

GAO

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MEDICARE

Enhancing Health Care
Quality Assurance

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Messrs. Chairmen and Members of the Subcommittees:

I am pleased to be here today to discuss quality health care for Medicare beneficiaries. As health care cost containment efforts have increased over the past several years, more attention has been paid to ensuring the quality of that care. Corporate purchasers of health care particularly want to identify and correct any problems that might result from restricting patients' choice of providers or from giving providers financial incentives that encourage them to withhold, delay, or limit needed care, or, on the other hand, that encourage them to overtreat. By evaluating both cost and quality, these purchasers believe they can select the plan that provides the best value.

Because of your interest in this subject, you asked us to discuss (1) what the Health Care Financing Administration (HCFA) is doing and plans to do to ensure that Medicare providers furnish quality care in both fee-for-service and managed care delivery systems and (2) experts' views on essential quality assurance components. Our discussion today reflects our past work and an ongoing study for the Subcommittee on Health.¹ To develop this information, we relied on our previous reports, interviews with HCFA program officials, and over 30 structured interviews with experts. We selected these experts to represent a wide range of perspectives: health plans, health care researchers, federal and state agencies, major purchasers of health care, and accrediting agencies. (See app. I for a list of related products and app. II for the experts we interviewed and their affiliations.)

In summary, HCFA has three quality assurance programs. These programs (1) assess whether fee-for-service institutional providers meet certain Medicare conditions of participation; (2) assess whether HMOs meet similar requirements; and (3) review inpatient care and ambulatory surgery furnished under fee-for-service arrangements or by HMO providers. Although these programs represent reasonable approaches, we have reported serious problems with their implementation. Except in a recently initiated pilot program, HCFA has no program that assesses care furnished to Medicare beneficiaries by physicians in their private offices.

Those we interviewed agreed that the federal government, as a purchaser of health care, must continue to play an important role in evaluating the quality of care provided to Medicare beneficiaries. They described an enhanced federal quality assurance strategy as one that (1) builds on existing federal, state, and private efforts; (2) encourages continuous quality improvement; (3) obtains multiple kinds of information about

¹We plan to issue a report to the Subcommittee on Health later this summer that will discuss quality assurance approaches in more detail.

providers--adequacy of basic organizational structures, performance measures, and patient satisfaction--and (4) makes information about providers available to beneficiaries and others in a manner that is useful and understandable. The experts identified enhanced roles that could be played by the federal or state governments and private entities in collecting and evaluating this information, but no consensus emerged on the most appropriate roles.

HCFA is beginning to enhance its quality assurance programs in several ways. These changes include a greater emphasis on continuous quality improvement, performance measurement, and patient satisfaction. Furthermore, HCFA is strengthening its collaboration with the private sector. The changes HCFA is making are ones that will take advantage of successful private sector approaches and are consistent with the ideas expressed by the experts we interviewed. But HCFA faces a challenge in implementing these changes in ways that avoid the kind of implementation problems that have occurred with its past efforts.

BACKGROUND

Widespread professional interest in monitoring the quality of health care services arose after World War II. Attention increased with passage of federal Medicare legislation in 1965 and, in the early 1970s, the Joint Commission on Accreditation of Healthcare Organizations' mandate that hospitals implement an internal quality assurance program to be accredited.

In 1985, the Department of Health and Human Services (HHS) initiated a nationwide program to expand Medicare beneficiaries' use of HMOs paid on a capitated basis.² At that time, federal quality assurance programs were designed to identify HMOs where providers may have withheld or denied treatment because of the financial incentives that result from capitation. In addition, as managed care options became more prevalent, states began to regulate them, and health care purchasers, such as employers, began to develop a greater interest in quality assurance as well.

Quality health care has been difficult for experts to define and measure, but most agree that clinical quality would include

- appropriateness--providers giving the right care at the right time,
- technical excellence--furnishing the care in the correct way,
- accessibility--patients being able to obtain care when needed, and
- acceptability--patients being satisfied with the care.

²Capitation requires an individual provider or managed care plan to furnish all necessary medical care in return for a predetermined monthly payment for each beneficiary enrolled.

These attributes would be measured using indicators that represent (1) structure of care--resources and organizational arrangements in place to deliver care; (2) process of care--physician and other provider activities carried out to deliver the care; and (3) outcomes of care--the results of physician and provider activities. Survey, certification, and accreditation activities generally look at structure measures; performance measurement systems focus on process and outcome measures.

Ensuring quality of care involves reaching consensus about standards and developing reliable and valid structure, process, and outcome measures. Then approaches must be developed to make it more likely that health care will be furnished in ways that will meet the standards. Approaches to ensuring quality have changed in recent years. Under the more traditional quality assurance approach, reviewers focus on a search for individual practitioners or "bad apples" who do not meet minimal acceptable standards of care. But this approach has shortcomings: it creates an adversarial relationship between the reviewers and those being reviewed, and it targets only those providing substandard care. Little attention is paid to those who may be providing care that is better than substandard but less than excellent. The alternative approach, continuous quality improvement, strives to make everyone's performance better, regardless of prior performance. At the same time, this approach acknowledges the importance of taking action, if necessary, against providers with consistently unacceptable performance. Although most health care providers and experts support this new approach, implementing such a dramatic change will take time.

In the private sector, large corporate purchasers of health care use a variety of tools to determine the health care providers with which they will contract. As a baseline, they look for individual providers who are licensed by the state or who are certified by their respective organizations, if state licensure is not required. Institutional providers are expected to hold a state license as well or be accredited by a major accrediting organization. But these structural measures--licensure, certification, and accreditation--have not proven to be fail-safe mechanisms for ensuring quality. As a result, the private sector has taken the lead in developing ways to compare providers using measures of performance, including the results of care provided and employees' satisfaction with their care.

HCFA'S CURRENT QUALITY ASSURANCE STRATEGIES

HCFA has three activities directed specifically toward ensuring that clinical quality standards are met.³ The oldest of these, the Medicare Provider Certification Program, has existed since Medicare's inception in 1965. It targets fee-for-service institutional providers of health care. A second certification program, the Federal Qualification Program for HMOs, determines whether HMOs meet similar preestablished standards. The third, the Medicare Peer Review Organization (PRO) Program has existed in some form since 1972. PROs review care furnished in hospitals and HMOs, although they are not precluded from reviewing care provided in other settings.

The Medicare Provider Certification Program

HCFA's fee-for-service provider certification program is oriented toward institutional providers, such as hospitals, skilled nursing facilities, and home health agencies. With respect to individual providers, such as physicians, HCFA accepts a valid state license as a sufficient basis for direct Medicare reimbursement.

Medicare law requires that if institutional providers of care are to receive direct fee-for-service Medicare reimbursement, they must meet certain physical and organizational conditions of participation. A full-service community hospital, for example, must meet 20 such conditions. These conditions relate to such matters as the hospital's governing body, physical plant, clinical and emergency services, nursing service, and food service. Each of these conditions of participation has multiple standards, most of which must be met if the institution is to comply with the condition.

Conditions of participation identify minimal conditions thought necessary for quality to occur. They relate almost exclusively to structural measures of quality. Furthermore, surveyors checking for compliance only determine whether the institution has established organizational policies and procedures to meet the conditions of participation. Little attention is paid

³In testimony before the Ways and Means Subcommittee on Health (Mar. 21, 1995), HCFA's Administrator also listed other quality assurance and improvement activities: provisions for beneficiary education; studies in state-of-the-art quality assessment; elimination of fraud and abuse, which are detrimental to quality; and use of clinical practice guidelines.

to how well those policies and procedures are adhered to or what the results are.⁴

HCFA contracts with state agencies to perform certification surveys for most types of institutional providers. These agencies periodically (usually annually) send survey teams to the institutions to check compliance. If the team finds that the institution is not in compliance with one or more standards, it will ask for a corrective action plan. For hospitals, home health agencies, and clinical laboratories,⁵ HCFA deems the accreditation of designated private accrediting organizations to be adequate assurance that a provider meets its conditions of participation.⁶ In deciding whether to accept accreditation by a private third party as a substitute for certification by a state agency under contract with HCFA, HCFA looks at the accrediting agency's survey procedures and compares its standards with HCFA's conditions of participation. Those standards must be at least as stringent as HCFA's conditions.⁷ (App. III shows the organizations whose accreditation is deemed equivalent to certification by HCFA; it also lists other organizations that accredit institutional health care providers or units within providers.) State agencies do validation surveys on a small proportion of those institutions whose accreditation is accepted for Medicare certification purposes.

For institutions surveyed directly by state agencies, HCFA personnel perform validation surveys on a small proportion of the institutions. HCFA personnel also survey state-owned institutional providers and clinical labs that are not approved by a Medicare-designated accrediting body.⁸

⁴The Joint Commission is developing a measurement system designed to measure outcomes. This system is intended to be used in conjunction with its current accreditation program.

⁵HCFA certifies clinical laboratories under the Clinical Laboratories Improvement Act (CLIA), rather than under the Medicare program.

⁶HCFA is considering extending deeming authority to private organizations that accredit ambulatory surgical centers.

⁷Procedures HCFA examines include survey procedures, qualification requirements for surveyors, surveyor training programs, procedures for notifying the surveyed entities of survey results, and time frames for conducting follow-up visits if deficiencies are found.

⁸HCFA exempts clinical laboratories in Washington State from inspection because of state licensure requirements that are at least as strict as those under CLIA. A HCFA official told us that a regulation that will exempt labs in two other states--New York

If problems noted as a result of any of these reviews remain uncorrected, or are of such severity as to seriously endanger beneficiaries, the institution's certification to receive Medicare reimbursements may be revoked. However, in our previous review of this program, we found that HCFA's application of termination procedures casts some doubt on its willingness to terminate any but the worst hospitals from the Medicare program.⁹

The Medicare HMO Qualification Process

HMOs that wish to serve Medicare beneficiaries must have risk or cost contracts with the Medicare program.¹⁰ To qualify for such contracts, HMOs must meet both the requirements of title 13 of the Public Health Service Act relating to federal qualification of HMOs and the requirements of the Medicare statute. As with fee-for-service providers approved under the Medicare Provider Certification Program, these requirements are primarily structural. They require, for example, that the HMO have an adequate governing body, that it have utilization review and quality assurance systems, and that it have an adequate grievance system.

HCFA personnel visit contracting HMOs at least once every 2 years to ensure that they are complying with title 13 and Medicare requirements. If an HMO is not in compliance, HCFA may terminate its contract or, in specific circumstances, require it to suspend enrollment. At this time, HCFA does not accept accreditation from any agency as evidence that an HMO meets federal standards.

We have been critical of HCFA for failing to aggressively enforce its quality assurance standards in this process. We have reported on these matters in the past and testified before the Subcommittee on Health, Committee on Ways and Means, earlier this year.¹¹ In the last 10 years, for example, HCFA has repeatedly found quality assurance problems in certain Florida HMOs. The most recent quality violations included incorrect diagnoses, treatments delayed or withheld, and test results not acted on. One of the

and Oregon--is awaiting publication in the Federal Register.

⁹Health Care: Actions to Terminate Problem Hospitals From Medicare Are Inadequate (GAO/HRD-91-54, Sept. 1991).

¹⁰An HMO that has a risk contract with HCFA is paid a fixed amount for each enrolled beneficiary based on the average Medicare costs for all beneficiaries in the HMO's service area. An HMO that has a cost contract is paid by HCFA a predetermined monthly amount per beneficiary on the basis of a total estimated budget.

¹¹Medicare: Opportunities Are Available to Apply Managed Care Strategies (GAO/T-HEHS-95-81, Feb. 10, 1995).

HMOs continued to enroll over 100,000 Medicare beneficiaries during a period of noncompliance without any HCFA intervention.

The Medicare Peer Review Organization Program

The PRO program has focused mainly on ensuring that Medicare beneficiaries received good quality of care in fee-for-service inpatient hospital and ambulatory surgical settings.¹² The program's primary methodology has been to review individual medical records, with a focus on process, to make a determination about the quality of care furnished a beneficiary. In addition, there has been a secondary focus on outcomes through focused case review of adverse events such as deaths and hospital readmissions within 15 days of a discharge.

Beginning in 1987, the Congress mandated that the PRO review be expanded to include the quality of care provided by Medicare risk HMOs. In conducting HMO reviews, PROs evaluate the medical records of both ambulatory and inpatient care for a sample of beneficiaries. In a previous report, we made several recommendations to HCFA regarding ways to strengthen the PRO review of risk HMOs.¹³ For example, we urged HCFA to incorporate the results of PRO efforts into HCFA's compliance monitoring process.

Although PROs have the authority to review fee-for-service ambulatory care, HCFA has been reluctant to venture into this area. At present, except for ambulatory surgical procedures, the only fee-for-service ambulatory review performed is a pilot project recently begun in three states. In this project PROs and 100 volunteer physicians in each state are cooperating to improve the quality of care provided to diabetics.

Concurrently, PROs in five other states are working cooperatively with 23 HMOs on a similar project. Both the fee-for-service and HMO initiatives will be based on collecting information from medical records about 22 specific performance measures such as the results of important laboratory tests.

HCFA PLANS FOR THE FUTURE

HCFA officials discussed with us several initiatives intended to improve HCFA's quality assurance approach. The initiatives are similar to the kinds of changes occurring in the private sector and in some cases include a closer collaboration with the private

¹²Before the 1984 implementation of Medicare Prospective Payment for Hospitals, federal oversight concentrated on utilization of hospital services rather than the quality of those services.

¹³Medicare: PRO Review Does Not Ensure Quality of Care Provided by Risk HMOs (GAO/HRD-91-48, Mar. 13, 1991).

sector. HCFA's initiatives include increasing the emphasis on continuous quality improvement, developing performance measures, and implementing a more in-depth survey of beneficiaries' satisfaction with HMOs.

HCFA is presently reengineering the entire PRO program to incorporate continuous quality improvement concepts. It found that the old model of review, which focused on individual aberrant cases, was confrontational, unpopular with the physician community, and of uncertain effectiveness. It is restructuring the PRO program to emphasize cooperative projects with providers designed to improve the overall quality of care beneficiaries receive. These projects, which have existed to a limited extent, will increasingly become the main focus of the program over the next 2 years.

HCFA recently announced it was joining a group of large corporate purchasers of health care to form a new organization called the Foundation for Accountability, or FACct. Among the many goals of this organization are compiling and reviewing the most promising performance measures available on health outcomes and health plan performance. Because this group represents over 80 million insured persons, HCFA and the other FACct members believe that health plans will adopt their measures and supply the results to them, other purchasers, and individual consumers. According to a HCFA program official, joining in these efforts will help to eliminate duplication of quality assurance efforts and increase the likelihood that managed care organizations will meet purchasers' needs.

Currently, HCFA's Office of the Actuary annually surveys some 12,000 beneficiaries, treated predominantly under fee-for-service arrangements, about their health status, access to care, and satisfaction with the care they receive. To get detailed patient satisfaction data on beneficiaries enrolled in managed care plans, HCFA's Office of Managed Care is considering an additional separate survey.

COMPONENTS OF AN ENHANCED QUALITY ASSURANCE APPROACH

Many of the experts we interviewed believed that the federal government should continue to play a role in ensuring that Medicare beneficiaries receive quality care regardless of whether that care is provided in an HMO, preferred provider organization (PPO), or fee-for-service setting.¹⁴ They cited the need for information such as (1) performance measures, (2) patient

¹⁴Our interviews were structured so that we covered the same questions with each person, but because we used primarily open-ended questions some issues were not discussed by each expert.

satisfaction surveys, and (3) assurance that basic structural standards have been met. Because each type of information has strengths and weaknesses, the experts recognize that no one technique can be relied upon as the sole determinant of whether an organization provides quality care. But they believed that all programs should foster continuous quality improvement efforts of providers. Furthermore, the experts believed that the strategies should build on existing federal, state, and private efforts.

Information to Measure Quality

Many experts said that performance measures, particularly those that reflect the outcomes of care, should be used to evaluate quality of care. Furthermore, attention must be given to collecting information about chronic conditions and other unique needs of the Medicare population. When information is gathered, it should be shared with beneficiaries to assist them in their health care purchasing decisions. Experts believed that performance measurement information could be collected by health plans or providers from their administrative databases or by sampling medical records. However, those we interviewed stressed that PROs or another independent third party would need to verify the accuracy of the data.

The importance of having standardized measures was also frequently cited. Some experts suggested that a national board, composed of public and private health care professionals representing regulators, providers, and purchasers, could be convened to establish a set of uniform measures. However, all agreed that, regardless of who performs the task, any effort to develop performance measures must be a collaborative one with "buy-in" from the provider community.

Most experts also recommended that patient satisfaction surveys be used to evaluate health care quality. Measuring patients' perceptions may include asking them about their satisfaction with the care furnished, their health status, and efforts they make to enhance their health. One expert said that patient survey results can be used to provide information to the consumer or purchaser, to guide a provider in its quality improvement efforts, and to make external comparisons between providers.

As with performance measures, experts stated that consumers like patient satisfaction information. Furthermore, patient satisfaction surveys are already commonly used by health plans and providers. But these surveys also have limitations. They may not produce reliable and valid data, and survey questions and sampling techniques have not been standardized. Other limitations include (1) the difficulty of reaching minorities and others with special needs, (2) the high cost of telephone surveys, and (3) the relative ease of introducing bias into the questionnaire.

Many of the experts said that health care organizations should continue to meet basic structural requirements for participation in the Medicare program. These requirements could be confirmed through a certification or accreditation process. When asked who should make the certification or accreditation visits, experts' opinions were evenly divided among HCFA, states, or another third party. Currently, HMOs and PPOs can seek voluntary accreditation from a third-party accrediting organization, such as the National Committee on Quality Assurance (NCQA) or the Joint Commission. One expert suggested that managed care organizations be given incentives to seek accreditation. For example, an accredited organization might be exempt from a HCFA site visit or perhaps be required to report a lesser amount of performance measurement data.

Some of the experts we interviewed raised questions about the basic concept of voluntary accreditation by a private third party. For example, one expert noted the inherent conflict of interest when an accrediting organization's revenues come from those they are accrediting, as is usually the case. Another noted that it is rare for a plan seeking accreditation not to receive it. However, this individual acknowledged that because accreditation is voluntary, only those who believe they will pass an accreditation survey will seek it. Another expert pointed out that it takes time to develop the systems necessary to be accredited by some organizations. New plans might not have those systems developed initially.

Continuous Quality Improvement

Experts consistently stated that a commitment to continuous quality improvement must be made by regulators, providers, and plans regardless of the quality assurance system implemented. Many managed care organizations implement their own internal quality assurance programs to help evaluate the care they are providing and to identify and correct any problems. Experts also recognized the value and importance of external oversight programs that are designed to ensure that providers are continually assessing and improving their delivery of care. Such oversight programs are an important tool to identify previously undetected problems, to provide management with constructive feedback, and to assist the providers and plans in improving their overall delivery of health services.

Build on Existing Strategies

Federal and state governments and the private sector have already undertaken a number of initiatives to obtain data about the quality of care. Building upon these efforts was viewed as desirable and beneficial. As discussed earlier, HCFA presently requires HMOs that participate in the Medicare program to have processes in place to identify and resolve quality assurance problems, and some state legislatures have imposed quality

standards on HMOs operating in their states. Additionally, the National Association of Insurance Commissioners is discussing the feasibility of developing a model uniform licensing act for all types of health insurers which will include requirements for quality assurance. In the private sector, NCQA and others have developed performance measures. Furthermore, NCQA, the Joint Commission, and others have established quality standards that must be met by any HMOs or PPOs that seek accreditation. And now many employers are requiring managed care plans to gain accreditation before contracting with them for health care services.

CONCLUDING OBSERVATIONS

The federal government, as a prudent purchaser, continues to play an important role in ensuring that Medicare providers meet the highest standards of quality in health care. HCFA has quality assurance programs with that goal, although we have identified problems in their implementation. The enhancements HCFA is making to its quality assurance approach are consistent with the direction in which the private sector is moving and with the consensus of the health care experts we interviewed. The challenge facing HCFA is to make the specific decisions about how these changes will be implemented, confirm that they are effectively implemented, and resolve the relative roles of federal and state governments and the private sector.

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Messrs. Chairmen, this concludes my formal remarks. I will be happy to answer any questions from you and other members of the Subcommittees.

For more information on this testimony, please call Sandra K. Isaacson, Assistant Director, at (202) 512-7174. Other major contributors included James A. Carlan, Jean Chase, Debra J. Carr, Nancy Donovan, Peter E. Schmidt, and Darrell Rasmussen.

RELATED GAO PRODUCTS

Community Health Centers: Challenges in Transitioning to Prepaid Managed Care (GAO/HEHS-95-138, May 4, 1995). Testimony on the same topic (GAO/T-HEHS-95-143, May 4, 1995).

Medicare: Opportunities Are Available to Apply Managed Care Strategies (GAO/T-HEHS-95-81, Feb. 10, 1995).

Health Care Reform: "Report Cards" Are Useful but Significant Issues Need to Be Addressed (GAO/HEHS-94-219, Sept. 29, 1994).

Home Health Care: HCFA Properly Evaluated JCAHO's Ability to Survey Home Health Agencies (GAO/HRD-93-33, Oct. 26, 1992).

Home Health Care: HCFA Evaluation of Community Health Accreditation Program Inadequate (GAO/HRD-92-93, Apr. 20, 1992).

Health Care: Actions to Terminate Problem Hospitals From Medicare Are Inadequate (GAO/HRD-91-54, Sept. 5, 1991).

Medicare: PRO Review Does Not Ensure Quality of Care Provided by Risk HMOs (GAO/HRD-91-48, Mar. 13, 1991).

Medicare: Physician Incentive Payments by Prepaid Health Plans Could Lower Quality of Care (GAO/HRD-89-29, Dec. 12, 1988).

Medicare: Issues Raised by Florida Health Maintenance Organization Demonstrations (GAO/HRD-86-97, July 16, 1986).

Problems in Administering Medicare's Health Maintenance Organization Demonstration Projects in Florida (GAO/HRD-85-48, Mar. 8, 1985).

EXPERTS INTERVIEWEDAmerican Association of Preferred Provider Organizations

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Gordon Wheeler, President and Chief Operating Officer

American Association of Retired Persons (AARP)

Mary Ellen Bliss, Regulatory Associate, Federal Affairs Department

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American Group Practice Association

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Department of Public Health

UNIVA Health Network
Dr. William Jesse, President and Chief Executive Officer

Utilization Review and Accreditation Commission
Randall H. Madry, Executive Director

Washington Business Group on Health
Sally Coberly, Director

APPENDIX II

APPENDIX II

Wisconsin Peer Review Organization
Dr. Jay A. Gold, Principal Clinical Coordinator

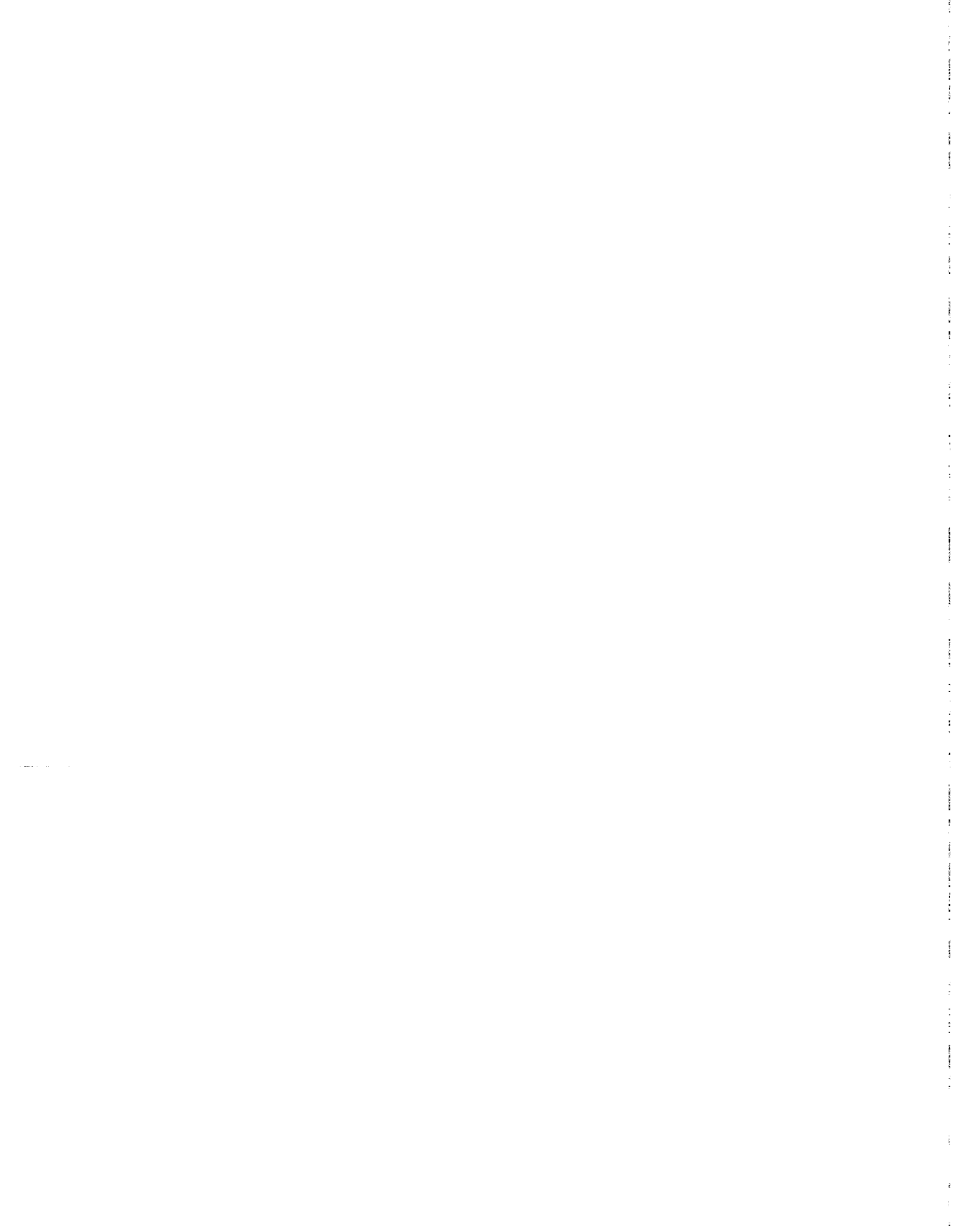
ACCREDITING ORGANIZATIONSTable I.1: Organizations Whose Accreditation HCFA Deems to Be Adequate Assurance That Providers Meet HCFA Conditions of Participation

Type of provider	Accrediting organization
Hospitals	Joint Commission on Accreditation of Healthcare Organizations American Osteopathic Association
Home health agencies	Joint Commission on Accreditation of Healthcare Organizations Community Health Accreditation Program
Laboratories under the Clinical Laboratories Improvement Act	Joint Commission on Accreditation of Healthcare Organizations College of American Pathologists American Society for Histocompatibility and Immunogenetics American Association of Blood Banks (pending) American Osteopathic Association (pending)
Ambulatory surgical centers	Status awaiting final publication and approval of <u>Federal Register</u> notice

Table I.2: Organizations That Accredite Institutional Health Care Providers or Units Within Providers

Accrediting organization	Type of provider accredited
Joint Commission on Accreditation of Healthcare Organizations	Hospitals, skilled nursing facilities, home health agencies, health networks, and others
American Osteopathic Association	Hospitals, laboratories
National Committee on Quality Assurance	Managed care plans
Commission on Accreditation of Rehabilitation Facilities	Rehabilitation facilities
Commission on Office Laboratory Accreditation	Physician office laboratories
College of American Pathologists	Laboratories
American Association of Ambulatory Health Care	Ambulatory health centers, ambulatory surgical centers
American Society of Histocompatibility and Immunology	Laboratories performing tissue-typing and related tests
American College of Surgeons	Trauma systems
American Speech and Hearing Association	Speech and hearing programs
Commission on Accreditation of Free Standing Birthing Centers	Free standing birthing centers
National Commission on Correctional Health Care	Health units in correctional facilities
American Association of Blood Banks	Laboratories
Utilization Review Accreditation Commission	Free standing utilization review programs and utilization review programs in HMOs and PPOs

American College of Radiology	Diagnostic and therapeutic radiology units in all settings
Community Health Accreditation Program	Home health agencies
American Accreditation Program, Inc.	PPOs



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