to mean small local geographic groups of people having standards unique to that group or area. We have modified § 494.90 to better clarify our meaning and have replaced the phrase with new wording, ''current evidence-based professionally-accepted clinical practice standards.''

Comment: One commenter recommended that a phrase be added to the first paragraph in § 494.90 of the ''Patient plan of care'' condition to clarify that community-accepted standards must reflect joint decision-making between the patient and the

interdisciplinary team to individualize optimal goals for patient.

Response: We have designated the patient as a member of the interdisciplinary team (if the patient desires) and expect that the patient would share in the goal-setting team decisions. We do not agree there is a need to modify the provision as suggested.

Comment: We received a few comments opposing the plan of care timetables in § 494.90 because commenters believed that the patient response to therapy would be impossible to predict. A commenter recommended that we clarify that the facility would not be responsible for setting and meeting timetables for meeting the patient's medical and psychosocial needs; the commenter argued that such policy would constitute micromanagement that added no value to patient care. The commenter stated there was no matrix (or method) in the literature that allowed prediction of a patient's response time. A commenter stated it was beyond the scope of practice for a dialysis center to set a timetable for patients to achieve ''measurable and expected outcomes,'' especially those with ESRD for more than 1 year, since problems are complex and professionals cannot predict how long they will take to solve.

Response: It is common practice for a plan of care to include the following elements for each patient problem or medical/nursing need identified: Goal, action plan, and target date to either meet the goal or check the patient's progress toward that goal. We recognize that patient outcomes are determined in part by factors outside of the dialysis facility's control, such as demographics, the systemic effects of the underlying renal disease, and patient preferences and adherence. Further, we recognize that health care delivery is dynamic and that not all patients may be achieving, for example, the expected delivered dose of dialysis at any specific point in time. If the patient is unable to achieve the desired health outcomes, the plan of care should be adjusted to reflect the patient's condition along with an explanation, and any opportunities for improvement in the patient's health should be identified. Care plans commonly include time frames and care plan goals are more meaningful when the facility identifies a target date to achieve a goal or reassess the patient's status. Therefore, we have adopted the provision as proposed.

Comment: A few commenters were concerned about the patient's ability to refuse to comply with the plan of care, which could nullify team efforts to meet the plan of care goals. One commenter suggested that CMS allow facilities to demonstrate that a patient's failure to comply with the treatment regimen justified failure to meet criteria within the plan of care. Another commenter recommended that the dialysis adequacy regulatory language be more flexible to account for patients who terminated treatment early, despite team intervention.

Response: These patient compliance concerns were discussed in the February 4, 2005 proposed rule (70 FR 6209). As noted above, we recognize that patient outcomes are determined in part by factors outside of the dialysis facility's control. If the patient is unable to achieve the desired health outcomes, the plan of care should be adjusted to reflect the patient's condition along with an explanation for the patient's inability to achieve the desired outcomes, and the team must identify any opportunities to improve the patient's health. This clarification has been added to the final rule at § 494.90(b)(3).

The patient is part of the team and should be working to meet the plan of care goals. We are requiring the interdisciplinary team to adjust the patient's plan of care to achieve revised goals if initial outcomes are not achieved. If a therapeutic goal is not met due to patient non-compliance, then interventions must be implemented to achieve better patient compliance. If reasonable measures have been taken and lack of patient compliance still prevents the goal from being met, the facility must document the interventions, the results of the interventions, and the plan to preserve patient health and safety within the limitations of poor patient compliance. Patient choices that create barriers to meeting the targets should be documented and addressed to a reasonable extent by the team. We are not requiring patients to meet plan of care goals as a condition for coverage of facility services.

Comment: We received several comments regarding § 494.90(a)(1), ''Dose of dialysis.'' Most commenters recommended using the K/DOQI adequacy standards for this requirement, and several, including the National Kidney Foundation, recommended that we add the specific K/DOQI guidelines as minimal standards to the plan of care requirements. Some commenters suggested we include patient volume status (that is, a measurement of body fluid removal) in the adequacy requirement. A few commenters opposed establishing specific targets in the plan of care requirement because they stated that would be too prescriptive and rigid, future advances may outdate targets, facilities would have to risk-adjust, and not all patients would be able to achieve 100 percent of the targets. Commenters suggested alternatives, including using guidelines of practice or consensus standards (like AAMI and CDC guidelines), and encouraging, but not requiring, that specific targets be met.

Response: The majority of commenters supported adding language to § 494.90(a)(1) to specify that the K/DOQI dialysis adequacy guidelines must be targeted for all patients. We agree that the KDOQI adequacy guidelines are the current evidence-based professionally-accepted clinical practice standards. We have added to § 494.90(a)(1) a reference to the 2006 KDOQI targets (that is, Kt/V of 1.2 for hemodialysis or weekly 1.7 for peritoneal dialysis); we are also allowing dialysis facilities to meet ''an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis that would allow for future advances in dialysis adequacy measurement.

While there may be a need to risk-adjust when measuring facility-wide performance, the ''Patient plan of care'' condition addresses individual patient care and allows for unique patient characteristics to be considered in the development of the plan of care goals, alleviating the need to risk-adjust. As discussed previously in this preamble, if a patient does not meet the plan of care goals, appropriate interventions must be employed and if the patient still cannot meet the goals, a proposed explanation of why goals were not met must be entered into the plan of care. The rule does not require patients to meet plan of care goals as a condition for coverage, but facilities must demonstrate that they are attempting to meet those goals to the extent possible.

Volume control, important to blood pressure management and cardiac health, is an essential component of dialysis care that requires ongoing attention from the care team. Therefore, we are incorporating it into the ''dose of dialysis'' plan of care element. We have modified § 494.90(a)(1) to read, ''The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; and achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.''

Comment: We received many comments regarding § 494.90(a)(2), the nutrition component of the ''Patient plan of care'' condition. Several commenters supported the inclusion of nutrition as a plan of care element. Two commenters objected to the use of serum albumin as a marker of nutritional status, saying it was a poor indicator. Other nutritional indicators favored by commenters include subjective global assessment (SGA), normalized protein catabolic rate, weight, height and appetite, body mass index (BMI), body surface area, lab values, prealbumin and cholesterol, and the use of multiple nutrition measures, and urea kinetic modeling. One commenter recommended that the nutrition plan of care include target outcomes to meet/exceed the K/DOQI clinical practice guidelines. Another commenter stated that if the target albumin level was not met, alternate indicators (adequate dialysis and normalized protein catabolic rate) should be allowed, as albumin is affected by inflammation and chronic disease.

Response: Serum albumin levels are closely linked to morbidity and mortality. According to the K/DOQI clinical practice guidelines (CPG), serum albumin is a valid and clinically useful measure of protein-energy nutritional status in maintenance dialysis patients, even though it may fall in the presence of inflammation and stress. Several commenters supported inclusion of BMI or body weight as a required nutritional indicator. Dialysis patients are weighed at least 6 times per week and inclusion of body weight does not increase burden to facilities. A monthly assessment of body weight allows facilities to calculate BMI (when the height is known), and track changes in body mass.

We agree that the use of multiple markers is necessary to adequately assess nutritional status. For example, the KDOQI CPG encourages facilities to perform SGAs bi-annually as they are considered to be a valid and clinically useful measure of protein-energy nutritional status in dialysis patients (CPG 9). The CPGs also state that catabolic rate or protein equivalent of total nitrogen appearance are valid and clinically useful measures of net protein degradation and protein intake in maintenance dialysis patients (K/DOQI CPG 8). Serum cholesterol and serum prealbumin are valid and clinically useful markers of protein-energy nutritional status in hemodialysis patients (K/DOQI CPG #4 & 6). Facilities may use additional markers and assessments as deemed appropriate by the registered dietitian and physician. We are retaining in § 494.90(a)(2) the requirement that the interdisciplinary team monitor serum albumin (a visceral protein) and body weight at least monthly as indicators of nutritional status. In addition, we are adding language to § 494.90(a)(2) to require that ''Additional evidence-based, professionally-accepted nutrition indicators may be monitored, as appropriate.''

Comment: Some commenters objected to the language in § 494.90(a)(2) that requires the interdisciplinary team to ''provide the necessary care and services to achieve and sustain an effective nutritional status,'' because Medicare does not cover nutritional supplements. One suggestion was to change the wording so that the facility ''monitors'' the patient's nutritional status. Another commenter suggested that facilities be allowed to give out supplements without being cited for providing beneficiaries with an impermissible ''enticement.''

Response: Facilities must provide nutrition assessment, counseling, and ongoing monitoring, and must review with the patient monthly laboratory blood test results relating to the dialysis patient's nutritional intake and nutritional status. The provision of nutritional supplements by the dialysis facility is not expected or required. To clarify this, we have revised the wording in § 494.90(a)(2) to read, ''provide the necessary care and counseling services * * *.'' Depending on the facts and circumstances of a particular case, a gift of nutritional supplements by a provider to a beneficiary of a federal health care program could violate the prohibition on beneficiary inducements (section 1128A (a)(7) of the Social Security Act), 42 U.S.C. § 1320a–7a(a)(7)) or the anti-kickback statute (1128B(b), 42 U.S.C. § 1320a–7b(b)). Questions regarding whether a particular arrangement may violate these statutes should be directed to the HHS Office of Inspector General.

Comment: We received many comments regarding the anemia management component of the ''Patient plan of care'' condition. While there was some support for § 494.90(a)(3) (now § 494.90(a)(4)) as written, many commenters recommended that we require that the KDOQI anemia CPGs be plan of care targets. One commenter urged that we consider having the healthcare team consider the new 2006 KDOQI CPGs as they develop the plan of care. One commenter stated the hematocrit and hemoglobin targets of 33.0 percent and 11 g/dl were too low and that a hematocrit of 36 percent should be the minimum target.

Response: The proposed rule included references to the KDOQI minimum target hemoglobin and hematocrit levels of 11 g/dL and 33 percent, respectively, at proposed § 494.90(a)(3) (now § 494.90(a)(4)). Although new 2006 KDOQI anemia CPGs modified the 2000 version, target hemoglobin and hematocrit CPGs continue to be evaluated as new scientific evidence emerges. We note that the FDA issued a November 16, 2006 alert to provide new safety information for erythropoiesis-stimulating agents based on information reported in two clinical studies in patients with chronic renal failure treated with an unapproved regimen of erythropoiesis-stimulating agent(s). In addition, on March 9, 2007, the FDA issued a stronger warning, entitled a ''Black Box'' warning (see *http://www.fda.gov/bbs/topics/NEWS/2007/NEW01582.html*). Clinical research data continue to emerge and the FDA continues to analyze this information.

In addition, the NKF convened a KDOQI workgroup in 2007 to review new anemia management information and develop an update to the NKF–KDOQI anemia management guidelines. The revised anemia management guidelines were published on September 10, 2007 (see *http://www.kidney.org/professionals/kdoqi/pdf/KDOQI_finalPDF.pdf* or the *American Journal of Kidney Diseases*, *Vol. 50(3), September 2007:* pp. 471–530) and included one clinical practice recommendation and one clinical practice guideline for dialysis and nondialysis patients with chronic kidney disease receiving erythropoiesis-stimulating agent(s) therapy. They are as follows:

1. ''The selected Hgb target should generally be in the range of 11.0 to 12.0 g/dL;'' (clinical practice recommendation) and

2. ''The Hgb target should not be greater than 13.0 g/dL'' (clinical practice guideline).

The KDOQI recommendation and guideline also discussed the ''need to maintain flexibility in medical decision making given the breadth of variability between patients' individual needs, values, functional status, disease burden, prognosis, and responsiveness to erythropoiesis-stimulating agent(s) therapy.''

As such, the appropriate minimum hemoglobin/hematocrit targets for dialysis patients may vary. Therefore, the interdisciplinary care team must assess each patient to identify his or her unique needs for anemia management,

considering renal community evidence-based professional standards of practice, such as those published by the FDA or the NKF's KDOQI guidelines.

Because the current science is evolving and it is probable that more information regarding dialysis patient anemia management needs and hemoglobin and hematocrit values will be forthcoming, we have not included hemoglobin/hematocrit target levels in the final rule. The plan of care must, however, reflect that individual patient anemia management is consistent with current renal community evidence-based professional standards of practice.

Comment: A few commenters stated that the proposed requirements for anemia management in § 494.90(a)(3) are not consistent with payment policy, since physicians could not start Epogen until hematocrit was below 30 percent. One commenter stated that the proposed requirement would push hematocrits above 36 percent and add to reimbursement problems (when the hematocrit goes above 37.5 percent). Another commenter noted that payment affects hemoglobin/hematocrit targets.

Response: The final rule does not specify a specific hemoglobin level. This change allows physicians and clinicians managing the patient to determine the hemoglobin/hematocrit level appropriate for each patient based upon the patient's comorbidities and clinical characteristics. We note that the FDA labeling for erythropoiesis-stimulating agent(s) (*http://www.fda.gov/cder/foi/label/2007/103234s5122lbl.pdf*) does not specify specific target hemoglobin, but warns prescribers to use the lowest dose of erythropoiesis-stimulating agent(s) to gradually increase the hemoglobin levels sufficient to avoid the need for red blood cell transfusion. In addition, the anemia management section in the final regulation decreases the focus on erythropoiesis-stimulating agent(s) and instead, at § 494.90(a)(4), focuses on the patient's overall anemia management needs: ''The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level. The dialysis facility must conduct an evaluation of the patient's anemia management needs.'' This evaluation would determine whether the patient would benefit from supplemental iron, erythropoiesis-stimulating agent(s), blood transfusions, or other medical interventions.

Comment: One commenter stated hemoglobin levels should be used, and not hematocrit levels, as the hemoglobin levels are more accurate and are not affected by blood volume.

Response: The KDOQI CPGs do include a preference for hemoglobin readings over hematocrit levels and many dialysis facilities have been focusing on hemoglobin levels when managing anemia, rather than hematocrit levels. Some facilities multiply the hemoglobin by three to arrive at a comparable hematocrit level. Currently, Medicare payment systems allow both hematocrit and/or hemoglobin levels to be reported. Therefore, to allow flexibility in this health and safety rule, we will allow use of either the hemoglobin or the hematocrit.

Comment: A commenter suggested that we remove specific references to ''erythropoietin'' to allow for possible future advances in technology. Another commenter recommended that anemia management be individualized without the use of a range of parameters (that is, a sliding scale) necessary for delivering medication.

Response: We agree with the commenter that a more general term should be used rather than ''erythropoietin.'' We have revised § 494.90(a)(4) by removing the term ''erythropoietin'' and adding the term ''erythropoiesis-stimulating agents'' to allow for new technology developments.

Standing physician orders are used in some dialysis units to improve efficiency and responsiveness to changes in the patient's anemia markers. We do not agree that there is a need to prevent facilities from using these types of tools to manage anemia in dialysis patients, provided the medication dose administered and lab tests obtained are approved by the physician and are appropriate for the individual patient. The physician is responsible for ordering medications and laboratory tests and may or may not prescribe standing orders or the use of an algorithm. However, medication type and quantities billed to Medicare must be consistent with the physician's orders.

Comment: We received many comments regarding the vascular access component of the patient plan of care. While there was support for including a vascular access plan of care component, several commenters requested clarification of what type of vascular access monitoring would be required. Some noted that a clinical physical exam, which included observation, auscultation and palpation, would be different from mechanical surveillance that could include transonic flow measurements. The latter, according to commenters, would require a change in payment policy. One commenter recommended referencing K/DOQI Vascular Access CPGs #10, 11, and 12 for specifics regarding monitoring, while the NKF suggested that monitoring include a clinical physical exam at least monthly to detect problems or persistent abnormalities that should prompt referral for access angiography. Another commenter asked what CMS meant by its proposed requirement that facilities ''provide necessary care and services to sustain vascular access,'' and stated that a facility could only evaluate, monitor, recommend, educate, and refer, but not provide all the services and care that might be needed.

Response: The vascular access monitoring that must be included in the patient plan of care is limited to a clinical physical exam, and we expect that persistent abnormalities should prompt a referral, which is in keeping with the K/DOQI Vascular Access CPGs. This physical monitoring includes clinical observation, auscultation, and palpation of the access. Additional information can be gained by comparing the patient's expected Kt/V (given the current dialysis prescription) to the actual Kt/V. When the actual Kt/V is significantly lower than the expected Kt/V, the facility should investigate reasons for the discrepancy, including the patency of the vascular access. The proposed ''necessary care and services'' provision in § 494.90(a)(4) of our regulation would be limited to those vascular access actions that are reasonably expected within the dialysis facility, (generally, vascular access monitoring, and appropriate and timely referral). We have modified proposed § 494.90(a)(4), now § 494.90(a)(5), which now reads in part, ''The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access.'' The current composite payment includes payment for clinical access monitoring. When intervention is indicated, Medicare covers certain diagnostic procedures.

Comment: A commenter stated that the plan of care should address issues related to vascular access outcomes and the RN should be responsible for access, initiating treatments and monitoring care. The commenter also suggested that vascular access treatment should be restricted to RNs or trained LPNs, because surgeons often complain of vascular access problems in patients under their care, which they believe is related to inadequate vascular access training and care.

Response: We appreciate the comment, however, it is not practical to limit cannulation and all access care to

RNs and trained LPNs. In many units, PCTs perform vascular access tasks under the direction of the licensed nursing personnel. We have strengthened patient care dialysis technician certification and training requirements at § 494.140(e). Only PCTs with proven cannulation competency should be inserting hemodialysis needles, under the direction of the RN.

Comment: Two commenters suggested that we require a facility to document the reason a fistula is not being used to provide vascular access, as well as when applicable, a plan to place an arteriovenous fistula in eligible patients.

Response: Current standards of practice recognize the health and economical benefits of arteriovenous fistulas over catheters or grafts used for hemodialysis. Vascular accesses must be patent over long periods of time and efforts should be directed towards obtaining and maintaining the most beneficial access type possible for each patient. While not all patients may be able to obtain a viable arteriovenous fistula, which generally lasts significantly longer than other access types, each hemodialysis patient should be assessed for possible arteriovenous fistula placement. To ensure adequate care planning for arteriovenous fistulas, we have added a phrase to the vascular access plan of care component at § 494.90(a)(5), to require the facility to evaluate ''whether the patient is a potential candidate for arteriovenous fistula placement.'' The interdisciplinary team must enter documentation into the medical record to demonstrate that this requirement has been met; this documentation may include reasons why a fistula is not being used in a particular patient's case.

Comment: A commenter recommended that evaluation of the hemodialysis patient for the appropriate vascular access type should be removed from the ''Patient plan of care'' condition, as this would be a nephrologist's responsibility. Another commenter asked whether the vascular surgeon's determination of what kind of access the patient needs (per K/DOQI Vascular Access CPG #10) would meet the patient plan of care requirement to evaluate the patient for the appropriate vascular access type.

Response: The interdisciplinary team, led by the nephrologist, must consider any vascular access determinations made by the vascular surgeon, but the team may not abdicate its role of promoting the placement of the safest access type possible for their patient.

Comment: Several commenters did not agree with the proposed role of the dialysis facility interdisciplinary team as related to transplantation referral. One commenter stated that transplant referral should not be in the plan of care condition because it is a transplant center responsibility. Several commenters stated that accountability for transplant referral rests with the nephrologist. Two commenters stated that the plan of care should simply include documentation of the patient's transplant status. Another commenter stated that if an eligible patient declines a transplant referral, this should be documented in the plan of care as an informed decision.

Response: The proposed requirement regarding the role of the dialysis facility interdisciplinary team in the transplant referral process originated with the existing requirement in part 405, subpart U (§ 405.2137(a)) that required the completion of a long-term care program that addressed the selection of a suitable treatment modality (that is, dialysis or transplantation) and dialysis setting for each patient. The intent was to ensure each patient received the appropriate modality of care and the appropriate care within that modality. The professional team, not solely the nephrologist, has historically been accountable for developing a plan of care that addresses whether the patient was a transplant candidate.

We proposed to clarify what would have to be included in the plan of care to include the plan for transplantation if the patient accepted the referral, the patient's decision if an eligible patient declined the transplantation referral, or reasons that the patient was not being referred as a transplantation candidate, as determined during the assessment. Many long-term care programs across the country address these issues currently and it is reasonable that these topics be addressed in any valid plan of care.

Facilities may want to develop their own policy identifying the role of the interdisciplinary team members in performing the actual transplant referral. The team member may be the nephrologist or another team member. In any case, the facility will be held accountable for ensuring that appropriate modalities are employed in treating chronic kidney disease patients. We are adopting the proposed transplant referral requirements at § 494.90(a)(7)(ii) in this final rule.

Comment: We received many comments regarding the proposed rehabilitation component of the ''Patient plan of care'' condition at § 494.90(a)(6), which read, ''The interdisciplinary team must provide the necessary care and services for the patient to achieve and sustain an appropriate level of productive activity, including vocational, as desired by the patient, including the educational needs of pediatric patients (patients under the age of 18 years).'' Many commenters supported inclusion of rehabilitation in the plan of care, while one commenter disagreed. Many commenters stated that the provision of necessary care and services for rehabilitation was beyond the scope of services offered by the dialysis facility. A few of these commenters stated that a requirement to provide rehabilitation services would constitute an unfunded mandate, and some commenters noted that social workers are not trained to do rehabilitation. One commenter recommended deletion of § 494.90(a)(6) (now § 494.90(a)(8)) and suggested that rehabilitation referrals be addressed under social services. Many commenters suggested a rewording of the requirement to be more consistent with the capabilities of the dialysis facility, and provided this wording: ''The interdisciplinary team must assist the patient to achieve appropriate level of rehabilitation and refer the patient to necessary services.''

Response: We concur with comments that the provision of the necessary care and services for rehabilitation is beyond the range of services offered by the majority of dialysis facilities. Physical therapy, occupational therapy, and academic tutoring services (for example) cannot realistically be provided by the facility staff. Therefore, in response to comments, we have changed the wording of the ''rehabilitation status'' component, now at § 494.90(a)(8), to read, ''The interdisciplinary team must assist the patient in achieving and sustaining an appropriate level of productive activity, as desired by the patient, including the educational needs of pediatric patients (patients under the age of 18 years), and make rehabilitation and vocational rehabilitation referrals as appropriate.''

Comment: A few commenters suggested that a staff person be identified who would be responsible for rehabilitation. One commenter suggested that the social worker has a major role while another commenter recommended that the medical director be responsible for ensuring that the team assist patients in rehabilitation and in making referrals.

Response: This final rule makes the interdisciplinary team responsible for the patient plan of care, including rehabilitation. Referrals may be made by the appropriate team member, which may be the physician and/or the nurse or social worker. The role of the medical director, as described in § 494.150, is to

be responsible for the delivery of patient care and outcomes in the facility; this would include rehabilitation outcomes.

Comment: One commenter suggested that rehabilitation referrals be made before starting dialysis, when there is the most potential for rehabilitation progress.

Response: While it may be desirable in some cases to provide a rehabilitation referral to the patient before the start of dialysis, this may not be possible because of patient illness associated with the symptoms of uremia, as well as issues related to payment for rehabilitation services.

Comment: A few commenters made suggestions regarding patient plan of care rehabilitation outcomes. One commenter stated that the final rule should clarify rehabilitation outcomes as broadly as possible, and success should be defined differently for each patient. Another commenter suggested adding sub-criteria for rehabilitation outcomes, since the proposed rehabilitation requirements were not measurable as written. A third commenter recommended that the optimum rehabilitation outcome would be to return the patient to his or her former occupation. Another commenter suggested that for pediatric patients, the rehabilitation goal should be to help the patients get a high school diploma/high school equivalency diploma (GED), and those interventions and any reasons for a decline in rehabilitation potential should be documented. A few commenters recommended that we add functional status to the rehabilitation section. One commenter stated that a shift in rehabilitation focus to functionality (activities of daily living) would be more appropriate, because the age of many patients would suggest that rehabilitation might not be realistic for them. Another commenter suggested that we make maximizing physical/mental functioning scores a rehabilitation goal, and aim to help patients maintain or improve vocational status as measured annually, using the employment categories on the CMS–2728 Medical Evidence form at *http://www.cms.hhs.gov/cmsforms/downloads/cms2728.pdf*.

Response: The introductory language to the ''Patient plan of care'' condition calls for the establishment of ''measurable and expected outcomes and estimated timetables to achieve these outcomes.'' This requirement will allow for individualized plans that lead to desirable outcomes for patients in all care areas listed in the patient's plan of care, including rehabilitation. Outcomes listed in the plan of care could include such targets as the return of the patient to a former occupation, attainment of a certification of education, return to normal activities within the patient's household, a certain level of functionality, or any another outcome that the team has determined is appropriate for the patient. Dialysis facilities have the flexibility to choose appropriate rehabilitation outcome targets, and we will not narrowly define them in this final rule.

Comment: Two commenters stated that any rehabilitation services to which a patient might be referred would be time-limited, and the patient may not reach his or her full rehabilitation level; they stated that the regulation would need to allow for this.

Response: If, while pursuing a rehabilitation goal, the team encountered limits on the patient's eligibility for services (for example, a limited number of physical therapy sessions), the plan, goals and timetables would need to be adjusted and the reason noted in the patient's record, as required at § 494.90(b)(3).

Comment: One commenter suggested that the care team be required to discuss with the patient whether to seek physical therapy, occupational therapy, counseling or vocational rehabilitation referrals.

Response: The patient is a member of the interdisciplinary team and, as such, should participate in team discussions regarding rehabilitation potential and goals.

Comment: A commenter recommended that we require a separate rehabilitation assessment initially and again every 3 to 6 months.

Response: The frequency of the rehabilitation assessment will be the same as the frequency of the comprehensive assessment, since this is a component of the assessment. (See § 494.80(b).)

Comment: We received many comments suggesting modifications to the components of the patient plan of care. Many commenters suggested that we add ''mineral metabolism/bone disease'' as a required component of the patient plan of care and referred to the NKF K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease (American Journal of Kidney Disease 42:S1–S202, 2003 (supplement 3)). Two commenters specifically suggested that we incorporate the K/DOQI CPGs for bone metabolism and disease in CKD patients.

Response: In response to comments and evidence supporting the importance of mineral metabolism management to the health of dialysis patients, we will add mineral metabolism to the list of required components of the plan of care by inserting the following language at § 494.90(a)(3): ''Provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease.'' Care and services are limited to those normally provided by the dialysis facility and would include appropriate referrals outside the dialysis facility when appropriate. Current professional practice standards include management of renal bone disease in dialysis patients, and we agree that mineral metabolism and bone disease management is well within the purview of the dialysis facility.

Comment: Many commenters supported adding a requirement for the interdisciplinary team to document in the medical record or plan of care the reasons a patient was not referred to home care, if applicable. Other commenters suggested adding medication therapy management and advance directives as additional plan of care components.

Response: The patient must be assessed at least annually for modality choice and level of participation in the dialysis care process. We agree with commenters that it is appropriate to have a plan of care component that corresponds with the treatment modality assessment required at § 494.80(a)(9) and § 494.80(a)(10), and it is appropriate to document the barriers to home dialysis. Therefore, we have added home dialysis to § 494.90(a)(7)(i), coupling home dialysis with transplantation status (proposed § 494.90(a)(5), now § 494.90(a)(7)(ii)) under a ''modality'' plan of care component. This new ''Modality'' plan of care provision reads, ''Modality: (i) *Home dialysis.* The interdisciplinary team must identify a plan for home dialysis or explain why the patient is not a candidate for home dialysis.'' This provision requires that, based on the most recent assessment, the plan of care must be revised to reflect modalities for which the patient is a candidate and the patient's preferences regarding modality.

Advance directives were added under the ''Patient's rights'' and ''Medical records'' conditions and therefore we will not require advance directives within the plan of care. Facilities have the flexibility to address advance directives within the plan of care when they deem it appropriate. Medication therapy management may be included within the action plan for various components of the plan of care.

Comment: A commenter suggested that the plan of care address cardiovascular health, and referred to the NKF K/DOQI Clinical Practice

Guidelines for Cardiovascular Disease in Chronic Kidney Disease (American Journal of Kidney Disease 45:S1–S154, 2005 (supplement 3)). The commenter stated that the NKF recommends that electrocardiograms be performed in all patients at the initiation of dialysis, once patients have achieved dry weight, and at 3 yearly intervals thereafter. In addition, appropriate blood pressure management is an important part of dialysis care and contributes directly to cardiovascular health.

Response: Cardiovascular disease is a concern for dialysis patients and is affected by renal bone disease, blood pressure, and fluid management as well as any other risk factors the patient may have. Dialysis patients often have a number of co-morbidities. The patient's medical history and co-morbidities are to be assessed as required at § 494.80(a)(1). Any problems identified by the comprehensive assessment are to be addressed in the patient plan of care as required at § 494.90. Since very little support came from commenters specifically to add a cardiovascular disease component to the plan of care, we have not added this requirement. However, dialysis-related cardiovascular health problems must be addressed in the plan of care whenever it is appropriate for an individual patient, as determined by the interdisciplinary team. Although core components of the plan of care are listed in this final rule, the interdisciplinary team has flexibility to add areas to the plan of care as identified in the comprehensive assessment.

Comment: We received many comments regarding whether a social services component should be required in the ''Patient plan of care'' condition. Most of the comments recommended that social services be part of the plan of care and referred to current research regarding social work services. Commenters stated that studies have shown that social work intervention improves patients' quality of life, their adherence to the ESRD treatment regimes and fluid restrictions, and improves medication compliance. Another example of improved outcomes provided by a commenter is that social work interventions can reduce patients' blood pressure and anxiety levels.

Commenters suggested including emotional and social well-being criteria in the final rule. Some commenters recommended including functional status measures that they believe correlate with better survival and hospitalization rates. Other commenters recommended requirements that would specify psychosocial criteria along with MSW tasks and responsibilities, and which would require that MSWs provide information and training to patients. Some commenters suggested adding specific language that would address measurable improvement in physical, mental, and clinical health outcomes * * *,'' ''psychosocial status and appropriate referral for services * * *,'' and would ''provide the necessary care and services to achieve and sustain effective psychosocial status * * *.'' Many commenters suggested that we require use of a tool to assist in measuring psychosocial status. Tools suggested include the Zung Self-Assessment Depression Scale or Hamilton Anxiety Scale, and a quality-of-life tool such as the SF–36, or SF–12 (version 2.0 tool), that commenters state are used to measure depression, functional status, and predict mortality and morbidity. Commenters cited research supporting social work interventions that they believe would contribute to meeting patient care team goals.

Response: In response to the large number of comments, and in light of current academic research supporting social service interventions to improve patient care, we are adding a social services component, called ''psychosocial status'' to the plan of care requirements at § 494.90(a)(6). We are requiring that a standardized tool, chosen by the social worker, be used to monitor patient status, and that counseling be provided and referrals be made as appropriate. This new requirement reads, ''The interdisciplinary team must provide the necessary monitoring and social work interventions, including counseling and referrals for social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis.''

The standardized tool should be a professionally accepted, valid, reliable tool, such as the SF–36, and should relate to the patient's functional health and well-being. The tool must be used as a monitoring aid that assists in determining the patient's psychosocial status. The SF–36 model uses metrics that measure physical health as related to functional level and presence of pain, and mental health as related to social functioning, emotional and mental health. Reliability and validity studies have been performed for this instrument. More information about the SF–36 may be found in numerous articles or on the Web at *http://www.sf-36.org/tools/sf36.shtml.* The SF–12 survey form was derived from the SF–36 form and scales the 36 question survey down to a 1-page, 2-minute version. However, we are not specifying which tool must be used in order to allow flexibility and to limit the amount of burden. The choice of which standardized tool to use is best left to the facility social worker.

Comment: Although most comments recommended that social services be part of the plan of care, two commenters disagreed, stating that social workers have too big a caseload and are not capable of providing professional counseling services. One commenter stated that until there is consensus on outcomes, CMS should not include an outcomes-based social service requirement in the plan of care. Commenters supporting social services in the plan of care submitted a lengthy list of references that highlight the importance of social services as related to improved patient outcomes.

Response: In the previous conditions (§ 405.2162) as well as in this final rule (§ 494.180(b)), dialysis facilities are required to have adequate staff available to meet the care needs of their dialysis patients. This requirement applies to the provision of social services as well. Facilities may want to assess the caseloads of social workers to ensure there are adequate staff to provide the appropriate level of social services, including counseling. Social workers who meet the qualifications at § 494.140(d) are capable of providing counseling services to dialysis patients. Furthermore, Medicare payment for social worker counseling services is included in the dialysis facility composite rate.

We are setting forth some process requirements within the ''Patient plan of care'' condition because measurable outcomes in all areas are not yet available. When evidence-based or consensus outcome measures and standards become available, we may consider whether some process requirements may be removed from the conditions for coverage in the future.

Comment: We received a comment recommending that consistent language be used for all plan of care elements so that for all care plan areas the dialysis facility ''must provide the necessary care and services to achieve and sustain an effective (treatment program).''

Response: Requiring the facility to provide all necessary care and services for all elements of the patient plan of care may overstep the facility's scope of practice in some areas, as pointed out by several commenters.

Comment: One commenter questioned the need to list components of the plan of care, since a qualified care team

would develop an appropriate plan, which would include measurable and expected patient outcomes conforming to community-accepted standards. The commenter stated this would not need to be mandated, nor should it.

Response: Although quality-oriented facilities may develop meaningful plans of care that include measurable outcomes, we do not agree that all facilities adequately develop and implement such a plan of care. This patient-centered condition serves to protect the health and safety of dialysis patients and to ensure that adequate patient care services are provided.

Comment: A commenter suggested that when referring to the interdisciplinary team implementing the plan of care at § 494.90(b)(1)(i) the phrase ''inclusive of the patient'' be added.

Response: The interdisciplinary team definition specifically includes the patient, and has been added to the first paragraph of this condition. We have added the phrase ''including the patient if the patient desires'' to § 494.90(b)(1)(i) to clarify that we expect that the patient will want to participate in devising the plan of care.

Comment: We received many comments regarding the proposed requirement at § 494.90(b)(1)(ii) suggesting that the patient sign the plan of care. A few commenters recommended the plan of care be signed by the patient's attending physician as well as the patient.

Response: The patient plan of care must be completed by the interdisciplinary team (§ 494.90(b)(1)(i)). It is standard practice for all team members, including the treating physician, that develop the plan of care to sign it, as they would for any other entries into the medical record. Therefore, we are changing the wording at § 494.90(b)(1)(ii) to reflect that all team members must sign the plan of care.

Comment: Commenters agreed with the proposed rule requirement that the plan of care be signed by the patient or the patient's designee. One commenter stated that at least one facility, to his or her knowledge, limits patient involvement exclusively to signing the care plan; the staff orders the patient to sign and the RN on-duty becomes offended if the patient actually reads the care plan. The commenter further noted that patients should be able to indicate the date they signed the care plan. Another commenter noted that the proposed rule did not require the patient to be involved in the development of the care plan, but only to sign it. This commenter was concerned that only paper compliance would be achieved with such a provision, and that enforcement regarding patient involvement would be difficult. One commenter recommended that facilities be required to conduct periodic patient care conferences. The commenter further stated that deleting survey tag V174 would be detrimental to quality of care and CMS should prevent a ''pass around the paper'' meaningless care plan development process.

Response: The role of the patient is central to providing quality dialysis care. Paper compliance without substantive compliance is unproductive. Specifically, the patient member of the interdisciplinary team has a role in converting the comprehensive assessment into a meaningful plan of care. Whenever possible, the patient (or designee) should assist in the identification of goals and in formulating the action plan to achieve these goals. The patient must be involved in care planning and actively participate in care plan development and review.

Survey tag V174, referred to by the commenter, required regularly scheduled conferences, with participation by the staff involved in the patient's care, to evaluate the progress each patient is making towards the goals in their long-term care program and patient care plan. However, this final rule also allows the facility flexibility to choose the methods to ensure patient participation. One means of providing an opportunity for participation is to have the patient attend the meeting in which the plan of care is developed and updated. This final rule makes very clear that the patient is part of the care team and can participate in the assessment and the plan of care activities if the patient desires to do so. While we have not required monthly care plan meetings specifically, the facility must demonstrate that there is an opportunity for patient involvement and participation. The facility has the flexibility to design a process. The patient signature on the plan of care is not sufficient to demonstrate patient participation. The new interpretive guidelines for this regulation will include direction to surveyors regarding enforcement of this provision.

Comment: A few commenters were concerned about dialysis facility responsibility for patient participation in cases where the patient chooses not to participate. Some commenters suggested that there be a provision in this final rule for situations in which the patient refused to sign the plan of care. The commenter suggested that in such cases, documentation provided by the facility explain that the patient had refused to provide a signature.

Response: We agree that as long as the patient has been provided sufficient opportunity to participate with the interdisciplinary team, the dialysis facility should not receive a citation for non-compliance with these conditions when the patient has refused to participate or sign the plan of care. We have modified the language at § 494.90(b)(1)(ii) to indicate that the facility must document a patient's refusal to sign the plan of care, along with the reason the signature was not provided.

Comment: We received many comments regarding the time period for commencing implementation of the patient plan of care (§ 494.90(b)(2)). The proposed rule specified that the plan of care would have to be implemented within 10 days of any comprehensive assessment. While there was some agreement with this proposal, many commenters stated that 10 days was too short. Some commenters suggested that we combine the assessment and plan of care time period to 30 days. Commenters suggested a myriad of alternative timeframes for implementing the plan of care, such as requiring implementation within 15 days of assessment completion, within 90 days of starting dialysis, within a certain number of dialysis treatments (to allow for the possibility of patient hospitalizations), or at the first team meeting following completion of the assessment. The reasons facilities gave for needing a longer plan of care implementation time included the shortage of staff, needing time for referrals and schedule coordination, the need for interpreters, accommodating monthly care plan meetings, and the difficulties involved in bringing the multidisciplinary team together monthly.

Response: We believe we must balance the health and safety needs of the patient against the staffing limitations of the facilities. The case loads of staff and constraints of facility processes should not outweigh the need to develop and implement the plan of care within a reasonable period of time. If a patient has received in-center dialysis for a 1-month period or 13 (thrice-weekly) hemodialysis treatments, that patient has likely been physically present in the dialysis facility for at least 40 hours. We believe that this should provide sufficient time for the interdisciplinary team to have completed an assessment and developed a plan of care that is ready for implementation. Thirty days is a reasonable timeframe for the initial

assessment and implementation of the plan of care in order to protect the health and safety of patients and prevent harm. Facilities may want to re-evaluate their processes, resources, and adequacy of staff if they find the 30-day deadline to be too difficult to meet. We have modified the requirement at § 494.90(b)(2), so that the interdisciplinary team has a timeframe of the latter of 30 days or 13 hemodialysis treatments from the date of admission to complete the assessment and implement the plan of care. This provision now addresses commenter concerns regarding time lapses when a patient is in the hospital. Referrals are considered to be a part of the implementation of the plan of care and would not be a reason to allow extended time periods to complete and implement the plan of care. In addition, we will allow a 15 day time period for the facility to implement any patient plan of care revision due to completion of a monthly assessment (done for unstable patients) or an annual assessment (completed for stable patients) (§ 494.90(b)(2)).

Comment: Many comments addressed proposed § 494.90(b)(4), which would require the dialysis facility to ensure that the patients are seen at least monthly by a physician providing ESRD care. Some commenters supported this provision and a few suggested that the visit could take place in the physician's office. Other commenters disagreed with the requirement but agreed with the intent, saying that physicians should see their dialysis patients at least monthly. Many commenters strongly disagreed with the provision, stating that the facility should not be accountable for physician visits. A few commenters stated that the payment G-codes provided enough incentive for facilities and that therefore this physician visit requirement was not needed. Other commenters suggested there was no evidence of any benefits that could be linked to monthly visits, and this would be especially burdensome for rural dialysis facilities. One commenter recommended that an exception be available for facilities in the Pacific Islands. Two commenters suggested that CMS had no authority to mandate these monthly physician visits according to section 1801 of the Social Security Act, which prohibits the federal government from exercising any supervision or control over the practice of medicine.

Response: We believe that it is in the best interest of the patient for dialysis facilities to ensure that a physician (or other practitioner, such as a PA, nurse practitioner, or clinical nurse specialist) visits each month. The Dialysis Outcomes and Practice Patterns Study (DOPPS) data demonstrate that physician contact correlates with the quality of care. The G-codes, established in the final rule, ''Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2004'' published November 7, 2003 (68 FR 63196, 63216), provide payment to physicians in incremental amounts depending on whether the patient was seen 1, 2–3, or 4 times during a given month. Although the payment G-codes provide some incentive for attending physicians to see their dialysis patients more often, physicians may still choose not to see their patients for a month or more. In this case, the patient still receives dialysis for which the facility receives payment. We do not believe that requiring monthly visits infringes on how physicians practice medicine and note that physician organizations that provided comment on the proposed rule supported the provision. We are retaining the proposed provision at § 494.90(b)(4) to ensure that patients receive face-to-face physician (or, as discussed below, ''physician extender'') visits at least monthly.

Comment: A few commenters suggested that physician assistants be allowed to perform monthly visits, while one commenter favored allowing a nurse practitioner to perform monthly visits.

Response: In response to comments, we have added nurse practitioners, clinical nurse specialists, and physician assistants as options for compliance with the provision requiring monthly visits by a physician. CMS has previously issued instructions regarding physician visits and payment via G-codes and these instructions clarify that a physician assistant, clinical nurse specialist, or a nurse practitioner may provide visits to dialysis patients instead of a physician. Physicians may use nurse practitioners, physician assistants, and clinical nurse specialists, who are able under the Medicare statute to furnish services that would be physician services if furnished by a physician and who are eligible to enroll in the Medicare program, to deliver some of the visits during the month.

Comment: We received many comments regarding proposed § 494.90(c), ''Transplantation referral tracking,'' which would require the interdisciplinary team to track the results of each kidney transplant center referral and monitor the status of any facility patients who are on the transplant wait list. In addition, this standard would require the team to communicate with the transplant center regarding patient transplant status at least quarterly or more frequently if necessary. Some commenters supported this standard as proposed and many commenters stated the dialysis facility should not be accountable for transplantation referral tracking once the referral has been made. Commenters who disagreed with this proposed provision stated that other parties have this tracking responsibility, including the transplant center, the transplant candidate, and/or the physician. Two commenters stated that this requirement creates a burden for dialysis facilities.

Some commenters acknowledged that the proposed (now final) transplantation center conditions of participation, published on March 30, 2007, included a proposed requirement for transplant centers to communicate with dialysis centers regarding transplant candidate status. A few commenters suggested that dialysis facility responsibility be limited to maintaining a list of patients on the transplant wait list. Several commenters stated that some transplant centers did not communicate with the dialysis facility, or that it was difficult to get information from the transplant center. One commenter suggested penalties for transplant centers that did not communicate with dialysis facilities, while another commenter suggested that incentives be provided to transplant centers to share information monthly on transplant candidates' work-up and listing status.

Response: Our intent is to ensure that the interdisciplinary team is aware of where the patient is in the referral and transplant evaluation process so that patients do not get ''lost'' along the way. We do not expect that the transplant referral tracking responsibilities borne by the dialysis facilities would be redundant with the responsibilities of the transplant center. We would expect the interdisciplinary team to be aware of whether the patient has completed the evaluation process, is wait-listed, ineligible for wait listing, or is awaiting living donation. Moreover, the dialysis facility is expected to alert the transplant center about changes in the patient's condition that would affect whether a patient was able to receive kidney transplantation. The transplantation center conditions of participation published on March 30, 2007 (72 FR 15198) require kidney transplant centers to communicate transplant patient status to the dialysis facility at § 482.94(c)(1) and § 482.94(c)(2) so that there is two-way communication.

Comment: A few commenters who agreed that there was a need for dialysis facility and transplant center communication did not agree with the

proposed quarterly frequency of this communication. One suggestion was to remove the ''quarterly'' language and replace it with ''when there is a change.''

Response: We agree. In response to comments, we have changed the frequency of required communication with the transplant center at § 494.90(c)(3) so that the regulation will require the interdisciplinary team to contact the transplant center ''at least annually, and when there is a change in transplant candidate status.'' Although the proposed ESRD conditions for coverage called for quarterly communication with the transplantation center, the transplantation center final rule (at § 482.94(c)(1)and (2)) requires that the transplant center notify the dialysis facility of the patient's transplant status only when there are changes in such status (72 FR 15276). Our purpose here is to provide a means by which up-to-date information can be made available to the transplant team so that eligible patients are wait-listed and so that patients offered a donor kidney are in a position to accept the transplantation. The dialysis team also needs up-to-date information so that the team can choose the most appropriate ESRD modality and setting for the patient and assist the patient in understanding the process used to obtain kidney transplantation.

Comment: Commenters made several additional transplant recommendations. One commenter suggested that an RN with specific transplant related duties is needed to act as transplant coordinator.

Response: While dialysis facilities may find it beneficial to have an RN transplant coordinator assist in transplant referral tracking, we do not believe it should be a requirement. We are allowing flexibility so that the tracking may be done by staff members chosen by the dialysis facility.

Comment: One commenter suggested that the dialysis facility and the transplant center have a written agreement with each other.

Response: If a dialysis facility finds it useful to have a written agreement with the transplant center, the dialysis facility has the flexibility to pursue this, but we do not believe it is necessary and will not require it.

Comment: One commenter suggested that there should be an internet database to facilitate communication between transplant centers and dialysis facilities.

Response: While there may be some benefit in having an internet database to facilitate communication between transplant centers and dialysis facilities, we will not burden dialysis facilities with developing such an internet database. We believe an active and ongoing communication and coordination process will suffice currently. As electronic health records become a reality in the future, there is the possibility that these records could facilitate dialysis facility and kidney transplant center communications and exchange of information.

Comment: One commenter suggested that the transplantation requirements should be consistent with the recommendations of the 2005 ESRD Network technical expert panel (TEP) that worked on developing transplant referral clinical performance measures. Another commenter stated that conditions for transplant center, physician and patient communications should be based on the study and endorsement of the American College of Physicians and physician organizations.

Response: The TEP referred to by the commenter was charged with developing dialysis facility-specific kidney transplant referral clinical performance measures. These measures would track steps in the transplant referral process. TEP membership included transplant surgeons, nephrologists, and dialysis facility representatives. The TEP recommended that this final rule include the proposed transplantation provisions at 494.90(c) in order to facilitate implementation of the kidney transplant referral CPMs they developed. We have adopted the proposed transplant provisions and believe this will alleviate the concerns of the commenters.

Comment: A few commenters responded to our query as to whether we should specify actions (that is, transplant referral activities and monthly blood draws for antigen/antibody testing) that must be included in the transplantation action plan. Two commenters stated that monthly transplant blood drawing should not be the responsibility of the dialysis facility. One commenter supported the concept that facilities should support patients in the process of a work-up for a transplant, which would include tracking tests, communication with transplant coordinators/surgeons, etc.

Response: We will not specify actions that must be included in the patient plan of care under the transplantation component, but encourage dialysis facilities to assess the circumstances and include appropriate actions in the plan of care as needed.

Comment: We received several comments supporting inclusion of the ''Patient education and training'' standard at § 494.90(d). Some commenters recommended the addition of other training topics, including patient education regarding arteriovenous fistulas, advance directives, and more. A commenter recommended that we require documentation in the medical record that patients were informed of the risks and benefits of various types of vascular access consistent with ''Fistula First'', and provide funding for this if needed.

Response: We agree that it is a reasonable expectation that dialysis patients be educated regarding the risks and benefits of various access types due to the impact of a vascular access on the patient's morbidity and mortality risks. Comments on this and other sections of these conditions strongly support adding a requirement ensuring that patients must be educated regarding the risks, benefits, and outcomes of various access types. These comments are in keeping with the National ''Fistula First'' quality initiative. Additionally, the Institute of Medicine (IOM) has encouraged the empowerment of patients to improve the quality of the healthcare system. Therefore, we have added new language to the ''Patient plan of care'' condition at § 494.90(d), Patient education and training, requiring that the plan of care include education and training on the benefits and risks of various vascular access types. We have also added infection prevention and personal care, and home dialysis and self-care training to this provision in response to comments as discussed under the ''Infection control'' and ''Care at home'' sections of the preamble.

Comment: One commenter believes that education for all life changes associated with dialysis is an unfunded mandate that will require additional personnel skilled in this training. The commenter also stated that patient education regarding employment, rehabilitation and transplantation is beyond the scope of the dialysis center nurses and technicians.

Response: Patient education is included in the Medicare composite rate paid for dialysis. We expect that the interdisciplinary team has the skills and expertise needed to educate dialysis patients about aspects of the dialysis experience, dialysis management, quality of life, rehabilitation, and transplantation.

d. Care at Home (Proposed § 494.100)

We proposed a separate condition for coverage for care at home requirements, which were previously located in four existing sections of 42 CFR part 405, subpart U. The requirement that services to home patients be at least equivalent to those provided to in-center patients was retained from existing § 405.2163. We addressed home

dialysis training in the proposed rule and proposed requiring the interdisciplinary team to provide training to the patient and/or the designated caregiver before the initiation of home dialysis. We proposed that the home training be provided by a facility approved to provide home dialysis services and that home and self-care training would have to be conducted by an RN. The proposed training would have to address specific needs of patients in several subject areas, including the nature and management of ESRD, techniques associated with the treatment modality, nutritional care plans, emotional and social well-being, methods to detect, report and manage potential complications, how to access and use available resources, how to self-monitor health status, how to handle emergencies, infection control precautions, and proper waste and disposal procedures. We also proposed a home dialysis-monitoring standard, which would have required the dialysis facility to document that the patient and/or caregiver received and demonstrated adequate comprehension of the training; retrieve and review self-monitoring data and other information at least every two months; and maintain this information in the medical record. We proposed to retain many of the existing regulations regarding home dialysis support services; however, the proposed support services standard was strengthened by requiring home dialysis patient consultation with the interdisciplinary team. The team also would have been held responsible for the development and periodic review of the patient's plan of care based upon the comprehensive assessment, and for addressing the patient's needs and achieving the expected outcomes of care. The proposed rule also would have expanded existing requirements to monitor the quality of water used by home hemodialysis patients. The proposed rule specifically included onsite evaluation of the water system, as well as adherence to applicable AAMI guidelines and immediate correction of any problems with the water treatment system. If problems could not be immediately corrected the facility would have to arrange for backup dialysis until the home dialysis water quality could be restored. At § 494.100(c)(1)(vi), the proposed rule would retain existing requirements that the dialysis facility be responsible for ''Purchasing, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician.'' The proposed rule also would have required facilities to plan for and arrange for emergency back-up dialysis services when needed. We also proposed that the facility maintain record-keeping systems that ensured continuity of care; this would have also been retained from existing provisions found at § 405.2163(e)(3).

Comment: Many commenters strongly supported the requirement that home dialysis patients receive services that are at least equivalent to those provided to patients in facilities. One patient remarked he felt his peritoneal dialysis care was not equivalent to in-center hemodialysis. Another commenter said home dialysis needs more attention in the final rule.

Response: We appreciate the positive response from commenters. All the ESRD conditions for coverage must be met regardless of whether the setting is in-center or at home. We have added language to clarify this in the first paragraph of § 494.100, to require that dialysis facilities meet all applicable conditions of this part. We would expect that under these new regulations, dialysis facilities would make any necessary changes to ensure that all patients receive the same quality of care regardless of the location of the service. We have increased the home dialysis focus of these conditions by making ''Care at home'' a separate condition for coverage.

Comment: A few commenters recommended that a new section be added to our regulation, to address patients performing self-care dialysis in the facility, and address policies and procedures for self-care in the facility. These commenters believed that stringent regulation and oversight was needed for self-care. One commenter suggested there should be requirements for self-care training for both patients and facility staff and that self-dialysis training should include treatment monitoring, machine monitoring, needle procedures, and infection control.

Response: We encourage self-care, both at home and within the facility, whenever the patient has the ability. Self-care can be supported in-center by Medicare-certified outpatient dialysis facilities. Dialysis facilities that provide self-care must meet these conditions for coverage and protect patient safety. We do not agree that additional regulations are needed regarding self-care.

Comment: One commenter remarked that the requirements as written would require all patient training to be completed before the initiation of home dialysis, and the commenter suggested that this was not practical because patients would lose interest in performing home dialysis before the instruction was complete.

Response: As required at § 494.100(a), the interdisciplinary team must oversee the training provided to the home dialysis patient and the designated caregiver before the initiation of home dialysis. Patients should not begin home dialysis before adequate training is complete and competency has been determined. We have maintained the language of the proposed rule.

Comment: One commenter agreed that initial home training should be conducted by a qualified RN. Some commenters remarked that the requirement for an RN to train home dialysis patients was excessively stringent and that an LPN was qualified to train these patients. Another suggested that an RN be responsible for home training but still have the ability to delegate parts of the training program to a trained LPN or PCT. Two commenters suggested the final rule allow PCTs, under the supervision of an RN, to provide patients with some or all home care training, with a final review and evaluation done by an RN. One commenter strongly opposed the provision at § 494.100(a), which required that the interdisciplinary team be responsible for providing self-dialysis training to home patients.

Response: The existing requirement at § 405.2162(c) mandates that an RN be in charge of self-care training. We believe that an RN, as an experienced health professional, fully understands the complexity and rationale for the dialysis process, and is the best-suited expert to conduct self-care training to patients. The requirement serves to protect the health and safety of the patient. Therefore, we have retained the proposed RN requirement in the final rule at § 494.100(a)(2), which stipulates that the RN must conduct the home training. The RN may use other members of the clinical dialysis staff to assist in providing the home training. However, the RN is responsible to ensure that the training is in accordance with the requirements at § 494.100.

In addition, we have modified the provision at proposed § 494.100(a), which would have required that the interdisciplinary team be responsible for providing the self-dialysis training to home patients, to clarify that the role of the interdisciplinary team is to oversee the home dialysis training.

Comment: Several commenters suggested that training topics should be determined by the facility rather than regulation. Some commenters suggested removing at least two of the proposed training topics (proposed

§ 494.100(a)(3)(iii), implementation of a nutritional care plan, and § 494.100(a)(3)(iv), how to achieve and maintain emotional and social well-being), since these topics are proposed to be covered in the ''Patient plan of care'' condition.

Response: Patient education and training are addressed in the ''Patient plan of care'' condition, which now requires that the care plan include education and training regarding home dialysis and self care, as appropriate, at § 494.90(d). All dialysis patients, whether home or in-center, are to receive counseling regarding nutrition and psychosocial well-being (§ 494.90(a)(2) and (6), respectively). We concur with the comments and believe it is redundant to include these topics under the self-care training standard at § 494.100(a). Therefore, we have removed ''implementation of a nutritional care plan'' at proposed § 494.100(a)(3)(iii) and ''how to achieve and maintain emotional and social well-being'' at proposed § 494.100(a)(3)(iv).

Comment: One commenter suggested removing the specific level of hemoglobin and hematocrit and replacing it with reference to evidence-based standards.

Response: We have modified the final rule at § 494.100(a)(3)(ii) because the proposed language was redundant. The ''Patient plan of care'' condition at § 494.90(a)(4) requires that the interdisciplinary team develop a plan of care that addresses anemia, and specifies the hemoglobin and hematocrit targets. In the final rule at § 494.100(a)(3)(ii), we have eliminated specific numerical values for hematocrit and hemoglobin but require that the patient be instructed on how to administer erythropoiesis-stimulating agent(s) in order to achieve and maintain a target level hemoglobin or hematocrit, as written in the patient's plan of care at § 494.90.

Comment: A few commenters suggested that the 2-month timeframe for monitoring home patients was excessively rigid and burdensome. Two of those commenters suggested a quarterly reporting timeframe that would coincide with monitoring. Two commenters suggested we change the timeframe to require monthly reporting.

Response: The goal of the standard at § 494.100(b)(2) is to have facilities effectively monitor the care of home dialysis patients to achieve desired outcomes. Monitoring patient records allows dialysis facility staff to compare the prescribed regimen to actual dialysis results. Home patients do not see facility staff as frequently as in-facility patients do and so we believe the 2-month monitoring schedule is reasonable.

Comment: One commenter agreed with the proposed rule but pointed out that home patients do not always provide documentation regarding their care at home. Another commenter remarked that non-compliant patients may not provide the required data and other information necessary for staff to carry out the mandatory review. This commenter suggested we add language that would enable staff to be in compliance on the basis of having made a ''good faith effort.''

Response: The home dialysis patient is part of the interdisciplinary team and should be working to meet the home dialysis plan of care goals. If home dialysis patients exhibit non-compliant behavior and/or their care plan goals are not met, then facilities must intervene. If facilities take reasonable measures and lack of patient compliance remains a problem, then the interdisciplinary team must document the interventions to address patient non-compliance, the results of the interventions, and the plan to protect patient health and safety within the limitations of poor patient compliance.

Comment: Several commenters remarked on the differences between hemodialysis and peritoneal dialysis modalities in the home setting. The commenters suggested that peritoneal dialysis visits only be required when medically indicated, since the water treatment issues associated with hemodialysis do not exist for these patients. Two commenters suggested that home monitoring visits be at the discretion of the interdisciplinary team. One commenter suggested that the proposal be revised to allow home visits ''as appropriate.'' Another commenter suggested that the final rule state whether the interdisciplinary team would be required to perform an assessment at a team meeting. Another commenter asked for clarification on whether the staff must visit a patient's home periodically. A commenter suggested that a physician be required to visit home patients only as medically indicated, while another commenter asked whether the physician would be required to see the home patient monthly. One commenter suggested we add a requirement that the home consultation be with ''all'' of the team members as needed. Two commenters suggested that ''periodic monitoring'' include ''at least annually.'' Other commenters suggested that the final rule specifically state that all home patients must be visited in the home at least periodically after home training is completed.

Response: Many of these concerns from commenters would be addressed in the patient's plan of care at § 494.90, which requires an appropriate plan of care based upon medically indicated needs, treatment, and services. Patient needs identified in the plan of care should drive the frequency of home visits of the interdisciplinary team members, including the physician. Regular contact with facility staff offers the patient an ongoing support service and an avenue for communicating questions and concerns. Our regulations require periodic monitoring and home visits by a team member as part of the patient plan of care; they are necessary in order to protect patient health and safety. We would expect that each home care patient, in addition to being visited, would have regular contact with dialysis facility staff. The initial home visit allows dialysis facility staff to ensure that the home patient has an acceptable environment in which to perform safe dialysis, and ensure there is adequate storage of supplies, etc. The dialysis facility should ensure that care being provided to home-care patients be equivalent to care provided to other facility patients.

Comment: A commenter suggested that we require at § 494.100(c)(1)(i) that home patient monitoring be completed as needed and only if geographically feasible, in accordance with the patient's plan of care. Another commenter remarked that facility staff should not be required to make home visits if patients live in dangerous areas or if it is unsafe for staff.

Response: Support services at standard (c) are required for all home patients, regardless of the setting or geographical location. At § 494.100(c)(1)(i), dialysis facility staff are required to periodically monitor the patient's home adaptation and visit the patient's home setting in accordance with the plan of care. All patients have the right to receive equal care that protects their health and safety, and CMS cannot establish a mandate that would allow discrimination in any form.

Comment: Two commenters remarked that while the proposed rule provides a new level of protection for the patient, the requirements would make home dialysis more expensive, which could be a deterrent for dialysis facilities to offer home dialysis. One commenter noted that weekly home hemodialysis water testing for new systems was too expensive, as was monthly bacteria testing. The commenter remarked that the final rule should recognize differences between hemodialysis and peritoneal dialysis, and that it is not

necessary to monitor water quality/dialyzer reuse with certain new home dialysis technologies. One commenter suggested that for preconfigured, 510(k) cleared systems designed, tested and validated to yield AAMI quality water and dialysate, that we should merely require the facility to monitor water quality in accordance with the systems' FDA-approved labeling under § 494.100(c)(1)(v). Another commenter remarked that AAMI recommendations were never intended for home hemodialysis, stating that home water quality should be monitored but not with the same frequency as in a facility setting. One commenter also asked how the conditions would stay current if the referenced guidelines were changed or updated.

Response: The subject of water quality was addressed in our discussion under § 494.40, where all related issues, including home dialysis issues, were thoroughly discussed. In accordance with that discussion, we have revised the final rule at § 494.100(c)(1)(v)(A) and § 494.100(c)(1)(v)(B), to require that the facility monitor the quality of water and dialysate used by home hemodialysis patients and conduct onsite evaluations and testing of the water system in accordance with the recommendations specified in the manufacturers instructions and the system's FDA-approved labeling for preconfigured systems designed, tested and validated to yield AAMI quality water and dialysate. Bacteriologic and endotoxin testing must be performed at least quarterly, or on a more frequent basis as needed, to ensure that the water and dialysate are within AAMI limits. We are requiring at least quarterly cultures and endotoxin testing to ensure that as new technologies come into use, the facility monitors home hemodialysis water systems so that patient safety is protected. As data and information become available regarding the long-term use and safety of new technologies, we may, in the future, re-evaluate the required frequency of water testing for these systems based on the scientific evidence.

Comment: One commenter agreed with the proposed rule that the dialysis facility should provide all support services regardless of whether or not any durable medical equipment is provided by that facility. Another commenter suggested adding the following language to the final rule at § 494.100(c) for Method I patients: ''The dialysis facility must purchase or lease and deliver the necessary home dialysis supplies and equipment.'' Two commenters remarked that equipment rental should be included in the proposed list of requirements at § 494.100(c)(2)(iii), as some providers rent dialysis equipment.

Response: We appreciate the positive comments regarding the need for facilities to provide support services for the home patient. Home dialysis patients who receive all equipment, supplies and support services from their ESRD facility are considered ''Home Dialysis Method I.'' Under ''Method II,'' a durable medical supply company provides all necessary equipment and supplies to the home dialysis patient, and a dialysis facility provides support services to the patient. In order to be responsive to commenters, we have added the terms ''renting'' and ''leasing'' to the final rule at § 494.100(c)(1)(vi), which now requires services provided by the facility to include, ''Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician.''

Comment: One commenter suggested that we add a requirement that a home dialysis provider have its own in-center facility within 35–50 miles of the patient's home, or an agreement with a designated backup in-center provider, including on-call availability of a nurse to permit a home patient to have access to care when equipment fails or in an emergency.

Response: In the proposed rule at § 494.100(c)(1)(vii), facilities are required to identify a plan and arrange for emergency back-up dialysis services in the event that they may be needed. We believe this requirement addresses the commenter's concern, while providing flexibility for facilities. Emergency preparedness is also addressed in the final rule at § 494.60(d), which requires facilities to implement processes and procedures to manage medical and non-medical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public.

Comment: One commenter stated that requiring facilities to deliver supplies and equipment to home patients would give an unfair advantage to Method II suppliers, especially for a clinic serving a large geographic area. Another commenter recommended that we consider allowing facilities to ''arrange'' for installation and maintenance of supplies and equipment, as it is standard industry practice for the manufacturer to install dialysis equipment.

Response: It appears these commenters may have misinterpreted some of the proposed rule language at § 494.100(c). The part 405, subpart U requires self-dialysis support services to be furnished either directly, under agreement or by arrangement with another ESRD facility (§ 405.2163(e)). We have added language to § 494.100(c)(1) of the final rule to clarify that, ''A home dialysis training facility must furnish (either directly, under agreement or by arrangement with another ESRD facility) home dialysis support services regardless of whether dialysis supplies are provided by the dialysis facility or a durable medical equipment company.''

As noted above, home dialysis patients who receive all equipment, and supplies from one durable medical equipment supplier and all other support services from their dialysis facility have opted for ''Home Dialysis Method II.'' Facilities are accountable for arranging and providing services and supplies to their patients as required. To allow maximum flexibility for facilities to carry out this requirement, facilities are permitted to determine the most effective and efficient way for them to operate within the context of the final rule.

Comment: One commenter suggested the proposed rule at § 494.100(c)(1)(vii) (identifying a plan and arranging for emergency backup) be modified to require that emergency backup dialysis services must be at a location convenient to the patient's home.

Response: We do not believe it would be beneficial to mandate emergency back up dialysis services that are convenient to the patient's home. The term ''convenient'' may have a wide range of interpretations and depending on how it is interpreted, could become an access to care barrier that reduces the availability of home dialysis. Some patients choose home dialysis because they live in a remote area where in-center dialysis is not available. If we required that back up dialysis for all home patients must be ''convenient'', this may cause dialysis facilities to discontinue home dialysis for patients who live in these remote areas for whom there is no convenient dialysis facility. We expect providers to work with patients, other providers and ESRD Networks to best meet the needs of patients. Facilities must have a reasonable emergency plan to deal with patients in need of backup dialysis services.

Comment: Two commenters suggested we delete proposed § 494.100(c)(1)(iii) through § 494.100(c)(1)(vii) because most of the requirements are already required of the facility with respect to all patients receiving care and services through the facility.

Response: The support services provision in the proposed rule at § 494.100(c)(1)(i) through § 494.100 (c)(1)(vi) would retain and expand existing part 405, subpart U requirements, as discussed in the ESRD proposed preamble (70 FR 6212). We also proposed the addition of § 494.100(c)(1)(vii), which would require the facility to plan for and arrange for emergency backup dialysis services when needed. Support services for home care patients are required by section 1881 of the Act and are necessary to ensure proper care and support. We have added a clarification to § 494.100(c)(1) to state that any home dialysis training facility must also ''furnish either directly, under agreement, or by arrangement with another ESRD facility.''

Comment: Some commenters suggested that separate sections were needed for home hemodialysis and peritoneal dialysis. One commenter remarked that this was necessary due to water quality issues. Another suggested that hemodialysis was more complex and that the proposed rule, as written, would impose an undue burden on peritoneal dialysis care.

Response: Hemodialysis water quality was addressed in the ''Care at home'' condition at § 494.100(c)(1)(v) in the proposed rule. The language in the final rule has been modified and is now consistent with the requirements in the ''Water and dialysate quality'' condition at § 494.40. The language at § 494.100(c)(1)(v)(A) and § 494.100(c)(1)(v)(B) requires that services include, ''Monitoring of the quality of water and dialysate used by home hemodialysis patients, including conducting an onsite evaluation and testing of the water and dialysate system in accordance with: (A) The recommendations specified in the manufacturers' instructions; and (B) the system's FDA-approved labeling for preconfigured systems designed, tested, and validated to yield AAMI quality water and dialysate; in addition, bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits.'' We have added a reference to dialysate in our final rule to be consistent with the AAMI RD52 guidelines that we have incorporated by reference. The interdisciplinary team is required to educate the patients or caregivers about water quality problems as required by § 494.100(a)(3)(iii).

Comment: One commenter remarked that Medicare should ''cover separately billable medication and biologicals for home patients, as it does for in-center patients, to improve their clinical outcomes.''

Response: This regulation does not address payment issues. The matter has been referred to the appropriate CMS coverage staff for consideration.

Comment: One commenter recommended that CMS contract with a Network to form a TEP to study current guidance for care at home and make recommendations.

Response: A TEP was convened in Baltimore on January 20 and 21, 2006, after the close of the proposed rule's comment period, to assist ESRD Network 9/10 in developing recommendations for providing staff-assisted dialysis in a long-term care facility. TEP members, including patients and professionals, represented various ESRD stakeholders involved in or impacted by dialysis in the LTC facility. The TEP's final recommendation to CMS was to suggest creation of a new model of care for staff-assisted dialysis in long-term care facilities, as the current method of home dialysis in such facilities did not appropriately meet the need. The final report ''Delivery of Dialysis Treatment Within the Long Term Care Facility'' can be found on The Renal Network Web site at *http://www.therenalnetwork.org/PF/LTC_feedback.html*.

Comment: We received many public comments regarding the issue of institutional dialysis or dialysis in a nursing home setting, which was discussed in the proposed rule preamble. Dozens of members from the renal, hospital, and nursing home industries commented and many were opposed to the current existing (2004) nursing home dialysis policy, which can be viewed at *http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter04-24.pdf* and *http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter04-37.pdf*. The majority of commenters had major concerns with this issue and expressed frustrations with existing payment systems. Commenters were concerned with the financial feasibility of providing dialysis to these patients at a certified dialysis facility within the nursing home or under the home dialysis model. Commenters believe that the reimbursement system should be adjusted for care provided in this setting. Accountability is another concern, as commenters were not clear regarding the division of responsibilities between the skilled nursing facility and the ESRD facility. Still other commenters stated that these patients should not be categorized as home-care patients because the majority are frail and often elderly, cannot participate in their own care, and cannot be trained. Many commenters suggested that CMS convene a Technical Expert Panel to address the issue of dialysis for nursing home residents and craft a separate rule following publication of this final rule.

Response: The proposed rule solicited comment regarding ''whether the current dialysis regulations need to be modified to protect this vulnerable (nursing home) population * * *'' (70 FR 6213). Commenters clearly believe that current regulations pertaining to the provision of dialysis to nursing home patients need to be revised. However, it is not clear now how we could best improve our health and safety regulations to meet our goal of providing safe, high quality, efficient dialysis care to vulnerable nursing home patients. Therefore, we are not issuing nursing home dialysis regulations in this final rule. Given the complex programmatic and fiscal issues associated with a new nursing home dialysis model, we intend to consider rulemaking as well as alternative actions in the future. Until that time the current policy (S&C–04–24 and S&C–04–37) will remain in effect.

e. Quality Assessment and Performance Improvement (Proposed § 494.110)

The February 4, 2005 proposed rule included a new condition that would require dialysis facilities to develop, implement, maintain, and evaluate an effective, data-driven, interdisciplinary QAPI program. This ongoing internal quality oversight program would focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The QAPI program would include adequacy of dialysis, nutritional status, anemia management, vascular access, medical injuries and medical errors identification, hemodialyzer reuse, (if applicable), and patient satisfaction and grievances. The dialysis facility would be required, not only to monitor its performance, but also to take actions that would result in sustained performance improvements. Priorities would have to be set for performance improvement activities, taking into consideration the prevalence and severity of identified problems and affect on clinical outcomes or patient safety. We proposed that any identified problems that threatened the health and safety of patients would be immediately corrected. We also proposed retaining the part 405, subpart U requirement that dialysis facilities participate in ESRD Network activities and pursue Network goals.

We received a large number of comments on the QAPI condition. The comments generally supported a QAPI condition. One commenter applauded the proposed requirement for prioritizing QAPI improvement activities and requiring facilities to have a plan for immediate correction of problems that might jeopardize patient health and safety.

Comment: A few commenters requested clarification of the term ''interdisciplinary team'' as used in subpart C.

Response: As stated earlier, we have clarified the meaning of ''interdisciplinary team'' under the ''Patient assessment'' (§ 494.80) and ''Plan of care'' (§ 494.90) conditions. The first sentence of the QAPI condition in the proposed rule required an ''interdisciplinary'' QAPI program. We have modified this requirement in the final rule to make clear that the professional members of the interdisciplinary team (physician, RN, social worker, and dietitian) must participate in the QAPI program. The facility has the option of including facility patients when appropriate. The first sentence of § 494.110 now reads, ''The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team.''

Comment: Two commenters were concerned that there was no mechanism to update QAPI measures, and suggested that CMS develop such a mechanism.

Response: QAPI measures were not proposed; however, QAPI topics were proposed at § 494.110(a)(2). Facilities may use indicators and measures of their choice as appropriate and necessary to implement the data driven QAPI program. We may update the QAPI topics as needed in future revisions of the ESRD conditions for coverage. Facilities may add topics to their QAPI program as needed to meet the unique needs of their facility.

Comment: A commenter suggested that if face-to-face QAPI meetings are expected, this should be specifically required in the regulation.

Response: The facility has the flexibility to develop and implement QAPI via processes of their own choosing, as long as the efforts result in a multidisciplinary, data-driven QAPI program that achieves improvement and meets the criteria stated in § 494.110. This might include face-to-face meetings or additional and alternate activities. We have not modified the regulatory language to specify processes or face-to-face meetings.

Comment: Two commenters suggested that we consider increasing the Network role in QAPI oversight.

Response: The Network role regarding the quality of ESRD care is defined at section 1881(c) of the Act, and implemented at 42 CFR 405.2112 and in the ESRD Network contract. We expect the ESRD Networks and the facilities to work collaboratively for the benefit of the patients that are being served. These conditions for coverage do not affect the ESRD Network role or requirements. The requirements regarding dialysis facility cooperation with its ESRD Network have been consolidated at § 494.180(i), as discussed under that section of this preamble.

Comment: A commenter stated that standard facility continuous quality improvement programs should satisfy QAPI requirements.

Response: We expect that some quality-oriented dialysis facilities already have in place effective full-scale quality improvement programs that would meet QAPI requirements.

Comment: Many commenters suggested additional QAPI topics that should be required, including: Infection control, renal bone disease, psychosocial status, transplantation, mortality reviews, staffing policy, errors, fluid status, staff education, home dialysis, surveillance of water treatment, venous catheter use reduction, fistula use, depression, hospitalizations, cardiovascular health, patient suggestions for QI and safety, and growth and development for pediatric patients under the age of 18. A large number of the comments supported inclusion of infection control and renal bone disease. Two commenters suggested that we omit the specific QAPI elements because while they are currently appropriate, they should not be codified.

Response: The proposed QAPI elements included adequacy of dialysis, nutritional status, anemia management, vascular access, medical injuries and medical errors identification, hemodialyzer reuse program, and patient satisfaction and grievances. The majority of comments strongly supported the QAPI topics that we proposed to be included in the facility QAPI program. We have added ''mineral metabolism and renal bone disease'' to the list of QAPI topics in this final rule at § 494.110(a)(2)(iii) due to its importance to quality dialysis care, its association with cardiac health, and the strong support received from commenters. Renal bone disease and mineral metabolism are routine components of dialysis facility QI programs and are easily monitored via lab values. CMS has recently pilot tested mineral metabolism/bone disease clinical performance measures and has added these as new ESRD clinical performance measures. We have also added ''infection control'' at § 494.110(a)(2)(ix), as discussed above in connection with § 494.30 ''Infection control'' condition. This QAPI component retains the same specificity and detail provided in the proposed rule under § 494.30. We believe that infection control is crucial to protecting patient health and safety. We do not intend to understate the importance of this issue simply because it was relocated in this final rule.

Fistula use and reduction in venous catheter use is encompassed by the vascular access topic, which is already included in the QAPI required topics. Therefore, we are not making any additional changes. Dialysis facilities should focus on the vascular access problems that have been identified as a priority for their facility.

Surveillance of the water system is already required by this final rule; the ANSI/AAMI RD 52 water purity guidelines, incorporated by reference in the ''Water and dialysate quality'' condition for coverage at § 494.40(a), specify surveillance and quality assurance procedures.

We encourage dialysis facilities to include social services and other suggested QAPI topics in their program when appropriate, but are not requiring these additional topics. The facility should identify additional QAPI components when it prioritizes improvement activities in accordance with standard § 494.110(c). We expect the dialysis facility to devote the needed resources to its QAPI program, which will be based on such prioritization of facility needs.

Comment: We received several comments on various aspects of proposed § 494.110(b), which includes monitoring performance improvement, taking actions that result in performance improvements, and tracking performance to sustain improvements. One commenter stated that when evaluating performance, new patients should be excluded for the first 3 months. Another commenter suggested that the facility be examined before requiring an improvement plan, in order for the surveyor to evaluate patient characteristics and to decrease risk of facilities ''cherry picking'' the healthiest patients. A commenter stated that patients will not be able to meet targets for albumin and anemia, and certain categories of patients should be excluded from the quality measure patient population. One commenter

suggested that it should be sufficient that facilities address the quality issues, while another stated that the facility can only address actionable issues. Some commenters said a risk adjustment is needed, but one commenter disagreed with a need for risk adjustment. Other commenters stated that patient non-compliance is a factor in meeting QAPI goals.

Response: The intent of § 494.110(b) was explained in the preamble of the proposed rule (70 FR 6217) where we stated, ''We will specifically expect a facility whose treatment outcomes vary significantly from accepted standards to identify the reasons for poor outcomes and implement improvement projects to achieve expected outcomes.'' The QAPI program is meant to have a facility-wide scope that seeks opportunities for improvement, whereas the ''Patient plan of care'' condition focuses on individual patient care. Since the QAPI program is an internal facility function, facilities may use their own risk adjustors and incident or prevalent patient designators within their QAPI programs as needed. However, both adjusted and unadjusted QAPI data must be available for our review. This QAPI condition does not require facilities to report QAPI data, although information about quality measurement and improvements would need to be available to the surveyor who assesses whether the QAPI program met the requirements of this condition. The risk adjustment aspect is discussed under the ''minimum facility-wide standards'' discussion below.

The QAPI requirement provides the facility with flexibility in identifying the QAPI goals and actions to undertake. We would expect the facility to undertake activities that are expected to improve health outcomes, and prevent and reduce medical errors.

We recognize that patient adherence to the treatment plan can be a factor in meeting facility QAPI goals. The issue of patient compliance was discussed earlier in this document under the ''Patient plan of care'' condition portion of the preamble. We addressed the need for interventions when the plan of care goals are not met and the required documentation of any barriers preventing the goals from being met. It is possible that some facilities may find during their prioritization of improvement activities that patient compliance trends need to be addressed within the QAPI program.

Comment: Several commenters supported a requirement for dialysis facilities to use a common patient experience of care or satisfaction tool. They stated that this would allow comparable information and spur improved performance, although one commenter stated this could be costly and burdensome. Two commenters support the use of a common tool that allows facilities to add unique facility-chosen questions. A few commenters supported a patient satisfaction survey, but not use of a common tool. While there was predominant support for the inclusion of patient satisfaction in the QAPI program requirement, few commenters specified their position on whether CMS should mandate the use of a common survey tool (that is, In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS)).

One commenter said that CMS should only specify that a survey be done and within specified intervals. Another commenter, opposing a common patient satisfaction tool requirement, stated regional differences may skew results. A large dialysis organization (LDO) stated they preferred their own patient satisfaction tool, which is used to benchmark and allows modifications to the questions over time. The LDO further stated that ICH CAHPS is not operational, and that pilot tests need to be reviewed. A few commenters recommended that a ''quality of life'' aspect be included in a patient survey.

Response: We are requiring that dialysis facilities include patient satisfaction as a component of their QAPI program. At this point in time we are strongly encouraging facilities to use the standardized ICH CAHPS tool to assess in-center hemodialysis patient experience of care, but we are not requiring use of this instrument. As the renal community becomes more experienced with using the ICH CAHPS instrument and recognizes benefits associated with its use, we would expect to see widespread voluntary use.

Providing patient experience-of-care information to beneficiaries is a priority for CMS as a component of our transparency initiative. Many of the questions in the Core ICH CAHPS Instrument are questions that were taken directly from existing surveys used by dialysis facilities that responded to our call for measures. A rigorously tested instrument, based on input from stakeholders and facilities, would supply valuable feedback to facilities for improving quality of dialysis care.

Creation of a standardized patient experience-of-care survey for dialysis patients is directly responsive to calls for CMS and the Secretary to collect this type of information in a variety of reports. The Office of the Inspector General (OIG) Report, entitled ''External Review of Dialysis Facilities'' (June 2000), recommended that CMS ''require dialysis facilities to monitor patient satisfaction'' particularly, as a way of bringing forth patient concerns that may not be captured by the current complaint systems. Likewise, in a Report to the Congress entitled ''Improving Payment for End-Stage Renal Disease Services'' (March 2000), the Medicare Payment Advisory Commission (MedPAC) recommended that CMS collect and analyze information on a regular basis on ESRD patients' satisfaction with the quality of and access to care. This recommendation was reiterated in MedPAC's report to the Congress ''Modernizing the Outpatient Dialysis Payment System'' (October 2003), which recommends that, ''The Secretary should also monitor patient satisfaction with care and other access indicators to determine whether patients face obstacles in obtaining needed care.'' Furthermore, the importance of a patient focus in the provision of healthcare services was emphasized in the IOM 2001 report, ''Crossing the Quality Chasm,'' that established patient-centered care as one of the industry's six aims for quality improvement. The IOM dimensions of patient-centered care include respect for patients' values, preferences, and expressed needs; coordination and integration of care; information, communication, and education; physical comfort; emotional support; involvement of family and friends; continuity and transition; and access to care. The ICH CAHPS survey instrument addresses all these areas in either the Core Instrument or supplemental questions.

Consumer testing of the DFC Web site, conducted on behalf of CMS by the Research Triangle Institute during 2002 and 2003, revealed that consumers most frequently requested patient satisfaction information or patient opinions about the care given in dialysis facilities to gauge the quality of care provided in a dialysis facility. The data collected from the core items in a common tool will allow consumers to make ''apples to apples'' comparisons among dialysis facilities. In addition, such information would allow dialysis facilities to benchmark their performance at local, regional, and national levels.

The ICH CAHPS core instrument and supplemental questions have been placed in the public domain. Any hemodialysis facility interested in using the survey should contact Charles Darby at *Charles.Darby@ahrq.hhs.gov.* The Agency for Healthcare Research and Quality welcomes input on experiences

that dialysis facilities may have in implementing the survey.

Comment: We received many comments regarding CMS use of facility-specific standards for enforcement of the conditions for coverage. While commenters supported CMS regulations that would hold facilities accountable for their performance via clinical data, there was much disagreement regarding the implementation approach.

Several commenters responded to our proposed rule preamble discussion (70 FR 6218) regarding the use of NKF K/DOQI clinical practice guidelines as the facility-specific minimum standards to be used for enforcement. One commenter recommended that CMS adopt evidence-based NKF–K/DOQI clinical practice guidelines for adequacy, anemia, and vascular access as facility-wide targets for enforcement. The commenter suggested that if problems were found, facilities could be required to provide a plan to improve care with active Network involvement. Two commenters supported minimum clinical standards using K/DOQI, stating that this could provide a basis for quality improvement and patient education on expected outcomes or goals. One commenter supported facility-wide measures without risk adjusters, arguing that no patient should be exempt from the coverage of evidence-based minimum threshold values, and pointing out that the purpose of QAPI is to identify and solve problems.

Most of the comments submitted on this minimum standards issue did not support immediate implementation of facility-level standards and thresholds in this final rule. The NKF communicated concerns about CMS use of their K/DOQI guidelines for enforcement without addressing factors such as case mix, effects of patient non-compliance, biologic variability, third party reimbursement, large numbers of outliers, and the inflexibility of the CMS regulation process. Another commenter suggested that CMS should be careful to avoid overly prescriptive language, requirements that create new indirect costs, and requirements that hold units accountable for things they cannot control. A commenter stated that some K/DOQI clinical practice guidelines are opinion-based, and some requirements apply to non-reimbursable practices and that only evidence-based criteria covered by Medicare should be considered for inclusion in the conditions for coverage.

A few commenters stated that not all patients would be able to meet the numerical outcome targets and should not be expected to meet them. Other commenters were concerned about unintended consequences. A commenter suggested that ''cherry-picking'' and other inadvertent consequences will result without an effective case-mix adjuster to avoid disadvantaging facilities that have a challenging case mix. The commenter further stated that the current Medicare Modernization Act case-mix adjuster (used to determine Medicare payment) is inadequate, disadvantages frail elderly patients, and that minimum standards should not be considered until an effective case-mix adjuster has been developed. Many commenters objected to implementation of facility-level performance standards without the use of case-mix adjusters and objected to using clinical practice guidelines written for individual patient care as facility-wide standards.

Some commenters noted that the NKF workgroups that developed the K/DOQI clinical practice guidelines never intended that they would be used for enforcement and pointed to the K/DOQI disclaimer regarding appropriate use of the clinical practice guidelines. A commenter stated that more study is needed to link existing evidence to intended outcomes. Another commenter stated that CMS needs to differentiate between standards and clinical guidelines. A commenter suggested that ''dynamic'' numerical standards do not belong in ''static'' federal regulations. The commenter also noted that no methodology exists to update numerical values, that serum albumin should not be a target marker, and that these values are often out of the facility's control for the majority of ESRD patients.

Commenters urged CMS to avoid direct extrapolation of standards from existing guidelines until voluntary consensus organizations develop real evidence-based standards and link a standard to a desired outcome. Many commenters supported minimum facility-level clinical performance standards development via a voluntary consensus process that allowed input from the renal community at large. Several commenters specifically supported the National Technology Transfer and Advancement Act of 1995 (NTTAA) process proposed at § 494.180(h)(3)(iv) as the voluntary consensus process to use. A commenter urged CMS to develop flexible, evidence-based standards with a methodology for periodic review. Another commenter endorsed the concept of using commonly agreed upon clinical standards, but was very concerned that frequent rulemaking would be required. One commenter questioned the need for minimum standards in these conditions given the difficulty of updating the conditions for coverage. Another commenter also stated that CMS should not link QAPI expectations to ''static standards.''

One commenter stated that the minimum facility standards proposal is focused totally on lab-based outcomes and this focus ignores more important clinical issues such as blood pressure treatment and cardiovascular disease risks that are not tied intimately to information technology systems and laboratory test outcomes. While multiple laboratory results may be available, other important factors such as the percentage of patients on ACE (angiotensin converting enzymes) inhibitors or beta-blockers are not readily available. Another commenter stated that there is an overdependence on K/DOQI in the proposal.

Although commenters agreed that CMS should hold dialysis facilities accountable for clinical outcomes and performance, the majority did not agree with implementing facility-level clinical performance standards based on the NKF K/DOQI clinical practice guidelines without a case-mix adjuster and without recognition of other factors that affect clinical outcomes.

Response: These conditions for coverage are an important component of the overall CMS quality improvement strategy. We intend to hold dialysis facilities accountable for the quality of care provided to patients using performance measures and clinical data. Commenters pointed out some factors that may impact a facility's ability to meet K/DOQI targets for 100 percent of their patients. While certain dialysis patient populations may have some unique characteristics, efforts should be made by dialysis facilities to meet clinical practice guidelines or come as close as possible to meeting those guidelines for all patients. This is required by the ''Patient plan of care'' condition at § 494.90. We do not intend for the implementation of facility-level clinical performance standards to negatively impact access to dialysis care and we do not hold facilities accountable for outcomes beyond their control. Currently we do not have a case-mix adjuster or other analytical means to ensure comparability between facility performance levels. We would like to address the concerns voiced by commenters before facility-level minimum standards are implemented. In response to comments, we will develop facility-level clinical performance standards via a voluntary consensus standards process indicated at § 494.180(h)(3)(iv). Once developed, these facility-level clinical performance

standards will be published in the **Federal Register** as a proposed rule.

Comment: A few commenters responded to our preamble discussion (70 FR 6218) regarding how current NKF–K/DOQI clinical practice guidelines could be used as minimum standards and what statistically-based thresholds could be employed.

One commenter who was not in favor of using the K/DOQI guidelines as minimum facility-level standards provided suggestions for possible statistical methodologies: using 2 standard deviations below the mean; or, using the 25th percentile for skewed distributions or alternatively using percentiles; however, using a set percentage cut-off as a standard would be arbitrary with no basis in science or evidence. Another commenter suggested that facility-specific ''clinical care measures should never appear on the oversight radar unless a certain percentage of patients fail to meet a particular measure.'' Another commenter recommended that facility-specific standards using K/DOQI be identified as goals and expectations ''for more than 80 percent'' of all patients. This commenter related concern about how minimum standards would be applied when facilities are surveyed and stated that the final rule must acknowledge that 100 percent of patients cannot achieve K/DOQI target minimums.

One commenter suggested that CMS set minimum outcome goals, then move up the thresholds incrementally, with annual readjustments. Another commenter suggested that facilities could develop a corrective action plan when a pre-determined portion of patients failed to meet selected clinical standards. This could be percentile-based or some other methodology but would have to be developed in collaboration with the dialysis industry.

Another commenter recommended a focused review by the servicing Network's Medical Review Board prior to implementation of a corrective action plan, to determine whether there may have been reasonable justification for poor performance. The focused review should be consistent with population studies, which are statistically sound, and not on percentile thresholds. A commenter suggested that K/DOQI clinical practice guidelines were developed only to ''inform and enhance decision-making,'' and believed that any process should include a review by Network Medical Review Boards prior to CMS taking enforcement action.

One commenter had a number of concerns. The first concern was that it would be impossible to predict if patients could achieve clinical outcomes. Another concern was that the proposal could create a potential paperwork burden. A third concern was that no improvement plan should apply unless a significant number of patients were involved. Another concern was that the proposal ignored issues like missed sessions and patient non-compliance. The commenter also suggested that an improvement plan could not guarantee better outcomes, and that the renal community should develop clinical standards and CMS should then incorporate them by reference into its regulations.

A commenter stated that the minimum standards proposal confuses process with outcomes. While a facility can order adequate dialysis, Epogen, iron, etc., it could not guarantee that numerical targets would be met. Documenting interventions and why goals were not met should be sufficient, not the mandatory requirements proposed.

Response: According to the 2006 Annual Report, End-Stage Renal Disease Clinical Performance Measures Project (*http://www.cms.hhs.gov/CPMProject*), which is based on data from October 2005 through December 2005 for hemodialysis patients and October 2005 through March 2006 for peritoneal dialysis patients, reports national rates of meeting K/DOQI based performance measures using a representative sample, 91 percent of hemodialysis patients are meeting the dialysis adequacy target, and 81–84 percent of dialysis patients have a hemoglobin of 11 g/dL or better are meeting the anemia targets. In determining facility-level minimum standards, we would not want to set our thresholds well below established performance levels that could serve to undercut current performance levels.

We have not included minimum facility-level clinical standards in this final rule. We intend to develop minimum facility-level clinical standards for enforcement using a voluntary consensus standards process, as proposed at § 494.180(h)(3)(iv).

f. Special Purpose Renal Dialysis Facilities (Proposed § 494.120)

We proposed to retain with modifications the ''Special purpose renal dialysis facilities'' condition from § 405.2164. This condition addresses the needs of patients who need dialysis on a short-term basis because of emergency conditions, or because they are staying at remote vacation camps. We proposed that such dialysis facilities would be approved to furnish dialysis services at special locations and that such vacation camps would have to be operated under the direction of a certified renal dialysis facility that would assume full responsibility for the care provided to patients. The proposed rule retained the limited 8-month approval period and the service limitation found at § 405.2164. We proposed that a special purpose facility would be approved as a vacation camp by demonstrating compliance with proposed § 494.30, most provisions of § 494.40, § 494.50, § 494.70(a) and § 494.70(c), § 494.100(c)(1)(v), § 494.130, § 494.150(c) and § 494.150(d), and § 494.170. We also proposed that a special purpose facility certified due to emergency circumstances could provide services only to those patients who would otherwise be unable to obtain treatments in the geographical areas served by the facility and was approved by demonstrating compliance with specified proposed conditions for coverage that included § 494.20, § 494.30, § 494.40, § 494.50, § 494.60, § 494.70(a) through § 494.70(c), § 494.130, § 494.140, and § 494.150, § 494.170, and § 494.180. The part 405, subpart U requirement, that a special purpose unit consult with the patient's physician, was retained; we added a provision that this consultation must occur before initiation of dialysis in a special purpose unit. Additionally, we proposed to require the special purpose unit to document care provided to the patient and forward that documentation to the patient's regular dialysis facility within 30 days.

Comment: Many commenters submitted suggestions and recommendations regarding requirements and/or certification for special purpose dialysis facilities, and several commenters made positive remarks regarding the proposed requirements and inclusion of vacation camps within this condition, including the 8-month approval period for special purpose facilities, as required at § 494.120(a). A commenter applauded the specific mention of vacation camps in this regulation, but advised that these vacation camps should be certified as ''safe environments'' for campers, while another commenter suggested the deletion of vacation camps from the final rule. One commenter suggested that the personnel requirements for the ESRD facility medical director, for those furnishing nursing services, and for patient care and water treatment technicians be met by the special purpose dialysis facility vacation camp if on-site dialysis is performed.

Another commenter suggested that the final rule requirements also address backup emergency care, and further suggested that the closest hospital and/

or children's hospital be notified and a process for emergency transportation be identified. One commenter suggested that ''certified facilities not be held accountable for services provided outside their domain.''

Response: We appreciate the positive comments on the proposed language regarding special purpose dialysis facility vacation camps. While we received a suggestion to delete vacation camps in the final rule, the majority of comments regarding vacation camps were positive. Thus, we will adopt vacation camp requirements in the final rule at § 494.120. We also received some positive remarks regarding the approval period of 8 months, discussed at proposed § 494.120(a), which will also be adopted in the final rule. We agree with the commenter that vacation camps should be a safe environment for campers. The facilities must comply with the conditions for coverage set out at § 494.120(c) to ensure that the vacation camp environment protects the health and safety of campers.

This condition addresses the possible needs of patients who, because of emergency conditions, or because they are staying at a remote vacation camp providing such services, need dialysis on a short-term basis. The commenters' concerns regarding certain personnel requirements, as well as responsibility and accountability for vacation camps, is addressed at § 494.120(c)(1). This standard mandates that special purpose dialysis services, provided at a vacation camp facility, be operated under the direction of a certified renal dialysis facility. The certified renal dialysis facility assumes full responsibility for the care provided to patients. Vacation camps must demonstrate compliance with the conditions for coverage set out at § 494.120(c)(1)(i) through § 494.120(c)(1)(viii), including infection control, water and dialysate quality, reuse of hemodialyzers, patients' rights, laboratory services, medical director responsibilities, medical records, and home monitoring of water quality. We agree with the commenter that it is important to take into consideration emergency backup care in vacation camps. Vacation camps will be held responsible for the care of their patients under § 494.120(c)(1), including emergency care when required; however, we will not specifically mandate that vacation camps notify hospitals and develop emergency transportation plans in this final rule. We believe that the requirement at § 494.120(c)(1) provides adequate protection for patients at vacation camps.

Comment: A commenter supported the requirements for emergency circumstance facilities, noting that recent natural disasters underscored the necessity for such facilities. Another commenter agreed with changes in the proposed rule that would make access to care for a patient in a disaster situation more readily available. One commenter suggested the proposed language at § 494.120(c)(2) was too restrictive and that the final rule should be revised by requiring such facilities to comply with the specified conditions ''where feasible.'' The commenter suggested that adding ''where feasible'' would be necessary in the event of a large emergency affecting a broad geographical area.

Another commenter suggested the requirement at § 494.120(c)(2)(i) regarding compliance with Federal, State, and local laws and regulations would be redundant for a facility that is quickly converted to a special purpose facility under emergent circumstances. The commenter suggested the adoption of State and local codes, as well as the International Code Council (ICC) requirements, in lieu of the LSC, would eliminate this problem of redundancy in many states. The ICC is an association dedicated to building safety and fire prevention, and they develop the codes used to construct residential and commercial buildings, such as health care facilities. Most U.S. cities, counties and states that adopt codes choose those codes developed by the ICC.

Response: In the event of a large disaster, section 1135 of the Act gives the Secretary the authority to waive regulatory requirements during national emergencies. During natural or man-made disasters, the proposed regulation at § 494.120(c)(2) allows for more flexibility than part 405, subpart U of our previous regulations in managing emergent circumstances. These facilities must comply with a condensed number of conditions, which include: § 494.20, compliance with Federal, State and local laws and regulations; § 494.60, physical environment; abbreviated sections of § 494.70, patient's rights; § 494.140, personnel qualifications; § 494.150, medical director; and § 494.180, governance. While we expect that special purpose facilities will comply with these requirements, we understand that there may be instances where this may not be possible and a waiver might need to be granted; however, we do not agree that the suggested language ''where feasible'' should be added to the final rule.

Comment: Two commenters agreed that physician contact during a disaster is ideal; however, they stated it may be impossible. These commenters recommended the addition of a provision to allow another physician to provide emergency care in extenuating circumstances at § 494.120(d). One commenter suggested we modify the requirement in the final rule to indicate, ''Standing orders or the patient's current orders may be followed until the time a physician may be reached.'' Another commenter suggested the wording in the final rule be changed to require ''nephrologist contact'' as opposed to ''physician contact.''

Response: We agree that it may not be possible to consult with the patient's physician during a disaster. To allow greater flexibility, in the event of disasters or emergencies, we have modified the wording in the final rule at § 494.120(d) to indicate that the facility must contact the patient's physician ''if possible'' prior to initiating dialysis in the special purpose renal dialysis facility. Additionally, we will retain the requirement for ''physician contact'' as proposed, because we believe this language will allow more flexibility for facilities.

Comment: It was suggested by a commenter that we modify the final rule to require forwarding of documentation of care at the special purpose facility to the patient's regular facility within 1 day of the last scheduled treatment, as opposed to 30 days as proposed at § 494.120(e). The rationale given was that hospitals as well as transient dialysis clinics must transfer patient care records within one day.

Response: It is the responsibility of the special purpose facility to communicate to the patient's permanent dialysis facility regarding the patient's status, and we recognize that it would be most desirable for this information to be forwarded in less than 30 days. However, we must also keep in mind that some circumstances may prevent such communication timeframes. For example, we have learned through recent events, such as Hurricane Katrina in 2005, that 30 days may not allow enough time for special purpose facilities to forward all documentation to the patient's permanent facility. Because we recognize this possible limitation, we have added language to allow greater flexibility for facilities. At § 494.120(e) the language has been modified in the final rule to require information be forwarded ''if possible'' within 30 days.

g. Laboratory Services (Proposed § 494.130)

We proposed to retain the existing requirements governing laboratory services previously set out at

§ 405.2163(b), with minor revisions. The dialysis facility must provide or make available laboratory services to meet the needs of their patients, and these services must be furnished by or obtained from a facility that meets the requirements for laboratory services in accordance with 42 CFR part 493.

Comment: One commenter recommended that we add language in the final rule to specify that facilities must have an agreement with a primary or secondary laboratory that meets the Certified Laboratory Improvement Amendments of 1988 (CLIA) requirement.

Response: CLIA certification is addressed at § 494.130 by reference to part 493. It states that all Medicare-certified laboratories performing laboratory tests be certified under CLIA. Therefore, we have adopted the language as proposed.

Comment: One commenter suggested the addition of language to the final rule saying that to ''ensure that composite rate lab tests for each ESRD beneficiary are accounted for in a single, centralized database for proper application of ESRD laboratory billing rules, composite rate lab tests performed by any other laboratory must be billed through the primary laboratory.'' Another commenter suggested adding language to specify that in the event a facility uses a secondary laboratory, it must enter into an agreement with the facility or the facility's primary laboratory to bill the facility or the primary laboratory for laboratory tests that are subject to ESRD laboratory billing rules. One commenter suggested we require a facility's primary laboratory to be the single laboratory permitted to bill Medicare for tests listed as composite rate laboratory tests. Another commenter suggested that local laboratories (in close proximity to an ESRD facility) should be able to bill for tests through a ''primary laboratory.'' One commenter remarked that the final regulation should address problems with Health Maintenance Organizations (HMOs) and mandate that required testing be conducted in laboratories equipped to do such testing. The commenter stated that HMOs often refuse referrals to properly equipped laboratories affiliated with the patient's ESRD unit.

Response: The commenters' concerns are related to Medicare payment for services and are therefore outside the scope of this rule. The commenters' concerns have been forwarded to the appropriate officials within CMS for consideration.

Comment: One commenter suggested the regulation require that primary laboratories agree to furnish the dialysis facility with laboratory test data electronically upon request so that the data can be submitted to ESRD Networks.

Response: The ESRD Conditions for Coverage cover dialysis facilities and do not extend to testing laboratories. Facilities must provide for or make available laboratory services to meet the needs of the ESRD patient. Laboratory services must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter (§ 494.130). However, dialysis facilities may enter into business agreements with laboratories willing to provide requested data electronically.

Comment: One commenter stated ''convenience'' lab draws need to be addressed in the final rule.

Response: We believe the commenter is referring to those laboratory tests, such as histocompatability tests, ordered by a patient's outside physician, which could be drawn in the ESRD facility while a patient is undergoing dialysis treatment. Drawing additional laboratory tests while the patient is undergoing treatment is convenient for the patient; individual facilities have the flexibility to determine if this is a service they wish to offer.

4. Subpart D (Administration)

a. Personnel Qualifications (Proposed § 494.140)

To avoid placing substantive requirements within the definitions section as written in part 405, subpart U (at § 405.2102), we proposed a separate condition to set forth requirements for dialysis facility staff qualifications. We proposed that the dialysis facility medical director be a physician who has completed a board approved training program in nephrology and has at least 12 months experience providing care to patients receiving dialysis. We did not retain transplantation experience as a qualification, which was previously set out at § 405.2102(d), because this rule applies to dialysis centers and not to transplantation centers. We proposed to carry forward the part 405, subpart U waiver provision for instances when a physician meeting the medical director qualifications is not available. We proposed that the facility nurse manager be an RN and a full time employee, as required under part 405, subpart U, and have at least 12 months of clinical nursing experience and an additional 6 months of dialysis experience. We proposed that the self-care home dialysis training nurse be an RN with at least 12 months of nursing experience and an additional 3 months of dialysis experience in the modality for which he or she would provide training. We proposed new qualifications for the charge nurse, who would be required to be an RN or licensed practical nurse (LPN) with 12 months of nursing experience, including 3 months of dialysis experience. We also proposed new qualifications for the staff nurse, who would have to be an RN or LPN and meet the State practice requirements. The proposed qualifications for the facility dietitian included the registered dietitian (RD) credential and at least one year of professional work experience as a RD. We proposed social worker qualifications that would require the social worker to have a master's degree in social work from a school of social work accredited by the Council on Social Work Education. Our proposed social worker qualifications did not include the grandfather clause (see § 405.2102, ''Qualified personnel'' paragraph (f)(2)), which allowed non-master's prepared social workers who were employed for at least two-years as of September 1976 to hold dialysis facility social worker positions when there was a consultative relationship with a master's prepared social worker. We proposed to recognize patient care dialysis technicians for the first time in the proposed conditions for coverage, and set forth proposed qualifications. We proposed that patient care dialysis technicians have a high school diploma or equivalency and at least 3 months experience under the direct supervision of an RN, and that they complete a training program that would include specified topics and be approved by the medical director and governing body. We proposed that the clinical staff meet State practice requirements (§ 494.140) and be licensed according to State provisions (§ 494.20 and § 494.140(e)(1)). We proposed new qualifications for the water treatment system technicians, who would complete a training program approved by the medical director and governing body. Personnel qualifications that were not carried forward from part 405, subpart U, included those for the chief executive officer, medical record practitioner, and the transplantation surgeon.

We received more comments (more than 150) on the proposed ''Personnel qualifications'' condition for coverage at § 494.140 than on any other condition.

Comment: A large number of commenters suggested that the title of this condition be changed to ''Personnel qualifications and responsibilities'' and

that the specific responsibilities of all members of the interdisciplinary team be included. Commenters suggested that the medical director and patient be excluded from assignment of responsibilities under the ''Personnel qualifications'' condition. Some commenters said that since medical director responsibilities were included at § 494.150, other team member responsibilities should be listed in the regulation as well. Some commenters stated that it would be helpful if clinical social worker responsibilities were listed in regulation; they state that social workers are unable to provide clinical social services to patients because they are often tasked with clerical work that fills the majority of their time.

Response: We have sought to be less prescriptive in this rule in order to allow dialysis facilities flexibility in meeting Medicare requirements. We expect that as professional caregivers, members of the interdisciplinary team are aware of their discipline's professional standards of practice and provide quality care to their patients in keeping with those standards. Under the ''Patient assessment'' and ''Patient plan of care'' conditions (§ 494.80 and § 494.90), we require that members of the interdisciplinary team complete a comprehensive assessment followed by a plan of care that identifies goals for patient care and the services that will be provided in order to meet those goals. This includes psychosocial and nutrition services to be provided by the social worker and the registered dietitian. The assessment and plan of care requirements necessitate that the RN, social worker, and dietitian provide appropriate professional care to each patient. Specifically, the dialysis facility must ensure that the social worker provides timely psychosocial assessments and social work interventions in accordance with the plan of care in order to meet these conditions for coverage. We are also requiring at § 494.140 that the interdisciplinary team, which includes the RN, social worker, and dietitian, play an active role in the QAPI program. This final rule requires that the interdisciplinary team provide appropriate care to dialysis patients and improve patient care on an ongoing basis. We do not agree that all the responsibilities of the entire interdisciplinary team need to be enumerated in regulation.

Comment: Many commenters objected to the change in medical director qualifications, as proposed in standard § 494.140(a), and recommended that the medical director be board-eligible or board-certified, as previously required at § 405.2102(e). These commenters included patient organizations, dialysis organizations, as well as physicians. One commenter stated that nephrology is a recognized sub-specialty, which requires specialized knowledge and training and that removing the ''board eligible or board-certified'' requirement could affect the continued existence of this sub-specialty. Another commenter said this ''board-certified'' requirement is the accepted industry standard for evidence of proficiency in a specialty. A commenter stated that to lower standards could jeopardize patient care across the nation and that board eligibility and certification needs to be recognized. Other commenters object to lowering of standards for this important position, except on a case-by-case basis. One commenter recommended that the medical director be required to be a nephrologist. Two commenters supported our proposed medical director qualifications.

Response: Many commenters communicated quality-of-care concerns regarding our proposed deletion of the requirement under former § 405.2102 that the facility medical director be ''board-eligible'' or ''board-certified'' in internal medicine or pediatrics. Our goal is to improve quality of care via this final rule and to ensure that the medical director has the appropriate qualifications. Therefore, in response to comments, we have revised the proposed requirement in the final rule, so that the medical director must be ''board-certified'' in internal medicine or pediatrics by a nationally recognized professional board at § 494.140(a). We are not including the term board-eligible,'' as it is no longer used, defined, or recognized by the American Board of Internal Medicine (*http://www.abim.org/cert/policies_ssneph.shtm*). We have retained the proposed requirement that the medical director complete a board-approved training program in nephrology.

Comment: A commenter recommended that the time period during which a physician is in a training program and providing care to dialysis patients should satisfy the 12-month experience requirement for medical directors. Another commenter requested clarification of whether or not experience gained during a training program could count towards the 12 months of experience for medical director qualifications. The commenter noted that if this time were not counted, then nephrologists completing their training programs could not become a medical director for at least 12 months.

Response: The required 12 months of experience caring for dialysis patients may include experience gained while a physician is enrolled in a nephrology-training program. This will be reflected in the interpretive guidelines for this regulation.

Comment: A commenter requested further clarification of the process that would allow a physician who does not meet the medical director requirements at § 494.140(a)(1) to serve as the medical director as permitted at § 494.140(a)(2).

Response: A physician who does not meet § 494.140(a)(1) requirements may only serve as the medical director when a qualified physician is not available, and when approved by the Secretary as required at § 494.140(a)(2). This provision was retained from part 405, subpart U. A dialysis facility seeking to place an alternate physician in the role of the medical director must contact their CMS Regional Office to make a request for the Secretary's approval.

Comment: While most commenters supported the proposed RN qualifications at § 494.140(b), one commenter suggested an increase in RN experience requirement, to 2 years of clinical and 1 year of dialysis experience. Another suggested that the RN experience qualification be reduced to 6 months. One commenter asked whether one RN could fulfill all four roles listed under nursing services (§ 494.140(b)) if he or she met all the qualifications.

Response: Very few commenters disagreed with the proposed experience qualifications for RNs; therefore, we will adopt the requirement for 12 months of nursing experience and 3 to 6 months of dialysis experience (depending on the role of the RN) in this final rule. A single RN may fulfill multiple nursing roles in the dialysis facility if he or she possesses the appropriate qualifications for each role and if this does not jeopardize the facility's ability to meet the staff requirement at § 494.180(b)(1).

Comment: A few commenters suggested a revision of the qualifications for the charge nurse. A commenter suggested that 12 months of experience for charge nurses be changed to 6 months because the nursing shortage necessitates not eliminating new nursing graduates from the hiring pool. Another commenter stated that 3 months of dialysis experience should not include ''orientation time,'' as 3 months of experience is barely adequate. Two commenters stated that they believe the 3 months of dialysis experience to be inadequate and recommended that the requirement be changed to at least 6 months, since some States, such as California, have no

minimum training requirements; the commenters believe that this endangered patients.

Response: There was disagreement among commenters regarding the proposed qualifications for charge nurses, with some commenters advocating longer experience requirements and others suggesting shorter experience requirements. Our goal for this provision is to ensure that a qualified nurse who can adequately protect patient safety acts as the charge nurse. We believe that the level of experience for charge nurses as stated in the proposed rule (12 months experience in providing nursing care, including 3 months of dialysis nursing care) is reasonable. Given that there is disagreement among commenters and no evidence was presented supporting a modification, we have adopted the charge nurse experience requirements as proposed at § 494.140(b)(3)(ii).

Comment: Many commenters objected to the proposed charge nurse qualifications, which commenters state would allow a licensed practical nurse to serve as a charge nurse, because state practice boards generally do not allow an LPN to supervise an RN. Some commenters stated that the level of responsibility for the charge nurse requires an RN, and LPNs are not qualified for this position. Other commenters stated that experienced dialysis LPNs are very capable individuals. Two commenters stated that due to the nursing shortage, an LPN should be allowed to act as the charge nurse only when an RN is not available. Another commenter stated that the nursing shortage should not be used to justify use of unqualified personnel. One commenter stated that LPNs could function as charge nurses without any RN supervision on-site, and another stated that the LPNs at her facility have more experience than the RNs. One commenter noted that LPNs are used more frequently by LDOs.

Response: We have revised the requirement formerly found at subpart U (§ 405.2162), so that an RN must be present in the facility, and an LPN could still act as a charge nurse if he or she met the proposed qualifications. We did not intend for a LPN to supervise an RN, as suggested by the commenters.

The RN must be present in the facility when patients are being treated, as required at § 494.180(b)(2). An LPN might act as the charge nurse but would not necessarily be supervising an RN. All dialysis nurses must adhere to their state practice requirements. We have modified § 494.140(b)(3)(iii) to clarify this by adding language to indicate that, if the charge nurse is a licensed practical nurse or licensed vocational nurse, that he/she must work under the supervision of a registered nurse when required by the State nursing practice act provisions.

Comment: A few commenters objected to proposed § 494.140(b)(1)(i), which requires the nurse manager RN to be a full-time employee of the facility, and recommended deletion of this requirement. Two commenters said it was unrealistic to require the nurse manager to be employed full-time because small rural units are only open part-time. Some units share the same nurse manager. A commenter stated that requiring a full-time employee as nurse manager would not be a good use of a scarce resource.

Response: The full-time requirement is not a new provision (refer to former § 405.2162(a)). Dialysis facilities should already be fully compliant with this provision. In the case of small dialysis facilities that are not open for at least 40 hours per week the ''full-time nurse'' would be employed at all times the facility is open. For example, a dialysis facility that is only open for 24 hours per week would only need to employ the nurse manager for 24 hours per week to satisfy this requirement. We have retained this requirement as proposed.

Comment: We received a few comments regarding the qualifications of the self-care training nurse.

Response: Please refer to the earlier discussion of self-care training nurse qualifications found under the discussion of § 494.100 in this preamble.

Comment: A commenter suggested that we change the position title ''self-care training nurse'' to ''self-care or home training nurse'' in order to specify that self-care nurses can train patients for in-home or in-facility dialysis.

Response: We agree, and have modified the position title at § 494.140(b)(2) to clarify that ''self-care'' includes home dialysis. The new position title is ''self-care and home dialysis training nurse.''

Comment: A commenter suggested that staff nurse requirements be the same as those proposed for PCTs, which are at least 3 months experience, following a training program that is approved by the governing body.

Response: We agree that the requirements should be similar. We have eliminated the experience requirements for both staff nurses (§ 494.140(b)(4)) and PCTs (§ 494.140(e)). Each professional, however, will be required to meet the training requirements appropriate to their specialty.

Comment: One commenter suggested that a statement be added to the final rule that would mandate that there could be no contract nurse(s) filling the roles of the nurse manager, self-care training nurse, or the charge nurse.

Response: We agree, and are adopting the proposed requirement at § 494.140(b)(1)(i) that the nurse manager be a full-time employee of the facility, which means this position cannot be filled by a contracted nurse. The self-care and home dialysis training nurse and the charge nurse positions do not have this restriction and may be either employees or contractors. Employees are subject to the following directions of an employer relative to what needs to be done and how it should be done. Contractors, on the other hand, are generally not held to how a job is done and the methods that are used. A nurse manager fills a critical role and it is important that his or her actions meet the needs of the facility's governing body. If a nurse under contract fills these roles, he or she must have the proper qualifications and complete the orientation for the position as required in this final rule at § 494.180(b)(3).

Comment: A commenter suggested we specify that RNs have training in the care of patients with chronic disease and physical, emotional, and psychosocial issues.

Response: We would expect that RNs have received training in each of these areas as part of their nursing curriculum. We do not agree there is a need to specify this training in regulation.

Comment: One commenter suggested that advance practice nurses should serve as ''case managers'' and be reimbursed for this role.

Response: This rule does not preclude the use of advance practice nurses in dialysis facilities, but we do not feel we should be this prescriptive because of the degree of regulatory burden imposed upon facilities. In addition, this final rule does not address reimbursement issues.

Comment: We received more than 15 comments on dietitian qualifications at § 494.140(c). The majority of commenters agreed and supported our proposal to require a ''minimum of one year's professional work experience in clinical nutrition as a registered dietitian''. One commenter suggested that the American Dietetic Association (ADA) registration is not enough and minimum experience criteria are needed.

The ADA agreed with the proposed qualifications for dietitians. The ADA noted that registered dietitians (RDs) also possess clinical knowledge and

skills to manage anemia and bone disease and to conduct urea kinetic analysis. The ADA stated that according to the Commission on Dietetic Registration, there are more than 72,000 RDs nationwide, and the supply of RDs is well established.

One commenter stated that 1 year of registered dietitian professional work experience in clinical nutrition is acceptable, but 2 years would be ideal. Newly hired RDs without renal experience should have a training period of at least 2 weeks with an experienced renal dietitian. This commenter also noted that the role of the dietitian has expanded and recommended that the responsibilities of dietitians include monitoring adherence and response to diet, and recommending interventions for improving nutritional status. The commenter provided examples of the expanded role of the dietitian, which included anemia manager, and bone and urea kinetic modeling manager, to improve clinical outcomes.

One commenter agreed with the proposed 1-year experience requirement since quality care depends on renal training and specialization, but said facility managers point to the difficulty of finding sufficient numbers of experienced dietitians. This commenter suggested that the one year of experience be preferred but not required.

Three commenters disagreed with the proposed 1-year professional experience requirement. One commenter stated the 1 year of professional work experience is unnecessary; only registration with the Commission on Dietetic Registration is needed. This commenter stated that instead, mentoring and direction from an experienced renal dietitian is needed. The commenter stated that the experience requirement would diminish the pool of qualified dietitians. Another commenter also stated that adding a year of experience as a requirement for RDs would create even more of a RD shortage and is not necessary given their extensive education.

Another commenter suggested that we delete ''as a registered dietitian'' from regulations text, so that experience obtained prior to becoming a registered dietitian could be counted, and professional work experience gained during an internship would apply. This commenter further suggested that all dialysis dietitians be required to participate in training from experienced dietitians.

Three commenters recommended that the dietitian qualifications match the medical nutrition therapy (MNT) regulation requirements, which call for a bachelor of arts degree or higher, an academic program in nutrition or dietetics, 900 hours of supervised dietetics practice, and being licensed or certified as a dietitian or nutritional professional by the State in which the professional is practicing. One of these commenters agreed with requiring a minimum of 1 year's professional work experience as a registered dietitian.

Response: The dietitian qualifications in subpart U at § 405.2102(b) specify at least 1-year experience in clinical nutrition. In this final rule, we redesignated proposed § 494.140(c)(3) as § 494.140(c)(2), which requires 1 year of professional work experience in clinical nutrition as a registered dietitian. Renal nutrition is a specialized area within the practice of dietetics. The dialysis facility dietitian must be able to perform independently complex nutritional assessments, evaluate laboratory results, and assist the interdisciplinary team in managing anemia, renal bone disease, and performing kinetic modeling. A typical therapeutic diet for a hemodialysis patient has multiple restrictions and is limited in sodium, phosphorus, potassium, fluid, and includes specified amounts of protein. Many patients must follow additional dietary restrictions such as low cholesterol or diabetic limitations. We believe that a registered dietitian would need at least one year of experience to perform this specialized work. The majority of commenters recognized the specialized work of a RD in the dialysis setting.

The MNT dietitian qualifications at 42 CFR 410.134 require the MNT provider to be a registered dietitian with the Commission on Dietetic Registration or to have a bachelor's degree or higher in nutrition or dietetics, 900 hours of supervised experience and state licensure, if applicable. The MNT dietitian qualifications allow a nutritionist who is not a registered dietitian to provide medical nutrition therapy. By contrast, dialysis dietitians must be registered dietitians under both the previous ESRD regulations and the proposed rule. We have not removed the registered dietitian qualification requirement, as we find no reason to do so.

We do not have evidence that there is a shortage of registered dietitians that necessitates deletion of the clinical experience requirement. While mentoring programs are desirable, we did not propose them and have not added this requirement to the final rule. Registered dietitians must be oriented to the facility and their work responsibilities (§ 494.180(b)(3)) and have an opportunity for continuing education and related development activities (§ 494.180(b)(4)).

Comment: Two commenters suggested including the word ''clinical'' in the ''professional work experience'' phrase so that foodservice experience does not apply.

Response: The proposed rule at § 494.140(c)(3), (now § 494.140(c)(2)), requires dietitians ''have a minimum of one year's professional work experience in clinical nutrition as a registered dietitian.'' This wording would preclude a dietitian who only has foodservice professional experience from qualifying for a position as a dialysis dietitian. We do not agree that a change in wording is needed here because clearly, the experience must be in ''clinical nutrition.''

Comment: One commenter recommended that dietitian-to-patient caseloads be limited to 90–100 patients per dietitian.

Response: We address adequate staffing under the ''Governance'' condition for coverage at § 494.180(b). Some States have implemented staff-to-dialysis patient ratios, and we defer to State provisions on this issue. Dialysis dietitian caseloads must not prevent RDs from providing care consistent with national standards of practice for dietitians. National standards have been published by the ADA entitled ''Standards of Practice in Nutrition Care and Updated Standards of Professional Performance'' in April 2005 (Kieselhorst, K.J., Journal of the American Dietetic Association, Vol. 105, No. 4, April 2005).

Comment: One commenter suggested that dietetic technicians be included in the final rule. The commenter stated that she strongly supported the use of dietetic technicians, registered (DTRs) under RD supervision and that DTRs are nationally certified and have education requirements similar to the RDs.

Response: We do not agree that RDs and DTRs have similar education requirements. According to the ADA, DTRs must complete at least a 2-year associate's degree while an RD must complete a minimum of a bachelor's degree at a U.S. regionally accredited college or university. A DTR must complete a dietetic technician program accredited and approved by the Commission on Accreditation for Dietetics Education (CADE), including 450 hours of supervised practice experience. An RD must complete a CADE accredited supervised practice program that typically runs 6 to 12 months in length. RDs and DTRs also have different continuing education requirements.

This final rule requires an RD to be a member of the dialysis facility interdisciplinary team, perform patient assessments, and participate in patient care planning and the QAPI program. The RD may use a DTR to provide assistance under RD supervision, but it is the RD who must meet these conditions for coverage. Therefore, we have not added DTRs to the ''Personnel qualifications'' condition.

Comment: We received more than 70 comments regarding social worker qualifications. The vast majority of commenters supported the proposed social worker qualifications, which require a master's degree in social work from a school of social work accredited by the Council on Social Work Education.

Commenters stated that dialysis patients have highly complex needs and require care from an MSW who has a ''specialization in clinical practice'' education. Commenters made the following statements in support of an MSW with a specialization in clinical practice. They stated that the nephrology social workers must be skilled in assessing for psychosocial influences and their interrelatedness in predicting treatment outcomes, and must be able to design interventions with the patient, the family, the medical team, and community systems at large to maximize the effectiveness of ESRD treatment. The additional training received by MSWs enables them to perform these complex professional tasks and ensure effective outcomes that have a direct relationship to morbidity and mortality. Masters-prepared social workers are trained to use validated tools, such as the SF36 (the Medical Outcomes Study 36-item short-form health survey) and the KDQOL (Kidney Disease Quality of Life), to improve care and to monitor the outcomes of directed interventions. Most nephrology social workers provide psychosocial services autonomously as primary providers without social work supervision or consultation, using highly developed social work intervention skills obtained in a master's level curriculum. The masters in social work degree provides an additional 900 hours of specialized training beyond a baccalaureate degree in social work. An MSW curriculum is the only curriculum that offers additional specialization in the Bio-Psycho-Social-Cultural, Person-in-Environment model of understanding human behavior. Undergraduate degrees or other mental health credentials do not offer this specialized and comprehensive training. The National Association of Social Workers Standards of Classification considers the baccalaureate degree as a basic level of practice, while the masters degree is considered a specialized level of professional practice and requires a demonstration of skill or competency in performance. These commenters provided references and citations along with these comments.

A few commenters suggested that the master's degree qualification be eliminated because it is difficult to recruit MSWs in some rural areas. A commenter stated that in California a licensed clinical social worker requires 2 years of supervision and two examinations, which makes it difficult to get a licensed clinical social worker license. Another commenter suggested that we keep the MSW requirement but include an ''exceptions process'' for units that cannot hire an MSW. Some commenters stated that bachelor's prepared social workers are competent as long as they are supervised by an MSW.

Response: We appreciate the large degree of support for the MSW qualification for social workers. We have revised the MSW requirement in § 494.140(d)(1) by adding ''specialization in clinical practice,'' as specified in part 405, subpart U, as the majority of comments supported this. The consensus among the commenters is that this level of knowledge and skill is needed to deal with an increasingly older, sicker, more complex dialysis patient population.

Comment: One commenter recommended that we delete § 494.140(d) in its entirety or delete any preamble references to MSWs performing counseling, long-term behavioral and adaptation therapy, and grieving therapy. The commenter stated that such counseling exceeds the expertise of MSWs, and that patients should be referred outside the units for this service. The commenter also claimed that an ''expansion'' of counseling requirements represents a potential $18 million burden to his large dialysis organization.

Response: The ''Personnel qualifications'' condition for coverage at § 494.140 does not specify tasks or responsibilities for dialysis facility social workers, but only their education and qualifications. The proposed rule preamble discussion provided examples of social worker services that facilities might offer, including counseling services, long-term behavioral and adaptation therapy, and grieving therapy (70 FR 6222) that would require the education and training of an MSW. The proposed rule's preamble discussion is consistent with part 405, subpart U social worker requirements at § 405.2163(c), which state that ''Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient.'' Social services needed for each patient should be determined during the assessment and identified in the plan of care.

Only one commenter suggested § 494.140(d) be deleted in its entirety, while a very large number of comments supported this requirement, and the consensus was to retain MSWs in dialysis units. MSWs are trained and competent to counsel patients. The social worker professional standards of practice (*http://www.socialworkers.org/practice/standards/NASWHealthCareStandards.pdf*) do include patient and family counseling within the scope of services provided by a social worker. MSW services, which include counseling, is incorporated into the Medicare composite payment rate and should not be outsourced or separately billed.

Comment: We received a large number of comments regarding our proposed deletion of the master's degree ''grandfather clause'' for social workers. Many commenters agreed with eliminating the ''grandfather clause'' because ''30 years was more than enough time for dialysis social workers to obtain masters degree.'' Commenters stated that MSW and BSW tasks could be broken out into separate job descriptions so that BSWs may assist MSWs. Commenters said that there was no MSW shortage.

A larger number of commenters suggested that we retain the ''grandfather clause'' for non-MSWs so that currently employed non-MSWs working as dialysis social workers do not lose their jobs. Some commenters suggested that experienced non-MSW social workers were competent and had much to offer dialysis patients. A few commenters recommended that we continue the grandfather clause until the year 2015 to allow current non-MSWs who met the subpart U requirements to finish out their careers.

Response: According to the definition of ''Qualified personnel'' at § 405.2102, a non-masters degree social worker may serve as an ESRD social worker (under § 405.2102(f)(2), qualified personnel) when he or she ''has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under paragraph (f)(1) of this definition'' (that is, has completed a course of study with

specialization in clinical practice at, and holds a masters degree from a graduate school of social work). This subpart U grandfather clause only applies to non-MSWs who have been practicing social work since 1974, and any ESRD social workers who do not have 2 years of experience prior 1976 must have a masters degree.

While we believe the number of non-masters-degree social workers still practicing over the past 32 years is small, we do not intend that these long-time employees should become unqualified for their jobs because of deletion of the ''grandfather clause.'' In response to comments we will adopt the proposed ''grandfather clause'' and add the existing provision from subpart U to the final rule at § 494.140(d)(2) to read as follows: ''Has served at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under § 494.140(d)(1) of this part.'' The grandfather clause may not be applied to social workers who do not meet the 1976 experience criterion. Bachelors-prepared social workers may function as assistants to the MSW. The MSW is the staff member who must satisfy these conditions for coverage.

Comment: A few commenters suggested that we eliminate the proposed § 494.140(d)(2) requirement, ''Meets the practice requirements for social services in the State in which he or she is employed.''

Response: Adherence to State scope-of-practice requirements is an appropriate minimum requirement for a federal health and safety regulation. This final rule supports compliance with State regulations. The final rule provision for meeting applicable scope-of-practice board and licensure requirements for dialysis facility personnel has been moved to the beginning of § 494.140 to avoid redundancy within the standards for each of the dialysis facility staff members.

Comment: Several commenters suggested that we add a social worker licensure requirement to § 494.140(d)(2).

Response: The proposed rule at § 494.20 required licensure for all staff. To prevent confusion regarding whether licensure is required under personnel qualifications, we have moved the requirement to the beginning of § 494.140, to read: ''All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed.''

Comment: Many social workers as well as some commenters who are not social workers suggested that a new social worker aide personnel standard be added to the final rule. The rationale given was that this new staff member could perform many of the clerical tasks (admissions, billing, transportation, transient patient paperwork, determining insurance coverage) often assigned to social workers, so that the social worker would be freed up to perform clinical social services, such as counseling, that would result in improved patient care and better outcomes. Many commenters stated this position should be required for dialysis facilities with more than 75 patients.

Response: This final rule requires each facility to have adequate staff to meet patient needs. Paragraph § 494.180(b)(1) applies to all dialysis staff, including social workers. The use of ancillary staff is not precluded by this regulation. Some dialysis facilities do employ staff to assist the social worker with clerical tasks, while other facilities may employ more than one social worker. Each facility should assess their staffing needs and determine appropriate staffing levels. While we agree that using an MSW to perform clerical tasks and manage patient financial information may not be the most effective or efficient use of trained and licensed professional clinical staff, we are not requiring that dialysis facilities employ social worker aides. We encourage dialysis facilities to use staff resources in the most effective and efficient manner to provide quality care to dialysis patients.

Comment: Many commenters suggested that the final rule state that MSWs could not be assigned non-MSW tasks. These commenters object to the number of clerical tasks that are assigned to social workers.

Response: Dialysis facilities have the flexibility to assess facility-staffing needs and use staff as necessary. This final rule requires social workers to provide appropriate clinical services to dialysis patients under the ''Patient assessment'' and ''Patient plan of care'' conditions for coverage (§ 494.80 and § 494.90 respectively). The social worker must also participate in the facility QAPI program (§ 494.110). The facility must have a sufficient social services staff to meet dialysis patient needs as required at § 494.180(b)(1), which applies to all dialysis staff, including social workers. We would expect that any tasks assigned to the social worker would not compromise the social worker's ability to meet his or her obligations to patients and these conditions for coverage. We have not added restrictions regarding staff assignments to this final rule.

Comment: Many commenters recommended that we specify a maximum MSW caseload or an MSW-to-patient ratio.

Response: As discussed above, adequate staffing is addressed under the ''Governance'' condition for coverage at § 494.180(b). Some states have implemented staff-to-dialysis patient ratios, and we defer to State provisions on this issue.

Nephrology social workers should adhere to the professional standards of practice for social workers. The National Association of Social Workers published ''NASW Standards for Social Work Practice in Health Care Settings'' in 2005. These professional practice standards may be found at *http://www.socialworkers.org/practice/standards/NASWHealthCareStandards.pdf*. The National Association of Social Workers and Council of Nephrology Social Workers jointly published ''NASW/NKF Clinical Indicators for Social Work and Psychosocial Service in Nephrology Settings'' in October 1994, which may be found at *http://www.socialworkers.org/practice/standards/nephrologysettings.asp*. In addition, the NKF has published the 2003 Council of Nephrology Social Workers ''Standards of Practice for Nephrology Social Work.'' These standards of practice include guidelines for clinical practice, a description of the nephrology social work role, as well as staffing information.

Comment: A commenter suggested that the final rule state that different facilities can share the same renal dietitian or social worker.

Response: Neither part 405, subpart U nor the proposed rule precludes facility sharing of renal dietitians and social workers, as long as each facility has adequate staff and staff hours to meet patient needs and provide care consistent with professional practice standards. Please refer to § 494.180(b)(1), which applies to all dialysis staff.

Comment: We received a very large number of comments on § 494.140(e), addressing patient care dialysis technician qualifications. Commenters generally supported the addition of technician qualifications and training requirements to the conditions for coverage.

More than 20 commenters, including the National Kidney Foundation, American Association of Kidney Patients, American Kidney Fund, CNSW, some of the ESRD Networks, the National Association of Nephrology

Technicians/Technologists, the Renal Support Network, and various ESRD suppliers and professionals, recommended that we require PCTs to be certified. Commenters stated that PCTs are now the predominant caregivers in ESRD facilities. Certification is necessary to protect patient health and safety in view of the ongoing nursing shortage. Commenters stated that certification is the first step towards minimal competency, and is the national trend; California, Arizona, Oregon, and Ohio now require PCT certification. Commenters state that a standardized curriculum and examination is desirable to improve quality of care.

Kidney Care Partners (KCP), which represents a coalition of renal stakeholders, including the large dialysis organizations; renal physician, nurse, and administrator organizations; and pharmaceutical companies, stated that it supported more consistent training and certification for patient care dialysis technicians. In the 109th Congress, they noted that S. 635 and H.R. 1298 introduced by Sens. Rick Santorum (R–PA) and Kent Conrad (D–ND) in the Senate and Reps. Dave Camp (R–MI) and William Jefferson (D–LA) in the House, would have required that patient care dialysis technicians receive uniform training and become certified, indicating at least a minimum level of competency to provide dialysis-related services. These technicians would have been required to repeat training or become recertified if 24 consecutive months had passed during which they had not performed dialysis-related services. Service providers and renal dialysis facilities would have been required to provide performance reviews and in-service education to assure ongoing competency. Although KCP recognized the importance of deferring to the States to regulate health care workers, they noted that the Medicare program had already established similar training requirements for unlicensed personnel in skilled nursing facilities. They urged us to incorporate these substantive requirements from the legislation (which expired without action at the end of the 109th Congress) into our final rule.

A commenter suggested that on-the-job training was only equal to an orientation and recommended national certification for PCTs. Another commenter advocating certification stated that dialysis patients have been asking for assurances of technician competency and certification would help assure such minimal competency.

One state surveyor opposed any language permitting the use of unlicensed personnel for the practice of nursing or medicine, and stated that our requirement should not conflict with State nursing and medicine practice acts. The commenter also argued that the use of unlicensed staff was dangerous.

One commenter opposed PCT certification, stating that it would not be prudent to add this requirement, pointing to the ''pro and con'' certification discussion in the proposed rule (70 FR 6223).

Response: PCTs perform a variety of clinical tasks (subject to the limitations of State law), that include preparing dialysis apparatus, performing equipment safety checks, initiating dialysis (including cannulation and venipucture with large gauge needles), intravenous administration of heparin and sodium chloride solutions, subcutaneous or topical administration of local anesthetics in conjunction with placement of dialysis needles, monitoring patients during dialysis, taking vital signs, documenting tasks and patient observations, and more. The proposed rule preamble discussed PCT certification, but recognized some barriers to national certification (70 FR 6223). The large majority of commenters did not agree that these potential barriers (state control, lack of renal community consensus at that time, burden and costs) outweighed the patient safety benefits of PCT certification.

Therefore, we have revised § 494.140(e) ''Patient care dialysis technicians'' by adding paragraph (e)(4), which requires that PCTs, ''Be certified under a State certification program or a national commercially available certification program as follows: (i) For newly employed patient care technicians, within 18 months of being hired as a dialysis patient care technician, or (ii) For patient care technicians employed on October 14, 2008, within 18 months after such date. We are allowing an 18-month time period for certification to ensure that a sufficient time period is available for PCTs to schedule a date to sit for the certification exam. Because we are allowing a lengthy time period to become certified, we are retaining the proposed rule's training program topics to ensure that non-certified PCTs have appropriate training before they begin to provide patient care as a PCT trainee.

National commercially available certification programs include those of the Nephrology Nursing Certification Commission (NNCC), the Board of Nephrology Examiners Nursing and Technology (BONENT), and the National Nephrology Certification Organization (NNCO). Dialysis facilities or dialysis corporations may conduct their own in-house certification programs and testing but it must be in addition to a certification program made available by an external body. The NNCC offers the Certified Clinical Hemodialysis Technician (CCHT) examination, which is offered as a valid measure of basic competency for hemodialysis PCTs. Technicians are eligible to take the CCHT examination with a suggested minimum of six months experience in nephrology technology. The CCHT examination measures performance in four dialysis practice areas: clinical (50 percent), technical (23 percent), environmental (15 percent), and role (12 percent). Information on the CCHT examination, a schedule of test sites and dates, and applications is available at *http://www.nncc-exam.org*. If the State has a certification and competency-testing program in place that is specific to dialysis PCTs, then State certification also satisfies this requirement.

We will be reviewing any new national commercially available certification programs that emerge in the future to determine whether a program meets the intent of these conditions for coverage. Based on these reviews, we will determine whether further rulemaking is necessary to ensure the competency of PCTs and to protect patient safety.

Comment: A small number of commenters did not agree that PCTs should have 3 months of experience following a training program under the ''direct'' supervision of an RN. While commenters agreed there should be PCT training, they did not agree that 3 months of experience should be under the ''direct'' supervision of an RN. Some of the commenters stated that the 3 months was too long a time period, and others said this would demand too much RN time. A few commenters stated the training program and 3 months of experience should be allowed to occur simultaneously. Some commenters sought clarification of the term ''direct supervision'', since RNs could supervise without constant one-on-one contact. Some commenters stated this was not good use of RN time and that other staff, for example, PCTs and LPNs, could mentor new PCTs. Two commenters agreed with the 3-month experience provision. One commenter stated that some State nurse practice acts delineate delegation of training by RNs.

Response: Since we are requiring that new PCTs complete an initial training

program and become certified within 18 months of beginning PCT employment, we are not finalizing the requirement that the PCT have at least 3 months of experience that was proposed at § 494.140(e)(3). In addition, this training program includes on-the-job training and experience that must be under the general supervision of a registered nurse. We agree with some commenters that PCT trainees may gain patient care experience during the up to 18-month period under the supervision of an RN with mentoring by LPNs, licensed vocational nurses (LVNs), and certified PCTs. Therefore, we have revised § 494.140(e)(3) to provide this clarification. This new wording allows new PCTs to be mentored by LPNs, LVNs, and certified PCTs under the guidance of an RN. Also, once certified, PCTs work ''under the direction of a registered nurse,'' instead of ''under the direct supervision of a registered nurse.''

We have moved the description of the PCT training program from proposed § 494.180(b)(5) to § 494.140(e)(3) in this final rule so that the PCT training requirements may be located in one section of the final rule.

Comment: One commenter suggested that we strengthen the training requirement so that training must be provided under the direct supervision of an ''RN with at least 6 months of experience of providing care in dialysis.''

Response: We do not agree with this comment. As stated in the previous response, PCT trainees may gain patient care experience during the up to 18-month period under the supervision of an RN with mentoring by LPNs, LVNs, and certified PCTs. We have revised § 494.140(e)(3) to provide this clarification. This new wording allows new PCTs to be mentored by LPNs, LVNs, and certified PCTs under the guidance of an RN. Once certified, PCTs work under a nurse's direction.

In addition, for nurse manager and charge nurse experience in this final rule we require all registered nurses to have 12 months experience in providing nursing care, including 3 months of experience in providing nursing care to patients on maintenance dialysis. We believe that this level of experience is sufficient for a nurse manager or charge nurse to be able to provide or oversee training to a PCT.

Comment: A commenter suggested that we revise proposed § 494.140(e)(3) and replace ''patient sensitivity training and care of difficult patients'' with ''conflict management and patient centered care.''

Response: We do not agree that the suggested more general wording adds clarification. Therefore, we have retained the proposed language.

Comment: Several commenters supported inclusion of § 494.140(f) ''Water treatment system technicians,'' as proposed. A few commenters suggested that we revise or expand § 494.140(f) to make the educational requirements the same as those proposed for PCTs. Another commenter recommended that water treatment training be required for all staff who work on the water treatment system.

Response: We have incorporated the AAMI RD52 2004 ''Dialysate for hemodialysis'' guidelines into this final rule at § 494.40(a). Section 9 of the guidelines entitled ''Personnel'' includes requirements for water treatment staff as follows:

Policies and procedures that are understandable and accessible are mandatory, along with a training program that includes quality testing, the risks and hazards of improperly prepared concentrate, and bacterial issues. Operators should be trained in the use of the equipment by the manufacturer or should be trained using materials provided by the manufacturer. The training should be specific to the functions performed (that is, mixing, disinfection, maintenance, and repairs). Periodic audits of the operators' compliance with procedures should be performed. The user should establish an ongoing training program designed to maintain the operator's knowledge and skills.

Any staff who operate the water treatment system must complete a training program that has been approved by the medical director and the governing body as required at § 494.140(f).

Comment: A few commenters suggested that advanced practice nurses and physician assistants be recognized in the final rule as ''physician extenders'' (that is, NPs, CNs, PAs (Nurse Practitioners, Clinical Nurse Specialists, and Physician Assistants)). Some commenters were concerned that excluding these professionals from the final rule might affect reimbursement.

Response: We recognize the contributions of physician extenders in dialysis facilities in providing quality dialysis care and note that the Medicare payment system recognizes the role of physician extenders. While we will not require dialysis facilities to have NPs, CNs, or PAs, they are subject to our requirement at § 494.140, which requires that ''all dialysis facility staff meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed.'' The provisions of this section will not affect reimbursement of physician extenders.

Comment: We received a very large number of comments regarding the proposed rule preamble discussion (70 FR 6224) regarding what role, if any, the pharmacist should play within a dialysis facility and what a dialysis facility's appropriate responsibility is for pharmaceutical services and the efficient use of medication.

More than 40 pharmacists recommended that we include a pharmacist on the facility interdisciplinary team, and submitted comments containing references and journal articles. According to the commenters, the DOPPS data showed that ESRD patients take 9–12 medications on average, per patient, and that there are complex interactions between many of these medications. Pharmacists receive specialized training for renal patient care; and pharmacists with such training should prepare facility protocols and policies to manage medications. Pharmacists believe they will be able to coordinate medication administered within facilities with medications administered outside the facility and over-the-counter drugs. The commenters stated that dialysis patients need comprehensive medication reviews at appropriate intervals, similar to the CMS-required monthly medication reviews in SNFs and ICFs. The pharmacists believed they could train other staff regarding various medications' relationships, which would improve quality of care and treatment plans. Pharmacist-consultants could work with patients and caregivers to coordinate medication use and dietary supplements. They observed that the Department of Veterans Affairs has assigned pharmacists to its dialysis clinics. They argued that comprehensive medication plans and reviews would increase patient safety and reduce overall program (Medicare) costs by preventing adverse ''medication events'' and reducing medication costs. They noted that expert knowledge of the new Part D formulary will be an important part of treating dialysis patients.

One commenter suggested dialysis patients should be recipients of dialysis-provided Medication Therapy Management Services for third-party payers that participate in Part D. In addition, the commenter indicated that Dialysis pharmacists would like to be able to bill for ESRD patient consultation using these codes.

Several commenters did not support including pharmacists on the dialysis facility interdisciplinary team. These

commenters suggested that pharmacist consultation should remain an option, not a requirement. One commenter stated there was no need for pharmacist participation. Other commenters stated that routine assessment of medications should not be required unless it was Medicare reimbursable. A commenter stated that this would be an unnecessary, burdensome requirement without benefit, since nephrologists have the necessary dosing and medication interaction knowledge; the average pharmacist salary is $73,000 annually, which was cost-prohibitive for his organization's 1,200 dialysis facilities. Another commenter said that RNs were the appropriate professionals to monitor patients' medications and to do patient teaching, and believes it could be confusing to the patient to further fragment care by introducing another discipline into the patient care scenario. This commenter did not believe there was a need for clinical pharmaceutical services beyond continuing staff education on new products for dialysis patients; the commenter stated that technology would improve medication management and safety. One commenter said that dialysis facilities lacked the expertise to manage a pharmacist properly. Another commenter suggested that since Medicare did not cover the cost of providing treatments and pharmaceuticals to patients, this suggestion was fiscally unrealistic.

Several commenters stated that pharmacist participation was desirable but not practical absent funding. A commenter stated that a routine pharmacist assessment for patient medications would be desirable and Medicare payment should be revised to allow direct reimbursement outside the composite rate. A few commenters suggested that we add a requirement for routine consultations with pharmacists to review policies on medication acquisitions, storage, administration, and medical record reviews.

Response: Pharmacists fully support a role for the pharmacist on the interdisciplinary team, while other commenters support an optional role for pharmacists in dialysis facilities.

The Medicare Part D reimbursement for pharmacists suggested by one commenter is limited, as pharmacist charges are paid on a case-by-case basis if an individual pharmacy plan has agreed to reimburse Medicare for this service under Part D.

Due to a lack of consensus among commenters, we are not requiring dialysis facilities to include pharmacists as members of the dialysis interdisciplinary team. We do, however, encourage dialysis facilities to use pharmacist expertise as appropriate. The facility policies and procedures referred to at § 494.150(c)(1) must include medication policies and procedures that adequately protect patient safety.

b. Responsibilities of the Medical Director (Proposed § 494.150)

We proposed to retain the condition addressing the facility's medical director (§ 405.2161) as a separate condition and strengthen the role of the medical director, at § 494.150. The medical director would be required to meet the qualifications for the position at proposed § 494.140(a) and would be responsible for the delivery of patient care and patient outcomes in the facility. The medical director would be responsible for operational responsibility for the facility's QAPI program. We proposed to retain the existing requirement at § 405.2161 for the medical director to ensure that staff in the facility are adequately trained. The existing requirement at § 405.2161 was modified in the proposed rule to require that the medical director participate in the development, periodic review, and approval of the patient care policies and procedures manual. We also proposed that the medical director be responsible to ensure these patient care policies and procedures are adhered to by staff who treat patients in the dialysis facility, including attending physicians and non-physician staff. The proposed rule also would require that the medical director be responsible for ensuring that the interdisciplinary team follows the facility's discharge and transfer policies and procedures.

Comment: Many commenters supported the proposed condition for the medical director, including the responsibilities laid out in the new condition. Commenters remarked that this condition assigned more accountability to the medical director for the overall care of patients.

Several other commenters suggested additional language in or revisions to the final rule. One commenter remarked that there should be a direct line of responsibility from the medical director to the care provided. One commenter suggested clearly delineating responsibilities by deleting the phrase ''but are not limited to'' in the last phrase of the proposed condition stem statement.

Another commenter recommended that we clarify that facilities should have only one medical director. The commenter went on to state that some facilities have multiple medical directors. Another commenter however, suggested it may be advantageous for the same individual to hold the medical director position for a defined number of facilities.

Response: We appreciate the comments regarding the proposed medical director condition for coverage. In response to comments, we have added language at § 494.150 to state explicitly that ''The medical director is accountable to the governing body for the quality of medical care provided to patients.'' In addition, the medical director has the responsibility of ensuring that all policies and procedures relative to patient care and safety are followed by all who treat the patient, as required at § 494.150(c)(2). This modification clearly holds the medical director responsible for the care that is furnished. Each facility must have a single medical director to carry out the responsibilities of this position.

We have retained the language in the final rule making the medical director responsible for matters that are related to health and safety standards for patient care. Individual dialysis centers may have individual needs that surpass these minimum requirements. Therefore, we are allowing facilities to have flexibility in their dealings with their medical directors. Regarding the number of facilities for which a physician may act as the medical director, this regulation requires that the medical director meet all conditions and responsibilities, regardless of whether he or she directs one facility or multiple facilities. However, each facility must have exactly one specific individual to be fully responsible for all matters under § 494.150.

Comment: Several commenters supported assigning responsibility for QAPI program to the medical director.

Response: We appreciate the supportive comments to retain the proposed language regarding responsibility for QAPI. Language at § 494.150(a) has been adopted in the final rule.

Comment: One commenter remarked that the wording at § 494.150 needs to be clarified. The commenter stated that ''the medical director is acting in an administrative leadership capacity'' and thus the final rule needs to take into account that responsibilities of the medical director should be performed in that context. One commenter suggested that the medical director undergo management training, as staff needs ''leadership from the top'' to effect necessary changes needed in quality control situations.

Response: The medical director is responsible for care provided by the facility. The governing body has the

flexibility to use the medical director in an administrative capacity as long as this does not prevent the medical director from performing the responsibilities required by this final rule. The final rule at § 494.180(b)(3) requires that the governing body ensure that all staff have appropriate orientation regarding their employment responsibilities, including medical directors employed by the facility. This requirement does not preclude the governing body from requiring that the medical director receive additional training deemed necessary to perform the duties of his or her position. The proposed language has been retained in the final rule.

Comment: One commenter suggested we add record-keeping to the list of responsibilities for which the medical director is ultimately held responsible.

Response: Record-keeping is a responsibility that falls under policies and procedures relative to patient care, and thus is covered under the purview of the medical director at § 494.150(c)(2)(i). In addition, there is a condition for Medical records, found at § 494.170, which stipulates what is required of the dialysis facility with respect to record-keeping. Therefore, we are not making the suggested additions to the final rule.

Comment: Another commenter suggested we add language to require the medical director to be present in the facility at least once a month.

Response: Dialysis facilities have the flexibility to address this issue in their agreement with their medical director. The medical director's presence must be frequent enough to perform his or her responsibilities as required by these conditions.

Comment: One commenter suggested that we add language stating that the medical director has the responsibility for assuring that pediatric patients have regular access to care from a nephrologist, dietitian, and a social worker with pediatric expertise.

Response: Dialysis facilities are required by this final rule to provide quality care and services that meet the needs of the patient, as identified during the comprehensive assessment and addressed in the plan of care. The patient assessment and patient plan of care required at § 494.80 and § 494.90 respectively, should accurately reflect the needs of all patients, including pediatric patients, and the proper resources should be obtained and used as necessary.

Comment: Some commenters remarked that the medical director should bear primary responsibility for infection control oversight in the dialysis unit, as opposed to a nurse.

Response: We determined that it would be practical to hold the medical director accountable for oversight of infection control as the leader of the quality improvement committee. We also proposed that the medical director be responsible for assessment and performance policies and procedures relative to patient care and safety at § 494.150(c)(2)(i). Upon consideration of comments, we have added infection control to the list of policies and procedures for which the medical director exercises oversight at § 494.150(c)(2)(i). In addition to this new requirement at § 494.150(c)(2)(i), we have also added ''patient admissions'' to the list of policies for which the medical director is responsible. This modification is in response to comments received on the ''Governance'' condition. Please see the ''Governance'' preamble discussion below for more information.

Comment: Some commenters expressed concern regarding oversight of the medical director's performance of his or her duties under § 494.150. The commenters remarked that the only mechanism to deal with a poorly performing medical director would be to dismiss him/her. Commenters went on to explain that it could be difficult to fill a vacant medical director position, which would be required to be done quickly in order to continue to be reimbursed by Medicare. It was recommended that CMS consider mechanisms by which medical directors who failed to fulfill their responsibilities as outlined in the conditions for coverage, could be disciplined by the facility. Commenters suggested perhaps there was a role for Network Medical Advisory Boards, State Licensing Boards or State Professional Boards to assist facilities in evaluating medical director performance and determining disciplinary action.

Response: The medical director is accountable to the governing body. The governing body is responsible for communicating expectations to the medical staff regarding their participation in improving the quality of medical care provided to facility patients, as required at § 494.180(c)(3). The governing body could develop a process to improve the medical director's performance. A facility's governing body could also contact the appropriate authorities, such as the Network Medical Advisory Boards, State Licensing Boards, State Professional Boards, and any other suitable agencies or organizations. We feel that this matter is best left to the governing body's discretion. We are making no changes based on this comment.

Comment: One commenter concurred with the language regarding the medical director's responsibility for managing problem nephrologists, but suggested that there be some reasonable basis for protecting the medical director from lawsuits related to this management activity. Another commenter asked for clarification regarding the legal liabilities for medical directors employed by large dialysis organizations (LDOs). The commenter questioned what recourse a medical director would have when he or she disagreed with the LDO.

Response: We do not have authority through this vehicle to provide legal protection for the medical director, moreover, these issues are generally matters of state law. Medical directors employed under a contract may negotiate the terms of that contract with business owners/center management within the state practice limitations, including issues such as legal liability, but such matters are not under the purview of this regulation.

Comment: Some commenters recommended that the medical director should have responsibility for ensuring that the ESRD facility supports the goals of the ESRD Network.

Response: The Medicare statute specifies that facilities must meet Network goals (section 1881 of the Act) in order to participate in Medicare. We do not agree it is necessary to add language to the medical director condition regarding responsibility for Network relationships. As stipulated at § 494.180(i), dialysis facilities must cooperate with the ESRD Network in fulfilling the terms of the Network's current statement of work. Section 494.180(a)(3) mandates that the chief executive officer or the administrator be responsible for the relationship with the ESRD Networks.

Comment: One commenter believed that the proposed new responsibilities for the medical director were overly burdensome with respect to very small dialysis units, where the medical director might be the only attending physician with an internal medicine practice. Another commenter disagreed with the proposed language, remarking that it was too restrictive and confusing for multi-facility organizations to have the medical director responsibilities assigned at the unit level. This commenter remarked further that policies were made at the corporate level and recommended that this requirement be removed entirely.

Response: As stated earlier, the majority of commenters supported the ''Medical director'' condition for coverage. No evidence was submitted to support removing the condition for coverage from the final rule. Several responsibilities addressed in the proposed condition are included in existing regulation at § 405.2161(b), and thus medical directors have previously been expected to ensure that the needs of the patient are properly addressed. We do not believe that the duties of the medical director are too burdensome, therefore, the proposed language will be retained in the final rule.

Comment: A commenter recommended that we add language in the final rule that would allow the medical director to have a major role in the appointment and selection process for hiring individuals who would have admitting privileges in the facility (specifically physicians, physician's assistants, and nurse practitioners).

Response: The medical staff appointments standard at § 494.180(c) places responsibility for medical staff appointments with the governing body. The governing body would address the question of whether medical directors would be included in medical staff appointment decisions. Regulatory language does not preclude the medical director from participating in the selection process; however, we are not going to require that medical directors participate in these decisions.

Comment: One commenter suggested changing the language of the final rule to reflect that most medical directors would normally not participate in developing policies and procedures for an ESRD facility. A commenter noted that policies and procedures are most often developed by the large dialysis organizations; however, medical directors may assist or be asked to assist in revisions. The commenter suggested we add ''participate in the development or refinement (of policies and procedures) * * *.'' in the final rule language. Another commenter suggested we change the language at § 494.150(c)(2) to indicate that the medical director would ''participate with the facility staff to ensure'' that the conditions of that paragraph were met. Another commenter remarked that the medical director could oversee and support the facility but could not ''ensure'' policies and procedures were adhered to by facility staff, as often the owner/chain refused to support their own policies and procedures.

Response: Regardless of whether policies and procedures are developed within the facility or via a corporate process, the medical director is responsible for ensuring that appropriate patient care polices are developed and implemented. The majority of commenters supported the proposed requirement without modification. The medical director is responsible for the clinical care provided in an ESRD facility and thus should be held accountable for that care. We expect the medical director would work with the governing body to ensure that appropriate patient care policies are developed and implemented within the facility.

Comment: We received many comments regarding the medical director's scope of authority within a facility. Some commenters recommended that the final rule mandate that medical directors be given the ability and the authority to monitor and improve the care provided by attending physicians, as well as the entire patient care team, including nurses, physician's assistants, dietitians, social workers and other staff; these commenters thought there ought to be more accountability for poor performers in the facility. Another commenter remarked that if attending physicians were uncooperative, then the medical director should assume responsibility for patient care. The commenter further remarked that the final rule language needs to be ''grounded in a realistic approach'' by which medical directors could influence attending physicians with competing goals. Some commenters suggested that § 494.150(c)(2)(i) be expanded to allow medical directors the ability and authority to monitor and improve care in the facility, including the care provided by attending nephrologists. Other commenters supported the idea that the unit's attending physicians be subject to peer review, under the direction of the medical director, and potentially subject to discipline (within the framework of due process procedures). One commenter remarked that governing bodies should be required, as part of their policies and procedures, to specify the extent of the medical director's authority to manage inadequately performing staff and attending physicians.

Response: The medical director is responsible for the delivery of patient care and outcomes in the facility, which includes responsibility for the QAPI program, staff education, training and performance as well as policies and procedures of the ESRD facility. To strengthen the ''Responsibilities of the medical director'' condition for coverage, we have added language to the first paragraph of § 494.150, reading ''The medical director is accountable to the governing body for the quality of medical care provided to patients.'' The role of the medical director is also strengthened in the final rule at § 494.150(c)(2)(i), to include patient admissions and infection control. Section 494.150(c)(2)(i) now requires the medical director to ensure that all policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and non-physician providers. We believe that the facility governing bodies will provide medical directors with adequate institutional authority to permit the medical directors to perform these duties effectively.

If the medical director is unsuccessful in achieving staff compliance or managing disciplinary issues involving attending physicians and has exhausted all options, we expect that the matter would be referred to the governing body, the ESRD Network or other appropriate authorities, such as the state agency and state licensing boards.

Comment: One commenter suggested the addition of a new § 494.150(c)(2)(iii) to require the medical director to ensure that ''staffing is sufficient to meet the acuity of patients treated in the facility.''

Response: We have not added the suggested language to the ''Responsibilities of the medical director'' condition. Staffing concerns are addressed under § 494.180(b), which pertains to adequate and trained staff in an ESRD facility. We also note that the medical director may not have the organizational authority to determine staffing levels within the facility.

Comment: One commenter suggested we add language in the final rule to read, ''the medical director will have direct communication with the patient's other physicians when new or existing co-morbid conditions arise during the course of dialysis treatment.''

Response: We have not added the suggested language in the final rule. We encourage communication and coordination of care among all parties involved in the patient's care and we expect this would be an effort of the attending physician in order to decrease fragmentation of patient care and to ensure proper care for each patient.

Comment: One commenter recommended increased cooperation between nephrologists and dialysis facilities, via the medical director, to assist patients with transplant eligibility.

Response: We have added language throughout the final rule, such as in § 494.70, § 494.80, and § 494.90, to

ensure that patients are aware of their modality choices, including transplant options. Additionally, the medical director is responsible to ensure that all policies and procedures affecting patient care are adhered to by all individuals who treat patients in the facility, including attending physicians and non-physician providers, as required at § 494.150(c)(2)(i).

c. Relationship With the ESRD Network (Proposed § 494.160)

Requirements found in existing § 405.2110 through § 405.2113, related to the designation of ESRD Networks, the functions of ESRD Networks, and the role of the medical review boards will remain unchanged in subpart U. These provisions focus primarily on the role and responsibilities of the Networks rather than dialysis facilities. We proposed to require that each facility cooperate with the ESRD Network serving its designated area in fulfilling the terms of the Network's scope of work contract with CMS, consistent with the requirement at § 405.2134.

Comment: Several commenters suggested we replace ''statement of work'' with ''goals and objectives.'' Another commenter suggested we expand the requirements beyond the contract scope of work to include explicit references to local projects. A couple commenters recommended we retain language from subpart U at § 405.2134 that states that facilities must ''participate in network activities.''

Response: We appreciate the positive comments. The final rule at § 494.180(i) requires that each facility cooperate with the ESRD Network serving its designated area in fulfilling the terms of the Network scope of work contract with CMS, which is similar to the requirement under existing § 405.2134 concerning participation in network activities. The ESRD Network scope of work includes goals, objectives, and local projects. Therefore, it is unnecessary to modify the requirements as suggested by the commenter. Facilities must continue to share information with the Networks as necessary to support Network goals and objectives.

Comment: One commenter recommended that we require random audits by the ESRD Networks to validate the accuracy of self-reported dialysis facility data.

Response: Random audits by ESRD Networks are outside the scope of this regulation. We are not revising our ESRD network regulations at this time.

Comment: One commenter agreed with the proposed language, remarking that roles and responsibilities of the Network should not be part of the conditions for coverage. Two commenters supported the requirement that mandates each ESRD facility to cooperate with its own Network to fulfill the terms of the Network contract scope of work. A commenter remarked that the scope of work should emphasize the coordination of Network activities across all Networks as well as a limited number of local and national initiatives. Another commenter recommended we require Networks to share more information with the State agency, especially during a state survey of ESRD facilities.

Response: As noted above, the ESRD Network Scope of Work (SOW) is outside the scope of this regulation.

Comment: One commenter recommended we expand the language in this regulation to include transplant centers, as well as dialysis centers, using the rationale that ESRD Networks provide oversight to both.

Response: A separate transplant center health and safety regulation was published on March 30, 2007 (72 FR 15198), which requires transplant centers to participate in Network activities. This requirement can be found at § 482.104(c). Therefore we are not modifying language at proposed § 494.160 to include the suggested language in the final rule. We note, that for reasons described in that section, we have moved the substance of proposed § 494.160 to § 494.180, and removed and reserved § 494.160.

d. Medical Records (Proposed § 494.170)

In keeping with our goals to eliminate unnecessary requirements and to reduce burden on dialysis facilities, we proposed a modified version of existing § 405.2139. The proposed rule emphasized that a facility must maintain complete medical records for all patients under its supervision, including home patients. We proposed not to prescribe the elements facilities would have to include in the patient medical record, as was required in subpart U. We proposed to retain with modifications a previous requirement at § 405.2139 that requires a facility to protect its patients' medical records against loss, destruction, or unauthorized use, and proposed to eliminate the requirement that the facility must have written policies and procedures for recordkeeping. We proposed an expansion of the existing requirements regarding medical record release. Medical records could be released when the patient transferred to another facility; under certain exceptions provided for in law; under a third party payment contract; subject to approval by the patient, or in the course of an inspection by authorized agents of the Secretary, and as required by the Medicare program. We proposed to retain with modifications the previous requirement at § 405.2139(d) that current medical records and those of discharged patients be completed promptly and that all clinical information pertaining to a patient be centralized. We proposed that the dialysis facility be responsible for completing, maintaining and monitoring medical records for its Method II home dialysis patients and its other home patients. Minor revisions were proposed to § 405.2139(e) regarding medical record retention. We proposed that medical records be retained for a period of time not less than that determined by the applicable State statutes governing records retention or the State's statute of limitations. In the absence of State statutes, records would be required to be retained for 5 years from the date of discharge for an adult; or for a minor, 3 years from date of discharge or until the patient becomes of age under State law, whichever was longer. We proposed the elimination of the prescriptive requirements in existing § 405.2139(f) regarding medical record accessibility. We proposed to retain the existing requirement at § 405.2139(g) to require the facility to provide prompt transfer of medical information between treatment facilities. We also proposed a modification of § 405.2137(b)(4) to require that the facility exchange all medical record information within one working day. Finally, we proposed the elimination of the existing requirement for the designation of a medical records supervisor.

Comment: One commenter fully supported the less prescriptive approach in the proposed condition, while another commenter remarked that the proposed reduction of regulatory requirements in this condition for coverage was too broad. Some commenters concurred with the deletion of the medical records supervisor, while others disagreed with the elimination of this position, citing that a designated staff member for this task is essential to ensure an adequate recordkeeping process.

Response: We appreciate the positive comments regarding the elimination of the medical records supervisor requirement in § 494.170. Eliminating process-type requirements is in keeping with our overall goals. Additionally, we believe that the deletion of the medical records supervisor requirement would result in a cost savings for facilities. There is no evidence that removing this requirement would result in poor

outcomes. Therefore, the medical records supervisor requirement has not been included in the final rule.

Comment: Several commenters disagreed with the proposed elimination of the requirement that facilities have written policies and procedures regarding record-keeping. One commenter argued that a facility must have written policies and procedures for record-keeping in order for required outcomes to be achieved. This commenter argued that allowing facilities the flexibility to decide what information to include in the medical record would not assure that outcomes were achieved.

Response: We have decided not to carry over the language from part 405, subpart U, in order to decrease prescriptive, non-outcome oriented requirements and to increase dialysis facility flexibility. As long as there is a system in place to achieve that outcome, we do not believe it is necessary to dictate prescriptive requirements. Facilities are still required to protect medical record information and keep all patient records confidential and demonstrate that all of these conditions for coverage have been met. We do not, however, preclude a facility from having record-keeping policies and procedures as they see fit.

Comment: Two commenters suggested that a reference be added to the final rule to state that a medical record could always be released to a patient, guardian or other legally appointed patient representative.

Response: Patients have the right to look at their own medical record. We proposed at § 494.170(a)(2) that all patient medical record information be kept confidential, except when released to an authorized person approved by the patient. Furthermore, patients have the right to be informed of their medical status as documented in the medical record unless the medical record contains a documented contraindication to do so, as required at § 494.70(a)(10). The proposed language will be retained in the final rule, as it protects the patient's medical record information, while allowing for the release of confidential information to the patient or the patient's representative. We also note that many of our protections correspond to more general protections under HIPAA, found at 45 CFR parts 160 and 164.

Comment: One commenter suggested proposed language at § 494.170(a)(2) and § 494.170(a)(3) was unnecessary because of HIPAA protections already in place. The commenter suggested we retain existing language at § 405.2139(b).

Response: The proposed language was carried through from part 405, subpart U, and we believe the language at § 494.170(a)(2) and § 494.170(a)(3) adds clarification regarding the circumstances under which a patient's medical record may be released and any appropriate authorizations that are needed for that release. As noted above, the proposed language was consistent with the HIPAA privacy regulations at 45 CFR parts 160 and 164 and remains in the final rule.

Comment: A commenter suggested adding language at § 494.170(b) to require that when records are stored electronically, the facility must have procedures to protect in-center and home dialysis patient information, and must back up data daily.

Response: The concern of this commenter is addressed at § 494.170(a)(1), which mandates patient records be safeguarded against loss, destruction or unauthorized use. This requirement must be followed regardless of whether a facility uses written or electronic medical records. Additionally, § 494.170(b)(3) charges dialysis facilities with responsibility for completing, maintaining and monitoring medical records for its home patients.

Comment: Many commenters made remarks regarding what information should be required in the patient's medical record. One commenter was concerned that the proposed condition was reduced too much, stating that medical records of ESRD patients were even now often incomplete, inaccurate and not in accordance with identified medical records standards. Two commenters suggested that the day-to-day events should be documented by the end of each shift in which they occurred, and another commenter suggested we retain existing language from § 405.2139, which specified the information that must be kept in the active patients' chart and readily available. Other commenters suggested a requirement specifying inclusion of treatment information, the treatment settings, safety checks, medical events, pre/post-patient assessments, medications, etc. Another commenter recommended that the final rule include a requirement for documentation of medical injuries and accidents, medication changes, as well as patient phone numbers and emergency contact numbers, which should be entered immediately in the patient's record and be updated if they changed. One commenter suggested a requirement that unusual events during treatment be documented.

Response: The existing part 405, subpart U language was removed from the proposed rule because we believe facilities should have the flexibility to decide what information would be included in the medical record, as long as the patient's medical needs were being addressed and these conditions for coverage were met. Medical professionals are expected to accurately record complete and pertinent information in their patients' medical records, including many of the issues identified by the commenters. Many of the topics identified by the commenters would have to be included in the patient's record in order to comply with the ''Patient assessment'' and ''Patient plan of care'' conditions at § 494.80 and § 494.90. All clinical information pertaining to a patient must be centralized in the medical record (§ 494.170(b)(2)). If a facility kept incomplete, inaccurate medical records, as suggested by the first commenter, this ''Medical records'' condition for coverage would not be met and would be cited during a facility survey.

Comment: One commenter suggested we add language to allow use of electronic medical records and recognize them as a satisfactory and secure system for keeping and protecting patient medical records.

Response: The proposed language at § 494.170(b) does not specify that medical records must be in ''hard-copy'' form only, and thus we see no need to make this suggested change in the final rule. We allow electronic health records, and in fact encourage them. In 2004, the President issued an executive order calling for the widespread adoption of interoperable health records within ten years, and the Department of Health and Human Services has been leading the nation's efforts in advancing the nationwide health IT agenda.

Comment: We received several comments regarding the timeframe for completion of medical records. One commenter supported a requirement that records be up-to-date and accurate. Some commenters suggested we specify a 30-day timeframe for completion of the medical record, while another remarked that the medical record should be updated within 2–4 days after any event so that the information would be available by the next dialysis treatment. One commenter remarked that the proposed language regarding prompt completion of medical records was sufficient. Another commenter suggested that we require all assessments to be placed in the front of the chart to improve availability.

Response: To ensure a comprehensive and accurate medical record, we feel that it is vital that charting be completed promptly. The language at proposed

§ 494.170(b) was retained from existing language in subpart U at § 405.2139(d), and we are codifying it in the final rule. Each member of the interdisciplinary team must have access to the most recent information on the patient's condition and prescribed treatment. It is a ''best practice'' to complete charting without delay to ensure patient health and safety during each treatment. Facilities may choose to establish policies regarding the method in which patient medical records are organized, but we will not mandate such a requirement in this regulation.

Comment: Some commenters pointed out that according to HIPAA regulation at 45 CFR § 164.530(j), documentation must be retained for 6 years.

Response: According to the HIPAA Privacy Rule at 45 CFR § 164.530(j)(2), certain written communications, policies and procedures must be retained for 6 years. Therefore, we agree with the commenters and we have modified standard (c) to stipulate that medical record documentation must be retained for 6 years for both adults and children. Standard (c) now reads as follows: ''In accordance with 45 CFR 164.530(j)(2), all patient records must be retained for 6 years from the date of the patient's discharge, transfer, or death.'' Note, proposed § 494.170(c)(1) has been redesignated to standard (c) and § 494.170(c)(2) has been removed.

Comment: Several commenters argued that transferring all medical records within one day was unreasonable, burdensome, and unnecessary, while other commenters supported the requirement. Another commenter remarked that discharged patient records, including mortality reviews, should be completed within 30 days. This commenter also stated 30 days was plenty of time to collect necessary data and was within the timeframe of one cycle of required monthly patient blood work from which thresholds were evaluated. One commenter remarked that the transfer of medical records information should be defined clearly to include at least the care plan, the three most recent dialysis flow sheets, the patient's medication list, lab reports, the comprehensive assessment, and any physician order(s). Still another commenter suggested the addition of language in the final rule to require information such as nutritional status, psychosocial status, and rehabilitation status be transferred within one working day. Another commenter suggested that it would be helpful to have standard criteria and a form for patients to use when traveling to another unit, in order to ensure that appropriate and consistent information is transferred.

Response: The proposed language at § 494.170(d) required the transfer of all medical record and other necessary information within one working day. We maintain that the requirement should apply not only to the care plan, but also to all medical record information. However, we recognize the commenters' concerns that there may be a substantial amount of documentation that may require more time for transfer. We have therefore revised the language at § 494.170(d), which now reads, ''When a dialysis patient is transferred, the dialysis facility releasing the patient must send all requested medical record information to the receiving facility within 1 working day of the transfer.'' Our goal is to minimize the potential for communication breakdown between facilities and ensure that patients continue to receive the necessary care and services. We are therefore requiring only that the minimum amount of medical information be forwarded as appropriate. Some information, such as recent lab results, may not be readily available within 1 day. This minimum information would likely include the physician orders, the patient assessment, and the patient plan of care, insurance information, the last three recent dialysis run sheets, and other pertinent information as necessary. Facilities may wish to create a standard medical record information transfer form as part of their policies and procedures regarding the transfer of patients, but we are not mandating it.

Comment: One commenter suggested we add the following language: ''Patients must have physician orders for all treatment parameters and these orders must be followed.''

Response: We expect that the facility is following physician orders for all of its patients, as required by State Practice Acts and in accordance with Federal, State and local laws and regulations, as required at § 494.20. Therefore, there is no need to add the suggested language in the medical records condition for coverage of this final rule.

Comment: Two commenters remarked that facilities need a centralized medication administration record in order to identify and track medication errors. Another commenter recommended that facilities be required to work towards a system to improve documentation of medication administration and decrease the incidence of potential medication errors. The commenter further suggested that the success or failure of these systems be followed by a quality assessment and performance improvement program within the facility.

Response: Under the final QAPI condition at § 494.110(a)(2)(vi), facilities must measure, analyze, and track medical injuries and medical errors. We believe this requirement addresses the commenters' concerns. Some facilities may choose to put into practice a specialized centralized medication administration record or some alternative process to assist in easier detection of medical errors.

e. Governance (Proposed § 494.180)

We proposed an updated version of § 405.2136 to modernize the requirements and delete unnecessary processes where possible. Consistent with § 405.2136, we proposed that the ESRD facility be under the control of an identifiable governing body, or designated person, with full legal authority and responsibility for the governance and operation of the facility. The proposed rule retained the requirement that a CEO or administrator be identified. Proposed administrator responsibilities would include management of staff appointments, fiscal operations, ESRD Network relationships, and allocation of staff and resources for the QAPI program. We proposed a standard similar to § 405.2162(b)(2) that would require that the governing body or designated person ensure that there was an adequate number of qualified and trained staff to provide a level of dialysis care to meet the needs of patients. The proposed licensed person on duty when patients were undergoing dialysis would be an RN who would be available in the event of a patient emergency. We proposed, consistent with part 405, subpart U, that dialysis facility employees have an opportunity for continuing education and related development activities. A new proposed provision specified a governing-body-approved, written patient care technician-training program that included eight mandatory topics. We proposed that the governing body be responsible for medical staff appointments and credentialing, and ensuring that all medical staff providing care in the facility were informed of facility policies and procedures and the QAPI program.

We proposed that the governing body ensure that the dialysis facility furnished directly services on its main premises or on other premises that were at least contiguous with the main premises. A new standard was proposed that would require the dialysis facility to implement an internal grievance process that included a procedure for the submission of grievances, facility timeframes for grievance review, and a description of how the patient (or

representative) would be informed of steps taken to resolve the grievance. The proposed rule also addressed a procedure that would have to be followed before a patient could be discharged involuntarily. We proposed to retain the § 405.2138(b)(2) provisions that allowed patient transfer or discharge because of non-payment, or because of facility inability to meet the patient's medical needs. We also proposed that a patient could be discharged or transferred because of disruptive patient behavior that seriously impaired the facility's ability to operate effectively. We proposed a process for involuntarily discharging or transferring a patient. These steps included reassessing the patient, documenting the problem and ongoing efforts to resolve the problem, obtaining a written discharge or transfer order signed by the attending physician and the medical director, documenting efforts to place the patient in another facility, and notifying the State survey agency and the ESRD Network.

The proposed rule included emergency coverage provisions at § 494.180(g) that were similar to those at § 405.2136(g)(2) and § 405.2160(a). This proposed standard would task the governing body with ensuring that patients and staff received written instructions for obtaining emergency medical care, that there was a roster with the names of physicians to be called for emergencies and their contact information, and that there was an agreement with a hospital capable of providing emergency medical care to dialysis patients at any time.

We specified in the February 4, 2005 proposed rule at § 494.180(h) that dialysis facilities would continue to be required to provide to CMS data and information for ESRD program administration, however, this data would be required to be sent electronically in a format and at a frequency specified by the Secretary. We added to the proposed requirements, a proposal that facilities submit data necessary for existing ESRD clinical performance measures, currently only collected on a sample of dialysis patients, and any future clinical performance standards developed in accordance with the National Technology Transfer and Advancement Act of 1995 process adopted by the Secretary. The final subsection of proposed § 494.180 would update § 405.2136(a)(1) to require the governing body to report ownership interests of 5 percent or more to the State survey agency, consistent with § 420.200 through § 420.206. We received more than 100 comments on § 494.180 ''Governance'' condition. Some commenters concurred with the condition as proposed, and many commenters suggested modifications.

Comment: Two commenters suggested that the final rule (at § 494.180(a)) limit the number of facilities a single CEO may serve, as it is not unusual for one CEO to cover 4 or more units.

Response: A facility CEO or administrator must have available sufficient time to carry out his or her responsibilities and requirements to allow the facility to fully comply with § 494.180. Although the CEO of a large facility may not have adequate availability to serve multiple dialysis facilities, it is possible that a CEO could adequately serve more than one small facility. We have not added a restriction to limit the number of dialysis facilities a CEO may serve, but require the CEO to satisfactorily fulfill the CEO responsibilities listed at § 494.180(a).

Comment: One commenter suggested that we not use the terms ''CEO'' and ''administrator'' interchangeably in the final rule. A second commenter recommended that we delete the term ''CEO'' from the final rule and use the term ''administrator.'' The rationale given by one commenter is that the terms imply different things; for example, an administrator manages a unit and a CEO has ultimate authority in the organization.

Response: The proposed rule specified that the CEO or administrator would exercise responsibility for the management of a specific facility and the provision of all dialysis services including, but not limited to, staff appointments, fiscal operations, the ESRD Network relationship, and allocation of resources. The term specifically does not refer to the CEO of a parent company or entity that owns or controls several facilities. We do not expect that there will be confusion about the use of the terms ''CEO'' or ''administrator,'' as the responsibilities are clearly specified in the final rule.

Comment: One commenter suggested that the CEO or administrator be responsible for addressing those financial collections issues with patients that affect the functioning of the facility or jeopardize the continuance of provision of dialysis services to the patient.

Response: As stated in the response above, the CEO or administrator is responsible for the fiscal operations of the facility. We are not detailing the tasks associated with this function in this regulation because financial issues are normally a component of the facility's business practices and are therefore not within the scope of this rule. Discharges of facility patients for non-payment are allowed as stated in § 494.180(f)(1), and we believe that facilities generally make every effort to collect payment for dialysis services.

Comment: We received more than 70 comments regarding our proposed requirement at § 494.180(b)(1), that the governing body ensures that there is an ''adequate number of trained and qualified staff.'' A few commenters concurred with standard (b) as proposed. One commenter stated that the term ''adequate staff'' is ''too open to interpretation'' and should be clearer.

More than 60 commenters recommended placing staffing ratios for various patient care staff in the final rule. Many commenters stated that huge case loads are affecting the quality of care, and that Medicare should designate at least an enforceable upper limit on the number of patients for each staff member. A commenter stated that ''California does not have any (staffing ratios) for dialysis facilities'' and she has ''seen as much as 1 RN for 21 patients in facilities by one corporate provider.'' This commenter stated that adequate staffing provisions are difficult to enforce and she has found facility staffing policies that allowed unsafe staffing levels. The commenter argued that to ensure the safety of the patients, minimum staffing ratios are necessary, and should be included in the CMS regulations. Commenters suggested staff-to-patient ratios for various dialysis staff; one commenter stated the RN-to-patient ratio should not exceed 1:10, and other commenters suggested PCT-to-patient ratios of 1:4.

Many commenters suggested a 1:75 MSW-to-patient ratio, and stated that it was impossible for MSWs to do case review and counseling with high patient ratios. Commenters stated that MSWs were assigned large caseloads of between 125 and 300 patients each, and cited a 2005 study (Bogatz, Colasanto, and Sweeney) in support of this contention. Some commenters recommended that we require use of a standardized acuity-based formula for adequate staff, such as the NKF Council of Nephrology Social Workers' ''Professional Advocacy for the Nephrology Social Worker, First Edition 2002'' (pages 9–11). One social worker stated she had 150 patients in 3 units and could therefore only triage and ''put out fires.''

The American Dietetic Association voiced concern that inadequate staffing would affect the quality of care and was aware of many situations where RD-to-patient staffing ratios was 1:200. The ADA further stated that if CMS did not at least reference an optimum RD

national staffing ratio, facilities ''will demonstrate a lack of restraint for large case loads'' and the positive expectations for the new conditions for coverage will not be seen and may even negatively impact patient-focused quality care. Some commenters suggested a RD-to-patient ratio of 1:100 to 125. Some commenters stated that K/DOQI recommends a RD-to-patient ratio of 1:100 and no more than 1:150. A commenter stated that Texas has implemented a RD to patient ratio of 1:125, and that RDs are increasingly directed to do non-RD work that reduces the time available for care of patients who are older and sicker. Some commenters pointed out that dietitians and social workers are often shared between multiple facilities.

Several commenters recommended adding a new requirement for use of an acuity-based staffing model. A commenter stated that software was available to help establish staff to patient ratios based on patient acuity. One commenter stated that acuity-based staffing would reduce facilities ''cherry picking'' patients that would likely occur if minimum facility-level standards were implemented. Some commenters would like to see staffing ratios included in acuity-based staffing plans. One commenter suggested convening an acuity-based staffing plan technical expert panel, and another, an acuity-based staffing plan demonstration. One commenter suggested that we require policies and procedures for staffing that identify numbers of patients, acuity levels, and patient-to-staff ratios.

Several commenters were opposed to both ratios and acuity-based staffing models, stating the current proposal provided necessary flexibility, and that facilities could assign adequate staff based on patient acuity. One commenter stated that CMS should not lock dialysis facilities into a ratio system in regulation, because regulations could take too long (as much as 20 years) to change. Another commenter stated there were no data to support mandated staff-to-patient ratios, and a case mix adjustment formula was needed to avoid facilities ''cherry picking'' patients. One commenter stated that acuity-based staffing ratios would foster confusion, ''up-coding,'' and additional paperwork burdens. The commenter further stated that if acuity-based ratios were adopted, then payment should be adjusted to allow providers to accommodate acuity-based staffing needs. A commenter stated that acuity-based staffing plans have been unsatisfactory and that the nursing shortage exacerbated problems. Another commenter stated that a federal acuity-based system was a bad idea, as there were too many variations from facility to facility, there would be conflicts with many State requirements, and this approach was very subjective.

Response: We solicited public comment in the proposed rule regarding whether we should include a requirement for an acuity-based staffing plan. The public comments were split on the acuity-based staffing plan issue. Clearly staffing is of concern to many commenters. While commenters agreed with the intent of the proposed adequate staff provision at § 494.180(b)(1), there was discontent related to how this provision would be interpreted and enforced. First, we would like to clarify that the adequate staff standard applies to all clinical patient care staff, including nurses, technicians, social workers, and dietitians who provide services to the dialysis patients. Appropriate staffing ratios are affected by a number of factors. These factors include patient acuity, level of staff expertise and skill mix, presence or absence of support staff/unlicensed personnel, available technology, distances between groups of patients served, efficiency of systems in place, scope of staff duties, degree of team work, State requirements, practice board-imposed limitations, number of meetings in which staff participation is required, paperwork demands, etc. We do not have a method available to identify and account for all of these types of characteristics in determining staff ratios that balance staff time to provide quality care and meet patient needs with the economic factors associated with dialysis facility labor costs. We are also concerned that any mandated minimum staffing ratios would be interpreted as the ''maximum ceiling'' that must be complied with which could lead to a decline in the number of patient care staff available.

''Adequate staff'' means staffing must be sufficient so that quality care is provided to dialysis patients that is consistent with the patient plan of care and professional practice standards. We are requiring under the ''Patient assessment'' and ''Patient plan of care'' conditions (§ 494.80 and § 494.90 respectively) that members of the interdisciplinary team complete a comprehensive assessment, followed by a plan of care that identifies goals for patient care and the services that will be provided in order to meet those goals. This includes psychosocial and nutrition services to be provided by the social worker and the dietitian. The assessment and plan of care requirements necessitate that the RN, social worker, and dietitian provide appropriate professional care to each patient. We are also requiring at § 494.110 that the interdisciplinary team, which includes the RN, social worker, and dietitian, play an active role in the QAPI program. This final rule requires that the interdisciplinary team provide appropriate care to dialysis patients and improve patient care on an ongoing basis. The dialysis facility may need to evaluate staffing levels as part of their action plan for the QAPI program. In order to clarify that the adequate staffing standard applies to all clinical staff, we have added language to the requirement at § 494.180(b)(1), requiring that the RN, social worker and the dietitian be available to meet patient clinical needs.

Comment: Two commenters suggested that we hold the medical director accountable for adequate staffing.

Response: We proposed that the governing body or designated person responsible must ensure adequate staffing. The medical director would generally not be responsible for hiring and firing, and replacing vacant positions, or developing the work schedules for dialysis facility. The final rule will continue to hold the governing body or designated person responsible for ensuring an adequate number of trained and qualified staff.

Comment: More than 15 commenters supported the proposal that an RN be present in the facility during dialysis (§ 494.180(b)(2)). Two commenters requested that this provision be limited to hemodialysis because 24-hour RN coverage for peritoneal dialysis patients would be too burdensome. A few commenters recommended that the final rule prescribe more than one RN in large units. One commenter suggested that the final rule state that the RN must not be merely ''available'' but ''a directed patient care giver that provides direct supervision of care.''

A few providers opposed the proposal that requires the presence of an RN, stating that an LPN would be sufficient. They suggested that the nursing shortage would make this provision difficult to meet, especially in rural locations, and the LPN was capable of fulfilling this role. They further stated that this provision could force dialysis facilities to close.

Response: We do not agree with these commenters that the RN shortages would create an access to care problem. Therefore, we are retaining the requirement that an RN be present in the facility at all times that patients were being treated so that a nurse would be available who had the experience and training to react to patient care emergencies that could occur in this

increasingly older and medically-complex patient population. We believe that the RN has a key role in patient assessment and supervising LPNs, LVNs, and PCTs, and is the appropriate staff member to be responsible for the nursing care provided. An RN may also be needed to answer clinical questions from patients and caregivers. The rapidly changing demographics of the dialysis patient population has resulted in an older, sicker patient population with more serious co-morbid conditions and elevated potential for medical emergencies. An RN has the professional training and expertise to properly react to emergencies. Therefore, we believe that having an RN on the premises when treatment is being provided is a necessary health and safety measure for all patients.

We agree with commenters that large dialysis facilities caring for large numbers of dialysis patients simultaneously could require the presence of more than one RN; however, we are not mandating more than one RN. The presence of one RN is a minimum requirement and large dialysis facilities have the flexibility to schedule more than one RN if patient acuity and the number of patients dialyzing at one time necessitates it.

The provision at § 494.180(b)(2) regarding RN presence during dialysis is applicable to in-center dialysis and does not apply to times when peritoneal dialysis patients are self-dialyzing at home. While an RN may not be available at the dialysis center at all times that a patient is performing home dialysis, there must be an emergency plan for when home patients have an urgent situation, as required at § 494.180(g). We have clarified the RN presence requirement by modifying § 494.180(b)(2)(i), to require a registered nurse must be present in the facility at all times that ''in-center dialysis patients'' are being treated. We have also added the phrase ''responsible for the nursing care provided'' to further clarify the role of the RN on duty.

Comment: One commenter asked whether an ESRD facility within a larger facility needs to have an RN present during dialysis if other RNs are in the larger facility.

Response: This provision requires the RN to be present in the dialysis unit regardless of where the facility is located.

Comment: A few commenters suggested that we require medical director training so that the medical director is fully informed of the expectations associated with her/his role. One commenter suggested adding a requirement to properly orient, train, and inform the medical director.

Response: We agree that the proposed orientation requirement at § 494.180(b)(3) should apply not only to employees, but also to the medical director and all dialysis facility staff, regardless of employee or contractual status. In this final rule, we have modified this provision to read as follows: ''All staff, including the medical director, have appropriate orientation to the facility and their work responsibilities.'' This requirement now applies to all dialysis facility staff.

Comment: We received several comments regarding the proposed requirement at § 494.180(b)(4), that ''All employees have an opportunity for continuing education and related development activities.''

One commenter suggested deletion of this requirement because facilities should not be ''obligated'' to provide developmental activities without funding.

Response: This continuing education provision was previously found at part 405, subpart U (§ 405.2136(c)(3)(viii)), and we are retaining it in the final rule. This requirement does not represent a new cost to dialysis facilities, since a normal cost of doing business is training and developing employees.

Comment: A commenter suggested that § 494.180(b)(4) be revised to read, ''all employees are provided continuing education and related developmental activities.'' Another commenter recommended the wording be modified to state that all employees ''must'' have opportunities for continuing education. A commenter suggested that we require mandatory training on quality improvement, quality standards, and the ESRD Network role. One commenter stated that § 494.180(b)(4) is vague and should include a requirement for mandatory continuing education for PCTs.

Response: We do not agree that inserting the word ''must'' after the word ''employees'' adds clarity. This provision requires the governing body or designated person responsible to ensure that employees have the opportunity for continuing education and development activities, which include education that is provided by the facility as well as education that is available outside the facility. We have not modified the wording to more narrowly define the continuing education opportunities as only those ''provided'' by the facility, nor have we added prescriptive language to define the areas in which the continuing education and development activities must occur. The facility has the flexibility to identify areas on which to focus educational efforts. Some areas might be identified via the QAPI program. Licensed, registered, or certified dialysis facility staff must meet certain ongoing educational requirements to maintain their licensures, registrations, and/or certifications, which are required under the ''Personnel qualifications'' condition.

Comment: Two commenters suggested that we require mandatory staff education on the patients' right to be free of verbal abuse by staff, as there have been ''numerous allegations'' of staff verbally abusing patients in the absence of such a requirement, and there was a need to maintain ''professionalism'' in facilities. The commenters stated that the line of professionalism was often crossed by staff in dialysis facilities.

Response: We are alarmed about allegations of dialysis patient abuse by facility staff. Any allegations of abuse should be immediately reported to the State survey agency and appropriate local authorities. We agree with the commenter regarding the need for staff to be knowledgeable about patient rights. A dialysis facility must inform patients of their rights and the facility must protect and provide for the exercise of those rights as required under the ''Patients' rights'' condition for coverage at § 494.70. These rights include the right to respect and dignity (§ 494.70(a)(1)). Dialysis facilities must ensure that patient rights are recognized and protected by all staff and would therefore need to educate staff regarding patient rights in order to achieve compliance with the conditions for coverage. Patient rights must be posted prominently in the facility. In addition, the medical director at § 494.150(c)(2)(i) must ensure all patient care staff adhere to all patient care policies. These policies would include protection of patient rights. We require, at § 494.180(b)(3), that all staff receive appropriate orientation to the facility and work responsibilities, which would include patients' rights training. However, we are not going to mandate that the facility provide training to staff on this matter because we do not want to prescribe or limit the orientation topics. Facilities must provide adequate staff training to ensure that they meet these conditions for coverage.

Comment: Several commenters concurred with the written PCT training program proposal at § 494.180(b)(5). One commenter was concerned that dialysis facilities would be allowed to ''police'' their own PCT training

programs, which could lead to a lack of consistency and validity.

Response: We appreciate the support for the PCT training requirements. We discussed PCT qualifications earlier in this preamble under ''Personnel qualifications.'' We have relocated the PCT training requirements from § 494.180(b)(5) and § 494.180(b)(6), to § 494.140(e)(3) and § 494.140(e)(4) so that all of the PCT qualifications may be found in one section of these conditions. We are requiring national PCT certification in this final rule. The certification exam would serve as a measure of PCT competency, and facilities would not be in the position of instituting their own certification programs.

Comment: We received many comments suggesting revisions to the content of the PCT training program. A large number of commenters recommended that we add a PCT training topic regarding patient psychosocial needs related to ESRD and its treatment regimens, and that this training be provided by the MSW. A commenter suggested adding ''communication and interpersonal skills, including patient sensitivity training and care of difficult patients.'' Another commenter suggested adding training on ethics and professionalism, and dealing with conflicts and challenging situations. A few commenters suggested PCT training on patient nutrition and psychosocial needs. One commenter recommended PCT training regarding possible symptoms and complications of dialysis, the potential for patients to live long and active lives on dialysis, and patient expectations.

Response: We do not agree that there is a need to expand the PCT training subject matter list. The proposed PCT training program (proposed at § 494.180(b)(5)) included the ''care of patients with kidney failure, including interpersonal skills'' and ''possible complications of dialysis.'' ''Care of patients with kidney failure'' (proposed § 494.180(b)(5)(ii)) would include psychosocial and nutritional aspects of care. The ''interpersonal skills'' training would include professional conduct and interactions during challenging situations. The ''complications of dialysis'' (proposed § 494.180(b)(5)(iv)) was already addressed in the proposed training topics list.

As discussed in the ''Personnel qualifications'' section of this preamble, we have moved the training list to § 494.140(e)(3). The training program must be approved by the medical director and the governing body. We are requiring certification of PCTs to ensure competency.

Comment: A commenter suggested that we retain all or part of existing § 405.2136(d) and § 405.2136(g).

Response: Standard 405.2136(d) required written personnel policies and procedures; and standard (g) addressed medical supervision and emergency coverage. Section 405.2136, standard (d) required that facility policies and procedures ensure the following: That all staff members are qualified to perform their duties; that a safe and sanitary environment exists for patients and staff; that trainees are directly supervised; that complete personnel records are maintained; that personnel policies including grievance policies are written and available; that all facility personnel are oriented and have continuing in-service training that is documented, and; that personnel manuals are maintained, updated, and available.

This final rule addresses staff qualifications at § 494.140, and a safe and sanitary facility environment is addressed throughout part 494, subpart B. Facility staff training and educational requirements are set out at § 494.180(b). In keeping with our goal of removing process requirements, we are not including personnel policy provisions in the final rule. Personnel policies and procedures are maintained as a usual business practice and do not need to be required by this regulation.

As for former § 405.2136(g), issues of emergency preparedness and emergency coverage are addressed in this final rule at § 494.60(d) and § 494.180(g), respectively. The substantive elements of medical supervision are encompassed within the ''Patient assessment'' (§ 494.80), ''Patient plan of care'' (§ 494.90), and ''Medical director'' (§ 494.150) conditions.

Comment: One commenter suggested adding a requirement for facilities to notify the State agency when there are changes in the governing body make-up, facility location, or medical staff.

Response: We do not believe that these specific procedural requirements should be included in the final rule. Communications of this type will be addressed via program instructions or interpretative guidelines as needed.

Comment: A commenter suggested that we require facilities to report all unusual incidents to the State agency.

Response: The condition at § 494.20 requires compliance with relevant Federal, State and local laws, some of which may include reporting requirements. We did not propose that facilities report unusual incidents to the state agency, although we are requiring that the State and ESRD Network complaint phone numbers be prominently posted (§ 494.70(c)). Dialysis facilities must report certain diseases to the state health department and must report certain incidents related to equipment failure to the FDA. We have not added any further reporting requirements to the ''Governance'' condition.

Comment: One commenter suggested that patients be able to nominate an individual to serve on the facility governing body.

Response: The governing body is an entity with full legal responsibility and accountability to operate the facility. Dialysis facilities have the option of having patient representation on their governing bodies if they choose. We support patient participation and encourage facilities to include patients in quality assessment and performance improvement efforts, and as representatives on facility committees and boards whenever appropriate.

Comment: Several commenters suggested that we add other staff (physician assistants, nurse practitioners, and clinical nurse specialists) to the § 494.180(c) list of medical staff that the dialysis facility would appoint and credential. One commenter stated that we should only refer to physician credentialing unless State law allows other professionals to be credentialed.

Response: The proposed rule addressed credentialing for physicians, physician assistants, and nurse practitioners. We have modified the language at § 494.180(c)(1) to include clinical nurse specialists since some dialysis facilities use these professionals. We agree with the commenter regarding congruency with State law. We have also added the phrase ''in accordance with State law'' at § 494.180(c)(1) to indicate that these credentialing requirements do not supersede State law regarding such ''physician extenders.''

Comment: A few commenters agreed that the governing body should support medical staff appointments. Two commenters stated the governing body should authorize and require the medical director to monitor and improve performance of attending nephrologists.

Response: The proposed language at § 494.180(c)(2) would require the governing body to ensure that all medical staff who provided care in the facility were informed of all facility policies and procedures, including the facility's quality assessment and performance improvement program. The medical director is accountable to the

governing body for the quality of care provided. As discussed earlier in this preamble we have modified the language at § 494.150 to include, ''The medical director is accountable to the governing body for the quality of medical care provided to patients.'' In recognition of the role of medical staff in providing quality care we have also added language at § 494.180(c)(3) to require the governing body to communicate expectations to the medical staff regarding staff participation in improving the quality of medical care provided to facility patients. The governing body must ensure that adequate resources are available to provide quality care. The medical director is responsible for patient outcomes and must ensure adequate cooperation from anyone who treats patients in the facility (§ 494.150(c)(2)). If the medical director is unable to secure cooperation from individuals providing treatment, including attending physicians, the problem should be referred to the governing body. If the governing body is unable to remedy the problem, the medical director should notify the state medical board and/or the ESRD Network.

Comment: One commenter suggested that more physician accountability could be achieved through periodic re-credentialing. Another commenter stated that facilities had little control over physicians, and suggested use of hospital credentialing as required by the Medicare hospital conditions of participation, as a model. The commenter also stated that if physicians did not participate in QAPI, they should lose their credentialing.

Response: The hospital conditions of participation at § 482.22 require that the medical staff operate under bylaws approved by the governing body, be responsible for the quality of medical care provided to patients, be composed of doctors of medicine or osteopathy and in accordance with State law, may be composed of other practitioners appointed by the governing body, conduct periodic appraisals of its members, examine credentials of candidates and make recommendations to the governing body based on qualifications established in the medical staff bylaws, be well organized and accountable to the governing body for the quality of care.

We believe that the proposed rule has been strengthened via language in the final rule at § 494.150, ''Responsibilities of the medical director'' that states, ''The medical director is accountable to the governing body for the quality of the medical care provided to patients.'' This is consistent with the hospital conditions of participation. We have also added language to § 494.180(c) that states not only is medical staff informed of facility policies and procedures and the QAPI program, but that the governing body must communicate to all medical staff the expectations for the role of the medical staff and required participation in improving the quality of medical patient care. The governing body has the flexibility to perform annual credentialing or to choose another credentialing frequency. During initial credentialing, the governing body should review previous medical staff positions and whether a physician or physician extender has had privileges revoked in any other facilities.

Comment: We received two comments regarding § 494.180(d) ''Furnishing services.'' One commenter suggested that we define the phrase ''(the facility's) main premises'' so as to include home dialysis, while another commenter would like a loosening of the ''on-the-premises'' provision to allow ''across the street'' units.

Response: The provision at § 494.180(d) that the governing body ensure that services are furnished directly on its ''main premises'' or on other premises that are ''contiguous'' with (that is, not physically separate from) the main premises, facilitates dialysis facility accountability for the patient care provided. Therefore, an ''across the street'' dialysis facility is not considered to be part of another dialysis facility but an independent facility. As such, it must meet all these conditions for coverage and be certified to receive Medicare payment.

Home dialysis services must be provided in the certified dialysis facility or at the patient's home, unless the patient requests an alternate location. Home dialysis by definition includes the patient's home as an acceptable location for the performance of dialysis, and therefore is an acceptable site for the provision of support services.

Comment: One commenter suggested the final rule state (at § 494.180(e)) that the facility must accept a grievance in any form (oral or written) presented.

Response: We agree that facilities should not limit acceptance of grievances to written grievances, and therefore, we have added the words ''oral or written'' at § 494.180(e) to allow patients more flexibility in how they communicate a grievance. The sentence now reads, ''The facility's internal grievance process must be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services.''

Comment: Two commenters suggested we require the internal grievance process to be posted. Another commenter recommended patient involvement in the design and administration of internal grievance process.

Response: We are not prescribing the manner in which a facility must make its grievance process known. The facility has the flexibility to inform patients of the grievance process as required under the ''Patients' rights'' condition at § 494.70(a)(14), using the methods of its choice.

Comment: One commenter recommended that we require routine reporting to the ESRD Network on the number and topics of complaints. A second commenter supported the concept of an internal grievance process, but suggested the addition of an expectation of timely investigation, documentation, and resolution, along with a quality assurance requirement to prevent any recurrences.

Response: Grievances resolved at the facility level might not need to be escalated to the ESRD Network level. Grievances are to be addressed in a reasonable fashion in a reasonable period of time. The grievance process must include a clearly explained procedure for the submission of grievances, timeframes for reviewing the grievance, and a description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance. Dialysis facilities must track grievances and patient satisfaction as part of the QAPI program in which trending and quality improvement efforts are expected (§ 494.110(a)(2)(viii)).

Comment: We received many comments supporting proposed § 494.180(f), ''Discharge and transfer policies and procedures.'' Several commenters endorsed the preamble language regarding the inappropriateness of patient discharges for non-compliance and recommended that we add language to the final rule stating that a patient cannot be discharged for non-compliance. A commenter stated that non-compliance could be due to lack of education on the effects of non-compliance. A few commenters suggested that recommendations from ''Decreasing Dialysis Patient-Provider Conflict National Task Force Position Statement on Involuntary Discharge'' developed by a national consensus conference held in October of 2003, be included. The report stated that patient non-adherence to the medical regimen was not an appropriate reason to discharge a patient, primarily because this type of behavior mainly

harmed the patient himself and not others, and because the patient could exercise his right to non-adhere to instructions. One commenter recommended that we include in the final rule the key elements from this report, which include the facility's right to refuse to treat violent, physically abusive patients; a physician right to terminate care only after taking ethical steps; and the recognition that both the unit and physician have legal obligations.

Some commenters stated that when an attending physician discharges a patient from care and another physician is not found to take over the patient's medical care, the dialysis facility has no choice but to discharge the patient. One commenter stated discharge should be allowed for patients whose behavior interferes with the plan of care, including non-compliance.

Response: The background section of the ''Decreasing Dialysis Patient-Provider Conflict National Task Force Position Statement on Involuntary Discharge'' (*http://www.esrdnetwork8.org/assets/pdf/DPCPositionStatement06.pdf*), adopted by the task force in January 2005, provides data on involuntary discharges. The number of involuntary discharges in 70 percent of dialysis facilities in 2002 was 458 (0.2 percent of 285,982 patients). ''Treatment non-adherence was the leading reason for discharge nationally at 25.5 percent (117 patients), followed by verbal threat at 8.5 percent (39 patients). Other reasons for discharge were lack of payment at 5.2 percent (35 patients), combinations of verbal abuse, verbal threat and physical threats at 5.2 percent (24 patients) and verbal abuse at 5 percent (23 patients).'' The report also stated that discharged patients were at high risk for morbidity and mortality and an unknown number of deaths have occurred due to lack of access to dialysis.

Patients may be involuntarily discharged for non-compliance by their physician because physicians have a right to end an established care relationship with a patient after providing the patient adequate notice (30 days) of the termination of the medical care and reasonable assistance in obtaining care elsewhere. If a physician discharges a patient from his or her personal care, the dialysis facility should locate another attending physician in the facility to provide ESRD care, or discharge the patient from the facility following the process required at § 494.180(f)(4).

The proposed rule preamble (70 FR 6202) stated, ''We would not expect a patient to be involuntarily discharged from a dialysis facility for failure to follow the instructions of a facility staff member.'' Facilities are expected to make ''good faith'' efforts to mitigate problems and prevent an involuntary discharge. The proposed circumstances under which involuntary discharge would be permissible, laid out at § 494.180(f)(1) through § 494.180(f)(4) were: Lack of payment; facility closes; the transfer is necessary for the patient's welfare because the facility can no longer meet the patient's documented medical needs; or the facility has reassessed the patient and determined that the patient's behavior is disruptive and abusive to the extent that the delivery of care to the patient or the ability of the facility to operate effectively has been seriously impaired.

The previous conditions for coverage at § 405.2138(b)(2), stated that patients could be transferred or discharged only for medical reasons or for the patient's welfare or that of other patients, or for nonpayment of fees (except as prohibited by title XVIII of the Act) and that facilities would have to provide the patients with advance notice to ensure orderly transfer or discharge. Neither the proposed rule nor subpart U encouraged the involuntary discharge of patients because of patient non-compliance. Aside from a minor grammatical change we have not modified the proposed language regarding the permissible conditions for an involuntary patient discharge in this final rule. This final rule requires that if there is a problem with non-compliance, the problem must be addressed in the plan of care and facility staff must take appropriate actions. Patient education and social work interventions may be appropriate. The facility must weigh the ethical issues regarding the discharge of a patient from a life-saving therapy against the gravity and consequences of any non-adherence problem.

Immediate discharge is addressed under ''Patients' rights'' in this final rule at § 494.70(b)(2) and at § 494.180(f)(4) and § 494.180(f)(5). Under § 494.70(b)(2) the patient has the right to receive written notice 30 days in advance of the facility terminating care after following the procedure described in § 494.180(f). Moreover, in the case of immediate threats to the health and safety of others, an abbreviated discharge procedure may be allowed. There may be situations where a patient's behavior is so egregious that a facility must discharge a patient with less than 30 days notice or even immediately. The facility must weigh the safety and care of other patients and staff against the consequences of continuing to provide dialysis care or conducting an expedited discharge of the patient from a lifesaving therapy. We proposed a process, which is retained in this final rule, that must be adhered to before a patient with disruptive or abusive behavior may be discharged.

We encourage facilities to use the materials and tool kit developed by the ''Decreasing Dialysis Patient-Provider Conflict National Task Force'' to proactively prevent conflicts and disruptive situations and to undertake appropriate actions when involuntary discharge is being considered. This kit is available from the ESRD Networks.

Comment: One commenter suggested revising proposed § 494.180(f)(3) to permit transfer under that paragraph when the transfer is necessary for the patient's welfare because the facility can no longer meet the patient's medical needs and goals as documented in the patient's plan of care as specified in § 494.90.

Response: The suggested additional phrase defines the medical needs as those specified in the plan of care and would therefore permit a facility to involuntarily discharge a patient if he/she did not meet care plan goals. We believe that the term ''medical needs'' is commonly understood and do not believe that failure to meet the plan of care goals should result in discharge of a patient. We are making no changes to this provision based on this comment.

Comment: A commenter recommended revising § 494.180(f)(4)(iii) to read, ''The governing body of facilities approached to accept the patient must ensure that the patient is not summarily declined a transfer without following the individual facility's policies and procedures for patient admission (including patient interview and medical records review, if applicable).''

Another commenter recommended the addition of a requirement for a facility admission policy that discourages discrimination. The commenter asked that our regulations address admission restrictions and discharges of patients who require a higher level of skilled care (ventilator, bed-bound, morbidly obese) since some current practices have caused access-to-care problems.

Response: Dialysis facilities should not deny admission to their facilities because they ''heard'' the patient was a ''problem'' without assessing the patient. Patient privacy rules must be observed and the admission review should include medical record information and not ''hearsay.''

Facilities should assess the medical needs of patients and the facility's ability to meet these medical needs. Facilities must comply with federal civil rights and anti-discrimination laws as required in § 494.20. Under our previous regulation, the facility was required to have admission criteria that insured equitable access to services, and to make such criteria readily available to the public (§ 405.2136(b)(3)). While we did not carry forward this provision in the proposed rule, in the final rule, we are holding the medical director responsible for the development, review, approval, and staff adherence to facility policies and procedures (§ 494.150(c)). Because facility admission policies would fall under the responsibilities of the medical director, we have added ''patient admissions'' to the list of policies and procedure categories for which the medical director is responsible (§ 494.150(c)(2)(i)). Dialysis facilities should offer equitable patient access to their facility and should have well defined ethical and legal admission policies. Facilities will be expected to adhere to their written admission policies.

Comment: One commenter agreed that both the governing body and the medical director should be responsible for ensuring that the facility complies with the involuntary patient discharge process. Another commenter suggested that only the governing body should be responsible.

Response: We believe that both the medical director and the governing body have an obligation to ensure that the facility appropriately conducts involuntary patient discharges.

Comment: Two commenters suggested adding ''patient choice'' to reasons for discharge so that when a dialysis patient voluntarily leaves, the facility does not have to implement the involuntary discharge procedure.

Response: We have renamed § 494.180(f) to include the word ''involuntary.'' The new title is ''Involuntary discharge and transfer policies and procedures.'' This clarifies that these provisions specifically apply to involuntary discharges, not all dialysis facility discharges.

Comment: A few commenters supported our proposal at § 494.180(f)(4)(ii), which would require both the attending physician and the medical director to sign an involuntary discharge order. One of the commenters stated that some patients have been involuntarily discharged from a dialysis facility without the attending physician's knowledge. A few other commenters suggested that one, not two physicians (attending physician and medical director), provide the discharge signature. Another commenter suggested that we only require the medical director's signature for involuntary discharges only.

Response: An involuntary discharge of a patient from dialysis, a life-saving therapy, is a last-resort action that can have grave consequences. We believe the responsibility for, and obligations to, the patient, are shared between the attending physician and the dialysis facility. In this situation, the medical director represents the dialysis facility. The medical director and the attending physician should concur that the last resort approach is needed before discharging the patient; otherwise, the involuntary discharge should not occur.

We agree that the medical director's discharge signature is only necessary when the discharge is involuntary. We have renamed standard (f) ''Involuntary discharge and transfer policies and procedures.'' This clarifies that these provisions apply to involuntary discharges, and not all dialysis facility discharges. The signature requirement has been redesignated in the final rule as § 494.180(f)(4)(ii).

Comment: Commenters offered varying interpretations of how facilities may satisfy the requirement at § 494.180(f)(4)(iii) regarding attempts to place the patient in another facility and documentation of that effort. One commenter stated that a ''good faith effort'' in finding a new facility should be enough, and the facility should not be held accountable for a patient's bad choices. Another commenter agreed, saying that facilities should document their attempt to place the patient in a new facility, and in some cases, difficult patients should make his or her own arrangements. Two commenters requested clarification of what would be required, and stated their belief that the responsibility for finding an alternate facility rested with the patient. Some commenters stated the facility should be required to provide a list of other nearby dialysis facilities and assistance with the transfer.

A few commenters suggested that the facility demonstrate its attempt to find an alternate placement ''by direct contact with the other facility.'' This suggestion is consistent with the ''Decreasing Dialysis Patient-Provider Conflict National Task Force'' recommendations. Another commenter recommended inclusion of a requirement for the discharging facility to make arrangements and pay for treatment at a hospital for the services they are refusing to provide, until a hearing is held.

Response: In response to comments, we have revised the provision to require that the facility must contact an alternate dialysis facility to attempt to place the patient who is involuntarily discharged and must document that effort.

Comment: We received several comments regarding the requirement at proposed § 494.180(f)(4)(iv) that the facility notify the State survey agency and the ESRD Network of an involuntary discharge. Several commenters suggested that we require ESRD Network involvement or a mandatory ESRD Network referral before an involuntary discharge. Two commenters said there should be Network notification 48 hours prior to an involuntary discharge. A commenter stated that notifying the State agency and the Network after the fact was too late; community human services agencies should be notified earlier in the process, in order to provide resource support to help prevent an involuntary discharge.

Response: We agree that the ESRD Network could be of more assistance in acting as a resource and resolving problems leading up to an involuntary discharge if notification were provided prior to the discharge. The proposed rule required notification of the State survey agency and the ESRD Network of the involuntary transfer or discharge without specifying when notice would be given. We have modified standard (f) to include a new requirement, now at § 494.180(f)(4)(ii) in this final rule, so that the facility must now notify its ESRD Network within the same time frame in which the patient is given written notice of the involuntary discharge (that is, 30 days). The proposed provisions at § 494.180(f)(4)(ii) through § 494.180(f)(4)(iv) have been renumbered in this final rule to reflect the insertion of the new paragraph (ii).

Comment: A few commenters suggested that the ESRD Network be involved in performing audits, patient placement, arbitration, and in finding alternate solutions related to dialysis facility grievances related to involuntary discharges.

Response: The extent of the role of the ESRD Network in involuntary discharges is defined by the ESRD Network scope of work. It would be inappropriate in these conditions for coverage to address Network authority or responsibilities.

Comment: One commenter stated the ESRD Network should be allowed to notify the State survey agency so the facility does not have to call both entities. Another commenter stated that notification of both State and Network

is too burdensome, and one (the ESRD Network) should be enough.

Response: We believe the burden of notifying both the ESRD Network and the State survey agency represents an acceptable level of burden. We have retained ESRD Network and State agency notification of an involuntary patient discharge in the final rule.

Comment: A commenter suggested facilities be encouraged to develop and share discharge criteria with patients to ensure they are fully informed of expectations, policies, and procedures.

Response: We refer the commenter to the ''Patients' rights'' condition. Patients have the right to be informed regarding the facility's discharge and transfer policies as required at § 494.70(b). Facilities must also inform patients of the rules and expectations of the facility regarding patient conduct and responsibilities (§ 494.70(a)(13)).

Comment: A few commenters recommended the addition of a final rule provision that would allow immediate patient discharge when an immediate serious physical threat to staff or patients exists. Two commenters noted that in these cases, there must be thorough documentation and a police report is normally filed.

Response: The proposed rule preamble (70 FR 6202) discussion recognized that there may be occasions when an immediate or an abbreviated patient discharge process may be appropriate in order to protect other patients and staff. We agree that it is reasonable to add language under the discharge standard in § 494.180. We also note that there may be instances when local law enforcement officials must be notified of questionable behavior. Therefore, in response to comments we have modified § 494.180(f) by adding, at (5) ''In the case of immediate severe threats to the health and safety of others, the facility may utilize an abbreviated involuntary discharge procedure.'' This abbreviated procedure allows less than a 30-day time period for the discharge notice. The facility must still provide patient assessment, interventions, and an effort for resolution to the extent possible based on the unique situation. Documentation in the medical record of the events leading up to the involuntary discharge is required in every case.

Comment: Two commenters suggested the addition of language to § 494.180(f)(4)(i) that would require counseling and support from the team to resolve patient behavioral issues and also require that the team inform patients of behaviors that could lead staff to notify police or referral for evaluation of risk to self or others. Some commenters stated there should be social worker involvement before a patient is involuntarily discharged. Another commenter suggested that we add a condition that no patient be involuntarily discharged except in an emergency situation without documentation that a program was implemented to resolve inappropriate behavior.

Response: The involuntary patient discharge requirements at § 494.180(f)(4)(i) address reassessments, ongoing problems, efforts made to resolve the problem, and documentation in the patient's medical record. These ''efforts made to resolve the problem'' may include counseling and support from the team to resolve behavioral issues. We are not narrowly defining or specifying what the ''efforts made to resolve the problem'' must encompass, as patient needs vary. The team must assess the patient and use appropriate interventions that address the patient's individual issues.

As stated above, patients have the right to be informed regarding the facility's discharge and transfer policies as required at § 494.70(b), which include policies regarding notification and referrals.

Comment: We received a few comments regarding § 494.180(g)(3), ''Emergency coverage.'' Some commenters supported our proposed requirement that each ESRD facility have an agreement with a hospital. One commenter suggested including a provision requiring that the agreement address psychiatric emergencies. Two commenters recommended requiring the facility to make an agreement only with hospitals that had the ability to provide inpatient dialysis, which the commenter argued was especially important in rural areas. One commenter stated that patients needed to know about the nature of the relationship between the dialysis unit and the hospital under agreement to provide emergency services.

A commenter stated that this provision should require the dialysis facility and hospital to agree to provide mutual aid in the event of a large disaster and suggested that each unit have one or more ''mutual aid agreements'' with other facilities both near and far. The commenter stated that the issues facing ESRD patients in the event of a disaster are not often considered by emergency planners.

Another commenter questioned the need for an agreement with a hospital, stating that hospitals were reluctant to enter into such agreements and that such agreements were not required of hospitals in their conditions of participation.

Response: The proposed provision regarding the hospital agreement is less prescriptive than part 405, subpart U requirement formerly found at § 405.2160. Instead of including process-oriented requirements, we proposed a requirement that was aligned with our intent to ensure access to suitable inpatient care for dialysis patients. We agree with the commenter that dialysis care should be available in any hospital with which an agreement is made. We have revised the final rule to require that dialysis facilities must have an agreement with a hospital that can provide routine and emergency dialysis services, and to specify this in the agreement. The provision at § 494.180(g)(3) now reads, ''The dialysis facility must have an agreement with a hospital that can provide inpatient care, routine and emergency dialysis and other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week * * *.''

One commenter (a state survey agency) noted that hospitals were often reluctant to enter into agreements with dialysis facilities, but no dialysis facilities related any difficulties in this regard in their comments. Therefore, we do not believe that this is a barrier to dialysis facility compliance with this provision.

Our final rule at § 494.60(d)(4)(iii) requires a dialysis facility to contact its local disaster management agency to make the agency aware of dialysis facility needs in the event of an emergency. This provision will ensure at least annual communication between the dialysis facility and the local disaster management program. We believe this addresses the commenter's concern about lack of contact with emergency planners.

Facilities also have the flexibility to include any of the additional commenter suggestions when writing their agreements and to communicate emergency services arrangements with patients as appropriate. We are not mandating these processes in this final rule.

Comment: We received many comments regarding proposed § 494.180(h), ''Furnishing data and information for ESRD program administration,'' which would require a dialysis facility participating in Medicare to furnish data and information electronically and in intervals specified by the Secretary. These data would include cost reports, administrative forms, patient survival data, ESRD clinical performance measures and any future standards developed in accordance with the

NTTAA process adopted by the Secretary.

Many commenters expressed support for the proposed electronic data collection. Some commenters recommended expansion of the ''Dialysis Facility Compare'' Web site at *http://www.cms.hhs.gov/dialysisfacilitycompare/* to include all data collected, home dialysis data, measurements of patient satisfaction, other relevant lab data, and facility aggregate functioning and/or well-being data.

Several commenters had concerns regarding the burden associated with electronic data collection. Two commenters stated that VISION (Vital Information System to Improve Outcomes in Nephrology) is not ready for full implementation and may not be universally applicable, and therefore a data collection requirement should be delayed.

One commenter stated that electronic reporting would duplicate the information collected by large dialysis organization information technology systems. A few commenters recommended that only one of electronic or paper data collection should be required, as both would be too burdensome. One commenter suggested that a timeline was needed to implement electronic reporting.

One commenter stated that providers should have the opportunity to provide input when CMS defines data collection efforts.

Response: The proposed rule would require the electronic submission of data necessary for CMS administration of the Medicare ESRD program. These electronic data specifically include administrative data (including, but not limited to the CMS–2728, Medical Evidence/Medicare entitlement form data and CMS–2746, ESRD death notification data, and the United States Renal Data System data) and the existing ESRD Clinical Performance Measures (CPM) data (CMS–820 and CMS–821), and any data necessary for future performance measures developed in accordance with a voluntary consensus standards process identified by the Secretary.

This final regulation requires facilities to provide data and other information that are necessary to support administration of the ESRD program. In order to increase efficiencies and improve the usefulness of these data, we are requiring electronic submission of necessary administrative data as well as specified data for calculation of ESRD CPMs.

This electronic data collection is consistent with the IOM's recommendation that ''* * * the Department of Health and Human Services should move forward expeditiously with the establishment of monitoring and tracking processes for use in evaluating the progress of the health system in pursuit of the above-cited aims'' (IOM 2001). It is also consistent with White House Executive Order 13410, *Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs,* issued on August 22, 2006, which states:

> ''Each agency shall implement programs measuring the quality of services supplied by health care providers to the beneficiaries or enrollees of a Federal health care program. Such programs shall be based upon standards established by multi-stakeholder entities identified by the Secretary or by another agency subject to this order. Each agency shall develop its quality measurements in collaboration with similar initiatives in the private and non-Federal public sectors.''

(*http://www.whitehouse.gov/news/releases/2006/08/print/20060822-2.html*) (71 FR 51089.)

Finally, it is consistent with recommendations from various governmental bodies that provide oversight of the Medicare program. For example, in a recent report (OEI–05–05–00300) titled ''Availability of Quality of Care Data in the Medicare End-Stage Renal Disease Program,'' the Department of Health and Human Services' Office of the Inspector General (OIG) recommended that CMS ''increase its efforts towards regularly collecting data from all patients and all facilities on all clinical performance measures identified by CMS to address quality of care issues in the ESRD program'' (HHS/OIG 2006). We have received recommendations to require facilities participating in Medicare to report on performance measures to stimulate improvements in the quality of care and to achieve a greater degree of accountability for performance. These recommendations come from the OIG in its reports ''External Quality Review of Dialysis Facilities/A Call For Greater Accountability'' and ''Availability of Quality of Care Data in the Medicare End-Stage Renal Disease Program'' (DHHS/OIG, 1999, 2006); from the IOM in its report ''Crossing the Quality Chasm, 2001'' (IOM, 2001); from the Medicare Payment Advisory Commission (MedPAC) in its report ''Improving Quality Assurance for Institutional Providers'' (MedPAC, 2000); and from the Government Accountability Office (GAO) in its report ''Dialysis Facilities: Problems Remain in Ensuring Compliance with Medicare Quality Standards'' (GAO, 2004). The requirement to submit data necessary to calculate specified CPMs is an important step in moving in this direction.

The electronic data provided to CMS will be used to monitor the performance of the public health system and dialysis facilities certified to care for Medicare beneficiaries with ESRD. The data will also be used to provide information to individuals who have or may develop ESRD and their caregivers to assist them in making health care decisions; to allow the identification of opportunities for quality improvement at a national, regional, or dialysis-facility level; and to help align our payment system with high-quality care through improvements in case-mix adjustment and the potential future use of payment for performance.

CMS, the ESRD Networks, dialysis facilities, and other interested stakeholders have used the ESRD CPMs to assess the care of a representative sample of individuals with ESRD in the areas of adequacy of dialysis, anemia management, nutrition (serum albumin), and more recently, vascular access (Centers for Medicare & Medicaid Services. 2005 Annual Report, End-Stage Renal Disease Clinical Performance Measures Project. Am J Kidney Dis 48:S1–106, 2006 (supp. 2)). CMS developed the ESRD CPMs to implement section 4558(b) of the Balanced Budget Act of 1997 (Pub. L. 105–33), which required the Secretary to develop and implement a method to measure and report on the quality of renal dialysis services provided under Medicare no later than January 1, 2000. These measures were developed based on widely accepted, evidence-based clinical practice guidelines and were subsequently used to guide national, regional, and facility based quality improvement efforts.

Beginning in the mid-1990s, the National Kidney Foundation's (NKF's) Dialysis Outcomes Quality Initiative (DOQI) development process released guidelines to help shape the development of clinical measures based on strength of evidence, clinical importance and feasibility. The NKF has since expanded and updated their early efforts and their Kidney Disease Outcomes Quality Initiative (K/DOQI) guidelines are widely accepted among the renal community. These may be a source of potential future CPMs that can be developed and supported by a broad cross-section of stakeholders, including clinical practitioners, industry representatives, professional associations, and others interested in assessment and improvement of the care provided to individuals with ESRD.

We proposed using the VISION application for the provision of electronic data but based on technological advances and public comments, we are implementing a new Web-based system, Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), for this purpose. VISION was a patient-specific, stand-alone, facility-based information system with software that resides on facility computers, which presents challenges for updating the software. We agree with commenters that VISION did not represent the best technology for widespread collection of data from dialysis facilities and large dialysis organizations.

Use of the CROWNWeb system will increase the efficiency of data collection both for CMS and for facilities, improve data quality, and provide a more stable and accessible platform for continual improvements in functionality. It will also complement the advanced information infrastructure used by many dialysis facilities.[1] We believe that CROWNWeb will not duplicate information technology systems in large dialysis organizations, but will facilitate data reporting and provide efficiencies.

We believe that the collection and reporting of ESRD CPMs has been an effective tool to facilitate ESRD quality improvement, and has allowed us to track positive improvements in several intermediate outcomes for individuals with ESRD. Therefore, we are requiring under the ''Governance'' condition for coverage (§ 494.180(h)), that the ESRD CPMs in effect on the date of the Final Rule's publication be included as the initial set of CPMs that all ESRD facilities are required to collect for all individuals with ESRD and submit to us electronically. We will carefully evaluate any revisions to current CPMs as well as any future CPMs developed in accordance with a voluntary consensus standards process for possible inclusion in these electronic reporting requirements. The Secretary will provide notice and an opportunity for comment in the **Federal Register** before any changes to the electronic reporting requirements based on the CPMs are enacted.

We recognize that electronic data reporting may result in some additional facility burden. However, the availability of batch data reporting will reduce the level of burden. We believe that there is a return on this investment for all primary stakeholders, including patients, dialysis facilities, and the public. CROWNWeb will allow for the more timely, accurate, and efficient use of data to support administration of the ESRD program by replacing the current predominately paper process with an electronic process that considers the capabilities of providers, which has tangible benefits for dialysis facilities, individuals who have or may develop ESRD, and other stakeholders. CROWNWeb provides facilities with the ability to submit the required data directly from their electronic health records, thus reducing burden and freeing facility personnel to concentrate on patient care. Another expectation is that claims payment will be improved due to improved quality and timeliness of patient eligibility and enrollment information. Finally, we expect that the new system will provide reports that will allow facilities to compare themselves with their peers.

CROWNWeb will also increase the transparency of the health care system for patients and thus, help empower patients to find better health care value and better health care quality as well as help assure appropriate patient access to care. For ESRD Networks, CROWNWeb will provide more timely, accurate, and complete information to inform quality improvement, and it would reduce Network resource use for data collection activities. For example, CROWNWeb will be able to recreate the data included on the current CMS 2744 Annual Facility Survey more timely as opposed to on the last day of the year and it would free up Network resources that currently perform a four-month manual reconciliation process. In addition, for all primary stakeholders, we expect that the new system will provide more timely report capabilities that will allow them to compare individual facilities and facility groups with various peer groups, national, and local benchmarks.

In February 2007, CMS' Quality Infrastructure Support (QIS) contractor held its first CROWNWeb CPM technical expert panel, which represented initial CROWNWeb users, including large and small dialysis organizations, dialysis professional societies, ESRD Networks, CMS, and associated Federal contractors, to survey primary stakeholders about desired/expected performance attributes of CROWNWeb relative to the CPMs, including feedback reporting. Based on the input received from members of the panel as well as ongoing input from the community at large through either publicized monthly calls and/or e-mail (*craft@nw7.esrd.net*), CMS' QIS contractor developed draft business requirements, which CMS evaluated, approved, and forwarded to its IT contractor for incorporation into CROWNWeb.

CROWNWeb will also facilitate greater transparency for patients through more timely, accurate, and complete reporting. In September 2002, CMS contracted with the Research Triangle Institute to conduct an evaluation of the content of DFC. The Final Report of the Evaluation of the Content Dialysis Facility Compare as submitted to CMS in March of 2004 (*http://www.cms.hhs.gov/DialysisFacilityCompare/03_Evaluation%20of%20DFC.asp.*) A revised version of the Web site, based on findings from the evaluation and integrating more user-friendly ''next generation compare'' software, was posted in June 2004 and CROWNWeb will provide the infrastructure so that DFC can provide additional value for persons who have or may develop ESRD and the caregivers who assist them in making health care decisions.

The electronic collection and reporting of CPM data via CROWNWeb for all individuals with ESRD will add significant value for facilities and individuals who have or may develop ESRD in three ways:

1. Validation and comparative reports can be viewed more timely once the data submission is complete since the CPM data are electronically available.

2. There is no claims time lag because the CPM measures are computed using clinical as opposed to administrative and claims information.

3. Facilities can see facility-specific information that compares themselves to various peer groups because the CPM data cover all Medicare-certified dialysis facilities and will include all patients.

While submission of data and information is an existing requirement in § 405.2133 and electronic submission of cost report data and information is an existing requirement in § 413.24, the requirement to provide CPM data is new. Additionally, the requirement to provide necessary administrative data in electronic format is a change from the paper-based process that has historically been used to support the ESRD program.

Initially, the data will consist of information necessary to calculate the ESRD CPMs and administrative data elements from existing data collections in effect as of publication of this final rule. In response to community input requesting time to get their information systems aligned with this new requirement as well as train necessary resources, we will delay the requirement for reporting the data

[1] This advanced information capability is detailed in the 2002 OIG series, ''Clinical Performance Measures for Dialysis Facilities,'' OEI–01–99–00052.

necessary to calculate the specified CPMs and other administrative data using the CROWNWeb system until February 1, 2009. Thereafter, all facilities must collect and report on an ongoing basis the necessary administrative data, and the CPM data at least annually for all eligible ESRD patients via CROWNWeb as specified by CMS. In the interim, dialysis facilities will use existing processes to collect and report necessary administrative data and data necessary to calculate ESRD CPMs for individuals with ESRD that are included in the national ESRD CPM sample. Thus, 2008 will be the last year we will collect data to calculate the existing ESRD CPMs on a 5 percent representative sample to fulfill section 4558(b) of the Balanced Budget Act of 1997 (Pub. L. 105–33). In 2009, we will be requiring facilities to collect and report CPM data on all ESRD patients in their facilities.

In order to provide support for facility-based quality assurance and performance improvement as specified in § 494.110, facilities may voluntarily submit specified CPM data via CROWNWeb more frequently than annually. In order to support national quality improvement efforts (for example, the Fistula First Breakthrough Initiative) as specified in the Relationship with the ESRD Network condition at § 494.180(i), facilities may be required to submit data for a subset of specified CPMs more frequently than on an annual basis. Thus, facilities may provide a more frequent subset of data either voluntarily or as required as part of a national quality initiative, but we will only require the submission of the complete set of data necessary to calculate specified CPMs on an annual basis in this final rule.

In response to the comment regarding including providers' input as we define data collection efforts, CMS and the ESRD Networks have a history of collaboratively working with the ESRD community on improving data quality. Between 2003 and 2005, CMS and the ESRD Networks partnered with the ESRD community to develop the Core Data Set, which created a common ''kidney data dictionary'' complete with standardized data elements, data definitions, and integrity constraints necessary for ESRD Networks to conduct quality improvement oversight activities and for CMS to conduct ESRD Program oversight activities.

In 2006, CMS funded a Quality Infrastructure Support (QIS) contractor to solidify the early work of the Core Data Set by soliciting ongoing input from the ESRD Networks and other stakeholders and summarizing it in recommended business requirements to CMS for the new information system. The process the QIS contractor used for incorporation of community input is referred to as CRAFT (CROWN Responsiveness and Feedback Tree) and includes public presentations (available at *http://www.esrdnetworks.org/2007CMSForumAMpresentations.htm*), monthly calls, technical expert panels, an e-mail suggestion box, focus groups, and site visits.

CROWNWeb supports the following existing systems, all of which will be integrated by CROWN, thus reducing the federal cost of administering the ESRD program.

- The ESRD Standard Information Management System (SIMS). SIMS supports the business processes of the ESRD Network Organizations and allows data exchange among the Networks, the facilities and CMS via a secure, web-enabled environment called the ''QualityNet Exchange.''
- The Renal Management Information System (REMIS). REMIS determines the Medicare coverage periods for ESRD patients and serves as the primary mechanism to store and access information in the ESRD program Management and Medical Information System Database. REMIS includes an operational interface to the SIMS Central Repository. (REMIS replaces REBUS, the mainframe Renal Beneficiary and Utilization System.)

CROWNWeb uses an encryption technology that assures privacy, confidentiality, and security for electronic communications and is consistent with applicable HIPAA and Privacy Act statutes and related regulations and would be available free-of-charge to all dialysis facilities with Internet access. CROWNWeb also meets applicable security criteria included in the CMS Information Security Acceptable Risk Safeguards (ARS) policy (*http://www.cms.hhs.gov/InformationSecurity/14standards.asp#TopOfPage*) which contains a broad set of CMS security controls based upon National Institute of Standards and Technology (NIST) requirements. We have further improved CROWNWeb's efficiency, functionality, and timeliness by working with dialysis organizations to develop a mechanism for accepting batch data submittals.

Comment: Two commenters stated that large dialysis organizations should not have to subsidize the small independent dialysis facility electronic data collections.

Response: We assume the commenters are referring to the proposed rule preamble discussion (70 FR 6231 and 70 FR 6241). The VISION software was intended to be available to all dialysis facilities. If an LDO opted not to use VISION, then file specifications would be developed and this approach might result in costs to those dialysis facilities. We are no longer planning to use the VISION software and our approach does not call for LDOs to ''subsidize'' small independent facilities.

Comment: We received several comments regarding the content of the clinical performance measures. One commenter stated support for using the same CPMs for home patients and in-center patients. Another commenter suggested that special consideration be given to small rural units and that we consider case-mix when developing new measures.

Some commenters suggested the addition of one of the following indicators for use as CPMs: Depression scale scores, infection control measures, K/DOQI Bone metabolism and renal bone disease, patient functioning and well being, and ESRD Network 9/10 technical expert panel recommended transplant referral measures.

Response: The development of new CPMs is not carried out via the conditions for coverage. Historically, we have funded the development of measures by contracting with an organization that possesses the technical knowledge and skills and who convenes a TEP to assist them in the development of the measures or in the review of the science or guidelines to determine when existing measures need to be updated. Facility-level measures that would be enforced under the conditions for coverage would be developed in compliance with the National Technology Transfer and Advancement Act of 1995 (NTTAA) by a voluntary consensus standards body (§ 494.180(h)(3)(iv)). This process allows transparency as the facility-level measures and thresholds are developed. The implementation of new facility-level measures adopted by the Secretary will be done via a future rulemaking process, which will allow for public comment.

Comment: One commenter stated that an outcomes approach requires measures and standards. Several commenters supported the proposal to develop federal standards using a voluntary consensus standards body as described by the NTTAA. Another commenter suggested that any changes in the CPMs should be done in partnership with nephrologists and key stakeholders in the renal community. One commenter stated voluntary consensus standards and quality thresholds should be defined by actual

data distributions of outcomes of each parameter, denoting thresholds at one and two standard deviations. The commenter stated clinicians would support this approach.

Response: We agree that an outcomes approach requires measures and standards. The proposed process of using a voluntary consensus standards body to arrive at facility-level standards has been retained in the final rule. Nephrology experts and stakeholders should participate in the voluntary consensus standards process in which the development of facility-level thresholds would occur. Public comment will also be invited during the rulemaking process that implements the facility-level measures that are adopted by the Secretary.

Comment: One commenter suggested that ownership information be available to any member of the public upon request.

Response: The proposed requirement at § 494.180(i) has been moved to now § 494.180(j), regarding disclosure of ownership, which is consistent with § 420.200 through § 420.206. Information subject to public disclosure is addressed at § 420.206(a). The public may request current dialysis facility ownership information from the State survey agency. We also refer the commenter to 42 CFR 431.115(e)(4) and § 455.104 which describe Medicaid and State Children's Health Insurance Program ownership disclosure provisions, respectively.

As stated previously in this section, we will delay the requirement for reporting the data necessary to calculate the specified CPMs and other administrative data using the CROWNWeb system until February 1, 2009. The delay affects the specific standard found at § 494.180(h). We are delaying this requirement in response to dialysis facility community input requesting time to align their information systems with this new requirement, as well as train necessary staff.

D. Other Proposed Changes and Issues

1. Proposed Cross-Reference Changes

We proposed to make technical changes in the following sections of the regulations to correct cross-references to the sections in part 405, subpart U that have been relocated or deleted: § 410.5, § 410.50, § 410.52, § 410.152, § 410.170, § 413.170, § 413.172, § 413.198, and § 414.330.

2. Proposed Additions to Part 488

We proposed to add a new subpart H to part 488. Proposed subpart H would consist of the existing sanction provisions in part 405 subpart U. The existing sanction provisions are in § 405.2180, § 405.2181, § 405.2182, and § 405.2184 and are summarized as follows:

- Section 405.2180 specifies the basic sanction, which is termination of Medicare coverage, and the basis for reinstatement of coverage after termination.
- Section 405.2181 specifies the alternative sanctions denial of payment of any patients accepted for care after the effective date of the sanction, and gradual reduction of payments for all patients) and the circumstances under which they might be imposed.
- Section 405.2182 specifies the notice procedures that we will follow and the appeal rights of sanctioned suppliers.
- Section 405.2184 specifies (in greater detail) the rights of suppliers that appeal proposed imposition of an alternative sanction.

We proposed to redesignate these provisions (with technical and cross-reference changes) as § 488.604, § 488.606, § 488.608, and § 488.610 respectively.

We did not receive any comments on these proposed changes. Therefore, we are finalizing these proposals without change.

E. Survey & Certification Comments

Comment: There were several comments, including comments from many national organizations, which recommended that CMS convene a panel of experts, with a broad representation of dialysis providers including nephrology health care professionals and patients, to contribute to the development of the Interpretive Guidelines for the ESRD conditions for coverage. Commenters remarked that there is a wealth of expertise available in the renal community, which would be of great value to CMS. Commenters also strongly recommended that CMS ensure ''consistency in enforcement through the state survey process,'' stating that there is a need for clear, specific interpretations so that national consistency can be achieved.

Response: We have used and will continue to solicit input from experts from the renal community as well as the general public in developing the Interpretive Guidelines.

Comment: Two commenters stated that ESRD surveys are not completed frequently enough to ensure ongoing compliance with the ESRD Conditions for Coverage. One national organization expressed concern about having effective surveillance and enforcement of the conditions for coverage. Two State health departments suggested CMS mandate ESRD facilities be surveyed at least every 3 years with follow-up surveys for 2 years when a facility has been noncompliant with one or more conditions. Commenters also recommended funding be increased for this activity.

Response: We issue a Mission and Priority Document (MPD) each year, which prioritizes the survey goals for the upcoming fiscal year. Budget restrictions, statutorily mandated surveys, and CMS initiatives influence the survey priorities of the MPD. In Fiscal Year 2006, ESRD surveys were moved up in priority because safety and health can be positively influenced by compliance with the conditions for coverage. Changes in funding for surveys and/or survey mandates would likely require Congressional action.

Comment: Two commenters remarked on the redundancies in the format of the CMS survey report, Statement of Deficiencies. It was pointed out that the report is difficult to read and one commenter urged that state surveyors be instructed to list deficiencies only once in the Statement of Deficiencies report for corrective action.

Response: We are working on limiting the repetitive citing of a deficient practice to egregious cases where serious problems must be cited under several survey tags. We are aware that the format of the survey report, Statement of Deficiencies, could be improved and are considering the best ways to improve it.

Comment: One commenter asked if State laws could only be cited during a Federal survey after the law has been cited by the appropriate State authority.

Response: In the CMS Federal survey process, citations for a lack of compliance with State laws occur after the State authority has made a final determination regarding compliance with State law.

F. Impact Analysis Comments

Comment: Many commenters stated that the new conditions for coverage need to be consistent with payment rules.

Response: Specific commenter concerns about proposed rule requirements that were perceived to be inconsistent with Medicare payment policy were addressed in earlier sections of this preamble as each provision was discussed. We have modified requirements to more accurately reflect the dialysis facility's role in cases where the proposed requirement arguably exceeded the scope of services that dialysis facilities

provide. For example, in response to comments, we revised the patient rehabilitation services requirement (§ 494.90(a)(8)) so that dialysis facilities would provide rehabilitation assistance and referral as appropriate, but would not be required to provide the actual rehabilitation services. Payment concerns regarding erythropoietin were addressed under the Patient plan of care preamble discussion (proposed § 494.90(a)(3)). Physician visit payment comments were addressed under the proposed § 494.90(b)(4) preamble discussion, and the monthly physician visit provision was deleted. We provided clarification of vascular access ''monitoring'' in our earlier preamble discussion (proposed § 494.90(a)(4)) so that our requirement is clearly aligned with payment policy. Concerns regarding the costs of LSC compliance were addressed under the ''Physical environment'' condition at (§ 494.60) and the small number of existing dialysis facilities that would have been required to retrofit sprinkler systems are now exempted from this provision if such retrofitting is not required by the facility's State law and CMS finds that State law adequately protects facility patients.

Comment: Some commenters recommended that Medicare payment be adjusted to provide reimbursement for dialysis facility costs resulting from implementation of the final rule.

Response: The Medicare reimbursement rates for dialysis facilities are divided into distinct categories. The first category is the composite rate that covers the provision of dialysis and associated services that are enumerated in the Medicare renal dialysis facility payment manual. The composite rate is set by the Congress, and may be influenced by the recommendations of MedPAC, which performs cost analysis and provides annual reports to the Congress. The MedPAC analysis includes a review of the dialysis facility cost report data, which will encompass any new costs facilities bear due to compliance with the new conditions for coverage, including some categories of overhead costs. We expect that the MedPAC analysis and recommendations will reflect any new across-the-board dialysis facility costs that are associated with this final rule. The second reimbursement category focuses on separately billable drugs and biologicals. The Medicare Modernization Act of 2003 (amending sections 1842(o) and 1847A of the Act) included provisions regarding medication and biologicals reimbursement rates. The new provisions call for the calculation of the drug average sales price plus an add-on payment that is adjusted on a quarterly basis. Dialysis payment adjustments for 2007 implemented by Medicare were published on December 1, 2006 in the Physician Fee Schedule rule (71 FR 69623) and established calendar year 2007 reimbursement rates. We are not making any changes to our payment methodologies based on the issuance of these conditions for coverage.

Comment: One commenter requested a reimbursement change to allow advanced practice nurses to be identified and Medicare reimbursed in the final rule.

Response: Services that would be provided by advanced practice nurses would be included either in the physician monthly charges or under the dialysis facility composite payment rate, depending on the role of the individual. Insofar as the commenter is advocating a pass-through for APNs, this is not being considered in this rule; however, we will take the commenter's suggestion under advisement.

Comment: A few commenters suggested that Medicare provide funding for the purchase of automated external defibrillators (AEDs) if they are required in the final rule.

Response: AEDs would be included under ''capital costs'' in the dialysis facility cost report. MedPAC reviews all costs and makes recommendations to the Congress regarding the appropriate dialysis facility payment update. Medicare does not pay separately for specific dialysis facility capital expenditures.

Comment: Several commenters included general remarks regarding the overall Medicare payment system. Commenters stated that Medicare does not appropriately fund the ESRD program and that dialysis facilities must ''subsidize'' the cost of care provided to Medicare beneficiaries. They also referred to the ESRD composite rate as the only Medicare prospective payment system without an annual update mechanism to adjust for changes in input prices and inflation. Commenters discouraged CMS from implementing new conditions for coverage that would add significant costs to providing care without directly providing benefits to patients, unless an annual update mechanism is established for the ESRD composite rate.

Response: Although an annual composite rate update mechanism has not been established by Congress, we note that the Tax Relief and Health Care Act of 2006 (Pub. L. 109–432, Division B, Title I, section 103(a)) provided an update of 1.6 percent to the composite rate component of the basic case-mix adjusted prospective payment system for dialysis services effective April 1, 2007. However, the issue of payment updates to dialysis facilities is determined by Congress and is outside the scope of these conditions for coverage. We have addressed specific concerns of commenters earlier in this preamble and have modified proposed requirements in several instances so that the provisions of this final rule do not exceed the scope of services that we could expect from Medicare-certified dialysis facilities.

III. Provisions of the Final Rule

In this final rule we are adopting the proposed provisions as set forth in the February 4, 2005, proposed rule, subject to the following revisions:

- Amend § 405.2102 ''Definitions'' by removing the definitions for ''Histocompatibility testing,'' ''Organ procurement,'' ''Renal transplantation center,'' ''Transplantation service,'' and ''Transplantation surgeon,'' leaving ''Network requirements'' the only remaining substantive component of the subpart.
- Amend § 405.2180 through § 405.2184 ''Termination of Medicare coverage'' and ''Alternative sanctions'' by recodifying these sections at § 488.604 through § 488.610 under Subpart H—Termination of Medicare Coverage and Alternative Sanctions for End-Stage Renal Disease (ESRD) Facilities.
- Amend § 414.330 ''Payment for home dialysis equipment, suppliers, and support services'' by revising paragraph (a)(2)(iii)(C) to change the reporting timeframe from every 30 days to at least every 45 days.
- Amend § 494.1 ''Basis and scope'' by—
  + Removing paragraph (a)(2).
  + Redesignating paragraphs (a)(3) through (a)(7) as (a)(2) through (a)(6), respectively.
  + Replacing the phrase ''recombinant epoetin alpha (EPO)'' with ''erythropoiesis-stimulating agent(s)'', in paragraph (a)(5).
  + Revising paragraph (a)(6) to read ''Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113), which requires Federal agencies to use technical standards that are developed or adopted by voluntary consensus standards bodies, unless their use would be inconsistent with applicable law or otherwise impractical.''
- Amend § 494.10 ''Definitions'' by—
  + Revising the definition for ''discharge'' to read ''means the termination of patient care services by a

dialysis facility or the patient voluntarily terminating dialysis when he or she no longer wants to be dialyzed by that facility.''

+ Removing the definition for the term ''interdisciplinary team.''

• Amend § 494.20 ''Compliance with Federal, State, and local laws and regulations'' by removing the phrase ''staff licensure and other personnel staff qualifications, fire safety, equipment, building codes, drugs and medical device usage.''

• Amend § 494.30 ''Infection Control'' by—

+ Expanding our incorporation by reference section (pages 20–21) of the CDC ''Recommended Infection Control Practices for Hemodialysis Units at a Glance,'' to include the corresponding narrative section (pages 18–28) with the exception of the hepatitis C screening found in ''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients,'' Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001. The recommendation found on pages 27 and 28 under the ''HBV-Infected Patient'' header section of RR05 requires a separate isolation room. Therefore, we are allowing dialysis facilities 300 days after the publication of the final rule in the **Federal Register** to comply with the requirements of this provision at (a)(1)(i). Specifically, this provision must be complied with by February 9, 2009.

+ Adding a dialysis isolation room waiver provision at (a)(1)(ii), which allows a new dialysis facility to request a waiver of the isolation room requirement, subject to the Secretary's approval, when dialysis isolation rooms are available locally that sufficiently serve the needs of patients in the geographic area.

+ Redesignating proposed paragraph (a)(2) as paragraph (a)(3).

+ Redesignating proposed paragraph (a)(3) as paragraph (a)(4).

+ Adding a new paragraph (a)(2) incorporation by reference for the ''Guidelines for the Prevention of Intravascular Catheter-Related Infections'' sections entitled ''Recommendations for Placement of Intravascular Catheters in Adults and Children'' parts I–IV; and ''Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters, in Adult and Pediatric Patients'' (Morbidity and Mortality Weekly Report, volume 51 number RR–10, pages 16 through 18, August 9, 2002, developed by the HICPAC).

+ Removing the requirement in paragraph (b)(2) that an infection control officer that is a registered nurse be designated as the infection control or safety officer, and adding infection control as a component of the quality assessment and performance improvement program required at § 494.110(a)(2)(ix).

+ Revising the proposed requirement at paragraph (b)(2) to clarify that clinical staff in a dialysis facility must demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules.

+ Redesignating paragraph (b)(2)(ii) as paragraph (b)(3) and revising to read as follows: ''Require all clinical staff to report infection control issues to the dialysis facility's medical director (see § 494.150 of this part) and the quality improvement committee.''

+ Removing and moving the monitoring standard paragraph (c) to the QAPI condition for coverage at § 494.110(a)(2)(ix).

+ Redesignating paragraph (d) as paragraph (c).

• Amend § 494.40 ''Water quality'' by—

+ Revising the title to read ''Water and dialysate quality.''

+ Revising paragraph (a) to read, Water and equipment used for dialysis meets the water and dialysate quality standards and equipment requirements found in the Association for the Advancement of Medical Instrumentation (AAMI) publication, ''Dialysate for hemodialysis,'' ANSI/AAMI RD52:2004, which are incorporated by reference. Incorporation by reference of the AAMI ''Dialysate for hemodialysis'' has been approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.''

+ Removing from paragraph (a)(2) the requirements for frequency of water purity testing.

+ Removing the proposed requirement at paragraph (b).

+ Redesignating paragraphs (c) through (e) as paragraphs (b) through (d), respectively.

+ Removing the stem statement from proposed paragraph (c), now paragraph (b), chlorine/chloramines.

+ Removing language from proposed paragraph (a)(2)(i)(B).

+ Removing redundant language at proposed paragraphs (a)(2)(ii)(C) and (a)(2)(ii)(D).

+ Clarifying the carbon tank requirement at proposed paragraph (c)(1), now paragraph (b)(1), so that the water treatment system must include a component or carbon tank which removes chlorine/chloramine, and that the backup component or second carbon tank must be ''in series'' with the first component.

+ Adding at redesignated paragraph (b)(2)(i) (proposed paragraph (c)(2)(i)) an alternative to permit the facility to test total chlorine for acceptable levels of less than 0.1mg/L as an alternative to testing free chlorine and chloramines levels, and adding a reference to the frequency of water testing specified in our incorporation by reference of ANSI/AAM RD52:2004.

+ Revising redesignated paragraph (b)(2)(ii)(A) (proposed paragraph (c)(2)(ii)(A)) to allow an alternate action to terminating dialysis treatments when chlorine/chloramines testing reveals high levels. We have added, ''Immediately take corrective action to bring chlorine or chloramine levels into compliance with paragraph (b)(2)(i) of this section and confirm through testing that the corrective action has been effective * * *.''

+ Redesignating proposed paragraph (c)(2)(ii)(B) as paragraph (b)(2)(ii)(C).

+ Revising redesignated paragraph (b)(2)(ii) (proposed paragraph (c)(2)(ii)) with new language. The provision reads ''Only allow use of purified water in a holding tank, if appropriate, and if testing shows water chlorine or chloramine levels that are in compliance with paragraph (b)(2)(i) of this section above * * *.''

+ Clarifying at redesignated paragraph (b)(2)(ii)(D) that corrective action taken must ensure ongoing compliance with acceptable chlorine and chloramines levels.

+ Adding ''endotoxin levels'' to the testing that must be done (when clinically indicated) at redesignated paragraph (d)(1), (proposed paragraph (e)(1)).

+ Adding a new standard at paragraph (e) that addresses in-center use of preconfigured hemodialysis systems. The standard requires that when facilities use a preconfigured, FDA-approved hemodialysis system designed, tested and validated to yield AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate, the system's FDA-approved labeling must be adhered to for machine use and monitoring of the water and dialysate quality. The facility must meet all AAMI RD52:2004 requirements for water and dialysate. Moreover, the facility must perform bacteriological and endotoxin testing on a quarterly, or more frequent basis, as needed, to ensure that the water and dialysate are within AAMI limits.

+ Removing proposed standard at paragraph (f) regarding unused mixed bicarbonate; use of mixed bicarbonate is

addressed in the ANSI/AAM RD52:2004 document, which is incorporated by reference.

• Amend § 494.50 ''Condition: Reuse of hemodialyzers and bloodlines'' by—

+ Removing the undesignated paragraph that states, ''The dialysis facility that reuses hemodialyzers or bloodlines must meet the requirements of this section. Failure to meet any of these requirements constitutes grounds for denial of payment for the dialysis treatment affected and termination from participation in the Medicare program.''

+ Incorporating by reference the AAMI reuse guidelines, ''Reuse of hemodialyzers,'' ANSI/AAMI RD47:2002/AL:2003 at paragraph (b)(1).

+ Clarifying at paragraph (b)(3) that bleach used on hemodialyzers is considered to be a ''cleaner'' in this application.

+ Adding endotoxin levels to the blood and dialysate culture testing that must be done when clinically indicated at paragraph(c)(2)(i).

• Amend § 494.60 ''Physical environment'' by—

+ Modifying the room temperature requirement at paragraph (c)(2) by removing the phrase ''that is comfortable for the majority of its patients'', so that the facility must ''Maintain a comfortable temperature within the facility and make reasonable accommodations for the patients who are not comfortable at this temperature.''

+ Adding a privacy provision at paragraph (c)(3), which reads, ''The dialysis facility must make accommodations to provide for patient privacy when patients are examined or treated and body exposure is required.''

+ Adding a new monitoring requirement at paragraph (c)(4) that states, ''Patients must be in view of staff during hemodialysis treatment to ensure patient safety (video surveillance will not meet this requirement).''

+ Revising paragraph (d)(1)(i)(B) to read, ''Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated.''

+ Revising the requirement at paragraph (d)(1)(i)(C) that the dialysis facility contact information must include an alternate emergency phone number for instances when the dialysis facility is unable to receive phone calls due to emergency, unless the facility has the ability to forward calls to a working phone number under such emergency conditions.

+ Revising paragraph (d)(3) by adding an automated external defibrillator as an alternative to the defibrillator.

+ Redesignating proposed paragraphs (d)(3)(i) and (d)(3)(ii) as paragraphs (d)(4)(i) and (d)(4)(ii).

+ Adding a new requirement at paragraph (d)(4)(iii) that the facility must, ''Contact its local disaster management agency at least annually to ensure that such agency is aware of dialysis facility needs in the event of an emergency.''

+ Revising paragraph (e)(1) to indicate that it is effective February 9, 2009.

+ Removing proposed paragraph (e)(2).

+ Adding a new paragraph (e)(2), to state that sprinkler systems are not required for dialysis providers using facilities built before 2008 on the rule's effective date, if their State law so permits.

+ Adding a clarifying phrase ''for individual dialysis facilities'' at paragraph (e)(4).

• Amend § 494.70 ''Patients' rights'' by—

+ Revising proposed paragraph (a)(5) to add the patients ''right to discontinue treatment'' as an option.

+ Revising proposed paragraph (a)(5) by redesignating the ''advance directive'' policy as paragraph (a)(6), and adding the phrase ''and the facility's policy regarding advance directives.''

+ Redesignating proposed paragraphs (a)(6) through (a)(16) as paragraphs (a)(7) through (a)(17), respectively.

+ Revising newly redesignated paragraph (a)(7), (formerly paragraph (a)(6)) to specify that patients have the right to receive resource information about dialysis modalities and options not offered by the facility, including alternative scheduling options for working patients.

+ Revising newly redesignated (a)(10) (formerly (a)(9)) to clarify that the patient has the right to be informed of his or her medical status by not only the physician, but the ''nurse practitioner, clinical nurse specialist or physician's assistant treating the patient for ESRD.''

+ Adding at paragraph (b)(1) a phrase, ''routine or involuntary'' to clarify that patients must be informed of both routine and involuntary discharge policies.

+ Removing the words ''reducing or'' and ''ongoing'' at paragraph (b)(2), and changing the word ''shortened'' to ''abbreviated.''

+ Adding ESRD Network ''mailing addresses'' to the list of information that must be posted in the dialysis facility at subsection (c).

• Amend § 494.80 ''Patient Assessment'' by—

+ Clarifying in the introductory paragraph that the patient may choose whether he or she wants to identify a designee to participate in the interdisciplinary team.

+ Clarifying the introductory paragraph to include ''a physician treating the patient for ESRD'' and removing our reference to the nephrologists.

+ Adding immunization history to the assessment criteria at paragraph (a)(3).

+ Modifying our reference to erythropoietin at paragraph (a)(4), by using the term ''erythropoiesis-stimulating agent(s).''

+ Clarifying at paragraph (a)(6) that the evaluation of patient nutritional status must be performed by a dietitian.

+ Clarifying at paragraph (a)(7) that the evaluation of patient psychosocial needs must be performed by a social worker.

+ Modifying the requirement in paragraph (a)(13) for evaluation of vocational and physical rehabilitation status and potential, so that the interdisciplinary team need only evaluate the patient for referral to vocational and rehabilitation services.

+ Modifying the title of paragraph (b), to clarify the meaning of ''new patient.'' It now reads ''Frequency of assessment for patients admitted to the dialysis facility.''

+ Modifying the time allowed to complete the initial patient assessment at paragraph (b)(1) from 20 days to 30 days, which corresponds to the implementation time for the plan of care. An alternate method of determining when the assessment must be completed (and plan of care implemented) was added; 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session to allow for occasions (such as hospitalizations) when the patient may be away from the unit. The assessment now must be completed within the latter of 30 days or 13 dialysis sessions.

+ Adding at paragraph (d)(2)(iv) the word ''concurrent'' and deleting ''with''.

• Amend § 494.90 ''Patient plan of care'' by—

+ Adding to the introductory text, ''The interdisciplinary team as defined at § 494.80 must develop and implement * * *.''

+ Removing the term ''community accepted'', from the introductory statement, and substituting ''professionally-accepted clinical practice,'' so that the ''outcomes'' specified in the patient plan of care may be ''consistent with current evidence-based professionally-accepted clinical practice standards.''

+ Adding ''manage the patient's volume status'' at paragraph (a)(1). We

are also adding the current NKF–KDOQI clinical practice guideline targets for dialysis adequacy (Kt/V of 1.2 for hemodialysis, and a weekly Kt/V of 1.7 for peritoneal dialysis), as well as an alternative equivalent of professionally-accepted clinical practice standards for adequacy of dialysis.

+ Revising paragraph (a)(2) to read, ''The interdisciplinary team must provide the necessary care and counseling services to achieve and sustain an effective nutritional status. A patient's albumin level and body weight must be measured at least monthly. Additional evidence-based professionally-accepted clinical nutrition indicators may be monitored, as appropriate.''

+ Adding new paragraph (a)(3), requiring the interdisciplinary team to provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease. The remaining plan of care components are renumbered to reflect the addition of a new paragraph (a)(3).

+ Revising proposed paragraph (a)(3) (now paragraph (a)(4)), to read in part, ''The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level. The patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs.''

+ Modifying the vascular access plan of care component at proposed paragraph (a)(4), now paragraph (a)(5), so that instead of providing the necessary care and services to achieve and sustain the vascular access, the interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The interdisciplinary team must also evaluate whether the patient is a potential candidate for arteriovenous fistula placement.

+ Adding a new psychosocial status requirement at paragraph (a)(6), requiring the interdisciplinary team to provide the necessary monitoring and social work interventions, including counseling and referrals for social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis.

+ Revising and redesignating proposed paragraph (a)(5) (now located at paragraph (a)(7)(i)), to require the interdisciplinary team to plan for home dialysis or explain why the patient is not a candidate for home dialysis.

+ Modifying the rehabilitation plan of care requirement, now at paragraph (a)(8), to require that the interdisciplinary team assist the patient in achieving and sustaining an appropriate level of productive activity, and make rehabilitation and vocational rehabilitation referrals as appropriate.

+ Clarifying at paragraph (b)(i) that the patient is to be included (if he or she desires) when the interdisciplinary team is completing the plan of care.

+ Clarifying the patient plan of care signature requirement (paragraph (b)(1)(ii)) to indicate that team members must sign the plan of care and, if applicable, the facility must document a patient's refusal to sign the plan of care, along with the reason the signature was not provided.

+ Modifying the plan of care implementation requirements (paragraph (b)(2)) so that the implementation of the initial plan of care must begin within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. Implementation of monthly or annual updates of the plan of care must be performed within 15 days of the completion of the additional patient assessments specified in § 494.80 of this part.

+ Adding language to paragraph (b)(3) that requires the plan of care to be adjusted when the plan of care outcome targets are not met to reflect the patient's condition along with an explanation, and that the team must identify opportunities for improvement.

+ Adding ''nurse practitioner, clinical nurse specialist, or physician's assistant'' as the types of professionals who can meet the monthly visit requirement at paragraph (b)(4).

+ Modifying the transplantation referral-tracking standard at paragraph (c)(3), by requiring that the interdisciplinary team communicate with the transplant center regarding patient transplant status ''at least annually, and when there is a change in transplant candidate status.''

+ Revising the standard at subsection (d), ''Patient education and training,'' to require that the care plan include training in infection prevention and personal care, home dialysis and self-care, and benefits and risks of various vascular access types.

• Amend § 494.100 ''Care at home'' by—

+ Clarifying in the introductory text that care at home services must meet all applicable conditions of this part.

+ Replacing the word ''provide'' with ''oversee'' at paragraph (a).

+ Replacing ''hematocrit level of at least 33 percent or a hemoglobin of at least 11 gm/dL'' at paragraph (a)(3)(ii) with the phrase ''target level hemoglobin or hematocrit as written in the patient's plan of care.'' We are also replacing ''erythropoietin administration'' with ''administration of erythropoiesis-stimulating agent(s).''

+ Deleting ''implementation of a nutritional care plan'' at proposed paragraph (a)(3)(iii). We are also deleting ''how to achieve and maintain emotional and social well being'' from paragraph (a)(3)(iv). The remaining paragraphs have been renumbered to reflect these revisions.

+ Adding that potential dialysis complication training includes addressing ''water treatment problems'' (new paragraph (a)(3)(iii)).

+ Clarifying at paragraph (c)(1) that a home dialysis training facility must furnish home dialysis support services either directly, under agreement, or by arrangement with another ESRD facility.

+ Modifying paragraph (c)(1)(v) to specify that the facility must monitor the quality of water and dialysate used by home hemodialysis patients and conduct onsite evaluations and testing of the water and dialysate system in accordance with (A) the recommendations specified in the manufacturer's instructions; and (B) the system's FDA-approved labeling for preconfigured systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate. The facility must meet testing and other requirements of AAMI RD52:2004. In addition, bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits.

+ Revising paragraph (c)(1)(v) (revised as paragraph (c)(1)(v)(C)) to change ''the water quality'' to ''any water and dialysate quality problem.''

+ Adding ''and dialysate'' at paragraphs (c)(1) and (c)(2).

+ Clarifying at paragraph (c)(2)(vi) that the dialysis facility may not only purchase, but may also lease or rent medically necessary home dialysis supplies and equipment.

• Amend § 494.110 ''Quality assessment and performance improvement'' by—

+ Clarifying in the introductory paragraph, that the QAPI program requires participation by the professional members of the

interdisciplinary team to meet these conditions for coverage.

+ Adding mineral metabolism and renal bone disease to the list of QAPI program components at paragraph (a)(2)(iii). The subsequent QAPI program components have been renumbered accordingly.

+ Adding infection control to the list of QAPI program components at paragraph (a)(2)(ix).

• Amend § 494.120 ''Special purpose renal dialysis facilities'' by—

+ Revising standard (d), to require the special purpose facility to contact the patient's physician ''if possible'' prior to initiating dialysis.

+ Revising standard (e), to require the special purpose facility patient documentation to be forwarded to the patient's usual dialysis facility, if possible within 30 days of the last scheduled treatment.

• Amend § 494.140 ''Personnel qualifications'' by—

+ Adding a requirement to the introductory text to read, ''All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed.'' References to State licensure and board of practice compliance for dialysis facility staff have been removed, where appropriate, in the later sections of § 494.140.

+ Revising paragraph (a)(1), to require the medical director be a board-certified physician in internal medicine or pediatrics by a professional board.

+ Revising the title of paragraph (b)(2) to read, ''Self-care and home dialysis training nurse.''

+ Adding a new provision at paragraph (b)(3)(iii) so that a charge nurse who is a licensed practical nurse or licensed vocational nurse, must work under the supervision of a registered nurse in accordance with State nursing practice act provisions.

+ Deleting proposed paragraph (c)(2).

+ Redesignating proposed § 494.140(c)(3) as § 494.140(c)(2).

+ Adding a ''specialization in clinical practice'' requirement to the social worker's master's degree provisions at paragraph (d)(1).

+ Adding the grandfather provision from part 405, subpart U for non-master's prepared social workers to paragraph (d)(2), to allow a dialysis social worker to qualify for this position if he or she has ''served at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under § 494.140(d)(2) of this part.''

+ Revising the patient care technician (PCT) qualifications at paragraph (e)(3), to remove the proposed requirement that the PCT have at least 3 months experience, and to require that the training program be only ''under the direction'' of a registered nurse, rather than ''under the direct supervision of a registered nurse.''

+ Revising paragraph (e)(3), to include the training program requirements from proposed § 494.180((b)(5).

+ Adding ''proper cannulation techniques'' to the training program subjects redesignated at paragraph (e)(3)(iii).

+ Adding ''and dialysate preparation'' to redesignated paragraph (e)(3)(v).

+ Adding a new requirement at paragraph (e)(4) that patient care dialysis technicians be certified under a State certification program or a national commercially available certification program. At paragraphs (e)(4)(i) and (e)(4)(ii), we are adding that newly employed patient care dialysis technicians must be certified within 18 months of being hired as a dialysis patient care technician and for dialysis patient care technician employed on the effective date of this rule within 18 months of such date.

• Amend § 494.150 ''Responsibilities of the medical director'' by—

+ Adding to the introductory paragraph, ''The medical director is accountable to the governing body for the quality of medical care provided to patients.''

+ Revising the requirement at paragraph (c)(2)(i) to read, ''All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers.''

• Amend § 494.160 ''Condition: Relationship with the ESRD Network'' by—

+ Redesignating the ''Relationship with the ERSD Network'' condition (at § 494.160) as § 494.180(i). The language for the ESRD Network requirements has been retained from the proposed rule.

+ Reserving section 494.160 without requirements.

• Amend § 494.170 ''Medical records'' by—

+ Adding at paragraph (b)(2) that the patient's record must indicate ''whether the patient has executed an advance directive.''

+ Revising language in standard (c) to read, ''In accordance with 45 CFR 164.530(j)(2), all patient records must be retained for 6 years from the date of the patient's discharge, transfer, or death.''

+ Revising language at paragraph (d), to require the dialysis transferring a patient to send to the receiving facility only ''all requested medical record information.''

• Amend § 494.180 ''Governance'' by—

+ Removing the sentence, ''The governing body receives and acts upon recommendations from the ESRD Network'' from the introductory paragraph.

+ Adding language at paragraph (b)(1), to require that the RN, social worker and dietitian members of the interdisciplinary team must be available to meet patient clinical needs.

+ Revising paragraph (b)(2) to read, ''A registered nurse, who is responsible for the nursing care provided, is present in the facility at all times that in-center dialysis patients are being treated.''

+ Revising paragraph (b)(3) to read, ''All staff, including the medical director, have appropriate orientation to the facility and work responsibilities.''

+ Removing the written training program requirements specific to dialysis patient care technicians from paragraphs (b)(5) and (b)(6) and adding them to paragraphs (e)(3) and (e)(4).

+ Revising paragraph (c), to indicate that the governing body is responsible for all medical staff appointments and credentialing in accordance with State law, including clinical nurse specialists.

+ Adding a new paragraph (c)(3), which requires the governing body to communicate ''expectations to the medical staff regarding staff participation in improving the quality of medical care provided to facility patients.''

+ Clarifying the standard at subsection (e) that patients may file ''an oral or written'' grievance with the facility.

+ Revising the title of standard (f), to read ''Involuntary discharge and transfer policies and procedures.''

+ Modifying paragraph (f)(4), to clarify the sequence of procedures when a patient is involuntarily discharged, and to require ESRD Network notification at the time the patient is provided 30 days advance notice of the discharge, instead of at the time of discharge or later. New paragraph (f)(4)(ii) now requires that the interdisciplinary team provides the patient with a 30 day notice of the planned discharge, and also notifies the ESRD Network of the planned discharge. The proposed provisions at proposed paragraphs (f)(4)(ii) through (f)(4)(iv) are renumbered to reflect insertion of a new paragraph (ii).

+ Revising new paragraph (f)(4)(iv), to require a facility contemplating an involuntary discharge to contact and attempt to place the patient in another facility, and to document that effort.

+ Adding a new provision at paragraph (f)(5), which reads, ''In the case of immediate severe threats to the health and safety of others, the facility may utilize an abbreviated involuntary discharge procedure.''

+ Adding ''routine and emergency dialysis'' to the services a hospital agrees to provide in an agreement with a dialysis facility at paragraph (g)(3).

+ Revising the proposed paragraph (h) introductory text to reflect an effective date of February 1, 2009 in the **Federal Register**.

+ Redesignating proposed paragraph (i) as paragraph (j).

+ Relocating the proposed ESRD Network-related requirements (proposed § 494.160) for dialysis facilities at new paragraph (i).

IV. Effective Dates for the Final Rule

The Administrative Procedure Act (APA) does not require that a final rule become effective within a certain maximum timeframe after publication in the **Federal Register**. However, under the APA, the effective date of a substantive rule must be no less than 30 days after its publication date, unless there is good cause for an earlier effective date (5 U.S.C. 553(b)). This final rule will be effective 180 days after its publication in the **Federal Register**. We are allowing dialysis facilities additional time beyond 180 days to come into compliance with three specific provisions of this final rule.

This final rule modernizes the existing ESRD dialysis facility conditions for coverage originally promulgated in 1976, which have not been revised in their entirety in 31 years. The ESRD conditions for coverage proposed rule (published on February 5, 2005 (70 FR 6184)) emphasized a patient-centered approach to care, thereby decreasing dialysis facility structure and process requirements while moving to an outcome-based orientation. This final rule will implement those proposed changes, while reflecting current professional standards of practice. In addition, they will update patient safety standards, provide a structure for internal facility quality improvement, and add a framework for external oversight. Because we are changing from a process-oriented to patient-centered approach, we believe that ESRD facility providers will need additional time to come into full compliance with the requirements of this final rule.

Under section 494.30(a)(1)(i), ''Infection control,'' certain facilities could be required to build isolation rooms as set out in ''HBV-Infected Patients'' found on pages 27 and 28 of RR05 (''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients,'') which has been incorporated by reference into our regulations. Some facilities would need additional time to implement this requirement, since construction of isolation rooms would require time for project development, construction approvals, architectural design, contractor bids and obtaining building permits. Therefore, we are allowing dialysis facilities 300 days after publication of this final rule to comply with the requirements found at § 494.30(a)(1)(i).

Under section 494.60(e)(1), ''Physical environment,'' facilities will be required to be in compliance with the 2000 edition of the Life Safety Code. If changes are required in the building structure, facilities will need time to make the appropriate changes. Therefore, we are allowing dialysis facilities 300 days after publication of this final rule time to comply with the requirements found at § 494.60(e)(1).

Under section 494.180(h), ''Governance,'' we are requiring facilities to submit certain data to CMS in an electronic format. Facilities may have to develop programs or obtain software that can be used to provide the data to CMS. This requirement may have a financial impact on some facilities and may also require them to make changes to their data systems to capture the data that they will be required to submit. We are allowing dialysis facilities until February 1, 2009 to comply with the requirements at § 494.180(h).

V. Reference Materials

A. Provisions of Part 494

This final rule contains a number of requirements that are not included in the existing regulations. For information and ease of reference, outlined below is a list of the new provisions, grouped by condition:

Condition	New provisions
Infection control (§ 494.30)	Infection control procedures (including the Recommended Infection Control Practices for Hemodialysis Units At A Glance CDC guidelines). § 494.30(a)(1)(i)—Patient isolation procedures.
Water quality (§ 494.40)	Incorporates by reference the updated 2001 American National Standard/Association for the Advancement of Medical Instrumentation guidelines for water purity.
Physical environment (§ 494.60)	§ 494.60(e)—Fire safety.
Patient rights (§ 494.70)	§ 494.70(a)(6)—Advance directives. § 494.70(a)(14)—Complaint systems. § 494.70(a)(15)—Complaint systems. § 494.70(b)—Discharge and transfer policies. § 494.70(c)—Posting of rights.
Patient assessment (§ 494.80)	§ 494.80(a)(2)—Appropriateness of dialysis prescription. § 494.80(a)(5)—Renal bone disease. § 494.80(a)(8)—Dialysis access type and maintenance. —Suitability for transplantation referral, including basis for referral or nonreferral. § 494.80(b)—Frequency of assessment. § 494.80(c)—Assessment of treatment prescription. § 494.80(d)—Patient reassessment.

Condition	New provisions
Patient plan of care (§ 494.90)	§ 494.90(a)(1)—Dose of dialysis. § 494.90(a)(2)—Nutritional status. § 494.90(a)(4)—Anemia. § 494.90(a)(5)—Vascular access. § 494.90(a)(7)—Home dialysis and transplantation status. § 494.90(a)(8)—Rehabilitation status. § 494.90(b)—Implementation of patient plan of care. § 494.90(b)(4)—Direct physician/patient interaction. § 494.90(c)—Transplantation referral tracking.
Care at home (§ 494.100)	§ 494.100(a)—Training. § 494.100(b)—Home dialysis monitoring. § 494.100(c)—Support services.
Quality assessment and performance improvement (§ 494.110).	§ 494.110(a)—Program scope. § 494.110(a)(2)(i)—Adequacy of dialysis. § 494.110(a)(2)(ii)—Nutritional status. § 494.110(a)(2)(iii)—Mineral metabolism and renal bone disease. § 494.110(a)(2)(iv)—Anemia management. § 494.110(a)(2)(v)—Vascular access. § 494.110(a)(2)(vi)—Medical injuries and medical error identification. § 494.110(a)(2)(vii)—Hemodialyzer reuse. § 494.110(a)(viii)—Patient satisfaction. § 494.110(a)(ix)—Infection control. § 494.110(b)—Monitoring performance improvement. § 494.110(c)—Prioritizing improvement activities.
Special purpose renal dialysis facilities (§ 494.120)	§ 494.120—Definition.
Personnel qualifications (§ 494.140)	§ 494.140(b)—Nursing services. § 494.140(e)—Dialysis technicians.
Responsibilities of the medical director (§ 494.150)	Quality assessment and performance improvement program. § 494.150(b)—Staff education, training, and performance. § 494.150(c)—Patient care policies and procedures.
Governance (§ 494.180)	§ 494.180(c)—Medical staff appointments. § 494.180(d)—Furnishing services. § 494.180(e)—Internal grievance process. § 494.180(f)—Involuntary discharge and transfer policies and procedures. Emergency coverage. Furnishing data and information for ESRD program administration. Relationship with the ESRD Network.

B. ESRD Crosswalk (Cross Refers Existing Requirements to Final Requirements)

Existing conditions (Part 405, Subpart U)	Existing citation	Final conditions (Part 494)	Final citation
Scope of subpart	405.2100(a)	Statutory basis	494.1(a).
	405.2100(b)	Scope	494.1(b).
Objectives of ESRD program	405.2101	Deleted.	
Definitions	405.2102	Definitions	494.10.
Agreement		Deleted.	
Arrangement		Deleted.	
Dialysis		Deleted.	
End-stage renal disease		Deleted.	406.13(b).
ESRD facility (introductory text)		Deleted.	
(a) Renal dialysis center		Deleted.	
(b) Renal dialysis facility		Definitions	494.10.
(c) Self-dialysis unit		Deleted.	
(d) Special purpose renal dialysis facility		Special purpose renal dialysis facilities.	494.120.
ESRD service (introductory text)		Deleted.	
(a) Dialysis service		Deleted.	
(1) Inpatient dialysis		Deleted.	
(2) Outpatient dialysis		Deleted.	
(i) Staff-assisted dialysis		Deleted.	
(ii) Self-dialysis		Definitions	494.10.
(3) Home dialysis		Definitions	494.10.
(b) Self-dialysis and home dialysis		Deleted.	
Furnishes directly		Definitions	494.10.
Furnishes on the premises		Deleted.	494.180(d).
Medical care criteria		Deleted.	
Medical care norms		Deleted.	
Medical care standards		Deleted.	
Medical care evaluation study		Deleted.	

Existing conditions (Part 405, Subpart U)	Existing citation	Final conditions (Part 494)	Final citation
Network, ESRD		Retained in 405, Subpart U.	405.2102.
Network, organization		ESRD Network organization	405.2102.
(a) Chief executive officer		Deleted.	
(b) Dietitian		Personnel qualifications	494.140(c).
(c) Medical record practitioner		Deleted.	
(d) Nurse responsible for nursing services		Personnel qualifications	494.140(b).
(e) Physician-director		Personnel qualifications	494.140(a).
(f) Social worker		Personnel qualifications	494.140(d).
Designation of ESRD networks	405.2110	Retained in 405, Subpart U.	
[Reserved]	405.2111	Reserved in Part 405 Subpart U.	
ESRD network organizations	405.2112	Retained in 405, Subpart U.	
Medical review board	405.2113	Retained in 405, Subpart U.	
[Reserved]	405.2114	Reserved in Part 405 Subpart U.	
Provider status: renal transplantation center or renal dialysis center.	405.2131	Deleted.	
[Reserved]	405.2132	Deleted.	
Furnishing data and information for ESRD program administration.	405.2133	Furnishing data and information for ESRD program administration.	494.180(h).
Participation in network activities	405.2134	Relationship with ESRD network	494.180(i).
Compliance with Federal, State, and local laws and regulations.	405.2135	Compliance with Federal, State, and local laws and regulations.	494.20.
Governing body and management (introductory text).	405.2136	Governance (introductory text)	494.180 (introductory text).
(a) Disclosure of ownership	405.2136(a)	Governance	494.180(j).
(b) Operational objectives	405.2136(b)	Deleted.	
(c) Chief executive officer	405.2136(c)	Designating a chief executive office or administrator.	494.180(a).
(d) Personnel policies and procedures	405.2136(d)(1)	Governance	494.180(b)(3) and (b)(4).
	405.2136(d)(3–5, 7)	Deleted.	
(d)(2) Infection control/Incident reports	405.2136(d)(2)	Infection control and Quality assessment and performance improvement.	494.30(a) and 494.110(a)(ix).
(d)(6) Facility personnel educational programs.	405.2136(d)(6)	Personnel qualifications	494.140(e).
		Governance	494.180(b)(3) and (b)(4).
		Infection Control	494.30(a).
(e) Use of outside resources	405.2136(e)	Deleted.	
(f) Patient care policies	405.2136(f)	Policies and procedures	494.150(c).
(g) Medical supervision and emergency coverage.	405.2136(g)	Furnishing services	494.180(d).
	405.2136(g)(1)	Patient plan of care	494.90 (introductory text).
	405.2136(g)(2)	Emergency Coverage	494.180(g).
(h) Medical staff	405.2136(h)	Medical staff appointments	494.180(c).
Patient long-term program and patient care plan	405.2137 (introductory text)	Patient plan of care	494.90 (introductory text).
(a) Patient long-term program	405.2137(a)	Deleted.	
(b) Patient care plan	405.2137(b)	Patient plan of care	494.90 (introductory text).
(b)(1) Personalized care plan	405.2137(b)(1)	Patient plan of care	494.90 (introductory text).
(b)(2) Developed by a professional team	405.2137(b)(2)	Patient plan of care	494.90 (introductory text).
(b)(3) The patient is involved	405.2137(b)(3)	Patient plan of care	494.90(b)(1).
		Patient's rights	494.70(a)(5).
(b)(4) Frequency of care plan review	405.2137(b)(4)	Patient plan of care	494.90(b)(2).
		Patient reassessment	494.80(d).
(b)(5) Transfer of care plan	405.2137(b)(5)	Medical records	494.170(d).
(b)(6) Care plan for the home dialysis patient	405.2137(b)(6)	Development of patient plan of care.	494.90(a)(4). 494.100(c)(1).
		Care at home	
(b)(7) Erythropoietin for the home dialysis patient.	405.2137(b)(7)	Patient plan of care	494.90(a)(4).
Patients' rights and responsibilities	405.2138(a)–(d)	Patients' rights	494.70(a).
		Medical records	494.170(a).
		Posting of rights	494.70(c).
	405.2138(e).	Internal grievance process	494.180(e).
		Patients' rights	494.70(a)(14) and (a)(15).
		Posting of rights	494.70(c).
Medical records	405.2139	Medical records	494.170 (introductory text).
(a) Medical record contents	405.2139(a)	Medical records	494.170(b).
(b) Protection of medical record information	405.2139(b)	Protection of patient's record	494.170(a).
(c) Medical record supervisor	405.2139(c)	Deleted.	
(d) Completion and centralization	405.2139(d)	Completion of patient records and centralization of clinical information.	494.170(b).

Existing conditions (Part 405, Subpart U)	Existing citation	Final conditions (Part 494)	Final citation
(e) Retention and preservation	405.2139(e)	Record retention and preservation.	494.170(c).
(f) Location and facilities	405.2139(f)	Deleted.	
(g) Transfer of medical information	405.2139(g)	Transfer of patient record information.	494.170(d).
Physical environment	405.2140(a) (introductory text).	Physical environment	494.60 (introductory text).
(a) Building and equipment	405.2140(a)(1)	Building	494.60(a) and (b).
(a)(1) Fire	405.2140(a)(2), (3)	Fire Safety	494.60(e).
(a)(2), (3) Equipment and areas are hazard free.	405.2140(a)(2), (3)	Equipment maintenance	494.60(b).
(a)(5) Water quality requirements	405.2140(a)(5)	Water and dialysate quality	494.40(a).
(b) Favorable environment for patients	405.2140(b) (introductory text).	Patient care environment	494.60(c).
(b)(1) Infection prevention	405.2140(b)(1)	Procedures for infection control	494.30.
(b)(2) and (b)(4) Adequate treatment areas/ Heating and ventilation systems.	405.2140(b)(2) and (b)(4)	Physical environment	494.60 (introductory text) and (c).
(b)(3) Nursing station	405.2140(b)(3)	Governance	494.180(g)(2).
(b)(5) Special dialysis solutions	405.2140(b)(5)	Deleted.	
(c) Contamination prevention	405.2140(c)	Infection control	494.30(a).
		Reuse of hemodialyzers	494.50.
(d) Emergency preparedness	405.2140(d)	Emergency preparedness	494.60(d).
Reuse of hemodialyzers and other dialysis supplies.	405.2150 (introductory text)	Reuse of hemodialyzers and bloodlines.	494.50 (introduction).
(a) Hemodialyzers	405.2150(a)(1) and (a)(2)	Reprocessing requirements for the reuse of hemodialyzers and bloodlines.	494.50(b).
	405.2150(a)(3)	Monitoring, evaluation, and reporting requirements for the reuse of hemodialyzers and bloodlines.	494.50(c).
(b) Transducer filters	405.2150(b)	Deleted.	
(c) Bloodlines	405.2150(c)	General requirements for the reuse of hemodialyzers and bloodlines.	494.50(a).
		Reprocessing requirements for the reuse of hemodialyzers and bloodlines.	494.50(b).
Affiliation agreement or arrangement	405.2160(a), (b)(1), (b)(3)	Governance	494.180(g)(3).
	405.2160(b)(2)	Transfer of patient record information.	494.170(d).
Director of a renal dialysis facility or renal dialysis center.	405.2161	Personnel qualifications	494.140 (introductory text).
		Medical director	494.140(a).
		Responsibilities of the medical director.	494.150.
Staff of a renal dialysis facility or renal dialysis center.	405.2162 (introductory text)	Governance	494.180(b).
(a) Registered nurse	405.2162(a)	Governance	494.180(b)(2).
		Personnel qualifications	494.140(b)(1).
(b) On-duty personnel	405.2162(b)	Governance	494.180(b)(1).
(c) Self-care dialysis training personnel	405.2162(c)	Care at Home	494.100(a)(2).
		Personnel qualifications	494.140(b)(2).
Minimal service requirements for a renal dialysis facility or renal dialysis center.	405.2163	Patient plan of care	494.90 (introductory text).
(a) Outpatient dialysis services	405.2163(a)(1)	Patient plan of care	494.90 (introductory text).
	405.2163(a)(2)	Patient plan of care	494.90 (introductory text).
		Care at home	494.100 (introductory text).
(b) Laboratory services	405.2163(b)	Laboratory services	494.130.
(c) Social services	405.2163(c)	Assessment criteria	494.80(a)(7).
		Support services	494.100(c).
		Psychosocial services	494.90(a)(6).
(d) Dietetic services	405.2163(d)	Assessment criteria	494.80(a)(5) and (a)(6).
		Patient plan of care	494.90(a)(2) and (a)(3).
(e) Self-dialysis support services	405.2163(e)	Support services	494.100(c).
(f) Participation in recipient registry	405.2163(f)	Deleted.	
(g) Use of erythropoietin at home	405.2163(g)	Patient assessment	494.80(a)(2), (4).
		Patient plan of care	494.90(a)(4).
		Care at home	494.100(a).
(h) Responsibilities of the physician/facility for use of erythropoietin at home.	405.2163(h)	Care at home	494.100(b) and (c).
Conditions for coverage of special purpose renal dialysis facilities.	405.2164	Special purpose renal dialysis facilities.	494.120.
(a) Special purpose renal renal dialysis facilities.	405.2164(a)	Special purpose dialysis facilities.	494.120.

Existing conditions (Part 405, Subpart U)	Existing citation	Final conditions (Part 494)	Final citation
(b) Consult patient's physician	405.2164(b)	Physician contact	494.120(d).
(c) Approval period	405.2164(c)	Approval period	494.120(a).
(d) Service limitation	405.2164(d)	Service limitation	494.120(b).
Termination of Medicare coverage	405.2180	Termination of Medicare coverage and alternative sanctions for ESRD facilities.	488.604.
Alternative sanctions	405.2181	Alternative sanctions	488.606.
Notice of sanction and appeal rights: Termination of coverage.	405.2182	Notice of appeal rights: Termination of coverage.	488.608.
Notice of appeal rights: Alternative sanctions	405.2184	Notice of appeal rights: Alternative sanctions.	488.610.

VI. Collection of Information Requirement

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements:

A. ICRs Regarding Payment for Home Dialysis Equipment, Supplies and Support Services (§ 414.330)

Section 414.330 states that suppliers must report to the ESRD facility providing support services, at least every 45 days, all data for each patient regarding services and items furnished to the patient in accordance with § 494.100(c)(2) of this chapter.

The burden to ESRD facilities associated with this requirement is the time and effort necessary to collect all data for each patient receiving home dialysis care with respect to services and items furnished. We estimate that there are approximately 24,657 patients receiving home dialysis care (approximately 5 percent of all dialysis patients), and that it would take a dialysis facility 1.5 hours annually to collect data for each patient. Therefore, we estimate a total annual burden of 36,986 hours.

B. ICRs Regarding Special Procedures for Approving End-Stage Renal Disease Facilities (§ 488.60)

Section 488.60 states that an ESRD facility wishing to be approved, or wishing to be approved for an expansion of dialysis services, for Medicare coverage, in accordance with part 494 of this chapter, must submit the documents and data as outlined in § 488.60(a)(1) through (a)(4).

As of the spring of 2007, there were 4,746 Medicare approved dialysis facilities (*http://www.medicare.gov/Download/DownloadDB.asp*). From 1998 to 2004, the average yearly growth (using USRDS data) in dialysis facilities seeking approval was 4.4 percent. We anticipate a similar rate of growth in dialysis facilities over the next few years. Thus, we believe that 218 new and renovated dialysis facilities will request Medicare approval in 2009 and that over the five-year period from 2009 to 2013 a total of 1,191 new and renovated dialysis facilities will request Medicare approval. We estimate the average number of new facilities per year requesting approval would be 238 facilities per year, over 5 five years. Since we are requiring compliance with the provisions of this rule 180–300 days after publication of this final rule, we are using 2009 estimates of the numbers for new and renovated dialysis facilities for one-time burdens.

We estimate that it will take 40 hours for each of the 238 new and renovated facilities to gather and submit the necessary documentation for consideration by the Secretary. The estimated annual burden is 9520 annual hours.

C. ICRs Regarding Infection Control (§ 494.30)

Section 494.30 discusses the conditions for infection control programs. Specifically, § 494.30(a)(1)(ii) states that when dialysis isolation rooms as required by § 494.30(a)(1)(i) are available locally that sufficiently serve the needs of patients in the geographic area, a new facility may request a waiver of the isolation requirement. The burden associated with this requirement is the time and effort necessary to draft and submit a waiver request to the Secretary. We estimate that 90 percent (about 214 per year) of new dialysis facilities would request a waiver. We estimate that it will take each facility approximately 1 hour to comply with this information collection request. The total estimated annual burden is 214 hours.

Section 494.30(b) outlines the standards for infection control program oversight. Section 494.30(b)(1) states that a facility must monitor and implement biohazard and infection control policies and activities within the dialysis unit. The burden associated with this requirement is the time and effort necessary to develop, draft, implement, and monitor the biohazard and infection control policies. This requirement is subject to the PRA; the burden is currently approved under OMB #0938–0386, with an expiration date of March 31, 2010.

Section 494.30(b)(3) states that a facility must require all clinical staff to report infection control issues to the dialysis facility's medical director and the quality improvement committee. We estimate that it would take staff 5 minutes per incident to notify the medical director and the quality improvement committee. Such infection control issues are rare, and so we estimate that only 1 percent of facilities would experience an incident annually. Therefore, for 54 facilities, we estimate a total annual burden of 4.5 hours.

Section 494.30(c) contains a reporting requirement. The facility must report incidences of communicable diseases as required by Federal, State, and local regulations. The burden associated with this requirement is the time and effort necessary to report incidences of communicable diseases to the appropriate Federal, State, or local agency. While this requirement is subject to the PRA, we believe the

burden is exempt as stated in 5 CFR 1320.3(b)(3). Facilities must report as required by Federal, State, and local regulations. The burden associated with this reporting requirement would exist in the absence of the Federal requirement contained in this regulation. Consequently, the burden is exempt from the PRA.

D. ICRs Regarding Water and Dialysate Quality (§ 494.40)

Section 494.40(b)(1) states that a facility's water treatment system must include a component or carbon tank which removes chlorine/chloramines along with a backup component or second carbon tank in series for chlorine/chloramines removal. Section 494.40(b)(1)(ii) further specifies the required course of action if the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (b)(2)(i) of this section. As stated in § 494.40(b)(1)(ii)(c), the facility must immediately notify the medical director. We estimate that it would take staff 5 minutes per incident to notify the medical director. Such incidents are rare, and so we estimate that only 1 percent of facilities would experience an incident annually. Therefore, for 54 facilities, we estimate a total annual burden of 4.5 hours.

Additionally, § 494.40(c) requires a facility to create a corrective action plan that ensures patient safety. Specifically, when water testing results, including but not limited to chemical, microbial, and endotoxin levels which meet AAMI levels or deviate from the AAMI standards, the dialysis facility must develop a corrective action plan. The burden associated with this requirement is the time and effort necessary to develop and implement a corrective action plan. We estimate that it would take 54 facilities 30 minutes each to develop and implement a corrective action plan that ensures patient safety. Therefore, we estimate a total annual burden of 27 hours.

Section 494.40(d) states that a dialysis facility must maintain active surveillance of patient reactions during and following dialysis. When clinically indicated, the facility must perform the tasks listed in § 494.40(d)(1)–(3). The burden associated with these requirements is the time and effort required to maintain active surveillance of patient reactions during and following dialysis. In addition, there is burden associated with the tasks listed in § 494.40(d)(1)–(3). While all of the requirements in § 494.40(d) are subject to the PRA, they are exempt as stated under 5 CFR 1320.3(h)(5); facts or opinions obtained initially or in follow-on requests, from individuals under treatment or clinical examination in connection with research on or prophylaxis to prevent a clinical disorder, direct treatment of that disorder, or the interpretation of biological analyses of body fluids, tissues, or other specimens, or the identification or classification of such specimens are not subject to the PRA.

E. ICRs Regarding the Reuse of Hemodialyzers and Bloodlines (§ 494.50)

Section 494.50(c)(1) states that a dialysis facility must monitor patient reactions during and following dialysis. As stated in § 494.50(c)(2), a facility must obtain blood and dialysate cultures and endotoxin levels, and undertake evaluation of its dialyzer reprocessing and water purification system. The burden associated with these requirements is the time and effort necessary to monitor and record patient reactions and to perform the tasks listed in § 494.50(c)(2)(i)–(ii). While these requirements are subject to the PRA, they are exempt as stated under 5 CFR 1320.3(h)(5); facts or opinions obtained initially or in follow-on requests, from individuals under treatment or clinical examination in connection with research on or prophylaxis to prevent a clinical disorder, direct treatment of that disorder, or the interpretation of biological analyses of body fluids, tissues, or other specimens, or the identification or classification of such specimens are not subject to the PRA.

Section 494.50(c)(2)(iii) requires a facility to report any adverse outcomes to FDA and other Federal, State, or local government agencies as required by law. The burden associated with this requirement is the time and effort necessary to report the adverse outcomes to the FDA and other Federal, State, or local government agencies as required by law. While this requirement is subject to the PRA, the burden is exempt as stated in 5 CFR 1320.3(b)(3). Facilities must report as required by law to Federal, State, and local government agencies. The burden associated with this reporting requirement would exist in the absence of the Federal requirement contained in this regulation. Consequently, the burden is exempt from the PRA.

F. ICRs Regarding Physical Environment (§ 494.60)

As required by § 494.60(b), a dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations. The burden associated with this requirement is the time and effort necessary to develop, implement, and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations. This requirement is subject to the PRA; the burden is currently approved under OMB #0938–0386, with an expiration date of March 31, 2010.

Section 494.60(d) contains the standard for emergency preparedness. Specifically, § 494.60(d)(1) states that a facility must provide appropriate training and orientation in emergency preparedness to the staff as specified in this section. Staff training must be provided and evaluated at least annually. Section § 494.60(d)(2) states that a facility must provide appropriate training and orientation in emergency preparedness to patients as specified in this section. The burden associated with this requirement is the time and effort necessary to provide emergency preparedness training and orientation to the staff and patients. This requirement is subject to the PRA; the burden is currently approved under OMB #0938–0386, with an expiration date of March 31, 2010.

Section 494.60(d)(4)(i)–(iii) lists the facility requirements for emergency plans. Section 494.60(d)(4)(i) states that a facility must have a plan to obtain emergency medical system assistance when needed. Section 494.60(d)(4)(ii) requires a facility to, at least annually, evaluate the effectiveness of emergency and disaster plans and update them as necessary. Section 494.60(d)(4)(iii) states that a facility must contact its local disaster management agency at least annually to ensure that such agency is aware of the dialysis facility's needs in the event of an emergency. The burden associated with the requirements in § 494.60(d) is the time and effort necessary to develop, maintain, and annually evaluate emergency and disaster plans. In addition, there is also burden associated with contacting its local disaster management agency on an annual basis. We estimate that it will take each of the 238 new facilities 5 hours to comply with the requirements in this section. We estimate that it will take 1 hour each for 5,415 existing facilities (estimated number of existing facilities per year, over five years, assuming 4.4 percent growth) to annually comply with the

requirements in this section. The total estimated annual burden for new and existing facilities is 6,605 hours.

G. ICRs Regarding Patients' Rights (§ 494.70)

Section 494.70 states that a dialysis facility must inform patients (or their representatives) of their rights and responsibilities when they begin their treatment. In addition, the dialysis facility must prominently display a copy of the patients' rights in the facility, including the current State agency and ESRD Network mailing addresses and telephone complaint numbers, where it can be easily seen and read by patients.

We estimate that it will take 5,415 facilities (estimated number of existing facilities per year, over five years, assuming 4.4 percent growth) 1.5 hours each on an annual basis to update their patient rights materials to comply with this requirement. While this requirement is subject to the PRA, the burden is currently is approved under OMB control number 0938–0386 with an expiration date of March 31, 2010.

H. ICRs Regarding Patient Assessment (§ 494.80)

Section 494.80 states that a facility's interdisciplinary team is responsible for providing each patient with an individualized and comprehensive patient assessment of his or her needs. Sections 494.80(a) through 494.80(d) discuss the standards for the components of the patient assessment. In addition to meeting the aforementioned standards, the comprehensive patient assessment must be documented and maintained in the patient's medical record.

The burden associated with the requirements in § 494.80 is the time and effort necessary for the interdisciplinary team to develop and implement an individual assessment for each patient and maintaining the assessment in the patient's medical record. This requirement is subject to the PRA; the burden is currently approved under OMB #0938–0386, with an expiration date of March 31, 2010.

I. ICRs Regarding Patient Plan of Care (§ 494.90)

Section 494.90(a) states that a facility's interdisciplinary team must develop and implement a written, individualized comprehensive plan of care that meets the all of the requirements of § 494.90. The burden associated with this requirement is approved under OMB #0938–0386, with an expiration date of March 31, 2010.

J. ICRs Regarding Care at Home (§ 494.100)

Section 494.100 details the conditions for care at home. Specifically, a facility's interdisciplinary team must provide training to the home dialysis patient, the designated caregiver, or the self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in § 494.10 of this part) and when the home dialysis caregiver or home dialysis mortality changes. Section 494.100(a) outlines the standards for training. As a requirement of the standards for home dialysis monitoring discussed in § 494.100(b), the dialysis facility must document in the medical record that the patient, the caregiver, or both received and demonstrated adequate comprehension of the training. In addition, the facility must retrieve and review complete self monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months and maintain this information in the patient's medical record. While these requirements are subject to the PRA, they are exempt as stated under 5 CFR 1320.3(h)(5); facts or opinions obtained initially or in follow-on requests, from individuals under treatment or clinical examination in connection with research on or prophylaxis to prevent a clinical disorder, direct treatment of that disorder, or the interpretation of biological analyses of body fluids, tissues, or other specimens, or the identification or classification of such specimens are not subject to the PRA. In addition, facilities are required to meet these requirements as stated under Federal, State, and local laws and thereby exempt under 5 CFR 1320.3(b)(3).

Section 494.100(c) contains the standards for support services. As required by § 494.100(c)(1)(i), a facility must periodically monitor the patient's home adaptation. Section 494.100(c)(1)(ii) requires a member of the facilities interdisciplinary team to coordinate the home patient's care. Section 494.100(c)(1)(iii) requires a facility to develop and periodically review each patient's plan of care. Section 494.100(c)(1)(v) requires that the facility must monitor the quality of water and dialysate used by home hemodialysis patients. The monitoring must include onsite evaluations and tests of the water and dialysate system. We estimate that facilities would have to meet these requirements for 24,657 care at home patients, and that it would take them approximately 6 hours per patient, per year. We estimate a total annual burden of 147,942 hours.

Section 494.100(c)(2) states that the dialysis facility must maintain a recordkeeping system that ensures continuity of care and patient privacy. The burden associated with this requirement is the time and effort necessary to develop a recordkeeping system and to maintain the records to ensure continuity of care and patient privacy. This requirement is subject to the PRA; the burden is currently approved under OMB #0938–0386, with an expiration date of March 31, 2010.

K. ICRs Regarding Quality Assessment and Performance Improvement (§ 494.110)

Section 494.110 discusses the conditions for quality assessment and performance improvement. The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven quality assessment and performance improvement program that reflects the complexity of the dialysis facility's organization and services. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.

Specifically, as part of the program scope in § 494.110(a)(2), a dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. The standard for monitoring performance improvement, § 494.110(b), states that a facility must continuously monitor its performance, take actions that result in performance improvement, and track performance to ensure improvements are sustained over time.

The burden associated with all of the requirements of this section is the time and effort necessary to develop, implement, maintain, evaluate, and demonstrate evidence of a quality assessment and performance improvement program. We believe that an overwhelming majority of dialysis facilities already have established and sustained QAPI programs. We estimate that only 10 percent of dialysis facilities need to develop and implement QAPI programs. It would take 517 facilities (10 percent of the estimated number of existing facilities in 2009 of 5,173, assuming 4.4 percent annual growth) each approximately 48 hours to meet these requirements. The one-time burden associated with this requirement is estimated to be 20,016 hours.

Additionally, all facilities would be subject to an annual burden to maintain, evaluate, and demonstrate evidence of a quality assessment and performance

improvement program. The facility must analyze and document the incidence of infection and identify trends and establish baseline information on infection incidence; and develop recommendations and an action plan to minimize infection transmission, promote immunization, and take actions to reduce future incidents. The burden associated with this requirement is the time and effort it would take for a facility to document the incidence of infection and develop recommendations and an action plan to reduce future incidents. We estimate it would take 5,415 facilities 12 hours annually each to meet this requirement, for a total annual burden of 64,980 hours.

L. ICRs Regarding Special Purpose Renal Dialysis Facilities (§ 494.120)

As required by § 494.120(d), a facility must contact the patient's physician, if possible, prior to initiating dialysis in the special purpose renal dialysis facility, to discuss the patient's current condition to assure care provided in the special purpose renal dialysis facility is consistent with the plan of care (described in § 494.90 of this part). The burden associated with this requirement is the time and effort necessary to contact the patient's physician to discuss the patient's current condition and to ensure that the care provided by the special purpose renal dialysis facility is consistent with the patient plan of care. This requirement is subject to the PRA; the burden is currently approved under OMB #0938–0386, with an expiration date of March 31, 2010.

Section 494.120(e) requires that a facility document all patient care provided in the special purpose facility and forward the documentation to the patient's dialysis facility, if possible, within 30 days of the last scheduled treatment in the special purpose renal dialysis facility. The burden associated with this requirement is the time and effort necessary to document the patient care and to forward the documentation to the patient's dialysis facility. The burden associated with this requirement is approved under OMB #0938–0386, with an expiration date of March 31, 2010.

M. ICRs Regarding Responsibilities of the Medical Director (§ 494.150)

In the proposed rule that published February 4, 2005 (70 FR 6184) we discussed the responsibilities of the medical director. However, we erroneously reported that the requirements were previously approved under OMB control number 0938–0086. This section does not impose any burden associated with information collection requirements.

N. ICRs Regarding Medical Records (§ 494.170)

Section 494.170 requires that a dialysis facility maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services, and on all other home dialysis patients whose care is under the supervision of the facility. The burden associated with this requirement is the time and effort necessary to maintain the required documentation in the medical record. This requirement is subject to the PRA; the burden is currently approved under OMB #0938–0386, with an expiration date of March 31, 2010.

Section 494.170(a)(3) requires that a dialysis facility obtain written authorization from the patient or legal representative before releasing information that is not authorized by law. The burden associated with this requirement is the time and effort necessary to draft the authorization form and to obtain the signature of the patient or the patient's legal representative. This requirement is subject to the PRA; the burden is currently approved under OMB #0938–0386, with an expiration date of March 31, 2010.

Section 494.170(c) contains a recordkeeping requirement. Facilities must maintain all patient records on file for 6 years from the date of the patient's discharge, transfer, or death. The burden associated with this requirement is the time and effort necessary to maintain the patient records for 6 years. While the burden associated with this requirement is approved under OMB #0938–0386, this information must be maintained in accordance with other Federal, State, and local laws. We believe this requirement is exempt under 5 CFR 1320.3(b)(3); the burden would exist in the absence of the Federal requirement contained in this regulation.

Section 494.170(d) states that when a dialysis patient is transferred, the dialysis facility releasing the patient must send all requested medical record information to the receiving facility within 1 working day of the transfer. The burden associated with this requirement is the time and effort necessary to disclose all requested medical record information to the receiving facility. This requirement is subject to the PRA; the burden is currently approved under OMB #0938–0386, with an expiration date of March 31, 2010.

O. ICRs Regarding Governance (§ 494.180)

Section 494.180(e) discusses the standard for a facility's internal grievance process. This section requires that the facility's internal grievance process be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services. In addition, § 494.180(e)(1)–(3) details the required contents of the process. The burden associated with this requirement is the time and effort necessary to develop and implement the internal grievance process. There is also burden associated with making patients aware of the process. We believe that all existing facilities already have internal grievance processes, as they are already required in conjunction with participation in ESRD Network activities. We acknowledge that there may be a very small number of facilities that do not have grievance processes in place, so we estimate that it would take 2 facilities 1.5 hours each to develop grievance processes and inform patients about them. Therefore, we estimate a total one time burden of 3 hours.

As required by § 494.180(f)(4), the interdisciplinary team must document the patient reassessments, ongoing problem(s), and efforts made to resolve the problem(s) and enter the information into the patient's medical record. In addition, the facility must notify the patient with a 30-day written notice of planned involuntary discharge, and also notify the ESRD Network that services the area and the State agency of the discharge.

The burden associated with this requirement is the time and effort necessary to document the reassessments in the medical records and the time and effort necessary to notify the patient and ESRD Network 30 days prior to the involuntary discharge and the State agency at the time of involuntary discharge. We estimate it would take 10 minutes per incident to record the documentation and provide such notification.

While this requirement is subject to the PRA, we have no way to accurately quantify the number of affected individuals. Our best estimate is that each facility would have less than one patient involuntarily discharged on a yearly basis. We estimate that the total annual burden for 5,415 facilities would be 903 hours.

The interdisciplinary team must obtain a written physician's order that must be signed by both the medical director and the patient's attending physician concurring with the patient's

discharge or transfer from the facility. They must also document any attempts to place the patient in another facility and notify the State survey agency of the involuntary transfer or discharge.

The burden associated with this requirement is approved under OMB #0938–0386, with an expiration date of March 31, 2010. However, the requirement for the second signature from the medical director is new. We estimate that it would take 5 minutes for the medical director to sign the discharge order. While this requirement is subject to the PRA, we have no way to accurately quantify the burden. Our best estimate is that each facility would have less than one patient involuntarily discharged on a yearly basis. We estimate that the total annual additional burden for 5,415 facilities would be 451 hours.

Section 494.180(g) discusses the standard for emergency coverage. As required by § 494.180(g)(2), the dialysis facility must have available at the nursing/monitoring station, a roster with the names of physicians to be called for emergencies, when they can be called, and how they can be reached. We estimate that it would take 5,415 facilities 10 minutes each to develop such a roster. We estimate that the total one-time burden would be 903 hours.

Section 494.180(g)(3) contains the requirement that a dialysis facility must have an agreement with a hospital that can provide inpatient care, routine and emergency dialysis, and other hospital services, and emergency medical care that is available 24 hours a day, 7 days a week. The burden associated with this requirement is the time and effort necessary for the dialysis facility to draft the agreement and to finalize the agreement with hospital. This requirement is subject to the PRA; the burden is currently approved under OMB #0938–0386, with an expiration date of March 31, 2010.

Section 494.180(h) states that a dialysis facility must furnish data and information electronically to CMS at intervals specified by the Secretary, which meet the requirements referenced in this section. The information collection activities discussed in this section are approved under the following OMB control numbers:

OMB control No.	Collection title	Expiration date
0938–0046	End-Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration	09/30/2010
0938–0386	Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services & Suppt Regs. at 42 CFR 405.2100–.2171.	03/31/2010
0938–0657	End State Renal Disease Network Semi-annual Cost Report Forms	12/31/2009
0938–0658	ESRD Network Business Proposal Forms	02/28/2010

These requirements are subject to the PRA, and are currently approved under the following OMB approval numbers: 0938–0046, 0938–0360, 0938–0386, 0938–0657, and 0938–0658.

Section 494.180(j) contains the standard for disclosure of ownership. In accordance with §§ 420.200 through 420.206 of this chapter, the governing body must report ownership interests of 5 percent or more to its State survey agency. The burden associated with this requirement is the time and effort necessary to disclose ownership interests to CMS. This requirement is subject to the PRA; the burden is currently approved under OMB control number 0938–0086 with an expiration date of December 31, 2008.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Regulation section(s)	OMB control number	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)
§ 414.330	0938–New	24,657	24,657	1.5	36,986
§ 488.60(a)(1–4)	0938–New	238	238	40	9520
§ 494.30(a)(1)(ii)	0938–New	214	214	1	214
§ 494.30(b)(1)	0938–0386				
§ 494.30(b)(1(ii)(c)	0938–New	54	54	.05	4.5
§ 494.40(c)	0938–New	54	54	.50	27
§ 494.60(b)	0938–0386				
§ 494.60(d)(2)	0938–0386				
§ 494.60(d)(4)(i)–(iii)	0938–New	238/5,415	238/5,415	5/1	6,605
§ 494.70	0938–0386				
§ 494.80	0938–0386				
§ 494.90	0938–0386				
§ 494.100(c)(1)(i)(ii)(iii)(v)	0938–New	24,657	24,657	6	147,942
§ 494.100(c)(2)	0938–0386				
§ 494.110	0938–New	5,415	5,415	12	64,980
§ 494.120	0938–0386				
§ 494.120(e)	0938–0386				
§ 494.170	0938–0386				
§ 494.170(a)(3)	0938–0386				
§ 494.170(c)	0938–0386				
§ 494.170(d)	0938–0386				
§ 494.180(e)(1)–(3)	0938–New	2	2	1.5	3
§ 494.180(f)(4)	0938–New	5,415	5,415	.10	903
§ 494.180(f)(4)(iii)	0938–New	5,415	5,415	.10	451
§ 494.180(g)(3)	0938–0386				
§ 494.180(h)	0938–0046	100,000	100,000	.75	75,000
	0938–0657	18	36	3	108
	0938–0658	18	36	30	1080

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN—Continued

Regulation section(s)	OMB control number	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)
§ 494.180(j)	0938–0086	125,000	125,000	.5	62,500
Total					336,803

** There are multiple regulation sections approved under this OMB control number. There is uniform burden per response.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements. These requirements are not effective until they have been approved by OMB. In addition, any burden requirements previously approved under an OMB control number will be re-examined and updated during the next OMB PRA review cycle.

VII. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

This rule is a revision of the Medicare conditions for coverage for end-stage renal disease (ESRD) dialysis facilities. The conditions for coverage are the basic health and safety requirements that an ESRD supplier of services must meet in order to receive payment from the Medicare program. This final rule incorporates new scientific advances and current medical practices utilized in treating ESRD while removing numerous burdensome process and procedural requirements contained in the 42 CFR part 405, subpart U conditions for coverage. While it is not possible at this point to determine definitively the additional costs and cost savings to the Medicare program resulting from this rule, we do not believe that the impact will be above the $100 million economically significant threshold; and therefore, believe that this final rule is not a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6.5 million to $31.5 million in any 1 year. Kidney dialysis centers with revenues at or below $31.5 million are small entities *http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf,* see Sector 62). According to 2004 revenue data, nearly 163 dialysis facilities (5.2 percent of all establishments) could be considered to be small entities. This rule will not have a significant economic impact on small entities. This regulation could cost these small facilities an average of $2,392 (about 2.4 percent of $100,000) for upgrades and improvements, and save small facilities up to $5,043 in the first year, resulting in an average net first-year cost savings of up to $2,651. The Secretary certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. Since this final rule applies only to dialysis facilities, it has no impact on small rural hospitals. The Secretary certifies that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $130 million. This rule has no impact on the expenditures of State, local or tribal governments, and the impact on private sector expenditures is estimated to be less than $130 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule will not have a substantial effect on State and local governments.

B. Anticipated Effects

1. Subpart A—General Provisions

Subpart A ''General Provisions,'' addresses the basis and scope (§ 494.1) of this regulation, definitions used in the new conditions for coverage (§ 494.10), as well as compliance with Federal, State, and local laws and regulations (§ 494.20). These provisions do not result in any new economic impact as the definitions do not include any new requirements and facility compliance with laws and regulations is consistent with the existing requirements at § 405.2135. We have removed the requirements found in 42 CFR part 405, subpart U, which specify qualifications that the dialysis facility CEO must have. This change may relieve a degree of burden for small businesses, as a greater number of candidates would qualify for this position, thereby affording facilities greater hiring flexibility. We have also removed the 42 CFR part 405, subpart U, medical record practitioner requirement (§ 405.2102, definition of ''Qualified Personnel'' at (c)). This may provide some burden relief specifically for small businesses. The medical record practitioner cost savings is computed in this impact analysis under the medical record condition for coverage.

2. Subpart B—Patient Safety

a. § 494.30 Infection Control

This final rule requires (at § 494.30(a)) compliance with the CDC ''Recommendations for Preventing

Transmission of Infections Among Chronic Hemodialysis Patients.'' Many of these infection control precautions are standard care practices and do not present any additional burden for dialysis facilities. We did receive a comment regarding the infection control precaution that calls for the use of disposables or dedication to single patient use those items that cannot be cleaned and disinfected. This commenter stated that use of disposable blood pressure cuffs is impractical, as is dedication of blood pressure cuffs for single patient use, and that disposable blood pressure cuff covers are not currently available.

However, according to information available on the Internet, disposable blood pressure cuffs are available (at a cost of approximately $6 each), as are disposable blood pressure cuff covers. A blood pressure cuff sleeve is available for 12 cents. In addition, easy-to-clean, one-piece, nylon latex-free blood pressure cuffs that are universally compatible with all blood pressure monitors, are available for about $7.00. The estimated burden for complying with the CDC infection precautions would be $7.00 per dialysis station with the cost varying depending on the size of the facility. Smaller dialysis facilities would have a smaller burden than large dialysis facilities. Since the CDC ''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients'' were published in 2001, some dialysis facilities have already updated their practices and are adhering to the CDC guidelines regarding dedicated use of non-cleanable items or use of disposables. We estimate that 75 percent of dialysis facilities still need to change their blood pressure cuff use practices to comply with the 2001 CDC infection control precautions. We estimate that in 2008 there will be 70,892 dialysis stations (based on an annual growth rate of 4.4 percent and USRDS data showing 79,567 dialysis stations in 2004) that need to be upgraded with a cleanable reusable blood pressure cuff. The associated first year cost is estimated to be $496,244 ($7.00 × 70,892 stations). The annual cost thereafter is estimated to be $49,624, to account for up to 10 percent of the blood pressure cuffs that may need to be replaced annually due to extreme contamination or damage.

One commenter stated that the CDC precautions regarding separate staff to care for HBV positive and HBV negative/susceptible patients will produce unintended adverse implications for smaller facilities and/or smaller dialysis shifts. This commenter further stated that this requirement may make it cost prohibitive for small facilities (< 9 stations) to admit HBV positive patients. The CDC ''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients,'' incorporated by reference in this final rule, state that staff members caring for HBsAG-positive patients should not care for HBV susceptible patients at the same time. This means a staff member could care for HBV protected dialysis patients who have been vaccinated and have developed sufficient antibodies to HBV while caring for an HBsAG-positive patient. The prevalence of HBsAG positivity and incidence of HBV infection in hemodialysis patients was 1.0 and 0.12 percent, respectively, in 2002 and had not changed substantially during the previous 10 years (Finelli, *et al.,* ''National Surveillance of Dialysis-Associated Diseases in the United States, 2002, Seminars in Dialysis—Vol. 18, No. 1 (January–February) 2005, pp. 52–61). We note that the hepatitis B vaccination is now administered universally in the U.S. as part of standard childhood immunizations. Dialysis facilities also offer the HBV vaccination and the number of patients immunized approaches 32 percent in hemodialysis patients age 65 and older (2004 USRDS data). Therefore, the number of dialysis patient acute hepatitis B cases is not expected to be great and the number of HBV immunized patients is expected to grow. We believe that when there is appropriate patient scheduling, the separate staff requirement will present minimal burden to dialysis facilities.

This final rule calls for adherence to the pertinent sections of the Healthcare Infection Control Practices Advisory Committee (HICPAC) guidelines for catheter-related infection prevention at § 494.30(a)(2). We heard from nephrology nurses in their comments that their organization ''has recognized the 'Guideline for Preventing Intravascular Device-Related Infections' as the appropriate standard of care. We encourage CMS to do likewise in the Final Rule.'' We believe that these HICPAC catheter infection prevention guidelines are the professional nursing standard of practice and no additional burden is imposed by this requirement.

We are requiring at § 494.30(a) that new dialysis facilities have an isolation room unless a waiver is requested and approved by the Secretary. Section 494.30(a)(1)(ii) states that when dialysis isolation rooms are available locally that sufficiently serve the needs of patients in the geographic area, a new dialysis facility may request a waiver of the isolation room requirement, subject to the approval of the Secretary. According to CDC data, the 2004 reported U.S. rate of viral hepatitis B cases was 2.1 per 100,000 population, and has decreased almost every year since a high of 11.5 per 100,000 in 1985 (*http://www.cdc.gov/hepatitis*). The prevalence of HBsAG positivity and incidence of HBV infection in hemodialysis patients was 1.0 and 0.12 percent respectively in 2002 and had not changed substantially during the previous 10 years (Finelli, *et al.,* ''National Surveillance of Dialysis-Associated Diseases in the United States, 2002, Seminars in Dialysis—Vol. 18, No. 1 (January–February) 2005, pp. 52–61). As stated earlier, the hepatitis B vaccination is now administered universally as part of standard childhood immunizations in the U.S. Therefore, the number of dialysis patient acute hepatitis B cases is expected to be small, and we believe that a large number of new dialysis facilities will request an isolation room waiver. We also believe that this process allows for variation in geographic isolation room needs that may present as the local population changes. We expect that the development and submission of this waiver will require the involvement of the facility administrator. This individual will need to determine the number of dialysis isolation rooms available in the facility's geographic area that could sufficiently serve its patients, prepare the waiver request, and submit the request to us. We believe that these tasks will require about 1 hour and should cost about $54.81 (*http://www.swz.salary.com*).

As of the spring of 2007, there were 4,746 Medicare approved dialysis facilities (DFC data: *http://www.medicare.gov/Download/DownloadDB.asp*). From 1998 to 2004, the average yearly growth (using USRDS data) in dialysis facilities was 4.4 percent. We anticipate a similar rate of growth in dialysis facilities over the next few years. Thus, we believe that 218 new dialysis facilities will request Medicare approval in 2009 and that over the five-year period from 2009 to 2013 a total of 1,191 new dialysis facilities will request Medicare approval. Since we are requiring compliance with this isolation room requirement 300 days after publication of this final rule, we are using 2009 estimates of the numbers for new and renovated dialysis facilities.

COST OF ISOLATION ROOM WAIVER REQUESTS

Year	New dialysis facilities (4.4% annual increase)	Ninety percent of new dialysis facilities	Estimated total cost for waiver requests ($54.81 × waiver requests from 90% of new facilities)
2009	218	196	$10,743
2010	228	205	11,236
2011	238	214	11,729
2012	248	223	12,223
2013	259	233	12,771
Total	1,191	1,071	[1] 58,702

[1] 5-year cost.

We believe that approximately 90 percent of the new dialysis facilities will request a waiver of the isolation room requirement. Thus, the estimated first year cost of complying with this waiver requirement is $10,743, and the estimated total five-year implementation cost for this requirement is $58,702.

Isolation room waivers may be granted at the discretion of, and subject to, additional qualifications as may be deemed necessary by the Secretary. We do not have data that shows the current percentage of dialysis providers that open new dialysis facilities with isolation rooms under the 42 CFR part 405, subpart U, requirements, nor do we currently have data that show whether there is a shortage of isolation rooms in some areas. The CMS regional offices will monitor and evaluate local dialysis isolation room needs. Since existing facilities may use a separate area, rather than an isolation room, it is likely that some HBsAg-positive patients dialyze in units without isolation rooms. Commenters shared concerns about the costs involved in converting existing dialysis facilities to include an isolation room. Some commenters questioned the need for an expense of an isolation room in all new dialysis units as specified in the CDC infection control precautions incorporated by reference. We have responded to isolation room comments by requiring existing facilities only to have a separate demarcated area, consistent with CDC recommendations, and allowing new dialysis facilities to request an isolation room waiver.

We believe the infection control provisions at § 494.30(a)(3) and (4) are consistent with the requirements at § 405.2140(c) and do not produce additional burden. In addition, we have moved some of the infection control requirements to the QAPI provisions at § 494.110(a)(ix). We have also removed the requirement at proposed § 494.30(b)(2) regarding the designation of an RN to act as an infection control officer. Several commenters stated that this proposed requirement would be unnecessarily burdensome. One commenter stated a burden of $67,000 in compensation for an additional full-time RN. We have modified the oversight requirements and removed the RN infection control officer provision; therefore, no additional burden is imposed. Infection control issues must be reported to the facility medical director and the quality improvement committee. We believe that it is standard practice to track incidents and identify problems related to infection control and that this requirement will not produce any additional burden. Dialysis facilities must also report incidences of communicable diseases as required by Federal, State, and local regulations. We expect that facilities are already compliant with communicable disease reporting requirements and that this provision does not represent any additional burden.

b. § 494.40 Water Quality

The water quality condition for coverage requires compliance with the ANSI/AAMI RD:52:2004 ''Dialysate for hemodialysis.'' These guidelines developed for dialysis facilities are the professional standard of practice and have been available for about 3 years. A facility's water treatment equipment, equipment maintenance and monitoring processes, and water testing procedures need to be consistent with the RD52 guidelines to provide sufficiently pure dialysate. We believe dialysis facilities strive to deliver dialysate for use in hemodialysis and in the reuse process that meets the AAMI water purity guidelines. The American Nephrology Nurses Association stated that they believe most facilities in the U.S. have already implemented a two carbon tank water treatment system with a minimum of 10 minutes empty bed contact time to prevent the exposure of patents to chloramines. We received several comments regarding the burden associated with the proposed frequency of chlorine/chloramine testing. We have modified the proposed water quality requirements and the frequency of chlorine/chloramines testing and require compliance with the AAMI RD:52 guidelines in this final rule. Since we believe that the vast majority of dialysis facilities adhere to the AAMI RD52 guidelines, this requirement would result in little additional burden.

c. § 494.50 Reuse of Hemodialyzers and Bloodlines

The Reuse of hemodialyzers condition for coverage requires compliance with the AAMI guidelines published in ''Reuse of Hemodialyzers'', third edition, ANSI/AAMI RD47:2002/A1:2003, which is incorporated by reference. These 2003 guidelines update RD47, second edition, published in 1993, which is incorporated by reference in 42 CFR part 405, subpart U. The majority of dialysis facilities choosing to perform hemodialyzer reuse likely have already updated their procedures and practices to conform to the current professional standard of practice in the area of reuse.

At § 494.50(c)(2) we require that blood and dialysate cultures and endotoxin levels be obtained when clinically indicated, while the former requirement at § 405.2150(a)(3) requires ''appropriate blood cultures'' and system evaluation. The dialysate cultures and endotoxin levels to be obtained when an adverse patient reaction to reuse is suspected may present a small additional burden to facilities. A colony count (culture) costs approximately $6, while the LAL endotoxin test costs about $10 to $35 per test, depending on the method utilized. We expect that since dialysis facilities must adhere to the new AAMI RD47 guidelines, adverse reactions related to hemodialyzer reuse occur infrequently and the cost burden is small. The remaining provisions of

§ 494.50 primarily provide clarifications that do not add burden. We did not receive any comments related to burden imposed by this condition for coverage.

d. § 494.60 Physical Environment

The ''Building'' and ''Equipment maintenance'' standards at § 494.60(a) and (b) contain requirements similar to some of the provisions at § 405.2140(a), and we believe do not impose any additional burden. Standard (c) ''Patient care environment'' is consistent with requirements at § 405.2140(b)(2). The provision regarding a comfortable room temperature closely resembles § 405.2140(b)(2). However, the requirement to ''make reasonable accommodations for the patients who are not comfortable at this temperature'' is new. Facilities could meet this requirement by providing blankets to patients as many other healthcare providers do, which could entail added burden, or the facility could simply allow patients to bring a clean blanket or cover to the dialysis facility. Although a facility would be required to adhere to infection control precautions if a patient's blanket became soiled during the dialysis session, we do not believe this second option would add any significant burden for the dialysis facility.

We are requiring, similar to § 405.2140(b)(2), that the dialysis facility make accommodations to provide for patient privacy when patients are examined or treated and body exposure is required. We believe that the vast majority of dialysis facilities are equipped with the movable privacy screens, partitions, or curtains that would be needed in order to meet this requirement.

Emergency preparedness requirements are found at § 494.60(d) in this final rule and correspond with the provisions at § 405.2140(d). The existing 42 CFR part 405, subpart U regulations require dialysis facilities to have written policies and procedures for handling emergencies with annual reviews, testing, and revisions, and staff training to handle any emergency or disaster. This final rule requires that the staff be able to demonstrate the ability to manage emergencies that are likely to occur in the facility's geographic area. Although an annual review will be required, the final rule does not require the involvement of the CEO in this activity. We estimate that a typical facility will expend 4 hours less of administrator's time for this activity at $51.93 per hour (*http://www.swz.salary.com*), with a net savings of $207.72 per year per facility for an overall savings for 4955 facilities of $1,029,253.

We added a clarification to the 42 CFR part 405, subpart U requirement that the staff inform patients of where to go during an emergency. Thus, this final rule requires that these instructions include direction for when the geographic area of the dialysis facility is evacuated. Some dialysis facilities may already include this level of detail in their emergency preparedness instructional materials; however, we expect that many facilities do not include this information. Adding these instructions to the patient educational materials may present a small burden for some dialysis facilities. A staff member would need to develop the instructions and materials. We estimate that it would take 2 to 3 hours to develop the instructions and material needed. Assuming that 90 percent of the dialysis facilities need to add this patient training to their program, we estimate a first year cost (using $39.14 per hour compensation (*http://www.swz.salary.com*) for a RN staff nurse) of $523,634 ($4955 \times 0.90 \times \$117.42$).

The final rule also adds a requirement to the 42 CFR part 405, subpart U provision that the dialysis staff must instruct the patients about who to contact during an emergency, so that when the dialysis facility is not operational, there is an alternate emergency telephone number (unless the facility has the ability to forward calls to another working phone number). Some facilities already may have a second emergency phone number or call forwarding for their patients to use in an emergency. Many phone service packages include call forwarding as a feature. In addition, some facilities may have obtained call forwarding or a second telephone line following the 2005 hurricane season in the south. Nevertheless, we believe many facilities may need to establish a communication system that would meet the intent of this rule, by for example, obtaining call forwarding service or an alternate number. Utilizing business phone services pricing figures available on the Internet, we estimate a monthly fee of $6.00 for remote access call forwarding services added onto a business phone service package. Alternately, we estimate the cost of an additional separate business phone number at less than $50 per month. If 25 percent of all dialysis facilities need to set up new remote call forwarding and another 25 percent initiate a new separate emergency phone number, we estimate the cost of this requirement to be approximately $69,384 ($1239 \times \$6$, plus $1239 \times \$50$).

This final rule requires at § 494.60(d)(1)(ii) that dialysis facility patient care staff maintain current cardiopulmonary resuscitation (CPR) certification. We believe that CPR training is provided for direct patient care staff in dialysis facilities in the U.S. and some units also offer CPR training and certification to staff that do not care directly for patients. One commenter stated that while many providers may certify patient care staff in CPR annually or every 2 years, there are also many who conduct CPR training without the expense of actual certification. The commenter further stated that CPR certification is too onerous and costly ($67,600 per dialysis facility to cover the cost of one full-time RN) as it may require a CPR instructor on staff. The commenter also stated that there is an American Heart Association (AHA) fee of $25 per person for certification. A search on the Internet reveals that AHA-certified CPR classes for healthcare professionals cost an average of $25 per person with group discounts available. The cost for the class members to become certified CPR instructors averages about $200 with a certification period of up to 2 years. We did not find a $25 AHA CPR certification fee that is separate from the class fees that are charged. Thus, if a dialysis facility chose to have a staff RN certified as an instructor, it would likely require only two to four half-day group CPR classes per year. We believe that CPR training provided to dialysis facility direct care staff should meet AHA standards and that CPR training with certification is the standard of practice among health care providers. We do not have data on any dialysis facilities that offer CPR training without AHA CPR certification, nor did the commenter provide data. No other commenters stated concerns about CPR certification costs for patient care staff. We believe the vast majority of dialysis facilities provide AHA certified CPR training to protect patient safety and to mitigate liability risk, and we believe that the costs associated with this training and certification are part of the usual and customary costs assumed by healthcare providers.

We are requiring that facilities have available a defibrillator or an automated external defibrillator (AED). Several commenters stated that an AED was more desirable and less burdensome than a traditional non-automated defibrillator, because the staff training and certification costs are much lower when an AED is used. Some commenters stated that use of non-automated defibrillators require staff to

be certified in Advanced Cardiac Life Support (ACLS) and that ACLS courses are not readily available to dialysis facilities, and are time consuming and costly. Commenters pointed out that AED training can be accomplished along with the usual CPR staff training. We have responded to commenters who were concerned about the burdensome costs of ACLS certification and training costs associated with the use of non-automated defibrillators by including AEDs as an acceptable alternative device in this final rule.

We are also requiring that certain emergency equipment be immediately available in the facility including oxygen, airways, suction, defibrillator or AED. The comparable 42 CFR part 405, subpart U requirement (§ 405.2140(d)(3)) is less specific and calls for an on-the-premises emergency tray, including emergency drugs, medical supplies, and equipment. We received comment that all 190 of the dialysis facilities owned by Dialysis Clinic, Inc. (DCI), a non-profit dialysis organization, are equipped with AEDs. Comments from Gambro noted that more than a third of their facilities are equipped with AEDs. According to USRDS data, in 2004 there were 585 Gambro dialysis facilities (34 percent equals 198 facilities equipped with AEDs). If we use 34 percent as our AED equipped estimate for the remaining dialysis facilities (1118 Fresenius, 626 DaVita, 417 Renal Care Group, 27 National Nephrology Associates, 934 independent—using 2004 USRDS data) the total number of dialysis facilities equipped with AEDs would be 1061. We presume that the 837 hospital based dialysis facilities (2004 USRDS data) already may have met the requirement, since they likely have immediate access to an in-hospital defibrillator. Based on the above figures we would expect that 2,286 dialysis facilities already are equipped with AEDs or defibrillators (DCI—190, Gambro—198, hospital-based—837, and 34 percent of all others—1061). We estimate that the remaining 2,669 dialysis facilities would need to purchase an AED or traditional defibrillator to comply with this final rule.

Commenters suggest that the cost of an AED is approximately $2,500. Our research shows that the sales price of an AED ranges from $900 to $2,600. Using a $2,000 price, we estimate that it will cost $5,338,000 for 2,669 dialysis facilities to purchase AEDs. One commenter stated that we should recognize the costs of maintaining an AED. The American Heart Association Web site suggests that, in general, AEDs require fairly low upkeep, but regular maintenance will ensure their readiness in the event of an emergency. AED maintenance includes preventive maintenance checks according to the manufacturer's recommendations and verifying battery installation and expiration, checking the status/service indicator light, inspecting exterior components and sockets for cracks or other damage, and checking AED related supplies (*http://www.americanheart.org/downloadable/heart/110262192170770-2272%20ImplementGuide.pdf*). We believe these visual checks will take about 5 minutes and can be done by a biomedical or patient care technician. Using an hourly compensation rate of $20.45 (*http://www.swz.salary.com*), this 5 minute task will cost $1.70 each month, times 12 months to equal $20.45 annually. If we multiply $20.45 times the 2,669 facilities that will need to purchase AEDs, the cost will be $54,581 per year.

Two commenters stated that suction machines are costly to maintain and are seldom used. However, suction machines are necessary emergency medical devices that are used to clear the airway of secretions or vomit. To comply with 42 CFR part 405, subpart U, the huge majority of dialysis facilities are equipped with suction machines and have the tubing and suction catheter available in the packaging available for use.

This final rule requires the facility to have a plan to obtain emergency medical system assistance when needed and to evaluate at least annually the effectiveness of emergency and disaster plans and update them as necessary, consistent with § 405.2140(d) requirements. A new provision calls for the facility to contact the local disaster management official at least annually to ensure that the agency is aware of dialysis facility needs in the event of an emergency. We believe this task will require one hour of time from either the administrator or the nurse manager. If we estimate the total compensation (wages plus benefits) for each as $54.81 and $51.93 respectively (*http://www.swz.salary.com*), and average them, we arrive at a cost of $53.37 per hour. Since there would be 4,955 dialysis facilities that need to comply, we estimate the burden associated with this requirement to be $264,448 during the first year.

This final rule requires that the facility meet the 2000 edition of Life Safety Code (LSC) requirements of the National Fire Protection Association. Most dialysis facilities currently meet most of the provisions required in Chapter 21 of the LSC, ''Existing Ambulatory Health Care Occupancies,'' because of state and local building codes as well as facilities' interest in liability mitigation. Commenters were most concerned about the cost of retrofitting sprinkler systems in existing dialysis facilities and the implications for facilities housed in a multi-tenant building. Commenters were also concerned with the effort and expense incurred in submitting a request for a LSC sprinkler waiver to the Secretary. In response to comments, we are defining compliance with the 2000 LSC to include ''grandfathering'' existing facilities without sprinkler systems that would have needed to comply with the LSC sprinkler provision or request a waiver. New dialysis facilities or facilities undergoing extensive renovation would need to install a sprinkler system, depending on the type of construction materials and facility location within the building. An example of a dialysis facility that would likely require a sprinkler system would be one housed in a wooden construction three-story building, or in a high rise building. High rise buildings are generally built with sprinkler systems to satisfy State and local regulations. We estimate that few newly constructed dialysis facilities would be burdened by the 2000 LSC sprinkler requirements in this final rule because current local and state fire safety building requirements must be met. However, there may be some burden for existing facilities with regard to the installation and maintenance of the fire department alarm connection. Based on information we received from the dialysis industry, we estimate that approximately 10 percent of dialysis facilities (496) will need to be upgraded to meet this requirement. In the proposed rule we estimated that the one-time cost to install a fire department or central monitoring station connection was $1,000 per facility and that the monthly fee for the monitoring station and telephone cost was about $80. We received a comment that the installation cost of an automated notification system in the Orlando, Florida area would exceed $3,000 and the monthly monitoring costs would be approximately $186 per month. The commenter stated that the CMS calculation was too low because it did not include the required back-up phone line, which would itself cost about $106 per month. Another commenter stated that the monthly monitoring cost would be about $180. Another provider informed us that the monthly monitoring cost was about $30 and the cost of installing a monitoring and

automatic notification system ranges from $10,000 to $25,000 depending on the building characteristics. We will use $136 as our estimated monthly cost of automatic notification system monitoring ($106 phone line fee plus $30 monitoring fee), and $5,000 as our estimated installation cost. Thus, we estimate the additional overall cost of compliance for 496 facilities that would need to perform upgrades in the first year will be $3,289,472 ($2,480,000 installation cost plus $809,472 monitoring costs), with the annual cost thereafter being $809,472 ($136 per month × 12 months × 496 facilities).

This estimate does not take into account any specific waivers or acceptance of a State code in lieu of the LSC that may decrease the burden. Some commenters were concerned about the cost of installing smoke barriers in buildings that are over 5000 square feet, which could be a significant cost because air ducts for heating and air conditioning would have to be updated with smoke partitions. If the health and safety of patients and staff are not adversely affected, this final rule would permit us to waive specific provisions of the LSC, which, if rigidly applied, would result in an unreasonable hardship on the facility. In addition, the proposed rule specifies that the Secretary may accept a State code in lieu of the LSC, if it adequately protects patients. We cannot estimate how many dialysis facilities will request a LSC waiver as many facilities already meet the 2000 LSC due to State and local regulations and liability mitigation efforts. Additionally, facilities would only consider applying for a waiver after a LSC inspection found that LSC provisions were not adequately implemented.

e. § 494.70 Patients' Rights

The 42 CFR part 405, subpart U regulations require dialysis facilities to have written patients' rights policies and procedures and sets out a list of persons to whom such patient rights policies must be made available. This final rule details basic information that must be provided to patients (to include for example, information regarding advance directives, how to contact entities in regard to complaints, and dialysis modalities not offered by the facility including scheduling options for working patients) and requires that patients' rights be prominently displayed. Some commenters stated that their facilities have already developed advance directive procedures that would help the facilities comply to the provision as stated in the proposed rule. One commenter recognized that many facilities are already informing patients of their right to have advance directives. Requiring minimum contents in the patients' rights condition, and requiring only that these rights be posted, will limit the administrative burden. We estimate that this will save the typical facility about 2 hours of staff (social worker) time at $34.52 per hour (*http://www.swz.salary.com*), that is, $69.04 annually, for an overall savings of $342,093 (4,955 facilities times $69.04).

The 42 CFR part 405, subpart U regulations required the facility to use translators when a significant number of patients exhibit language barriers. This final rule modifies this requirement and specifies that information be given to patients in a manner that assures their understanding. However, translators could still be used and facilities will have more flexibility in overcoming language barriers in lieu of hiring translators. This may result in a net reduction in facility costs.

The previous regulations required that advance notice be given to patients who are being terminated from a dialysis facility. This final rule is more specific and requires that written notice be given 30 days in advance. However, since involuntary terminations are a relatively infrequent occurrence and we are only adding a requirement regarding when the advance notice of involuntary discharge must be given, we consider the financial impact on dialysis facilities to be negligible.

We expect that each facility must update their patient rights materials to meet the requirements of this final rule. If this task required 1 hour of social worker time at $34.52 per hour compensation, this provision would cost $171,047 (4,955 facilities times $34.52).

f. § 494.80 Patient Assessment

The ''Patient assessment'' condition for coverage includes assessment criteria that must be included in each comprehensive patient assessment. The frequency of assessment is identified as initial, 3 months after the initial assessment, and annually for stable patients and monthly for patients who are not stable. The adequacy of the patient's dialysis prescription must be assessed at least monthly for dialysis patients and every four months for peritoneal patients. Commenters agreed that quality oriented dialysis facilities meet these new requirements already and that the patient assessment condition for coverage should not present any new burden to most dialysis facilities.

g. § 494.90 Patient Plan of Care

The ''Patient plan of care'' condition for coverage requires that the facility write and implement a plan of care after performing the comprehensive assessment. The facility must address eight clinical areas in the plan of care, utilizing standards that are consistent with accepted professional standards of practice. In this final rule, we have included a ''psychosocial status'' care plan component that requires that professional social work services be provided and that a standardized mental and physical assessment tool be utilized. The 42 CFR part 405, subpart U requirements were similar and included a provision requiring that the qualified social worker be responsible for conducting psychosocial evaluation, and that the social services provided maximize the social functioning and adjustment of the patient (§ 405.2163(c)). We do not believe that this final rule requirement adds new burden.

Title 42 CFR part 405, subpart U provisions call for an initial short term care plan, an initial long term care plan, an updated short term plan of care every 6 months for stable patients or monthly for unstable patients, and an annual review of the long-term care plan. The short term patient care plan is developed by a professional team consisting of at least the ESRD physician, an RN, the social worker, and the dietitian. The annual long-term program must be developed by a team which includes the dialysis facility physician-director, a physician-director of a self-care center, a transplant surgeon, an RN, a social worker, and a dietitian. This final rule removes the requirement for a separate long-term care program and reduces the frequency of formal care planning (after the first six months that a patient is on dialysis) from biannually to annually and reduced the burden of facility staff. We estimate that the burden associated with formal full interdisciplinary team care planning will be lessened by more than 50 percent starting in the seventh month that a stable patient is on dialysis. Assuming the team meets formally to review and update the plan of care and spends at least 15 minutes on each care plan we estimate an annual cost savings of about $57.11 per patient per year for stable patients after the first year of dialysis.

INTERDISCIPLINARY TEAM SHORT TERM CARE PLANNING COSTS UNDER PREVIOUS REGULATION

	Hourly compensation (*swz.salary.com*)	
Staff Registered Nurse	$39.14	
Dietitian	36.74	
Social Worker	34.52	
Attending Physician	118.05	
Total per hour	228.45 per hour	Cost of 15 minutes of team time for 1 care plan for 1 patient = $57.11.

According to the USRDS, in 2004 there were 335,963 dialysis patients. If we add a 3 percent annual growth rate, our 2008 estimate of patients would be 378,129. We will assume that about 90 percent of dialysis patients are stable (378,129 × 0.90 = 340,316 stable patients). If we multiply the cost savings of $57.11 times the estimated number of stable point prevalent dialysis patients we find an annual costs savings estimate of $19,435,447. If we divide this total savings by the number of dialysis facilities (4,955) we see an average cost savings of $3,922 for each dialysis facility annually. There are further savings not shown here associated with the new patient plan of care requirements because the self-care dialysis physician-director, medical director, and the transplant surgeon do not need to participate in routine long-term care planning, as was previously required. One commenter stated that this change ''will be beneficial to transform the current paper shuffling process into a practical course of action.'' Another commenter stated that deletion of care plan review by the transplant surgeon is a positive change and allows more efficiency. This reduction in burden may be particularly helpful for small businesses, as process is reduced as well as the amount of staff time required for care planning, allowing more time for direct patient care.

This final rule includes transplantation referral tracking, at least annual communication with the transplant center, and patient education and training. In response to comments regarding the burden of quarterly communications, we are requiring at least annual communication with the transplant center, rather than quarterly contact as in the proposed rule. We believe that many dialysis facilities do track the status of their transplant referred patients and also provide patient education on a regular basis. We believe these requirements fall within the scope of reasonable services that a dialysis facility should provide and do not represent new burden. We received comment that the new patient assessment and patient plan of care provisions would increase burden because dialysis facilities would need to redesign their standards and procedures, modify their electronic medical record systems, develop processes for implementing these requirements across all facilities, and retrain all employees. We expect that quality oriented dialysis facilities already meet the majority of requirements contained in this final rule. Dialysis facilities must update systems, processes, and staff training on a regular basis as part of their usual business practices, in order to stay current and respond to new technology and new medical information that becomes available. Our goal is to provide a burden analysis of costs that are newly required by this final rule. Facilities may choose to make additional changes to systems, processes, and staff's training that go beyond what is specifically required by this final rule. These additional costs cannot be predicted, and we have not included usual or optional facility activities and their associated costs in this burden analysis.

h. 494.100 Care at Home

Many of the requirements in the ''Care at home'' condition for coverage are consistent with 42 CFR part 405, subpart U requirements and statutory provisions and do not represent new burdens. New requirements in this final rule include the retrieval and review of self-monitoring patient data at least every 2 months and inclusion of services furnished by a durable medical equipment supplier in the record-keeping system. We believe that this task would present a minimal burden to home dialysis facilities.

We received comments that the economic impact of this condition for coverage would be moderate to significant because it requires that self-care training be conducted by a RN, and according to the commenter, facilities would likely have to hire additional personnel. We do not agree with this comment that additional burden is imposed by this final rule. The 42 CFR part 405, subpart U regulations required at § 405.2162(c) that ''if the facility offers self-care training, a qualified nurse is in charge of such training (see § 405.2102).'' Section 405.2102 requires that an RN who is in charge of self-care dialysis training must have at least 3 months of the total required (18 months) ESRD experience in training patients in self-care. This final rule requires at § 494.140(b)(2) that the self-care training nurse be an RN with at least 12 months experience in providing nursing care and an additional 3 months of experience in the specific modality for which the nurse will provide self-care training (15 months experience in total). The requirement at § 494.100 provides that self-care training must be conducted by a registered nurse who meets the requirements of § 494.140(b)(2). In both the previous regulations and this final rule, self-care dialysis training must be ''conducted,'' that is, led, guided, and managed by an RN with the specified dialysis experience.

i. § 494.110 Quality Assessment and Performance Improvement

This final rule requires dialysis facilities to develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program. Facilities will use quality data internally, in a formal Quality Assessment and Performance Improvement (QAPI) program that each facility has the flexibility to develop in accordance with its own priorities. The two-thirds of dialysis facilities that are part of large dialysis organizations are likely already complying with this requirement and many other facilities also use quality data as part of their standard practices. We estimate that the

QAPI requirements would impose a new burden on no more than 10 percent of the dialysis facilities.

Assuming that a facility was initiating a QAPI program only as a result of this final rule, this may entail a one-hour meeting of four staff persons monthly, that is, 48 staff hours of meeting time. Assuming a staff cost of $234.83 per hour (combined costs using hourly compensation figures as follows; nurse manager—$41.58, social worker—$34.52, dietitian—$36.74 and medical director—$121.99 per hour), the total additional cost to the facility would be $2,817.96 annually. The total cost for 496 facilities would be $1,397,708.

j. § 494.120 Special Purpose Renal Dialysis Facilities

We do not believe that this condition for coverage imposes any new burdens.

k. § 494.130 Laboratory Services

We do not believe that this condition for coverage imposes any new burdens.

l. § 494.140 Personnel Qualifications

This condition for coverage delineates the qualifications personnel must have to provide care in a Medicare certified dialysis facility. We do not believe any additional burden is imposed by the qualification provisions for medical directors, nurses, dietitians, or social workers. The final rule patient care technician qualifications include new requirements including a high school diploma or equivalency, completion of a training program, and state certification within 18 months of being hired or within 18 months of the effective date of this final rule.

This final rule adds new technician qualification requirements, including completion of a training program for water treatment system technicians and a written training program for dialysis patient care technicians that addresses operation of kidney dialysis equipment and machines and the provision of patient care. The training programs would be developed or adopted by the facility and must be approved by the medical director and the governing body of the facility. The training program may include written, audiovisual, and computer based instruction. Since the major dialysis organizations all have training programs for their dialysis patient care technicians and water treatment technicians, and the majority of dialysis facilities are affiliated with these chains, a large portion of facilities already meet this requirement. In addition, at least 11 States already have some form of credentialing (training; competency exam; certification) requirements for dialysis patient care technicians. Even facilities that are not affiliated with major dialysis organizations and are in a State where there are no credentialing requirements for dialysis technicians are not likely to be burdened with the requirement to develop a dialysis training program, since they can request medical director and governing body approval to use a packaged curriculum, which has been developed by organizations in the renal field and is currently available to any dialysis facility without cost.

During the comment period, many commenters voiced concerns related to the proposed rule provision that required 3 months of dialysis patient care technician experience following a training program must be under the ''direct supervision of a registered nurse.'' Commenters asserted that this requirement presented a large burden, as RNs do not have time to constantly directly oversee technicians in training and recommended that LPNs and experienced technicians be allowed to assist with directing patient care technician trainees. In response to comments, we revised this requirement in this final rule, so that the patient care technician training program must be under the direction of an RN and constant one-on-one RN supervision is not required (unless mandated by state provisions). This would allow other staff to act as preceptors under the supervision of an RN. State board of practice provisions must be adhered to so that technicians in training as well as experienced technicians function under the auspices of licensed nurses.

Patient care technician certification under a state certification program or a nationally recognized certification program is required in this final rule, in response to commenter concerns of patient safety and increased risks associated with the prevalent and increasing use of uncertified personnel providing clinical patient care. Hemodialysis technicians, who may be uncertified and unlicensed, commonly perform clinical duties, which include dialysis machine setup, clinical observations and assessments of patients, cannulation, and administering local anesthetics, drugs including heparin, and saline solutions (subject to state nursing board of practice provisions). Several states already require certification of dialysis patient care technicians including California, Connecticut, Kentucky, New Mexico, Ohio, Oregon, Virginia, and West Virginia. According to the Nephrology Nursing Certification Commission (NNCC) ''2005–2006 Annual Report Certification: Your Commitment to Quality'' (*www.nncc-exam.org/about/annualReport2007.pdf*) as of December 2005, there were 1,425 Certified Clinical Hemodialysis Technicians (CCHT), while the Board of Nephrology Examiners Nursing and Technology (BONENT) states in a private communication there are 2,445 BONENT certified hemodialysis technicians. We do not have data on the number of National Nephrology Certification Organization (NNCO) certified nephrology technicians. Although there are three different certification exams available nationally, only one, the Certified Clinical Hemodialysis Technician (CCHT) examination, is specifically geared towards entry level dialysis technicians. Eligibility to take the CCHT exam includes a recommended six months (1,000 hours) of experience in nephrology technology, while the other two exams (given by BONENT and NNCO) require 12 months of experience prior to the exam. We would expect that the majority of dialysis patient care technicians seeking certification to meet our requirement would take the CCHT examination offered by the NNCC.

Hemodialysis technicians applying to take the CCHT examination must be high school graduates or have GEDs, successfully complete a training program for hemodialysis patient care technicians that includes both classroom instruction and supervised clinical experience, and meet state experience requirements. Currently, the examination application fee is $125 and the certification maintenance fee is $50 every 2 years. The exam is offered at hosting ANNA chapters and dialysis facilities around the country, as well as in unison with dialysis conferences. A dialysis facility may host an examination when there are at least five participants, and, if there are at least 10 participants, the NNCC exam manager fee of $150 is refunded. We believe that the flexibility of CCHT examination scheduling will alleviate the need for dialysis technicians to travel or incur overnight costs in order to become certified. We are allowing an 18-month time period so that patient care technicians have sufficient time to successfully complete the certification examination. The cost of taking the certification examination and maintaining certification would likely be borne by the technician, just as nurses, dietitians, and social workers frequently bear the costs of professional examination, registration, and licensing fees. Dialysis patient care technicians will need to complete a training program before taking the exam and would likely be employed by a dialysis

center at the time when taking the examination and so would have an income from which to pay the necessary fee. Dialysis facilities have the option of whether to provide a certification fee benefit.

We have retained the proposed requirement that water treatment system technicians complete a training program that has been approved by the medical director and the governing body. This requirement is in keeping with 42 CFR part 405, subpart U requirements (§§ 405.2136(c)(3)(viii), 405.2136(d)(6), 405.2161(b)(2), and 405.2162), which specify governing body and medical director responsibilities related to proper orientation and training of staff, and we do not believe that this training requirement will result in new burdens.

m. § 494.150 Responsibilities of the medical director

We have revised and clarified the responsibilities (found at §§ 405.2161, 405.2136(f), and 405.2137(a)(1)) and accountability of the medical director in this final rule. We do not believe that these requirements add new burdens.

n. § 494.170 Medical Records

In this final rule, essential requirements in regard to retention, preservation, and transfer of medical records are retained. However, the existing regulations are highly prescriptive in not only requiring the designation of a medical records supervisor, but in detailing that person's duties, specifying categories of information to be included in the medical record, requiring written policies and procedures to protect medical records information, and even addressing spatial issues in regard to the maintenance and processing of medical records. This final rule deletes many of these requirements, giving the facility flexibility in deciding how the medical records are to be maintained and what is to be in them, as long as they facilitate positive patient outcomes. This reduces burden on the dialysis facilities. We estimate that this will save the typical facility about 40 hours of a medical records professional's time, at $21.09 per hour (*http://www.swz.salary.com*), that is, $844 annually, for an overall savings of $4,180,038.

o. § 494.180 Governance

This condition for coverage updates § 405.2136, entitled ''Governing body and management'' and deletes several of the process requirements (for example, those under standard (b), ''operational objectives,'' and (d) ''personnel policies and procedures''). We believe the updated standards related to the CEO or administrator, adequate number of qualified and trained staff, medical staff appointments, furnishing services, emergency coverage, and disclosure of ownership do not produce any additional burdens over previous 42 CFR part 405, subpart U requirements. We do note that 42 CFR part 405, subpart U requires the presence of a licensed physician, RN, or LPN when patients are being dialyzed, and our final rule specifies an RN presence. We believe that the majority of dialysis facilities strive to maintain a RN presence in the facility whenever patients are being dialyzed and expect that this modification would produce little additional burden.

Standard (e) of the Governance condition for coverage requires a facility to implement an internal grievance process. The previous requirement at § 405.2138(e) stated that all patients would be encouraged and assisted to understand and exercise their rights, and that grievances and recommended changes in policies and services could be addressed to facility staff, administration, the network organization, etc. We believe that many dialysis facilities have implemented an in-house grievance process; however, it is likely that approximately 15 percent of dialysis facilities may not have processes that would meet our new requirements. We estimate that it would take eight hours for a nurse manager (at $41.58 per hour) to develop and implement an appropriate grievance process at a cost of $333 per facility. The estimated total cost for 15 percent (743) of facilities to meet this requirement is $247,152.

This final rule implements a discharge process that must be used if facilities must discharge patients against their will. We expect that this process would be needed infrequently (less than once per year) and only be used as a last resort.

Furnishing Data and Information for the ESRD Program

This final rule requires that all dialysis facilities furnish data and information electronically and in intervals specified by the Secretary, including cost reports, administrative forms, patient survival data, ESRD Clinical Performance Measures (CPMs) data, and any future standards developed in accordance with a voluntary consensus standards process identified by the Secretary. While submission of data and information is an existing requirement in § 405.2133 and electronic submission of cost report data and information is an existing requirement in § 413.24, the requirement to provide CPM data above the national statistical sample is new. Additionally, the requirement to provide necessary administrative and CPM data in electronic format is a change from the paper-based process that has historically been used to support the ESRD program.

We previously proposed using the VISION application as the electronic medium for the data collection required by the new conditions for coverage (70 FR 6231). VISION was a patient-specific, stand-alone, facility-based information system with software that would reside on facility computers, which presented challenges for updating the software. We agree with commenters that VISION did not represent the best technology for wide-spread collection of data from dialysis organizations. As discussed earlier in this preamble (under section § 494.180(h)), we are now implementing a new web-based application, CROWNWeb, for this purpose. This new approach is superior to the VISION application in that it will increase the efficiency of data collection, improve data quality, provide a more stable and accessible platform for continual improvements in functionality, and complement existing information infrastructures used by many dialysis facilities. We have recalculated the burden and cost savings related to electronic data reporting using CROWNWeb.

The collection and reporting of ESRD CPMs has, to date, been an effort among CMS, the ESRD Networks, dialysis facilities, and other interested stakeholders to assess the care of a representative statistical sample of individuals receiving dialysis, and all pediatric, and Veteran's Administration dialysis patients, in the areas of adequacy of dialysis, anemia management, nutrition (serum albumin), and more recently, vascular access (Centers for Medicare & Medicaid Services. 2006 Annual Report, ESRD Clinical Performance Measures Project, *http://www.cms.hhs.gov/CPMProject*). The ESRD CPMs were developed to implement section 4558(b) of the Balanced Budget Act (BBA) of 1997 (Pub. L. 105–33). This provision required the Secretary to develop and implement a method to measure and report on the quality of renal dialysis services provided under Medicare no later than January 1, 2000.

The collection and reporting of ESRD CPMs has been an effective tool to facilitate ESRD quality improvement, and has allowed us to track overall positive improvements in several intermediate outcomes for individuals

receiving dialysis. We believe an expansion of the CPMs from the statistical sample of about five percent to all individuals with ESRD and receiving dialysis will create minimal additional burden. During the last 3 years, over 70 percent of dialysis facilities have demonstrated an ability to successfully submit data to CMS that could be used to compute all 13 of the existing CPMs for all their patients.[2] Two of the primary reasons provided by the large dialysis organizations for their participating in this activity included:

1. They believed it was less of a burden to electronically submit data for all of their patients than for facility staff to spend 30 minutes to fill out each entire CPM form for the sample of about five percent.

2. They believed more transparency in the ESRD Program would allow favorable quality of care comparisons to other dialysis organizations.

We received a comment that this electronic data submission requirement would produce a burden to dialysis facilities due to the need to perform information technology enhancements for increased data transmission. Two commenters stated that the software necessary to report data and information electronically in the specified format should be made available to all dialysis providers free of charge. Commenters further stated that CMS should also provide funding for travel related to training and financial relief for the abstracting and key-entry of CPM data and internet service provider (ISP) costs. Some commenters recommended that software implementation should not require duplicate data entry into multiple systems. Commenters did not provide data or dollar figures that would assist us in determining the cost of our electronic data reporting requirement.

We believe that because of the streamlining of data submissions with the CROWNWeb application, these new requirements for additional electronic data will actually result in less overall facility burden compared to existing data submissions. We also believe this activity will lead to a substantial long-term return on investment for all stakeholders-patients, facilities, and the public. We have invested the necessary time and resources to develop a stable and accessible platform, CROWNWeb, for the submission of electronic data. CROWNWeb includes two methods for electronically submitting data, a single-user interface (SUI) and electronic data interchange (EDI). With the SUI, users can log-on to CROWNWeb and enter required data through the interface while with EDI, technologically advanced users can submit required data in batches from their own clinical information systems and thus greatly reduce any facility burden necessary to meet these new requirements.

CROWNWeb enables the protection of the privacy, confidentiality, and security of information transmitted electronically. It uses Web-based technology and is available free-of-charge to all facilities with Internet access and has little to no impact on facility computer systems. CROWNWeb meets all applicable security criteria included in the CMS Information Security Acceptable Risk Safeguards (ARS) policy (*http://www.cms.hhs.gov/InformationSecurity/14_standards.asp*), which contains a broad set of CMS security controls based upon National Institute of Standards and Technology (NIST) requirements. Additionally, CROWNWeb does not leave persistent files on a facility's computer because temporary files stored locally during a CROWNWeb session are purged when the user exits CROWNWeb. The only persistent files that will be left on the facility's computer are related to the installation of Adobe Acrobat Reader, which is a free, universal tool that is necessary to view some reports generated by CROWNWeb. Also, CROWNWeb currently requires a Windows XP service pack 2 or greater, and Internet Explorer 6 or greater.

Any potential facility burden related to electronic data reporting falls into three main categories: (1) Technology hardware and enhancements, (2) personnel time and travel for training, and (3) personnel time for submitting the additional data. We believe very few dialysis facilities would have to purchase computer hardware to implement this requirement, possibly no more than 155 (3 percent of total number of facilities projected in 2009; when electronic data submission will be required). Our estimate on the number of facilities required to purchase computer hardware is derived from data revealing that a majority of dialysis facilities currently submit some kind of electronic data to CMS and thus, have the necessary computer hardware to support CROWNWeb. We estimate the cost, with installation to be $1,000. Thus, the total cost for purchasing hardware would be $155,000, and this cost would only apply in the initial year of implementation. We estimate new ISP costs for a minimal broadband connection to be $360 annually ($360 × 155 facilities = $55,800), and this would be an on-going annual cost. Facilities without access to a broadband connection might have an interruption of other services while using CROWNWeb, and they may choose instead to contract with a third party to submit data on their behalf.

Based on feedback we have received from facilities involved in CROWNWeb testing, we do not believe dialysis facilities will need more than the basic training that CMS will provide free-of-charge over the internet in order to use CROWNWeb. CMS will provide geographically representative in-person training sessions that will be available for those facilities who would like to receive their training in-person, but we do not believe this type of training is required in order to use CROWNWeb. Additionally, we expect that ESRD Networks will play a valuable role in educating facilities and that the ESRD Networks as well as our IT contractor will provide technical assistance to facilities. For personnel time, we estimate that each of the 5,173 facilities (the number of facilities projected in 2009, using 4.4 percent annual growth rate) will have at least one person at the level of nurse manager ($41.58) or higher that will take the Web-based training in order for the facility to meet the new requirement. Thus, we estimate the cost of training in the initial year to be at least $430,187 (5,173 users×2 hours×$41.58). Many facilities will also want to train the unit secretary; therefore, we are also adding the training costs of $227,612 for secretaries who are compensated at approximately $22.00 per hour (5,173 facilities×2 hours×$22.00). Therefore, our total training cost estimate is $657,799.

Table 1 shows the estimated 2009 costs of the data submissions from dialysis facilities, utilizing 2006 methods. In 2006 data were submitted to CMS and the ESRD Networks under the following categories: laboratory data, Fistula First vascular access data, CPMs, quarterly patient rosters, network patient activity report (NPAR), the medical evidence form (CMS–2728), and the death notification form (CMS–2746). For each category, the table shows the associated factors for all the 2006 methods of submitting data, which include paper submissions, EDI submissions, and a hybrid combination submission method that includes both EDI and paper. Column A shows the number of dialysis facilities estimated to participate in 2009 data submissions, while column B shows the number of forms submitted for each year. Column C reveals the annual frequency of data submission. Column D shows the estimated number of labor minutes that

[2] These organizations collect data on all 13 CPMs and their advanced information capability is detailed in the 2002 OIG series, ''Clinical Performance Measures for Dialysis Facilities,'' OEI–01–99–00052.

would be required for the submission of a single form. The number of forms; times the annual frequency; times the number of labor minutes, is totaled and converted to hours in column E. Other additional facility data reporting costs, such as mailing costs, are shown in column F. The total dollar figures shown in column G reflect the sum of the hours shown in column E times $22.00 in labor costs; plus the costs shown in column F. The $3,966,601 total at the bottom of table 1 reflects the estimated dialysis facility costs of submitting data to CMS and the ESRD Networks in 2008, using the data submission methods available prior to implementation of this final rule.

TABLE 1.—ESTIMATED 2009 ANNUAL FACILITY DATA BURDEN UNDER EXISTING DATA SUBMISSION METHODS

Project (level of data)	Method	A. Number of facilities	B. Number of forms	C. Data frequency	D. Time to collect/enter data (minus)/ each	E. Total labor time (approximate hours)	F. Other facility costs	G. Total facility costs
Lab Data (patient)	paper	542	41192	annual	25	17163	*$1,512	$379,098
	EDI	3622	275272	annual	0	0	0	0
Fistula First (summary)	paper	1551	1551	monthly	10	3102	0	68,244
	EDI	3622	3622	monthly	0	0	0	0
CPM <5 percent (patient) ‡	paper	1551	3655	annual	30	1828	**5,099	45,315
	hybrid	3622	8531	annual	15	2133	**5,927	52,853
NPAR (patient) ‡‡	paper	5173	5173	monthly	30	31038	0	682,836
	EDI	0	0	monthly	0	0	0	0
Quarterly Roster (pt) ‡‡	paper	5173	5173	quarterly	120	41384	0	910,448
	EDI	0	0	quarterly	0	0	0	0
2728 (patient)	paper	5173	111705	once	15	27926	**623,314	1,237,686
	EDI	0	0	once	0	0	0	0
2746 (patient)	paper	5173	91396	once	10	15233	**254,995	590,121
	EDI	0	0	once	0	0	0	0
Total								3,966,601

Note: For ease of interpretation and since the number of users is very small, this table does not include any consideration of facility-use of CROWNWeb's predecessor software, VISION.
EDI: Electronic Data Interchange.
B: For patient-level data, assumes the average facility size of 76 patients.
E: Total Time (hours) = B * C * D ÷ 60.
F: Includes mailing costs but not long-distance fax charges or paper/printing costs. Note: certified mailing is in the process of being required for all communications involving personal health information.
G: Total Costs ($) = E * ($22 dollars per hour wage for medical secretary) + F.
*Assumes first class certified mailing of $2.79 for every facility.
**Assumes first class certified mailing of $2.79 for each patient and for the 2728, a second mailing to the Social Security Administration (SSA).
‡CPM sample has been stable at about 12,000 each year.
‡‡With the Network Patient Activity Report (NPAR), facilities notify networks of incremental changes whereas with the Quarterly roster, facilities verify all patients.

We recreated Table 1 to estimate the burden of data submission under this final rule using the CROWNWeb process (shown in Table 2). Using the new process, the personnel time necessary to submit data to meet the new requirements (columns D and E) is markedly decreased.

TABLE 2.—ANNUAL FACILITY DATA BURDEN UNDER FINAL RULE § 494.180(H)

Project (level of data)	Method	A. Number of facilities	B. Number of forms	C. Data frequency	D. Time to collect/enter data (minus)/ each	E. total time (approximate hours)	F. Other facility costs	G. Total facility costs
ClinicalPART (patient) ‡	paper	0	0	annual	30	0	$0	$0
	SUI	1035	78660	annual	25	32775	0	721,050
	EDI	4138	314488	annual*	0	0	0	0
AdminPART (patient) ‡‡	paper	0	0	monthly	70	0	0	0
	SUI	1035	1035	monthly	70	14490	0	318,780
	EDI	4138	4138	monthly	0	0	0	0
2728 (patient)	paper	0	0	annual	15	0	0	0
	hybrid	5173	111705	annual	15	27926	*306,900	921,272
	EDI	**NA	0	annual	0	0	0	0
2746 (patient)	paper	0	0	annual	10	0	0	0
	hybrid	5173	91396	annual	5	7616	0	167,552
	EDI	**NA	0	annual	0	0	0	0
Total								2,128,654

EDI: Electronic Data Interchange.
SUI: Single-user web interface.
B: For patient-level data, assumes the average facility size of 76 patients.
E: Total Time (hours) = B * C * D / 60.

F: Includes mailing costs but not long-distance fax charges or paper/printing costs. Note: certified mailing is in the process of being required for all communications involving personal health information.
G: Total Costs ($) = E * ($22 dollars per hour wage for medical secretary) + F.
* Assumes first class certified mailing to SSA of $2.79 for each patient.
** Based on prioritization due to volume, facility preferences, and need to include SSA in EDI, all of the data necessary for the complete submission of the 2728 and 2746 are not included in the EDI functionality for initial CROWNWeb releases.
*** The Fistula First data included in ClinicalPART will also be required monthly.
† The required Clinical Patient Attributes and Related Treatment (ClinicalPART) dataset replaces the previous lab data, Fistula First, and CPM data submissions.
‡‡ The required Administrative Patient Attributes and Related Treatment (AdminPART) dataset replaces both the Network Patient Activity Report (NPAR) and the Quarterly roster.

By creating efficiencies via integrating various datasets and complementing the advanced information systems used by most dialysis facilities, we will be able to expand the CPM data collection from about a five percent statistical sample to 100 percent of dialysis patients, while also reducing facility data collection and data entry burden by about $1.8 million (the sum of Table 2 subtracted from the sum of Table 1 equals $1,837,947). Table 3 computes the estimated costs discussed above for computer hardware, Internet access, training costs for two facility staff members, and the labor cost savings for data entry and data submission. Our total of about minus $0.97 million reflects an overall first year cost savings that accompanies implementation of electronic data submission required by this final rule. The estimated $1.8 million annual labor cost savings is expected every subsequent year (not counting inflation) on an ongoing basis.

TABLE 3.—COST ESTIMATE FOR § 494.180(H)

$155,000	Computer hardware (first year).
55,800	Broadband internet access (first year and ongoing).
657,799	Training (first year).
2,128,654	Labor (first year and ongoing) (Represents a savings of $1,837,947 which is the difference between total costs in Table 1 and total costs in Table 2).
$2,997,253	Total Cost (first year).
$969,348	Total Cost savings (first year) (Represents the difference between total costs in Table 1 and the first year costs of $2,997,253).

In addition to the short-term return on investment to facilities, we believe that there is also an ongoing return on this investment for all other primary stakeholders—including patients, dialysis practitioners, and the public. CROWNWeb will allow for the more timely, accurate, and efficient use of data to support administration of the ESRD program by replacing the predominately paper process that currently exists with an electronic process that respects the capabilities of providers and has tangible benefits for dialysis facilities, individuals who have or may develop ESRD, and other stakeholders. CROWNWeb will allow facility submission of required data directly from their electronic health records rather than redundant data entry, freeing facility personnel to concentrate more on patient care. Another expectation is that claims payment will be improved due to improved quality and timeliness of patient eligibility and enrollment information. In the future, we expect that the system could include claims data, and serve to inform a facility of, for example, patient hospitalization. A major benefit of the new system for facilities will be reports that will allow facilities to compare their patient outcomes with those of their peers. CPM electronic data collection for all dialysis patients allows facility level comparisons and tracking. Information about patient outcomes will be available in a much more timely fashion than currently exists, and performance improvement activities may be implemented and evaluated in quicker succession to optimize patient outcomes. For individuals with ESRD, CROWNWeb will increase the transparency of the health care system and empower patients to find better health care value and quality, while assuring access to care, especially in times of disaster/emergency. For ESRD Networks, CROWNWeb will not only provide timelier, more accurate, and more complete information to inform quality improvement, it will make unnecessary certain activities that require a significant amount of Network resources. For example, CROWNWeb will be able to recreate the data included on the CMS 2744 Annual Facility Survey in a more timely fashion then is currently possible, and will free up Network resources that currently perform a four month manual reconciliation process. And for all primary stakeholders, we expect that the new system will either facilitate or provide timelier reports that will allow them to compare individual facilities and facility groups with various peer groups and national and local benchmarks.

Impact Summary

The following chart provides an overall estimate of the impact of the final rule on dialysis facilities:

Requirement	First year costs	Second year costs
BP Cuffs (cleanable or disposable)	$496,244	*$49,624
Isolation Room Waiver Process	0	*10,743
Evacuation Instructions	523,634	0
Emergency Phone Number	69,384	*69,384
Automated External Defibrillator (AED)	5,338,000	0
AED Maintenance	54,581	*54,581
Contacting Local Disaster Official	264,448	*264,448

Requirement	First year costs	Second year costs
LSC Automatic Notification System	3,289,472	*809,472
Update of Patient Rights	171,046	0
QAPI Program Implementation	1,397,708	*1,397,708
Develop New Grievance Process	247,151	0
ESRD CPM Electronic Reporting:		
Hardware	.....	155,000
Internet access	.....	*55,800
Training	.....	657,799
Total Cost	11,851,668	3,524,559
Cost savings	**First year savings**	**Second year savings**
CEO Emergency Preparedness Time	$1,029,253	*$1,029,253
Patient Rights decreased administrative burden	342,093	*342,093
Patient Plan of Care, annually not biennially	19,435,447	*19,435,447
Medical Records Personnel no longer required	4,180,038	*4,180,038
Data Submission Labor	.....	*1,837,947
Total Cost Savings	24,986,831	26,824,778
Net Savings	13,135,163	23,300,219

*Ongoing annual costs/cost savings.

Effects on the Medicare and Medicaid Programs

This final rule contains provisions that will protect patient health and safety and lead to improvements in patient care. Several of the expected improvements in patient care may also result in more efficient, cost effective care. For example, improved infection control practices may lead to fewer hospitalizations and better patient quality of life. An increased focus on the transplantation modality may lead to a greater number of patients on the transplant list, and perhaps more living-donor transplantations.

This final rule contains several provisions that directly and indirectly promote the use of the most optimal dialysis access for each patient. These provisions include § 494.80(a)(8), § 494.90(a)(5), § 494.90(d), § 494.110 (a)(2), § 494.140 (e)(3)&(4), § 494.180 (c)(3), and § 494.180 (h)(3)(iv). We expect that these new requirements are improvements that will result in lower rates of access failure and an increase in the number of working arteriovenous fistulas (AVF). AVFs offer the most benefits to patients of the three possible hemodialysis access types. Examples of these benefits include longer average patency of all access types, very low rate of infection, need for only a minor surgery, and healing and sealing post-cannulation (*http://www.fistulafirst.org/tools.htm#Education*). According to the 2006 USRDS Atlas, the per patient per year (pppy) Medicare costs using 2004 data for dialysis patients with an AVF was $55,112; the pppy cost with a graft was $65,556; and the pppy costs with a catheter $75,345. Although this is raw data, we can see that there is a significant Medicare savings associated with AVF. According to 2005 ESRD CPM project, 31 percent of hemodialysis patients were dialyzing using an AVF in 2004 (*http://www.cms.hhs.gov/CPMProject*). More current Fistula First October 2006 data (*http://www.simsproject.com/downloads.php?p=ff*) shows an AVF rate of 44.4 percent for patients. If the AVF rate further improves by 5 percent in all hemodialysis patients (309,269 in 2004 according to USRDS data) 15,464 more patients would have AVFs (with an average pppy savings of $15,000). If this were to occur the potential Medicare savings could be approximately $230 million per year. For purposes of this Impact Analysis, we have used the savings ($230 million) that could result from 5 percent additional AVF patients. We believe savings are possible assuming the medical costs associated with creating AVFs for these 5 percent additional patients are in line with current costs, and that the cost differential between patients with AVFs and those with catheters remain comparable.

This final rule also promotes patient independence and the use of home dialysis whenever appropriate. The provisions that encourage home dialysis include § 494.70(a)(7), § 494.80(a)(9), § 494.90(a)(7), and § 494.90(d). We expect that the requirements of this rule will increase the percentage of patients on home dialysis. According to USRDS data the 2004 hemodialysis pppy Medicare costs equal $67,733, while the peritoneal pppy costs equal $48,796. We do not have USRDS home hemodialysis pppy Medicare costs although home hemodialysis is less costly than in-center hemodialysis and home peritoneal dialysis is less costly than home hemodialysis. Approximately 92 percent of U.S. dialysis patients receive in-center hemodialysis. Based on the difference between 2004 hemodialysis and peritoneal pppy costs, savings of as much as $18,937 pppy could be obtained with patients opting for peritoneal dialysis. If 5 percent additional patients were to opt for home peritoneal dialysis, which provides added health and quality of life benefits, that could account for 15,464 patients. The potential annual savings for these 5 percent additional patients (15,464 × $18,937) could be as much as $295 million. Combining potential savings from 5 percent additional patients who opt for AVFs and 5 percent additional patients who opt for home dialysis, the total Medicare allowed charges could be reduced by up to $525 million annually. However, these examples are only illustrative in nature and are based on limited analytics. Therefore, they are not incorporated in the quantitative cost analysis of the RIA, but are presented to illustrate the possibility for Medicare savings.

C. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/OMB/circulars/A004/A-4.PDF*) in the table below, we have prepared an accounting statement

showing the classification of the expenditures and savings associated with the provisions of this final regulation. This table provides our best estimate of the total annualized monetized costs and savings.

PRIMARY ESTIMATE FOR 2008

Annualized monetized facility costs	$11,851,668
Annualized monetized facility cost savings	24,986,831
Annualized monetized facility net cost savings	13,135,163
Effects on State, local, and tribal governments	0
Benefit effects on small businesses	2,651

D. Alternatives Considered

1. Maintenance of Existing Regulations

One alternative would be to keep the existing regulations. However, the current regulations inhibit our ability to ensure better outcomes of patient care, collect electronic data for quality assurance and quality improvement, incorporate new CDC and AAMI guidelines and fire safety standards and reduce current facility burden by eliminating numerous process and procedural requirements.

2. Infection Control

One alternative was not including an exception to the CDC recommendation for monthly and semiannual screening for hepatitis C. We retained the exception because blanket screening for hepatitis C is not a Medicare-covered service.

Another alternative was to include only the ''Recommended Infection Control Practices for Hemodialysis Units At a Glance'' (At a Glance) precautions found in the CDC RR05 report and not including the narrative section explaining the infection control precautions. Our proposed inclusion of only the ''At a Glance'' two-pager synopsis of the CDC hemodialysis infection control precautions caused confusion as evidenced by the comments we received requesting clarification of various precautions. A third alternative was to require compliance with AIA Guidelines for Design and Construction of Hospitals and Health Care Facilities. The AIA guidelines provide instructions regarding dialysis unit design as it relates to infection control. While some states have adopted specific AIA guidelines as minimal standards, we believe it would be too burdensome on dialysis facilities to incorporate AIA guidelines as federal requirements. Commenters did not support inclusion of the AIA guidelines in these conditions for coverage.

3. Water Quality

One alternative was to require compliance with portions of the previous AAMI guidelines—ANSI/AAMI RD5: 1992 Appendix B5. However, this document has been rescinded by ANSI/AAMI and has been replaced by updated documents. Although we proposed compliance with portions of the AAMI document—RD62: 2001, which is directed to manufacturers, we are including in this final rule an incorporation by reference of ANSI/AAMI RD52:2004. This RD52 document reflects the state-of-the-art water quality guidelines for end users of water purification systems. Commenters urged us to include the RD52:2004 incorporation by reference as the most appropriate set of recommendations for dialysis facilities.

4. Reuse of Hemodialyzers

One potential cost-saving alternative was to remove the requirement that dialyzers exposed to more than one germicide were acceptable for reuse. We decided against this because exposure to different germicides may cause membrane leaks and we have no scientific evidence to support the safety of using hemodialyzers exposed to more than one germicide. Commenters agreed with this approach.

5. Physical Environment and Emergency Preparedness

One alternative was to remove the requirement that every dialysis facility have a defibrillator. We retained this proposed provision because a Seattle study (Becker, pp. 1509–1512) identified dialysis centers as having a relatively high incidence of cardiac arrests over a seven year period. Also, automated external defibrillators are now required on airliners and in other public places because the technology is simple to use, staff can be trained on the use of such equipment, and the technology has been proven to save lives.

A second alternative was to allow a waiver or phase-in period for defibrillators in small rural dialysis facilities. Many commenters agreed that dialysis facilities should be equipped with a defibrillator, preferably an AED. Commenters urged that a waiver not be available to rural facilities and stated that these dialysis facilities may have the greatest need for AEDs since emergency medical technical support may be located a long distance from the dialysis facility.

6. Patients' Rights

One alternative was to remove the patients' right to be informed of the availability of advance directives. We retained this proposal nonetheless because of the nature of ESRD and the aging dialysis population.

Another alternative considered was not including that dialysis facilities have an internal grievance procedure. We did not adopt this alternative because we believe an internal grievance process is essential to allow patients to express their concerns directly to the facility in which they receive dialysis.

7. Patient Assessment

One alternative was to include ''extremely frail patients'' in the provision to reassess unstable patients monthly. This proposal was not adopted in order to ensure that dialysis facilities retain the flexibility to make clinical determinations on a case-by-case basis.

Another alternative was to remove the proposed 3-month timeframe to reassess new patients. However, we believe that initial patient adjustment to dialysis is crucial in setting the stage for successful treatment of ESRD and the reassessment done at 3 months will facilitate better patient outcomes.

8. Patient Plan of Care

One alternative was to retain the existing requirement for an individualized care plan with a six month review and a long-term program with an annual review. We did not adopt this approach because it was less burdensome to include a single individualized plan of care (without a long-term program) to be reviewed annually for stable patients.

9. Quality Assessment and Performance Improvement

One alternative was to require a QAPI program without specific criteria. We determined, based on the work of the NFK–K/DOQI committees (adequacy, nutrition, anemia, and vascular access), AAMI guidelines (reuse), specific recommendations from the OIG (medical error identification and patient satisfaction), and public comments on our proposed rule, that there was a sufficient basis to include basic criteria.

10. Special Purpose Renal Dialysis Facilities

One alternative was to remove this condition entirely based on historically low levels of participation. We determined that eliminating this condition would be detrimental to the small number of vacation camps that choose to participate and it would also

inhibit access to care during natural disasters.

Another alternative was to retain the current certification requirements. We believe that the current certification requirements are onerous; we believe that this is demonstrated by the lack of participation in Medicare by vacation camps. We believe reducing the number of certification requirements addresses this issue. The final rule requirements represent a reduction in administrative burden for special purpose units.

11. Personnel Qualifications

One alternative was to retain the existing requirement that a licensed practical nurse, RN, or physician must be on the premises during dialysis. We are requiring that a registered nurse be on the premises during dialysis to protect patient health and safety and believe that this does not represent a significant increase in burden for dialysis facilities. In response to comments, we included a provision for the temporary use of an experienced LPN for infrequent occasions when the lack of an RN would force the facility to close for the day.

Other options were to propose no or merely minimal Federal requirements for dialysis technicians. We determined that Federal requirements are needed at this time because dialysis technicians are the primary caregivers in most dialysis facilities. Commenters support the inclusion of qualification criteria for patient care technicians.

12. Medical Director

One alternative was to propose to eliminate the medical director condition and propose that other health care professionals run dialysis facilities. However, a June 2000 OIG report strongly recommended that we strengthen the role of the facility's medical director. In response to that recommendation, we have retained the condition with a clarification of the medical director's responsibilities to include overseeing both the QAPI program and all involuntary patient transfers or discharges. We do not believe that this approach would impose an additional cost burden on dialysis facilities.

13. Governance

One alternative considered was to remove the proposal for a 30-day advance notice before involuntary patient discharge or transfer and retain the previous requirement (see § 405.2138(b)(2)) for patients to be ''given advance notice to ensure orderly transfer or discharge.'' We did not adopt this alternative because: (1) A 30-day advance notice for discharge and transfer has been consistent with the existing requirements in NFs, SNFs, and hospital swing-beds for over 12 years; (2) the dialysis patient population is increasingly older and many are nursing home residents with co-morbid conditions; and (3) large dialysis organizations have emerged that can offer more flexibility and options for a patient involuntarily discharged from a facility by providing numerous units nearby or within commuting distance of that patient's place of residence. We have retained the proposed provision to waive the 30-day notice under extraordinary circumstances.

This final rule contains a requirement for every dialysis facility to report ESRD CPM Project data to CMS. One option considered was to require that less than 100 percent of facilities participate. However, section 4558(b) of Pub. L. 105–33 requires CMS to monitor the quality of care delivered to dialysis patients. To date, CMS has been collecting a five percent CPM patient sample on a voluntary basis. CPM electronic data collection has been pilot-tested and is expected to be ready for general use in 2008. The large dialysis organization facilities and many other dialysis facilities already collect this data for benchmarking and quality improvement purposes, and therefore, this will not create a significant new burden for the industry. However, small rural facilities may need time to come into compliance, and therefore, we are including a phase-in period.

E. Conclusion

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 494

Health facilities, Incorporation by reference, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

■ 1. The authority citation for part 405, subpart U is revised to read as follows:

Authority: Secs. 1102, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320b–8, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

§ 405.2100 and § 405.2101 [Removed and Reserved]

■ 2. Section 405.2100 and § 405.2101 are removed and reserved.

■ 3. Section 405.2102 is amended by adding the definition of ''ESRD Network organization'' in alphabetical order to read as follows:

§ 405.2102 Definitions.

* * * * *

ESRD Network organization. The administrative governing body to the network and liaison to the Federal government.

* * * * *

§ 405.2131 and § 405.2133 through § 405.2140 [Removed and Reserved]

■ 4. Section 405.2131 and § 405.2133 through § 405.2140 are removed and reserved.

§ 405.2150 [Removed and Reserved]

■ 5. Section § 405.2150 is removed and reserved.

§ 405.2160 through § 405.2164 [Removed and Reserved]

■ 6. Sections 405.2160 through § 405.2164 are removed and reserved.

§ 405.2180 through § 405.2182 [Removed and Reserved]

■ 7. Sections 405.2180 through § 405.2182 are removed and reserved.

§ 405.2184 [Removed and Reserved]

■ 8. Section 405.2184 is removed and reserved.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 9. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395(m), 1395hh, and 1395ddd).

§ 410.5 [Amended]

■ 10. In § 410.5(a), the reference ''Part 405, subpart U: End-Stage Renal Disease Services,'' is revised to read ''Part 494: End-Stage Renal Disease Facilities.''

§ 410.50 [Amended]

■ 11. In § 410.50(b), the reference ''§ 405.2163(b)'' is revised to read ''§ 494.130''; and the reference ''subpart M of part 405'' is revised to read ''part 494.''

§ 410.52 [Amended]

■ 12. Section § 410.52 is amended as follows:

■ A. In paragraph (a)(4), the reference to ''§ 405.2163'' is revised to read ''§ 494.90(a)(4).''

■ B. In paragraph (a)(4), the word ''epoetin (EPO)'' is revised to read ''erythropoeisis-stimulating agents.''

■ C. In paragraph (b), the parenthetical statement ''(Section 405.2137 of this chapter contains specific details.)'' is revised to read ''(Section 494.90 of this chapter contains details on patient plans of care).''

§ 410.152 [Amended]

■ 13. In § 410.152(e)(1), ''subpart U of part 405'' is revised to read ''part 494.''

§ 410.170 [Amended]

■ 14. In § 410.170(c), the reference to ''§ 405.2137(b)(3)'' is revised to read ''§ 494.90.''

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 15. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Public Law 106–133 (113 Stat. 1501A–332).

■ 16. In § 413.170, paragraph (a) is revised to read as follows:

§ 413.170 Scope.

* * * * *

(a) Setting forth the principles and authorities under which CMS is authorized to establish a prospective payment system for outpatient maintenance dialysis furnished in or under the supervision of a dialysis facility under part 494 of this chapter (referred to as ''facility''). For purposes of this section and § 413.172 through § 413.198, ''outpatient maintenance dialysis'' means outpatient dialysis provided by a dialysis facility, home dialysis or self-dialysis as defined in § 494.10 of this chapter and includes all items and services specified in § 410.50 and § 410.52 of this chapter.

* * * * *

■ 17. In § 413.172, paragraph (b) is revised to read as follows:

§ 413.172 Principles of prospective payment.

* * * * *

(b) All approved ESRD facilities must accept the prospective payment rates established by CMS as payment in full for covered outpatient maintenance dialysis. Approved ESRD facility means—

(1) Any independent or hospital-based facility (as defined in accordance with § 413.174(b) and § 413.174(c) of this part) that has been approved by CMS to participate in Medicare as an ESRD supplier; or

(2) Any approved independent facility with a written agreement with the Secretary. Under the agreement, the independent ESRD facility agrees—

(i) To maintain compliance with the conditions for coverage set forth in part 494 of this chapter and to report promptly to CMS any failure to do so; and

(ii) Not to charge the beneficiary or any other person for items and services for which the beneficiary is entitled to have payment made under the provisions of this part.

* * * * *

§ 413.198 [Amended]

■ 18. In § 413.198(a), the phrase ''approved under subpart U of part 405,'' is revised to read ''under part 494.''

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 19. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

§ 414.330 [Amended]

■ 20. Section 414.330 is amended as follows:

■ A. In paragraph (a)(2)(iii)(B), the reference ''subpart U of part 405'' is revised to read ''part 494.''

■ B. In paragraph (a)(2)(iii)(B)(*1*), the references ''subpart U (Conditions for Coverage of Suppliers of ESRD Services)'' are revised to read ''part 494 (Conditions for Coverage for End-Stage Renal Disease Facilities).''

■ C. In paragraph (a)(2)(iii)(B)(*7*), the references ''subpart U (Conditions for Coverage of Suppliers of ESRD Services)'' are revised to read ''part 494 (Conditions for Coverage for End-Stage Renal Disease Facilities).''

■ D. Paragraph (a)(2)(iii)(C) is added to read as follows:

§ 414.330 Payment for home dialysis equipment, supplies, and support services.

(a) * * *

(2) * * *

(iii) * * *

(C) Agrees to report to the ESRD facility providing support services, at least every 45 days, all data (meaning information showing what supplies and services were provided to the patient and when each was provided) for each patient regarding services and items furnished to the patient in accordance with § 494.100(c)(2) of this chapter.

* * * * *

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 21. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302 and 1895hh); Continuing Resolution Pub. L. 110–149 H.J. Res 72.

■ 22. Section 488.60(a) is revised to read as follows:

§ 488.60 Special procedures for approving end-stage renal disease facilities.

(a) *Consideration for approval.* An ESRD facility that wishes to be approved or that wishes an expansion of dialysis services to be approved for coverage, in accordance with part 494 of this chapter, must secure a determination by the Secretary. To secure a determination, the facility must submit the following documents and data for consideration by the Secretary:

(1) Certification by the State agency referred to in § 488.12 of this part.

(2) Data furnished by ESRD network organizations and recommendations of the Public Health Service concerning the facility's contribution to the ESRD services of the network.

(3) Data concerning the facility's compliance with professional norms and standards.

(4) Data pertaining to the facility's qualifications for approval or for any expansion of services.

* * * * *

Subpart G [Added and Reserved]

■ 23. A new subpart G is added and reserved.

■ 24. A new subpart H is added to read as follows:

Subpart H—Termination of Medicare Coverage and Alternative Sanctions for End-Stage Renal Disease (ESRD) Facilities

Sec.
488.604 Termination of Medicare coverage.
488.606 Alternative sanctions.
488.608 Notice of alternative sanction and appeal rights: Termination of coverage.
488.610 Notice of appeal rights: Alternative sanctions.

Subpart H—Termination of Medicare Coverage and Alternative Sanctions for End-Stage Renal Disease (ESRD) Facilities

§ 488.604 Termination of Medicare coverage.

(a) Except as otherwise provided in this subpart, failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in part 494 of this chapter will result in termination of Medicare coverage of the services furnished by the supplier.

(b) If termination of coverage is based solely on a supplier's failure to participate in network activities and pursue network goals, as required at § 494.180(i) of this chapter, coverage may be reinstated when CMS determines that the supplier is making reasonable and appropriate efforts to meet that condition.

(c) If termination of coverage is based on failure to meet any of the other conditions specified in part 494 of this chapter, coverage will not be reinstated until CMS finds that the reason for termination has been removed and there is reasonable assurance that it will not recur.

§ 488.606 Alternative sanctions.

(a) *Basis for application of alternative sanctions.* CMS may, as an alternative to termination of Medicare coverage, impose one of the sanctions specified in paragraph (b) of this section if CMS finds that—

(1) The supplier fails to participate in the activities and pursue the goals of the ESRD network that is designated to encompass the supplier's geographic area; and

(2) This failure does not jeopardize patient health and safety.

(b) *Alternative sanctions.* The alternative sanctions that CMS may apply in the circumstances specified in paragraph (a) of this section include the following:

(1) Denial of payment for services furnished to patients first accepted for care after the effective date of the sanction as specified in the sanction notice.

(2) Reduction of payments, for all ESRD services furnished by the supplier, by 20 percent for each 30-day period after the effective date of the sanction.

(3) Withholding of all payments, without interest, for all ESRD services furnished by the supplier to Medicare beneficiaries.

(c) *Duration of alternative sanction.* An alternative sanction remains in effect until CMS finds that the supplier is in substantial compliance with the requirement to cooperate in the network plans and goals, or terminates coverage of the supplier's services for lack of compliance.

§ 488.608 Notice of alternative sanction and appeal rights: Termination of coverage.

(a) *Notice of alternative sanction.* CMS gives the supplier and the general public notice of the alternative sanction and of the effective date of the sanction. The effective date of the alternative sanction is at least 30 days after the date of the notice.

(b) *Appeal rights.* Termination of Medicare coverage of a supplier's ESRD services because the supplier no longer meets the conditions for coverage of its services is an initial determination appealable under part 498 of this chapter.

§ 488.610 Notice of appeal rights: Alternative sanctions.

If CMS proposes to apply an alternative sanction specified in § 488.606(b), the following rules apply:

(a) CMS gives the facility notice of the proposed alternative sanction and 15 days in which to request a hearing.

(b) If the facility requests a hearing, CMS provides an informal hearing by a CMS official who was not involved in making the appealed decision.

(c) During the informal hearing, the facility—

(1) May be represented by counsel;

(2) Has access to the information on which the allegation was based; and

(3) May present, orally or in writing, evidence and documentation to refute the finding of failure to participate in network activities and pursue network goals.

(d) If the written decision of the informal hearing supports application of the alternative sanction, CMS provides the facility and the public, at least 30 days before the effective date of the alternative sanction, a written notice that specifies the effective date and the reasons for the alternative sanction.

■ 25. A new part 494 is added to read as follows:

PART 494—CONDITIONS FOR COVERAGE FOR END–STAGE RENAL DISEASE FACILITIES

Subpart A—General Provisions

Sec.
494.1 Basis and scope.
494.10 Definitions.
494.20 Condition: Compliance with Federal, State, and local laws and regulations.

Subpart B—Patient Safety

494.30 Condition: Infection control.
494.40 Condition: Water and dialysate quality.
494.50 Condition: Reuse of hemodialyzers and bloodlines.
494.60 Condition: Physical environment.

Subpart C—Patient Care

494.70 Condition: Patient rights.
494.80 Condition: Patient assessment.
494.90 Condition: Patient plan of care.
494.100 Condition: Care at home.
494.110 Condition: Quality assessment and performance improvement.
494.120 Condition: Special purpose renal dialysis facilities.
494.130 Condition: Laboratory services.

Subpart D—Administration

494.140 Condition: Personnel qualifications.
494.150 Condition: Responsibilities of the Medical director.
494.160 [Reserved]
494.170 Condition: Medical records.
494.180 Condition: Governance.

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. l302 and l395hh).

Subpart A—General Provisions

§ 494.1 Basis and scope.

(a) *Statutory basis.* This part is based on the following provisions:

(1) Section 299I of the Social Security Amendments of 1972 (Pub. L. 92–603), which extended Medicare coverage to insured individuals, their spouses, and their dependent children with ESRD who require dialysis or transplantation.

(2) Section 1861(e)(9) of the Act, which requires hospitals to meet such other requirements as the Secretary finds necessary in the interest of health and safety of individuals who are furnished services in the institution.

(3) Section 1861(s)(2)(F) of the Act, which describes ''medical and other health services'' covered under Medicare to include home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies.

(4) Section 1862(a) of the Act, which specifies exclusions from coverage.

(5) Section 1881 of the Act, which authorizes Medicare coverage and payment for the treatment of ESRD in approved facilities, including institutional dialysis services, transplantation services, self-care home dialysis services, and the administration of erythropoiesis-stimulating agent(s).

(6) Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113), which requires Federal agencies to use technical standards that are developed or adopted by voluntary consensus standards bodies, unless their use would be inconsistent with applicable law or otherwise impractical.

(b) *Scope.* The provisions of this part establish the conditions for coverage of services under Medicare and are the basis for survey activities for the purpose of determining whether an ESRD facility's services may be covered.

§ 494.10 Definitions.

As used in this part—

Dialysis facility means an entity that provides outpatient maintenance dialysis services, or home dialysis training and support services, or both. A dialysis facility may be an independent or hospital-based unit (as described in § 413.174(b) and (c) of this chapter) that includes a self-care dialysis unit that furnishes only self-dialysis services.

Discharge means the termination of patient care services by a dialysis facility or the patient voluntarily terminating dialysis when he or she no longer wants to be dialyzed by that facility.

Furnishes directly means the ESRD facility provides the service through its own staff and employees or through individuals who are under direct contract to furnish these services personally for the facility.

Home dialysis means dialysis performed at home by an ESRD patient or caregiver who has completed an appropriate course of training as described in § 494.100(a) of this part.

Self-dialysis means dialysis performed with little or no professional assistance by an ESRD patient or caregiver who has completed an appropriate course of training as specified in § 494.100(a) of this part.

Transfer means a temporary or permanent move of a patient from one dialysis facility to another that requires a transmission of the patient's medical record to the facility receiving the patient.

§ 494.20 Condition: Compliance with Federal, State, and local laws and regulations.

The facility and its staff must operate and furnish services in compliance with applicable Federal, State, and local laws and regulations pertaining to licensure and any other relevant health and safety requirements.

Subpart B—Patient Safety

§ 494.30 Condition: Infection control.

The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.

(a) *Standard: Procedures for infection control.* The facility must demonstrate that it follows standard infection control precautions by implementing—

(1)(i) The recommendations (with the exception of screening for hepatitis C), found in ''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients,'' developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html.* The recommendation found under section header ''HBV-Infected Patients'', found on pages 27 and 28 of RR05 (''Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients''), concerning isolation rooms, must be complied with by February 9, 2009.

(ii) When dialysis isolation rooms as required by (a)(1)(i) are available locally that sufficiently serve the needs of patients in the geographic area, a new dialysis facility may request a waiver of such requirement. Isolation room waivers may be granted at the discretion of, and subject to, additional qualifications as may be deemed necessary by the Secretary.

(2) The ''Guidelines for the Prevention of Intravascular Catheter-Related Infections'' entitled ''Recommendations for Placement of Intravascular Catheters in Adults and Children'' parts I–IV; and ''Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters, in Adult and Pediatric Patients,'' Morbidity and Mortality Weekly Report, volume 51 number RR–10, pages 16 through 18, August 9, 2002. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html.*

(3) Patient isolation procedures to minimize the spread of infectious agents and communicable diseases; and

(4) Maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the—

(i) Handling, storage, and disposal of potentially infectious waste; and

(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.

(b) *Standard: Oversight.* The facility must—

(1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit;

(2) Ensure that clinical staff demonstrate compliance with current

aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and

(3) Require all clinical staff to report infection control issues to the dialysis facility's medical director (see § 494.150 of this part) and the quality improvement committee.

(c) *Standard: Reporting.* The facility must report incidences of communicable diseases as required by Federal, State, and local regulations.

§ 494.40 Condition: Water and dialysate quality.

The facility must be able to demonstrate the following:

(a) *Standard: Water purity.* Water and equipment used for dialysis meets the water and dialysate quality standards and equipment requirements found in the Association for the Advancement of Medical Instrumentation (AAMI) publication, ''Dialysate for hemodialysis,'' ANSI/AAMI RD52: 2004. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html.* Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201–4598.

(b) *Standard: Chlorine/chloramines.*

(1) The water treatment system must include a component or carbon tank which removes chlorine/chloramine along with a backup component or second carbon tank in series for chlorine/chloramine removal;

(2) (i) If the test results from the port of the initial component or carbon tank referred to in section 6.2.5 of AAMI RD52:2004 are greater than 0.5 mg/L for free chlorine or 0.1 mg/L for chloramines, or equal to or greater than 0.1 mg/L of total chlorine, then the second component or carbon tank which removes chlorine/chloramine must be tested;

(ii) If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (b)(2)(i) of this section the facility must—

(A) Immediately take corrective action to bring chlorine or chloramine levels into compliance with paragraph (b)(2)(i) of this section and confirm through testing that the corrective action has been effective, or terminate dialysis treatment to protect patients from exposure to chlorine/chloramine;

(B) Only allow use of purified water in a holding tank, if appropriate, and if testing shows water chlorine or chloramine levels that are in compliance with paragraph (b)(2)(i) of this section; and

(C) Immediately notify the medical director; and

(D) Take corrective action to ensure ongoing compliance with acceptable chlorine and chloramine levels as described in paragraph (b)(2)(i) of this section.

(c) *Standard: Corrective action plan.* Water testing results including, but not limited to, chemical, microbial, and endotoxin levels which meet AAMI action levels or deviate from the AAMI standards must be addressed with a corrective action plan that ensures patient safety.

(d) *Standard: Adverse events.* A dialysis facility must maintain active surveillance of patient reactions during and following dialysis. When clinically indicated (for example, after adverse patient reactions) the facility must—

(1) Obtain blood and dialysate cultures and endotoxin levels;

(2) Evaluate the water purification system; and

(3) Take corrective action.

(e) *Standard: In-center use of preconfigured hemodialysis systems.* When using a preconfigured, FDA-approved hemodialysis system designed, tested and validated to yield AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate, the system's FDA-approved labeling must be adhered to for machine use and monitoring of the water and dialysate quality. The facility must meet all AAMI RD52:2004 requirements for water and dialysate. Moreover, the facility must perform bacteriological and endotoxin testing on a quarterly, or more frequent basis, as needed, to ensure that the water and dialysate are within AAMI limits.

§ 494.50 Condition: Reuse of hemodialyzers and bloodlines.

(a) *Standard: General requirements for the reuse of hemodialyzers and bloodlines.* Certain hemodialyzers and bloodlines—

(1) May be reused for certain patients with the exception of Hepatitis B positive patients;

(2) Must be reused only for the same patient; and

(3) Must be labeled for multiple reuse in accordance with the premarket notification provisions of section 510(k) of the Food, Drug, and Cosmetics Act and 21 CFR 876.5860.

(b) *Standard: Reprocessing requirements for the reuse of hemodialyzers and bloodlines.* A dialysis facility that reuses hemodialyzers and bloodlines must adhere to the following reprocessing guidelines:

(1) Meet the requirements of AAMI published in ''Reuse of Hemodialyzers,'' third edition, ANSI/AAMI RD47:2002 and RD47:2002/A1:2003. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html.* Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201–4598.

(2) Reprocess hemodialyzers and bloodlines—

(i) By following the manufacturer's recommendations; or

(ii) Using an alternate method and maintaining documented evidence that the method is safe and effective.

(3) Not expose hemodialyzers to more than one chemical germicide, other than bleach (used as a cleaner in this application), during the life of the dialyzer. All hemodialyzers must be discarded before a different chemical germicide is used in the facility.

(c) *Standard: Monitoring, evaluation, and reporting requirements for the reuse of hemodialyzers and bloodlines.* In addition to the requirements for hemodialyzer and bloodline reuse specified in paragraphs (a) and (b) of this section, the dialysis facility must adhere to the following:

(1) Monitor patient reactions during and following dialysis.

(2) When clinically indicated (for example, after adverse patient reactions), the facility must—

(i) Obtain blood and dialysate cultures and endotoxin levels; and

(ii) Undertake evaluation of its dialyzer reprocessing and water purification system. When this

evaluation suggests a cluster of adverse patient reactions is associated with hemodialyzer reuse, the facility must suspend reuse of hemodialyzers until it is satisfied the problem has been corrected.

(iii) Report the adverse outcomes to the FDA and other Federal, State or local government agencies as required by law.

§ 494.60 Condition: Physical environment.

The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.

(a) *Standard: Building.* The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff, and the public.

(b) *Standard: Equipment maintenance.* The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.

(c) *Standard: Patient care environment.*

(1) The space for treating each patient must be sufficient to provide needed care and services, prevent cross-contamination, and to accommodate medical emergency equipment and staff.

(2) The dialysis facility must:

(i) Maintain a comfortable temperature within the facility; and

(ii) Make reasonable accommodations for the patients who are not comfortable at this temperature.

(3) The dialysis facility must make accommodations to provide for patient privacy when patients are examined or treated and body exposure is required.

(4) Patients must be in view of staff during hemodialysis treatment to ensure patient safety (video surveillance will not meet this requirement).

(d) *Standard: Emergency preparedness.* The dialysis facility must implement processes and procedures to manage medical and nonmedical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.

(1) *Emergency preparedness of staff.* The dialysis facility must provide appropriate training and orientation in emergency preparedness to the staff. Staff training must be provided and evaluated at least annually and include the following:

(i) Ensuring that staff can demonstrate a knowledge of emergency procedures, including informing patients of—

(A) What to do;

(B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated;

(C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and

(D) How to disconnect themselves from the dialysis machine if an emergency occurs.

(ii) Ensuring that, at a minimum, patient care staff maintain current CPR certification; and

(iii) Ensuring that nursing staff are properly trained in the use of emergency equipment and emergency drugs.

(2) *Emergency preparedness patient training.* The facility must provide appropriate orientation and training to patients, including the areas specified in paragraph (d)(1)(i) of this section.

(3) *Emergency equipment.* Emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available.

(4) *Emergency plans.* The facility must—

(i) Have a plan to obtain emergency medical system assistance when needed;

(ii) Evaluate at least annually the effectiveness of emergency and disaster plans and update them as necessary; and

(iii) Contact its local disaster management agency at least annually to ensure that such agency is aware of dialysis facility needs in the event of an emergency.

(e) *Standard: Fire safety.*

(1) Except as provided in paragraph (e)(2) of this section, by February 9, 2009. The dialysis facility must comply with applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference at § 403.744(a)(1)(i) of this chapter).

(2) Notwithstanding paragraph (e)(1) of this section, dialysis facilities participating in Medicare as of October 14, 2008. Utilizing non-sprinklered buildings on such date may continue to use such facilities if such buildings were constructed before January 1, 2008 and State law so permits.

(3) If CMS finds that a fire and safety code imposed by the facility's State law adequately protects a dialysis facility's patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the Life Safety Code.

(4) After consideration of State survey agency recommendations, CMS may waive, for individual dialysis facilities and for appropriate periods, specific provisions of the Life Safety Code, if the following requirements are met:

(i) The waiver would not adversely affect the health and safety of the dialysis facility's patients; and

(ii) Rigid application of specific provisions of the Life Safety Code would result in an unreasonable hardship for the dialysis facility.

Subpart C—Patient Care

§ 494.70 Condition: Patients' rights.

The dialysis facility must inform patients (or their representatives) of their rights (including their privacy rights) and responsibilities when they begin their treatment and must protect and provide for the exercise of those rights.

(a) *Standard: Patients' rights.* The patient has the right to—

(1) Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with ESRD;

(2) Receive all information in a way that he or she can understand;

(3) Privacy and confidentiality in all aspects of treatment;

(4) Privacy and confidentiality in personal medical records;

(5) Be informed about and participate, if desired, in all aspects of his or her care, and be informed of the right to refuse treatment, to discontinue treatment, and to refuse to participate in experimental research;

(6) Be informed about his or her right to execute advance directives, and the facility's policy regarding advance directives;

(7) Be informed about all treatment modalities and settings, including but not limited to, transplantation, home dialysis modalities (home hemodialysis, intermittent peritoneal dialysis, continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis),and in-facility hemodialysis. The patient has the right to receive resource information for dialysis

modalities not offered by the facility, including information about alternative scheduling options for working patients;

(8) Be informed of facility policies regarding patient care, including, but not limited to, isolation of patients;

(9) Be informed of facility policies regarding the reuse of dialysis supplies, including hemodialyzers;

(10) Be informed by the physician, nurse practitioner, clinical nurse specialist, or physician's assistant treating the patient for ESRD of his or her own medical status as documented in the patient's medical record, unless the medical record contains a documented contraindication;

(11) Be informed of services available in the facility and charges for services not covered under Medicare;

(12) Receive the necessary services outlined in the patient plan of care described in § 494.90;

(13) Be informed of the rules and expectations of the facility regarding patient conduct and responsibilities;

(14) Be informed of the facility's internal grievance process;

(15) Be informed of external grievance mechanisms and processes, including how to contact the ESRD Network and the State survey agency;

(16) Be informed of his or her right to file internal grievances or external grievances or both without reprisal or denial of services; and

(17) Be informed that he or she may file internal or external grievances, personally, anonymously or through a representative of the patient's choosing.

(b) *Standard: Right to be informed regarding the facility's discharge and transfer policies.* The patient has the right to—

(1) Be informed of the facility's policies for transfer, routine or involuntary discharge, and discontinuation of services to patients; and

(2) Receive written notice 30 days in advance of an involuntary discharge, after the facility follows the involuntary discharge procedures described in § 494.180(f)(4). In the case of immediate threats to the health and safety of others, an abbreviated discharge procedure may be allowed.

(c) *Standard: Posting of rights.* The dialysis facility must prominently display a copy of the patient's rights in the facility, including the current State agency and ESRD network mailing addresses and telephone complaint numbers, where it can be easily seen and read by patients.

§ 494.80 Condition: Patient assessment.

The facility's interdisciplinary team consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian. The interdisciplinary team is responsible for providing each patient with an individualized and comprehensive assessment of his or her needs. The comprehensive assessment must be used to develop the patient's treatment plan and expectations for care.

(a) *Standard: Assessment criteria.* The patient's comprehensive assessment must include, but is not limited to, the following:

(1) Evaluation of current health status and medical condition, including co-morbid conditions.

(2) Evaluation of the appropriateness of the dialysis prescription, blood pressure, and fluid management needs.

(3) Laboratory profile, immunization history, and medication history.

(4) Evaluation of factors associated with anemia, such as hematocrit, hemoglobin, iron stores, and potential treatment plans for anemia, including administration of erythropoiesis-stimulating agent(s).

(5) Evaluation of factors associated with renal bone disease.

(6) Evaluation of nutritional status by a dietitian.

(7) Evaluation of psychosocial needs by a social worker.

(8) Evaluation of dialysis access type and maintenance (for example, arteriovenous fistulas, arteriovenous grafts, and peritoneal catheters).

(9) Evaluation of the patient's abilities, interests, preferences, and goals, including the desired level of participation in the dialysis care process; the preferred modality (hemodialysis or peritoneal dialysis), and setting, (for example, home dialysis), and the patient's expectations for care outcomes.

(10) Evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s). If the patient is not suitable for transplantation referral, the basis for nonreferral must be documented in the patient's medical record.

(11) Evaluation of family and other support systems.

(12) Evaluation of current patient physical activity level.

(13) Evaluation for referral to vocational and physical rehabilitation services.

(b) *Standard: Frequency of assessment for patients admitted to the dialysis facility.* (1) An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.

(2) A follow up comprehensive reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care specified in § 494.90.

(c) *Standard: Assessment of treatment prescription.* The adequacy of the patient's dialysis prescription, as described in § 494.90(a)(1), must be assessed on an ongoing basis as follows:

(1) *Hemodialysis patients.* At least monthly by calculating delivered Kt/V or an equivalent measure.

(2) *Peritoneal dialysis patients.* At least every 4 months by calculating delivered weekly Kt/V or an equivalent measure.

(d) *Standard: Patient reassessment.* In accordance with the standards specified in paragraphs (a)(1) through (a)(13) of this section, a comprehensive reassessment of each patient and a revision of the plan of care must be conducted—

(1) At least annually for stable patients; and

(2) At least monthly for unstable patients including, but not limited to, patients with the following:

(i) Extended or frequent hospitalizations;

(ii) Marked deterioration in health status;

(iii) Significant change in psychosocial needs; or

(iv) Concurrent poor nutritional status, unmanaged anemia, and inadequate dialysis.

§ 494.90 Condition: Patient plan of care.

The interdisciplinary team as defined at § 494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards.

(a) *Standard: Development of patient plan of care.* The interdisciplinary team must develop a plan of care for each patient. The plan of care must address, but not be limited to, the following:

(1) *Dose of dialysis.* The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; and achieve

and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.

(2) *Nutritional status.* The interdisciplinary team must provide the necessary care and counseling services to achieve and sustain an effective nutritional status. A patient's albumin level and body weight must be measured at least monthly. Additional evidence-based professionally-accepted clinical nutrition indicators may be monitored, as appropriate.

(3) *Mineral metabolism.* Provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease.

(4) *Anemia.* The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level. The patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs. For a home dialysis patient, the facility must evaluate whether the patient can safely, aseptically, and effectively administer erythropoiesis-stimulating agents and store this medication under refrigeration if necessary. The patient's response to erythropoiesis-stimulating agent(s), including blood pressure levels and utilization of iron stores, must be monitored on a routine basis.

(5) *Vascular access.* The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement. The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis.

(6) *Psychosocial status.* The interdisciplinary team must provide the necessary monitoring and social work interventions. These include counseling services and referrals for other social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis.

(7) *Modality.* (i) *Home dialysis.* The interdisciplinary team must identify a plan for the patient's home dialysis or explain why the patient is not a candidate for home dialysis.

(ii) *Transplantation status.* When the patient is a transplant referral candidate, the interdisciplinary team must develop plans for pursuing transplantation. The patient's plan of care must include documentation of the—

(A) Plan for transplantation, if the patient accepts the transplantation referral;

(B) Patient's decision, if the patient is a transplantation referral candidate but declines the transplantation referral; or

(C) Reason(s) for the patient's nonreferral as a transplantation candidate as documented in accordance with § 494.80(a)(10).

(8) *Rehabilitation status.* The interdisciplinary team must assist the patient in achieving and sustaining an appropriate level of productive activity, as desired by the patient, including the educational needs of pediatric patients (patients under the age of 18 years), and make rehabilitation and vocational rehabilitation referrals as appropriate.

(b) *Standard: Implementation of the patient plan of care.*

(1) The patient's plan of care must—

(i) Be completed by the interdisciplinary team, including the patient if the patient desires; and

(ii) Be signed by team members, including the patient or the patient's designee; or, if the patient chooses not to sign the plan of care, this choice must be documented on the plan of care, along with the reason the signature was not provided.

(2) Implementation of the initial plan of care must begin within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. Implementation of monthly or annual updates of the plan of care must be performed within 15 days of the completion of the additional patient assessments specified in § 494.80(d).

(3) If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must—

(i) Adjust the plan of care to reflect the patient's current condition;

(ii) Document in the record the reasons why the patient was unable to achieve the goals; and

(iii) Implement plan of care changes to address the issues identified in paragraph (b)(3)(ii) of this section.

(4) The dialysis facility must ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically while the hemodialysis patient is receiving in-facility dialysis.

(c) *Standard: Transplantation referral tracking.* The interdisciplinary team must—

(1) Track the results of each kidney transplant center referral;

(2) Monitor the status of any facility patients who are on the transplant wait list; and

(3) Communicate with the transplant center regarding patient transplant status at least annually, and when there is a change in transplant candidate status.

(d) *Standard: Patient education and training.* The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, in aspects of the dialysis experience, dialysis management, infection prevention and personal care, home dialysis and self-care, quality of life, rehabilitation, transplantation, and the benefits and risks of various vascular access types.

§ 494.100 Condition: Care at home.

A dialysis facility that is certified to provide services to home patients must ensure through its interdisciplinary team, that home dialysis services are at least equivalent to those provided to in-facility patients and meet all applicable conditions of this part.

(a) *Standard: Training.* The interdisciplinary team must oversee training of the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in § 494.10) and when the home dialysis caregiver or home dialysis modality changes. The training must—

(1) Be provided by a dialysis facility that is approved to provide home dialysis services;

(2) Be conducted by a registered nurse who meets the requirements of § 494.140(b)(2); and

(3) Be conducted for each home dialysis patient and address the specific needs of the patient, in the following areas:

(i) The nature and management of ESRD.

(ii) The full range of techniques associated with the treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's

prescription of Kt/V or URR, and effective administration of erythropoiesis-stimulating agent(s) (if prescribed) to achieve and maintain a target level hemoglobin or hematocrit as written in patient's plan of care.

(iii) How to detect, report, and manage potential dialysis complications, including water treatment problems.

(iv) Availability of support resources and how to access and use resources.

(v) How to self-monitor health status and record and report health status information.

(vi) How to handle medical and non-medical emergencies.

(vii) Infection control precautions.

(viii) Proper waste storage and disposal procedures.

(b) *Standard: Home dialysis monitoring.* The dialysis facility must—

(1) Document in the medical record that the patient, the caregiver, or both received and demonstrated adequate comprehension of the training;

(2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and

(3) Maintain this information in the patient's medical record.

(c) *Standard: Support services.*

(1) A home dialysis facility must furnish (either directly, under agreement, or by arrangement with another ESRD facility) home dialysis support services regardless of whether dialysis supplies are provided by the dialysis facility or a durable medical equipment company. Services include, but are not limited to, the following:

(i) Periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel in accordance with the patient's plan of care.

(ii) Coordination of the home patient's care by a member of the dialysis facility's interdisciplinary team.

(iii) Development and periodic review of the patient's individualized comprehensive plan of care that specifies the services necessary to address the patient's needs and meets the measurable and expected outcomes as specified in § 494.90 of this part.

(iv) Patient consultation with members of the interdisciplinary team, as needed.

(v) Monitoring of the quality of water and dialysate used by home hemodialysis patients including conducting an onsite evaluation and testing of the water and dialysate system in accordance with—

(A) The recommendations specified in the manufacturers' instructions; and

(B) The system's FDA-approved labeling for preconfigured systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate. The facility must meet testing and other requirements of AAMI RD52:2004. In addition, bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits.

(C) The dialysis facility must correct any water and dialysate quality problem for the home hemodialysis patient, and if necessary, arrange for backup dialysis until the problem is corrected if—

(*1*) Analysis of the water and dialysate quality indicates contamination; or

(*2*) The home hemodialysis patient demonstrates clinical symptoms associated with water and dialysate contamination.

(vi) Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician.

(vii) Identifying a plan and arranging for emergency back-up dialysis services when needed.

(2) The dialysis facility must maintain a recordkeeping system that ensures continuity of care and patient privacy. This includes items and services furnished by durable medical equipment (DME) suppliers referred to in § 414.330(a)(2) of this chapter.

§ 494.110 Condition: Quality assessment and performance improvement.

The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team. The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.

(a) *Standard: Program scope.*

(1) The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.

(2) The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves. The program must include, but not be limited to, the following:

(i) Adequacy of dialysis.

(ii) Nutritional status.

(iii) Mineral metabolism and renal bone disease.

(iv) Anemia management.

(v) Vascular access.

(vi) Medical injuries and medical errors identification.

(vii) Hemodialyzer reuse program, if the facility reuses hemodialyzers.

(viii) Patient satisfaction and grievances.

(ix) Infection control; with respect to this component the facility must—

(A) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence;

(B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and

(C) Take actions to reduce future incidents.

(b) *Standard: Monitoring performance improvement.* The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time.

(c) *Standard: Prioritizing improvement activities.* The dialysis facility must set priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes or patient safety. The facility must immediately correct any identified problems that threaten the health and safety of patients.

§ 494.120 Condition: Special purpose renal dialysis facilities.

A special purpose renal dialysis facility is approved to furnish dialysis on a short-term basis at special locations. Special purpose dialysis facilities are divided into two categories: vacation camps (locations that serve ESRD patients while the patients are in a temporary residence) and facilities established to serve ESRD patients under emergency circumstances.

(a) *Standard: Approval period.* The period of approval for a special purpose

renal dialysis facility may not exceed 8 months in any 12-month period.

(b) *Standard: Service limitation.* Special purpose renal dialysis facilities are limited to areas in which there are limited dialysis resources or access-to-care problems due to an emergency circumstance. A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic locality served by the facility.

(c) *Standard: Scope of requirements.*

(1) *Scope of requirements for a vacation camp.* A vacation camp that provides dialysis services must be operated under the direction of a certified renal dialysis facility that assumes full responsibility for the care provided to patients. A special purpose renal dialysis facility established as a vacation camp must comply with the following conditions for coverage—

(i) Infection control at § 494.30;

(ii) Water and dialysate quality at § 494.40 (except as provided in paragraph (c)(1)(viii) of this section);

(iii) Reuse of hemodialyzers at § 494.50 (if reuse is performed);

(iv) Patients' rights and posting of patients' rights at § 494.70(a) and § 494.70(c);

(v) Laboratory services at § 494.130;

(vi) Medical director responsibilities for staff education and patient care policies and procedures at § 494.150(c) and § 494.150(d);

(vii) Medical records at § 494.170; and

(viii) When portable home water treatment systems are used in place of a central water treatment system, the facility may adhere to § 494.100(c)(1)(v) (home monitoring of water quality), in place of § 494.40 (water quality).

(2) *Scope of requirements for an emergency circumstance facility.* A special purpose renal dialysis facility set up due to emergency circumstances may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic areas served by the facility. These types of special purpose dialysis facilities must comply with paragraph (c)(1) of this section and addition to complying with the following conditions:

(i) Section 494.20 (compliance with Federal, State, and local laws and regulations).

(ii) Section 494.60 (physical environment).

(iii) Section 494.70(a) through section 494.70(c) (patient rights).

(iv) Section 494.140 (personnel qualifications).

(v) Section 494.150 (medical director).

(vi) Section 494.180 (governance).

(d) *Standard: Physician contact.* The facility must contact the patient's physician, if possible, prior to initiating dialysis in the special purpose renal dialysis facility, to discuss the patient's current condition to assure care provided in the special purpose renal dialysis facility is consistent with the patient plan of care (described in § 494.90).

(e) *Standard: Documentation.* All patient care provided in the special purpose facility is documented and forwarded to the patient's usual dialysis facility, if possible, within 30 days of the last scheduled treatment in the special purpose renal dialysis facility.

§ 494.130 Condition: Laboratory services.

The dialysis facility must provide, or make available, laboratory services (other than tissue pathology and histocompatibility) to meet the needs of the ESRD patient. Any laboratory services, including tissue pathology and histocompatibility must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter.

Subpart D—Administration

§ 494.140 Condition: Personnel qualifications.

All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed. The dialysis facility's staff (employee or contractor) must meet the personnel qualifications and demonstrated competencies necessary to serve collectively the comprehensive needs of the patients. The dialysis facility's staff must have the ability to demonstrate and sustain the skills needed to perform the specific duties of their positions.

(a) *Standard: Medical director.*

(l) The medical director must be a board-certified physician in internal medicine or pediatrics by a professional board who has completed a board-approved training program in nephrology and has at least 12-months of experience providing care to patients receiving dialysis.

(2) If a physician, as specified in paragraph (a)(1) of this section, is not available to direct a certified dialysis facility another physician may direct the facility, subject to the approval of the Secretary.

(b) *Standard: Nursing services.*

(1) *Nurse manager.* The facility must have a nurse manager responsible for nursing services in the facility who must—

(i) Be a full time employee of the facility;

(ii) Be a registered nurse; and

(iii) Have at least 12 months of experience in clinical nursing, and an additional 6 months of experience in providing nursing care to patients on maintenance dialysis.

(2) *Self-care and home dialysis training nurse.* The nurse responsible for self-care and/or home care training must—

(i) Be a registered nurse; and

(ii) Have at least 12 months experience in providing nursing care and an additional 3 months of experience in the specific modality for which the nurse will provide self-care training.

(3) *Charge nurse.* The charge nurse responsible for each shift must—

(i) Be a registered nurse, a licensed practical nurse, or vocational nurse who meets the practice requirements in the State in which he or she is employed;

(ii) Have at least 12 months experience in providing nursing care, including 3 months of experience in providing nursing care to patients on maintenance dialysis; and

(iii) If such nurse is a licensed practical nurse or licensed vocational nurse, work under the supervision of a registered nurse in accordance with state nursing practice act provisions.

(4) *Staff nurse.* Each nurse who provides care and treatment to patients must be either a registered nurse or a practical nurse who meets the practice requirements in the State in which he or she is employed.

(c) *Standard: Dietitian.* The facility must have a dietitian who must—

(1) Be a registered dietitian with the Commission on Dietetic Registration; and

(2) Have a minimum of 1 year professional work experience in clinical nutrition as a registered dietitian.

(d) *Standard: Social worker.* The facility must have a social worker who—

(1) Holds a master's degree in social work with a specialization in clinical practice from a school of social work accredited by the Council on Social Work Education; or

(2) Has served at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under § 494.140(d)(1).

(e) *Standard: Patient care dialysis technicians.* Patient care dialysis technicians must—

(1) Meet all applicable State requirements for education, training, credentialing, competency, standards of practice, certification, and licensure in the State in which he or she is employed as a dialysis technician; and

(2) Have a high school diploma or equivalency;

(3) Have completed a training program that is approved by the medical director and governing body, under the direction of a registered nurse, focused on the operation of kidney dialysis equipment and machines, providing direct patient care, and communication and interpersonal skills, including patient sensitivity training and care of difficult patients. The training program must include the following subjects:

(i) Principles of dialysis.

(ii) Care of patients with kidney failure, including interpersonal skills.

(iii) Dialysis procedures and documentation, including initiation, proper cannulation techniques, monitoring, and termination of dialysis.

(iv) Possible complications of dialysis.

(v) Water treatment and dialysate preparation.

(vi) Infection control.

(vii) Safety.

(viii) Dialyzer reprocessing, if applicable.

(4) Be certified under a State certification program or a national commercially available certification program, as follows—

(i) For newly employed patient care technicians, within 18 months of being hired as a dialysis patient care technician; or

(ii) For patient care technicians employed on October 14, 2008, within 18 months after such date.

(f) *Standard: Water treatment system technicians.* Technicians who perform monitoring and testing of the water treatment system must complete a training program that has been approved by the medical director and the governing body.

§ 494.150 Condition: Responsibilities of the medical director.

The dialysis facility must have a medical director who meets the qualifications of § 494.140(a) to be responsible for the delivery of patient care and outcomes in the facility. The medical director is accountable to the governing body for the quality of medical care provided to patients. Medical director responsibilities include, but are not limited to, the following:

(a) Quality assessment and performance improvement program.

(b) Staff education, training, and performance.

(c) Policies and procedures. The medical director must—

(1) Participate in the development, periodic review and approval of a ''patient care policies and procedures manual'' for the facility; and

(2) Ensure that—

(i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; and

(ii) The interdisciplinary team adheres to the discharge and transfer policies and procedures specified in § 494.180(f).

§ 494.160 [Reserved]

§ 494.170 Condition: Medical records.

The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.

(a) *Standard: Protection of the patient's record.* The dialysis facility must—

(1) Safeguard patient records against loss, destruction, or unauthorized use; and

(2) Keep confidential all information contained in the patient's record, except when release is authorized pursuant to one of the following:

(i) The transfer of the patient to another facility.

(ii) Certain exceptions provided for in the law.

(iii) Provisions allowed under third party payment contracts.

(iv) Approval by the patient.

(v) Inspection by authorized agents of the Secretary, as required for the administration of the dialysis program.

(3) Obtaining written authorization from the patient or legal representative before releasing information that is not authorized by law.

(b) *Standard: Completion of patient records and centralization of clinical information.*

(1) Current medical records and those of discharged patients must be completed promptly.

(2) All clinical information pertaining to a patient must be centralized in the patient's record, including whether the patient has executed an advance directive. These records must be maintained in a manner such that each member of the interdisciplinary team has access to current information regarding the patient's condition and prescribed treatment.

(3) The dialysis facility must complete, maintain, and monitor home care patients' records, including the records of patients who receive supplies and equipment from a durable medical equipment supplier.

(c) *Standard: Record retention and preservation.* In accordance with 45 CFR § 164.530(j)(2), all patient records must be retained for 6 years from the date of the patient's discharge, transfer, or death.

(d) *Standard: Transfer of patient record information.* When a dialysis patient is transferred, the dialysis facility releasing the patient must send all requested medical record information to the receiving facility within 1 working day of the transfer.

§ 494.180 Condition: Governance.

The ESRD facility is under the control of an identifiable governing body, or designated person(s) with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility.

(a) *Standard: Designating a chief executive officer or administrator.* The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, including, but not limited to—

(1) Staff appointments;

(2) Fiscal operations;

(3) The relationship with the ESRD networks; and

(4) Allocation of necessary staff and other resources for the facility's quality assessment and performance improvement program as described in § 494.110.

(b) *Standard: Adequate number of qualified and trained staff.* The governing body or designated person responsible must ensure that—

(1) An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients; and the registered nurse, social worker and dietitian members of the interdisciplinary team are available to meet patient clinical needs;

(2) A registered nurse, who is responsible for the nursing care provided, is present in the facility at all times that in-center dialysis patients are being treated;

(3) All staff, including the medical director, have appropriate orientation to the facility and their work responsibilities; and

(4) All employees have an opportunity for continuing education and related development activities.

(c) *Standard: Medical staff appointments.* The governing body—

(1) Is responsible for all medical staff appointments and credentialing in accordance with State law, including attending physicians, physician assistants, nurse practitioners, and clinical nurse specialists; and

(2) Ensures that all medical staff who provide care in the facility are informed of all facility policies and procedures, including the facility's quality assessment and performance improvement program specified in § 494.110.

(3) Communicates expectations to the medical staff regarding staff participation in improving the quality of medical care provided to facility patients.

(d) *Standard: Furnishing services.* The governing body is responsible for ensuring that the dialysis facility furnishes services directly on its main premises or on other premises that are contiguous with the main premises and are under the direction of the same professional staff and governing body as the main premises (except for services provided under § 494.100).

(e) *Standard: Internal grievance process.* The facility's internal grievance process must be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services. The grievance process must include:

(1) A clearly explained procedure for the submission of grievances.

(2) Timeframes for reviewing the grievance.

(3) A description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance.

(f) *Standard: Involuntary discharge and transfer policies and procedures.* The governing body must ensure that all staff follow the facility's patient discharge and transfer policies and procedures. The medical director ensures that no patient is discharged or transferred from the facility unless—

(1) The patient or payer no longer reimburses the facility for the ordered services;

(2) The facility ceases to operate;

(3) The transfer is necessary for the patient's welfare because the facility can no longer meet the patient's documented medical needs; or

(4) The facility has reassessed the patient and determined that the patient's behavior is disruptive and abusive to the extent that the delivery of care to the patient or the ability of the facility to operate effectively is seriously impaired, in which case the medical director ensures that the patient's interdisciplinary team—

(i) Documents the reassessments, ongoing problem(s), and efforts made to resolve the problem(s), and enters this documentation into the patient's medical record;

(ii) Provides the patient and the local ESRD Network with a 30-day notice of the planned discharge;

(iii) Obtains a written physician's order that must be signed by both the medical director and the patient's attending physician concurring with the patient's discharge or transfer from the facility;

(iv) Contacts another facility, attempts to place the patient there, and documents that effort; and

(v) Notifies the State survey agency of the involuntary transfer or discharge.

(5) In the case of immediate severe threats to the health and safety of others, the facility may utilize an abbreviated involuntary discharge procedure.

(g) *Standard: Emergency coverage.*

(1) The governing body is responsible for ensuring that the dialysis facility provides patients and staff with written instructions for obtaining emergency medical care.

(2) The dialysis facility must have available at the nursing/monitoring station, a roster with the names of physicians to be called for emergencies, when they can be called, and how they can be reached.

(3) The dialysis facility must have an agreement with a hospital that can provide inpatient care, routine and emergency dialysis and other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week. The agreement must:

(i) Ensure that hospital services are available promptly to the dialysis facility's patients when needed.

(ii) Include reasonable assurances that patients from the dialysis facility are accepted and treated in emergencies.

(h) *Standard: Furnishing data and information for ESRD program administration.* Effective February 1, 2009, the dialysis facility must furnish data and information to CMS and at intervals as specified by the Secretary. This information is used in a national ESRD information system and in compilations relevant to program administration, including claims processing and reimbursement, quality improvement, and performance assessment. The data and information must—

(1) Be submitted at the intervals specified by the Secretary;

(2) Be submitted electronically in the format specified by the Secretary;

(3) Include, but not be limited to—

(i) Cost reports;

(ii) ESRD administrative forms;

(iii) Patient survival information; and

(iv) Existing ESRD clinical performance measures, and any future clinical performance standards developed in accordance with a voluntary consensus standards process identified by the Secretary.

(i) *Standard: Relationship with the ESRD network.* The governing body receives and acts upon recommendations from the ESRD network. The dialysis facility must cooperate with the ESRD network designated for its geographic area, in fulfilling the terms of the Network's current statement of work. Each facility must participate in ESRD network activities and pursue network goals.

(j) *Standard: Disclosure of ownership.* In accordance with § 420.200 through § 420.206 of this chapter, the governing body must report ownership interests of 5 percent or more to its State survey agency.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

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Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

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Michael O. Leavitt,

Secretary.

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