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Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Interim Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–1325–IFC]

RIN 0938–AN58

Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B

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

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period implements provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 that require the implementation of a competitive acquisition program for certain Medicare Part B drugs not paid on a cost or prospective payment system basis. Beginning January 1, 2006, physicians will generally be given a choice between obtaining these drugs from vendors selected through a competitive bidding process or directly purchasing these drugs and being paid under the average sales price system.

DATES: *Effective date:* The amendments to § 414.906(c); § 414.908(b), (c), (d), and (e); § 414.910, and § 414.912(a) are effective on July 6, 2005. All other amendments are effective September 6, 2005.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 6, 2005.

ADDRESSES: In commenting, please refer to file code CMS–1325–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/regulations/ecomments*. (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1325–IFC, P.O. Box *8013*, Baltimore, MD 21244–*8013*.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Lia Prela, (410) 786–0548.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in further considering issues and developing policies. You can assist us by referencing the file code CMS–1325–IFC and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all electronic comments received before the close of the comment period on its public Web site as soon as possible after they have been received. Hard copy comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Information on the competitive acquisition program, including a copy of this interim final rule with comment period, can be found on the CMS homepage. You can access this data by going to the following Web site: *http://www.cms.hhs.gov/providers/drugs/compbid*.

To assist readers in referencing sections contained in this preamble, we are providing the following table of contents.

Outline of Contents

In addition, because of the many organizations and terms to which we refer by acronym in this interim final rule with comment period, we are listing these acronyms and their corresponding terms in alphabetical order below.

Alphabetical List of Acronyms Appearing in the Interim Final Rule With Comment Period

ABN—Advanced Beneficiary Notice
ASP—Average sales price
AWP—Average wholesale price
BBA—Balanced Budget Act of 1997, Pub. L. 105–33
CAP—Competitive Acquisition Program
CERT—Comprehensive Error Rate Testing
CFR—Code of Federal Regulations
CMS—Centers for Medicare & Medicaid Services (formerly Health Care Financing Administration)
COBC—Coordination of Benefits Contractor
DAW—Dispense as written
DME—Durable medical equipment
DMERC—Durable medical equipment regional carrier
DOJ—Department of Justice
EAC—Estimated acquisition cost
ESRD—End-stage renal disease
FAR—Federal Acquisition Regulation
FDA—Food and Drug Administration
GAO—Government Accountability Office
GPOs—Group Purchasing Organizations
GPO Access—Government Printing Office Access
HCPCS—Healthcare Common Procedure Coding System
HHS—Health and Human Services
HIC—Health Insurance Number
HIPAA—Health Insurance Portability and Accountability Act of 1996, Public Law 104–191
ICD–9—International Classification of Diseases—Ninth Edition
IVIG—Intravenous immune globulin
LCDs—Local coverage determinations
MMA—Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
MSN—Medical summary notice
NDC—National Drug Code
OIG—Office of Inspector General
OPPS—Outpatient prospective payment system
PPAC—Practicing Physicians Advisory Council
PIN—Provider identification number
PSCs—Program Safeguard Contractors
RAC—Recovery Audit Contractor
RFA—Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354)
RFI—Request for information
RTI—Research Triangle Institute
UPIN—Unique provider identification number
WAC—Wholesale acquisition cost

I. Background

A. Covered Drugs and Biologicals

Medicare Part B currently covers a limited number of prescription drugs. For the purposes of this interim final rule with comment period, the term ''drugs'' will hereafter refer to both drugs and biologicals. Currently covered Medicare Part B drugs generally fall into three categories: Drugs furnished incident to a physician's service, drugs administered via a covered item of durable medical equipment (DME), and drugs covered by statute.

1. Drugs Furnished Incident to a Physician's Service

Injectable or intravenous drugs as well as non-injectable or non-intravenous drugs are administered incident to a physician's service as specified under section 1861(s)(2)(A) of the Social Security Act (the Act). Under the ''incident-to'' provision, the physician must incur a cost for the drug, and must bill for it. The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (Pub. L. 108–173, enacted on December 8, 2003) revised the ''incident-to'' provision, permitting payment of ''incident-to'' drugs under the CAP even though the physician participating in the CAP would not, in fact, incur a cost for the drug or actually bill for the drug. The Act limits ''incident-to'' coverage to drugs that are not usually self-administered. Examples include injectable drugs used in connection with the treatment of cancer (such as epoetin alpha), intravenous drugs used to treat cancer (such as paclitaxel and docetaxel used to treat breast cancer), injectable anti-emetic drugs used to treat the nausea resulting from chemotherapy, infliximab or other similar products used to treat rheumatoid arthritis, rituximab or other similar products used to treat non-Hodgkin's lymphoma, and Dermagraft or other similar products used to treat skin ulcers.

2. Durable Medical Equipment (DME) Drugs

DME drugs are administered through a covered item of DME, such as a nebulizer or pump. Two of the most common drugs in this category are the inhalation drugs albuterol sulfate and ipratropium bromide.

3. Statutorily Covered Drugs and Other Drugs

Drugs specifically covered by statute include—immunosuppressive drugs; hemophilia blood clotting factor; certain oral anti-cancer drugs; oral anti-emetic drugs; pneumococcal, influenza and hepatitis B vaccines; antigens; erythropoietin for trained home dialysis patients; certain other drugs separately billed by end-stage renal disease (ESRD) facilities (for example, iron dextran, vitamin D injections); and osteoporosis drugs.

4. Types of Providers

Types of providers and suppliers that are paid based on the current ASP system for all or some of the Medicare covered drugs they furnish include the following: physicians and certain non-physician practitioners, pharmacies, DME suppliers, hospital outpatient departments, and ESRD facilities.

5. Drugs Paid on a Cost or Prospective Payment Basis

Drugs paid on a cost or prospective payment basis that are outside of the scope of this interim final rule include—drugs furnished during an inpatient hospital stay (except clotting factor); drugs paid under the outpatient prospective payment system (OPPS); drugs furnished by ESRD facilities whose payments are included in Medicare's composite rate; and drugs furnished by critical access hospitals, skilled nursing facilities (unless outside of a covered stay), comprehensive outpatient rehabilitation facilities, rural health facilities, and federally qualified health centers.

B. Revised Drug Payment Methodology

The MMA revised the drug payment methodology by creating a new pricing system based on a drug's Average Sales Price (ASP). The MMA also provides for a program beginning in 2006 to give physicians a choice between—(1) Obtaining these drugs from vendors selected through a competitive bidding process; or (2) directly purchasing these drugs and being paid under the ASP system.

Effective January 2005, Medicare pays for the majority of Part B covered drugs using a drug payment methodology based on the ASP. In accordance with section 1847A of the Act, manufacturers submit to us the ASP data for their products. These data include the manufacturer's total sales (in dollars) and number of units of a drug to all purchasers in the United States in a calendar quarter (excluding certain sales exempted by statute), with limited exceptions. The sales price is net of discounts such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927 of the Act). The Medicare payment rate is based on 106 percent of the ASP (or for single source drugs, 106 percent of wholesale acquisition cost (WAC), if lower), less applicable deductible and coinsurance. The WAC is defined, with respect to a drug or biological, as the

manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

C. Competitive Acquisition Program (CAP)

Section 303(d) of the MMA provides for an alternative payment methodology for most Part B covered drugs that are not paid on a cost or prospective payment basis. In particular, section 303(d) of the MMA amends Title XVIII of the Act by adding a new section 1847B, which establishes a competitive acquisition program for the acquisition of and payment for competitively biddable Part B covered drugs and biologicals furnished on or after January 1, 2006.

Beginning January 1, 2006, physicians will have a choice between—(1) Obtaining these drugs from entities selected to participate in the CAP in a competitive bidding process; or (2) acquiring and billing for Part B covered drugs under the ASP system. The provisions for acquiring and billing for drugs through this new system, as well as additional information about this new drug payment system are described in this interim final rule.

The CAP may provide opportunities for Federal savings to the extent that aggregate bid prices are less than 106 percent of ASP. However, the CAP has other purposes than the potential to achieve savings. The competitive acquisition program provides opportunities for physicians who do not wish to be in the business of drug acquisition. Engaging in drug acquisition may require physicians to bear financial burdens such as employing working capital and bearing financial risk in the event of non-payment for drugs. The CAP is designated to reduce this financial burden for physicians. In addition, physicians who furnish drugs often cite the burden of collecting coinsurance on drugs, which can represent a substantial dollar amount to a beneficiary and physicians' practice. The competitive acquisition program eliminates the need for physicians to collect coinsurance on CAP drugs from Medicare beneficiaries.

D. Requirements for Issuance of Regulations

Section 902 of the MMA amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances. We intend to publish the final rule within the 3-year timeframe established under section 902 of the MMA.

II. Provisions of the March 4, 2005 Proposed Rule and Our Summary of and Responses to Public Comments

We received approximately 570 timely pieces of correspondence containing multiple comments in response to the March 4, 2005 proposed rule. Summaries of the public comments and our responses are set forth in the various sections of this preamble under the appropriate heading.

A. Policy for the CAP

1. General Overview of the CAP

In the March 4, 2005 proposed rule, we discussed the activities to implement the CAP that need to be completed before January 1, 2006, including—designating or developing quality, service, and financial performance standards for vendors; creating a pricing methodology; designing and running a bidding process from solicitation through contract award; providing physicians with an opportunity to elect to participate and select a vendor; educating beneficiaries about the program; and other activities specified in section 1847B of the Act.

The statute provides some flexibility in the development of the CAP by requiring an appropriate ''phase-in'' of the program and providing the Secretary with the discretion to select appropriate categories of drugs and appropriate geographic areas for the program. Section 1847B(a)(1)(B) of the Act states that for purposes of implementing the CAP, ''the Secretary shall establish categories of competitively biddable drugs and biologicals. The Secretary shall phase in the program with respect to those categories beginning in 2006 in such manner as the Secretary determines to be appropriate.'' Additionally, the statute states that the competitive acquisition areas for the CAP on which contracts are to be awarded (and vendors chosen) are ''appropriate geographic regions established by the Secretary.''

We also briefly discussed the activities we had initiated to enable us to implement the statutory provisions of section 1847B of the Act including:

- The award of a contract to Research Triangle Institute (RTI) to obtain information and develop alternatives regarding the implementation of a drug and biological competitive bidding program.
- Convening a Special Open Door Listening Session on April 1, 2004, to gather input and allow interested parties to hear and be heard by other members of the healthcare industry.
- Establishment of an electronic mailbox, *MMA303DDrugBid@cms.hhs.gov,* for interested parties to submit comments on the CAP program before the issuance of the March 4, 2005 proposed rule.
- Issuance of a Request for Information (RFI) on December 13, 2004 to assess public interest in bidding on contracts to supply drugs and biologicals for the CAP.

Comment: A few commenters referenced the discussion in the proposed rule concerning the activities that we initiated to implement the statute. These commenters questioned the fact that we only received 15 responses from the issuance of an RFI, given the number of Medicare beneficiaries, specialty groups (particularly oncology), State organizations, and providers that could be impacted by the proposed rule. Another commenter commended us for acknowledging the need to gather information and obtain industry input through informal processes and encouraged us to continue to solicit input from the public through formal and informal means, while an additional commenter implored us to give serious consideration to the comments on the proposed rule from affected specialty societies.

Response: The discussion in the March 4, 2005 proposed rule provided examples of activities and resources we used to establish the framework for the proposed rule. The reference to 15 responses was specific to the RFI that we issued on December 13, 2004, which was vendor interest specific. As mentioned in the March 4, 2005 proposed rule, our contractor, RTI, also consulted with groups and organizations, including medical specialty organizations and a national oncology practice to obtain input concerning establishment of a CAP program. As with any rulemaking process, we have given serious consideration to the comments from both specialty groups as well as individuals on the proposed rule.

Comment: Some commenters were supportive of the proposal for the CAP, with several commenters stating that the current buy and bill reimbursement system has created undue barriers. These commenters believe the CAP would at least provide an alternative to buy and bill arrangements for consumers and providers, by simplifying the reimbursement process.

Response: As discussed in the March 4, 2005 proposed rule, and also later in this preamble, participation in the CAP is voluntary on the part of the physician. As pointed out by commenters, implementation of the CAP provides an alternative to the current buy and bill system. To the extent that a physician or physicians' group believes that the CAP is not a viable alternative to the current buy and bill system, that physician or physicians' group can continue to use the current system and not elect to participate in the CAP.

Comment: Many commenters believe that we should beta test the CAP or have a limited trial period or phase-in of some sort, to confirm the quality of the CAP before full implementation. These commenters expressed concern that introducing the CAP system, particularly given the short timeframe, without any formal testing or analysis is risky to patient care because it is a dramatic potential change to the current system. Some commenters referenced the Government Accountability Office's (GAO) final report assessing the durable medical equipment, prosthetic, orthotics, and supplies (DMEPOS) competitive bidding demonstrations that suggests that further demonstrations be conducted for the DMEPOS before implementation. These commenters believe the GAO report supports taking a slower approach for implementing the CAP for Part B drugs. The commenters suggested that a slower approach would allow us to refine our application and vendor selection process. Other commenters, while cognizant of the January 2006 effective date, suggested we delay the effective date of the CAP to allow us to fully structure the CAP to meet congressional objectives and benefit physicians without compromising beneficiary access to drug therapies and treatment. In addition, commenters argued that the introduction of Part D beginning in 2006 may cause significant stress to providers and beneficiaries, and introducing the CAP at the same time could create confusion.

Response: Although we understand the concerns of the commenters, we believe the regulatory framework established through this rulemaking provides a firm basis for implementing the CAP program in January 2006. We recognize that the timeframe for implementation is ambitious but we believe that it is important to provide the physicians' community with an alternative to the current buy and bill system as soon as possible. In addition, the statute also requires that we coordinate the physician's election to participate in the CAP with the Medicare Participating Physician Process described in section 1842(h) of the Act. The use of a designated carrier for processing vendor claims is one of the approaches we will be using to ensure a smooth implementation. Other aspects of the CAP discussed later in the preamble also provide information on how we are addressing the implementation of CAP within this restricted timeframe. Additionally, the Congress did not intend this to be a demonstration, but instead established the CAP as an operational program.

We recognize that the Medicare community will be faced with many new challenges and options in 2006. We will be working to ensure that providers and beneficiaries are aware of these new choices and programs and that the transition is as smooth as possible.

Comment: One commenter requested that we continue to issue guidance to further clarify and refine the CAP requirements. The commenter also encouraged us to continue our efforts to educate and seek input through venues such as the ''Open Door'' sessions.

Response: We agree that it is important to continue our educational efforts and obtain feedback from the provider community and plan to convene special ''Open Door'' sessions as part of the implementation of the CAP. Additional discussion of this important aspect of the CAP is provided later in the preamble.

Comment: A few commenters expressed concern that we were limiting the CAP to oncology drugs.

Response: As discussed in the proposed rule, we were considering several alternative approaches to phasing in the CAP with respect to drug categories, one of which was initially including only all oncology drugs. The specific drug categories for the CAP that will be effective January 1, 2006 are discussed in detail later in this section of the preamble.

Comment: A number of commenters raised concerns about maintaining the safety of the drug delivery system or ''medication pipeline,'' particularly in light of the frequent changes in the disease status of certain patient populations (for example, cancer patients).

Response: We understand the commenters concerns, and, as discussed in more detail later in the preamble, we have established financial and quality standards to ensure that reputable and experienced vendors are chosen to participate in the CAP. We have also indicated that under the dispute resolution requirements, issues connected with drug quality will be given top priority.

Comment: One commenter stated that private insurers have tried models similar to the CAP and all of them have resulted in minimal savings but increased administrative overhead and patient inconvenience.

Response: We are mindful of the points that the commenter raised concerning private insurers attempts at similar models and have sought to address these points in establishing the CAP as reflected in the requirements we are establishing concerning the operational aspects of CAP (section II.B of this interim final rule) as well as those discussed in the CAP contracting process (section II.C of this interim final rule).

Other Comments

We also received many comments concerning: Payment for drug administration services, infusion services, and evaluation and management services for cancer patients; the chemotherapy demonstration project; price controls for drugs; and the new Medicare Part D Prescription Drug Program. These issues were outside the scope of this rulemaking, and, therefore, we will not be responding to these comments as part of this interim final rule.

Comment: Several commenters contended that our proposed rule did not satisfy all the requirements of the Administrative Procedure Act (APA). In particular, these commenters pointed out that the proposed rule did not include a specific proposal about the drug categories that would be adopted in the initial implementation of the CAP, or a specific proposal about the competitive acquisition areas that would be established. The commenters contended that the proposed rule therefore did not provide sufficient factual detail and rationale to permit interested parties to comment meaningfully. These commenters contend that CMS must either publish a second proposed rule providing specific proposals on these issues, or at least present our decisions about these matters in the context of an interim final regulation with opportunity for public comment. Other commenters recommended that we implement the

CAP through the issuance of an interim final rule. This would provide an extended opportunity for public comment and facilitate the approval of required program modifications.

Response: We do not believe that our proposed rule failed to satisfy the requirements of the APA. In our March 4, 2005 proposed rule, we presented specific options concerning the drug categories and competitive acquisition areas that we were considering for adoption in the final rule. We also discussed the advantages and disadvantages of each option to provide a basis for informed comment, and we received several comments on these options. These comments addressed in detail the options that we discussed, and addressed the specific considerations that we had discussed. The commenters offered specific recommendations and proposals based on the options that we had presented. The comments themselves thus are convincing evidence that our proposed rule provided adequate basis for meaningful comment from interested parties. Although we do not believe that we are required under the provisions of the APA to publish another proposed rule with more specific proposals, as requested by some commenters, we are exercising our discretion and publishing this rule as an interim final rule to allow our provisions to take effect and to provide the public with the opportunity to comment on our final provisions. We believe that additional public comment on this new and complex program would be valuable. We especially welcome comments on issues related to phasing in the program. For example, we describe below how we have decided to exercise our statutory authority to determine and phase in categories of drugs under the CAP. We specifically invite comments on the further development of appropriate drug categories after this initial stage of implementing the program. We also welcome comments on other issues regarding the CAP program.

Regulations

In the March 4, 2005 rule, we proposed to codify the requirements and provisions for the CAP in regulations at 42 CFR Part 414, Subpart K. We proposed to revise the heading for subpart K to read ''Payment for Drugs and Biologicals under Part B''; amend existing sections and section headings; and add new definitions and sections to set forth the proposed requirements with respect to the CAP. Specifically, we proposed to make the following changes:

- Revise existing § 414.900, which sets forth the basis and scope for subpart K;
- Revise § 414.900(b)(ii) to clarify that the hepatitis vaccine referred to in this paragraph is the hepatitis ''B'' vaccine;
- Add new § 414.906 through § 414.920 to address requirements with respect to payment under the CAP; and
- Revise § 414.902 to add definitions pertaining to the new CAP addressed in new § 414.906 through § 414.920.

We did not receive comments on the proposed organization of subpart K or the proposed changes to § 414.900, which sets forth the basis and scope for subpart K or § 414.900(b)(ii). Therefore, we finalize them as proposed. Specific comments pertaining to the proposed definitions for the CAP as well as proposed sections § 414.906 through § 414.920 are addressed later in this preamble.

2. Categories of Drugs To Be Included Under the CAP

Section 1847B of the Act describes a program that will permit physicians to elect to obtain drugs from vendors rather than purchasing and billing for those drugs themselves. The statute, therefore, most closely describes a system for the provision of and the payment for drugs provided incident to a physician's service. For example, under the mechanisms described in the statute:

- Only physicians are expressly given an opportunity to elect to participate in the CAP.
- The second sentence of section 1847B(a)(1)(A) of the Act explicitly indicates that such section shall not apply in the case of a physician who elects section 1847A of the Act to apply.
- Physicians who elect to obtain drugs under the CAP make an annual selection of the contractor through which drugs will be acquired and delivered to the physician under Part B.
- Section 1847B(a)(3)(A) of the Act specifically applies the CAP to drugs and biologicals that are prescribed by a physician who has elected the CAP to apply.
- Payment for drugs furnished under the CAP is conditioned upon drug administration.
- The requirement for submission of information that will be used by in the contract for collection of cost sharing applies to physicians.
- The primary site for delivery of drugs furnished under the CAP is the physician's office.
- The statute requires the Secretary to make available to physicians on an ongoing basis a list of CAP contractors.
- The statute explicitly defines a ''selecting physician'' to be one who has elected the CAP program to apply.

Section 1847B(a)(1)(B) of the Act specifically requires the Secretary to establish categories of drugs that will be included in the CAP, and requires the Secretary to phase-in the program with respect to these categories, as the Secretary determines to be appropriate. Section 1847B(a)(1)(D) of the Act further authorizes the Secretary to exclude competitively biddable drugs and biologicals from the competitive bidding system if the application of competitive bidding to those drugs and biologicals—

(1) Is not likely to result in significant savings; or

(2) Is likely to have an adverse impact on access to those drugs and biologicals.

Finally, the statute defines the term ''competitively biddable drugs and biologicals'' for purposes of the CAP as ''a drug or biological described in section 1842(o)(1)(C) of the Act and furnished on or after January 1, 2006.'' As discussed in the March 4, 2005 proposed rule, the drugs described in section 1842(o)(1)(C) of the Act include most drugs paid under Medicare Part B and not otherwise paid under cost-based or prospective payment basis. Medicare Part B covered vaccines, drugs infused through a covered item of DME, and blood and blood products (not including clotting factor and intravenous immune globulin (IVIG)) are not included under this definition because they are expressly excluded from section 1842(o)(1)(C) of the Act. The statutory definition of ''competitively biddable drugs'' therefore includes drugs administered incident to a physician's service (for example, drugs commonly furnished by oncologists), drugs administered through DME (for example, inhalation drugs) with the exception of DME infusion drugs, and some drugs usually dispensed by pharmacies (for example, oral immunosuppressive drugs). Although the statutory definition includes all these categories of drugs, as noted above, the specific mechanisms described under section 1847B of the Act relate to the provision of and the payment for drugs provided incident to a physician's service. Given our concerns about the clear direction of the statute that the election to participate in this program rests with physicians, in the proposed rule we indicated that we do not believe it is possible to include drugs other than those administered as incident to a physician's service as part of this program. However, we also recognized that the statute provides a potentially broader definition of ''competitively biddable drugs and

biologicals'' in section 1847B(a)(2)(A) of the Act. We, therefore, requested comments on whether, in the light of these mechanisms, the CAP is properly restricted under the statute to drugs administered incident to a physician's service.

We also solicited comments on how an expansion of the drugs covered under this program might work, given that the option to participate clearly rests with the physician.

Comment: Many commenters supported our proposal to restrict the CAP, at least initially, to drugs administered incident to a physician's service. Some of these commenters endorsed the more restrictive reading of the statute, under which the CAP is properly restricted to drugs administered incident to a physician's service. A congressional commenter advised that the intent of the Congress was to include all physician injectable drugs within the CAP. Other commenters expressed the view that the statute would allow the program to include drugs administered incident to a physician's service (for example, drugs commonly furnished by oncologists), drugs administered through DME (for example, inhalation drugs) with the exception of DME infusion drugs, and some drugs usually dispensed by pharmacies (for example, oral immunosuppressive drugs). However, some of these commenters also supported restricting the program, at least initially, to drugs administered incident to a physician's service as an appropriate exercise of the Secretary's authority to phase-in the drug categories established under the CAP. A few commenters supported including some categories of drugs administered through DME or drugs usually dispensed by pharmacies in the CAP, either initially or at an early stage of implementing the program. These commenters generally cited the statutory definition of ''competitively biddable drugs,'' which in and of itself is broad enough to include drugs administered incident to a physician's service, drugs administered through DME (with the exception of DME infusion drugs), and some drugs usually dispensed by pharmacies. Some of these commenters acknowledged that the general statutory structure of the program, which defines acquisition mechanisms applicable only to physicians, raises practical and/or legal issues about including drugs administered through DME and drugs usually dispensed by pharmacies within the program.

Response: We continue to believe that, given the clear direction of the statute that the election to participate in this program rests with physicians, it is not advisable to include drugs other than those administered as incident to a physician's service as part of this program. As we discuss further below, we, therefore, will implement the CAP initially for a broad range of drugs administered incident to a physician's service. However, we will continue to consider whether the statute allows extension of the program to Part B drugs that are administered through DME or dispensed by pharmacies. We will continue to analyze whether drugs other than those administered as incident to a physician's service can be included in the CAP within the parameters of the statute. At the same time, we have no present plans to expand the program beyond the class of drugs administered incident to a physician's service. If we were to determine that it was warranted to expand the program beyond the category of drugs furnished incident to a physician's service, we would first publish a proposed rule and allow for public comment before proceeding, as necessary.

The March 4, 2005 proposed rule included discussions on the merits of several options for defining the drug categories to be included within the CAP, as well as for phasing in the program with respect to drug categories. These are summarized below:

Drugs Furnished Incident to a Physician's Service

Under this option, all drugs furnished incident to a physician's service would be included in the CAP. The majority (more than 80 percent) of Medicare Part B drug expenditures are for drugs furnished incident to a physician's service, such as chemotherapy drugs. Therefore, it is important to include all drugs furnished incident to a physician's service to provide an alternative to physicians who did not want to purchase drugs directly. It may also provide more opportunity for realizing savings to the program than some other options.

Phasing in CAP Drugs by Physician Specialty

Another option would be to phase-in the program by implementing the CAP initially for a limited set of drugs that are typically administered by a single physician specialty, such as a set of drugs commonly furnished by oncologists. Drugs commonly furnished by additional specialties could be included over the next few years of the program. Drugs typically furnished by oncologists constitute a large portion of the Part B drug market. Drugs typically administered by other physician specialties represent smaller portions of physician-administered drugs. A basic decision with respect to a phase-in for drugs administered in physician offices would be whether to begin implementation of the program only with drugs typically administered by oncologists, or with some set of drugs that other specialties (for example, urology) tend to administer.

A few of the alternative approaches that could be used to phase-in the CAP with respect to drug categories discussed in the proposed rule were:

- Initially include all drugs typically administered by oncologists within the program.
- Begin with some set of the drugs that are typically administered in physician offices by other specialties (for example, drugs typically administered by urologists).
- Implement the CAP for all Part B drugs that are furnished incident to a physician's service.

We stated that we were actively considering all these options, and encouraged comments on all the options that we have discussed. We also welcomed recommendations of other options for consideration that could be adopted. We especially encouraged comments from physicians concerning their preferences about how a phase-in should be designed and more generally how the categories of drugs under the CAP should be structured.

Comment: Many commenters (especially from the oncology community) recommended beginning the phase-in with drugs that are typically used by some specialty that is less drug-intensive than oncology. However, many other commenters recommended beginning a phase-in with oncology drugs, on the grounds that doing so would provide much of the potential benefit of the CAP immediately. Other commenters, including some members of the oncology community, recommended inclusion of all physicians' drugs within the program immediately, in order to provide an alternative method of obtaining drugs for all physicians. A congressional commenter recommended that the program start with a sufficiently large category of drugs to provide a sufficiently sized market for vendors and that the program ramp up quickly to include all physician-administered Part B drugs.

Response: We have been convinced by the commenters that it is feasible and appropriate to implement the CAP initially for the broad range of drugs administered incident to a physician's service. As we discuss in more detail

below, in response to these comments, we have identified a set of 169 drugs that are most commonly administered incident to a physician's service for inclusion in the initial stage of the CAP. We have not included drugs with very low volumes of billing by physicians because we believe including such drugs at this time would impose a greater burden on vendors, and undercut the goal of providing a sufficiently sized market. As described in further detail below, in response to concerns raised by commenters we have also not included certain drugs whose patterns of use do not make them suitable for inclusion under the CAP. For example, certain vaccines, such as tetanus and diphtheria vaccines, are most commonly used in emergency situations. These drugs are therefore poorly suited for the normal ordering and billing procedures contemplated by the CAP statute. Physicians often will not be in the position to submit to their approved CAP vendor in advance a patient-specific order for these drugs. Although section 1847B(b)(5) of the Act outlines special rules to allow approved CAP vendors to resupply drugs used in emergency situations, we do not believe that it is advisable to include within the CAP drugs for which this special mechanism will be routinely employed, at least during this initial stage of implementing the program. (It is important to note that the statute specifically excludes pneumococcal vaccine, influenza vaccine, and hepatitis B vaccine from the CAP.) As we discuss in response to the specific comments below, we have also not included, at least initially, certain types of drugs that pose special issues. For example, we have not included drugs that pose special implementation issues such as some controlled substances and orphan drugs.

Comment: One commenter asked about the status of opioid medications administered intrathecally through implanted variable-rate infusion devices (for example, Prialt®). The commenter notes that historically, when these pain medications have been furnished by physicians in their offices, they have been covered and billed through the local carriers as drugs administered incident to physicians' services, rather than as drugs infused through covered durable medical equipment billed through the DMERCs. In the light of this, the commenter requested that we confirm specifically that those medications will be eligible for the CAP, at least once the program is fully phased in.

Response: We agree in principle that opioid medications administered intrathecally through implanted variable-rate infusion devices could be included under the CAP, when they are administered by physicians in their offices incident to their services. In the specific case of Prialt®, we have not been able to include the drug in this initial phase of the CAP because it is very new and has not yet been assigned a code. (We discuss treatment of new drugs in greater detail below.) However, our analysis has suggested that some pain medications may be inappropriate for inclusion in the CAP, at least in the initial stage. Specifically, we are concerned that the special recordkeeping and other requirements that apply to Schedule II, III, and IV controlled substances would make inclusion of these drugs in the CAP problematic. Under the CAP, the approved CAP vendor retains title to the drug, even after it is shipped to the physician, which may make it more difficult to ensure compliance with the special rules for controlled substances. We, therefore, are not including Schedule II, III, and IV controlled substances in the initial stage of implementing the CAP. We welcome comments on the implications of these special requirements for including these drugs in the CAP during later stages of implementation.

Comment: Several commenters recommended that we exclude orphan drugs from the CAP. (''Orphan drug'' is defined by FDA, under 21 CFR 316.3(b)(10), as a ''drug intended for use in a rare disease or condition as defined in section 526 of the Federal Food, Drug, and Cosmetic Act.'') These commenters pointed out that orphan drugs often pose access challenges. Specifically, one commenter noted that vendors may not be able to provide orphan drugs adequately in a timely manner. The same commenter noted that CMS has provided a special exception for payment of orphan drugs in the outpatient prospective payment system.

Response: We agree with the commenters that access problems provide a sound reason for not including some orphan drugs from the CAP, at least in the initial stages of the program. However, we do not believe that it is necessary to decline to include all orphan drugs from the program, even in this initial stage of implementation. This is because many orphan drugs are not approved exclusively for the treatment of orphan indications, but they are also approved for other non-orphan indications that affect broader groups of the public. In contrast, other orphan drugs are approved exclusively for the treatment of orphan indications. The latter group of orphan drugs poses much more severe access issues than other orphan drugs precisely because their use is generally limited to relatively rare orphan indications. As one commenter noted, we provide special payment consideration under the outpatient prospective payment system (OPPS) to this latter set of orphan drugs. Specifically, we designate drugs that meet the following criteria as single indication orphan drugs under the OPPS:

- The drug is designated as an orphan drug by the FDA and approved by the FDA only for treatment of only one or more orphan conditions(s); and
- The current United States Pharmacopoeia Drug Information (USPDI) shows that the drug has neither an approved use nor an off-label use for other than the orphan condition(s).

In this interim final rule, we, therefore, are not including those orphan drugs that meet the above criteria within the CAP, at least during the initial stage of implementing the program. Under these criteria, the following drugs are not included, at least for the initial stage of CAP:

J0205 (Injection, Alglucerase, per 10 units);
J0256 (Injection, Alpha 1-proteinase inhibitor, 10 mg);
J9300 (Gemtuzumab ozogamicin, 5mg);
J1785 (Injection, Imiglucerase, per unit);
J2355 (Injection, Oprelvekin, 5 mg)
J3240 (Injection, Thyrotropin alpha, 0.9 mg);
J7513 (Daclizumab, parenteral, 25 mg);
J9010 (Alemtuzumab, 10 mg);
J9015 (Aldesleukin, per single use vial);
J9017 (Arsenic trioxide, 1 mg);
J9160 (Denileukin diftitox, 300 mcg); and
J9216 (Interferon, gamma 1–b, 3 million units).

We welcome comments on whether these drugs should be included in the CAP during later stages of implementation.

Comment: Several commenters also recommended that we not include contrast agents within the CAP. Some of these commenters recommended permanent exclusion of contrast agents from the program. Others recommended that we phase-in these agents during later stages of implementing the CAP. Contrast drugs are used only in diagnostic imaging tests. The commenters cited various reasons for excluding contrast agents. These included the difficulty of determining appropriate categories for these products, fast pace of change in this

field, and the rapid changes in coding and payment for these products. These changes may not yet be well understood among physicians, and this may hamper their ability to select the vendor that provides the most appropriate contrast agents for their patients.

Response: We agree with the commenters that the rapid pace of change in this field, in conjunction with major changes in coding and payment in recent years, may pose special possibilities for confusion during the initial stage of the CAP. We, therefore, are not including contrast agents under the CAP during this initial stage of implementing the program. We, however, will consider including them as we refine and develop the drug categories under the program in future stages of implementation.

Comment: Several commenters requested that CMS clarify whether carriers' least costly alternative (LCA) policies would apply under the CAP. Most of these commenters maintained that those policies should not be applied under the CAP. For example, one commenter argued that substituting one manufacturer's price for another is inconsistent with a system of establishing prices for HCPCS codes on the basis of submitted bids. Others pointed out that it would be administratively difficult to apply LCA policies within the CAP claims processing system.

Response: As we note in section II.B of this interim final rule, least costly alternative policies are established by our contractors. Nothing in this interim final rule is intended to disrupt the longstanding ability of contractors to apply this policy under section 1862(a)(1)(A) of the Act. Section 1862(a)(1)(A) provides that notwithstanding any other provision in the Medicare statute (that is, including section 1847B), no payment may be made under Part A or Part B for any expenses incurred for items and services that are not reasonable and necessary. Medicare carriers establish local coverage determinations (LCDs), under which coverage for a particular drug is limited to the coverage level for its least costly alternative. As stated in the March 2005 proposed rule, physicians who submit claims under the CAP must comply with applicable LCDs.

However, we acknowledge that the existence of LCA policies, and the fact that they will apply under the CAP just as they apply outside the CAP, have obvious implications for the provision of certain drugs under the CAP. If a carrier applies an LCA policy to a particular drug, the approved CAP vendor's claim for that drug, when ordered by a participating CAP physician in that carrier's jurisdiction, would be subject to LCA. We are aware of one instance in which every carrier has applied the ''least costly alternative'' policy to a drug that would otherwise meet the criteria outlined in this section for inclusion in the CAP. Every carrier has applied an LCA policy to injectable forms of leuprolide (not, however, to leuprolide implant). Under these polices, claims for leuprolide are paid at the level of its least costly alternative (goserelin). We are implementing the CAP initially through a single, broad drug category and a single, national competitive acquisition area; therefore, because leuprolide is subject to LCA policies in all carrier jurisdictions, its inclusion in the current CAP drug category would have the effect of requiring vendors to supply the drug at the cost of goserelin in each instance in which a participating CAP physician orders it, regardless of the price established for leuprolide under the bidding and single price determination processes that we describe below, and regardless of the geographic location (and local carrier jurisdiction) of the participating CAP physician. For this reason, we have decided to exercise our authority under 1847B(a)(1)(B) not to include leuprolide in this initial stage of implementing the CAP. This decision is based on our authority under the CAP statute, and does not affect the applicability of LCA policies to leuprolide. We welcome comments on how to deal with this issue in later stages of implementing the program.

Comment: We received a number of comments recommending that we exclude blood clotting factors and intravenous immune globulin (IVIG) from the CAP. A number of these commenters recommended that we employ the authority under section 1847B(a)(1)(D) of the Act to exclude these products on the grounds that their inclusion within the program would not result in significant savings or would have an adverse impact on access. Many of these commenters also argued that IVIG is implicitly excluded from the CAP by section 1842(o)(1)(E)(ii) of the Act (section 303(b)(1)(E)(ii) of the MMA), which provides that the payment for IVIG ''in 2005 and subsequent years'' is the amount determined under the ASP system. Some commenters also pointed to the Conference Report on the MMA, which states that ''[c]ompetitively biddable drugs and biologicals exclude IVIG products and blood products.'' Other commenters contended that IVIG is inappropriate for inclusion under the CAP because it is frequently not administered incident to a physician's services. A number of commenters also pointed out that hemophilia patients commonly receive treatment with blood clotting factor at special treatment centers, or self-administer blood clotting factor at home. As in the case of IVIG, these commenters contended that blood clotting factor is therefore inappropriate for inclusion in a program intended and designed primarily for drugs administered incident to a physician's services.

Response: In this interim final rule, we continue to rely solely on the Secretary's statutory authority under section 1847B(a)(1)(B) of the Act to establish categories of drugs that will be included in the CAP, and to phase-in the program with respect to these categories. Using this authority, we have not included blood clotting factors or IVIG within the CAP. If we were to consider including blood clotting factors or IVIG, we would first publish a proposed rule and seek public comment.

We are also exercising our statutory authority to establish and phase-in drug categories in deciding not to include other immune globulins from the CAP in this initial stage of implementing the program. As in the case of tetanus and diphtheria vaccines, these products are commonly used in emergency situations, and are therefore poorly suited for the normal ordering and billing procedures contemplated by the CAP statute. We do not believe that it is advisable to include within the CAP drugs for which the special emergency mechanism will be routinely employed, at least during this initial stage of implementing the program. In addition, immune globulins are considered by some to belong to the category of blood products, which are explicitly excluded under the definition of competitively biddable drugs (see section 1847B(a)(2)(A) of the Act). Although we do not necessarily agree that immune globulins are properly classified as blood products within the meaning of the statute, we will not include them in our initial drug category in order to provide opportunity for further comment on whether they should properly be excluded on a permanent basis.

Comment: Numerous members of the mental health community (physicians, representatives of mental health clinics, and other mental health professionals) have requested inclusion of physicians' injectable psychiatric medications (for example, long-acting anti-psychotic drugs) in the initial phase-in of the CAP.

These commenters contend that including these medications within the CAP would enhance access to treatments of proven therapeutic value to a very vulnerable population. Some commenters specifically requested inclusion of these drugs in the CAP in order to make it more feasible for community mental health centers (CMHCs) to acquire and provide these therapies for their patients. Other commenters also noted that coinsurance for these drugs can be approximately 50 percent (in contrast to the 20 percent coinsurance for other Part B drugs) under the mental health limit (section 1833(c) of the Act, § 410.155 of our regulations).

Response: We will include drugs commonly billed incident to the services of psychiatrists in this initial stage of implementing the CAP. The single drug category that we are establishing for this initial stage of the program does in fact include many of the drugs that commenters specifically recommended for inclusion in the CAP. However, it is important to note that, under the statutory structure of the CAP as we are implementing it, CMHCs themselves will not be able to elect to participate in the CAP for provision of Part B drugs. This is because, as we have noted before, the specific mechanisms described under section 1847B of the Act as we have implemented them relate to the provision of and the payment for drugs provided incident to a physician's service. Therefore, only physicians are eligible to elect participation in the CAP for provision of the drugs that they administer incident to their services.

The issue of the appropriate coinsurance for mental health drugs in the light of the mental health limit provision is outside the scope of this regulation.

Comment: Several commenters asked for clarification of how codes for drugs that are not otherwise classified (NOC codes, including codes J3490, J3590, J7199, J7599, J7699, J7799, J9999, and Q0181) would be treated for purposes of the CAP.

Response: We do not believe that it would be appropriate to include the drugs billed under these codes within the CAP. Bidding and determination of payment for these codes would present insurmountable problems and pose unwarranted risks for potential vendors under the CAP. These are codes into which new drugs are assigned before receiving an appropriate permanent code. Some new drugs are assigned to these codes on a temporary basis, and each code thus represents a shifting collection of miscellaneous, unrelated products. It is not feasible for potential vendors to develop meaningful bids on these codes, given the fact that the codes represent such disparate products and that the specific drugs assigned to these codes are constantly changing.

Comment: Some commenters recommended that we establish narrowly defined drug categories. These commenters argued that broader categories would place a greater burden on vendors, who would have to bid and supply all drugs within broad categories. However, other commenters strongly supported the establishment of drug categories that are broadly defined to include all the drugs typically administered by a given medical specialty. These commenters argued that broadly defined categories would simplify the program for vendors, physicians, and the agency. Specifically, broad categories would allow most physicians to be able to choose one CAP vendor to meet all their Part B drug needs. One commenter in particular recommended establishing a single category including all Part B drugs administered incident to a physician's services. This commenter argued that such a broad category would make the CAP most accessible to all physicians, and allow vendors to bid on a wide array of products, give them a wider market, and allow for greater flexibility in designing their bids.

Response: We are persuaded that establishing relatively broad categories of drugs is the most appropriate and feasible approach for implementing the CAP, at least in the initial stage. We agree with the commenters that broad categories will promote greater access to the program for physicians, and provide vendors with flexibility in designing their bids. Broad categories will also, as noted by a number of commenters, allow most physicians to meet all (or almost all) their Part B drug needs.

We are also convinced by the arguments for establishing one broad category, at least for this initial stage of implementing the CAP. Such a broad category would make the CAP most accessible to all physicians. It would also allow vendors to bid on a wide array of products, give them a wider market, and provide them with greater flexibility in designing their bids. We, therefore, believe that employing a single category for the broad range of drugs administered incident to a physician's service is an appropriate measure, at least for the initial stage of implementing the CAP. We intend this single drug category as an interim measure, for this initial stage of implementing the program. We believe that establishing a single, broad drug category in this initial stage of implementing the CAP is an appropriate exercise of the Secretary's authority under the statute to establish categories of competitively biddable drugs and to phase-in the program with respect to those categories. We expect to phase-in multiple drugs categories, probably defined around the drugs commonly used by physicians' specialties (for example, urology, rheumatology), as we refine and develop the CAP. We welcome comments on how to develop and refine multiple drug categories for later stages of implementing the program.

As described below, we are therefore providing in this interim final rule for the establishment of a single category consisting of 169 drugs commonly provided incident to physicians' services. This broad category incorporates drugs commonly used by a wide range of specialties that bill for Part B drugs. The category also incorporates approximately 85 percent of physicians' Part B drugs by billed charges. In response to commenters' concerns, we have elected not to include at this time certain low volume drugs, as described further below.

The procedure that we used to select drugs for CAP bidding employed multiple sources of data to find Part B-covered drugs that are used in sufficient quantities by a variety of Part B-administering physicians. We believe that the broad drug category that we have developed through this procedure should tend to increase the interest of potential vendors and physicians in participating by making it more likely that (1) the fixed costs of being a vendor can be covered across the broad array of Part B physician-administered drugs that are included; (2) the impact of spoilage can be reduced; and (3) physicians electing can select one vendor to provide all, or almost all, of the Part B drugs that they administer. We derived our basic utilization data (restricted to physicians' specialties administering drugs in an office setting) from 2003 claims, the most recent available data. We supplemented these data with data on 2004 Medicare Part B drug utilization in office settings extracted from the Part B Extract and Summary System (BESS) to provide volume data on new drugs.

In the light of these considerations, we employed the following specific steps to develop a single category of the drugs most commonly used incident to a physician's services:

(1) We determined the claims volume for all Part B drugs in calendar year 2003. We did so by counting, in the claims from both the 100 percent carrier

and DMERC SAFs for 2003, the number of separate claims on which each Part B drug HCPCS appeared as a line item. If a particular HCPCS appeared multiple times on a single claim (for example, if the dates of service for the claim spanned more than a single day), this claim would only count once toward the HCPCS' claim count. We also tabulated separate counts for a number of physicians' specialties, specifically:

- Oncology specialties (including hematology, hematology/oncology, medical oncology, surgical oncology, urology, gynecology/oncology, and interventional radiology).
- Ophthalmology.
- Psychiatry (psychiatry, addiction medicine, and neuropsychiatry).
- Rheumatology.
- We determined separate counts for each of these specialties in order to be able to ensure that a broad spectrum of the Part B drugs used by physicians was included in this initial drug category for the CAP. In some cases (oncology, rheumatology) we included a separate count for the specialty because of the significance of drug billing by physicians in the specialty relative to overall billing for Part B drugs. In other cases (psychiatry, ophthalmology), we included distinct counts in order to respond adequately to comments specifically recommending the drugs commonly billed by those specialties for inclusion in the program. By specifically considering these drugs, we are responding to comments from member of these specific specialties in favor of including these drugs under the CAP. In addition, many of these drugs are highly specialized and unlikely to be present in the utilization data for other specialties. (Many other specialties are represented in this analysis because the drugs they commonly administer are also furnished by specialties that are specifically included. For example, most drugs commonly billed by urologists are also commonly billed by oncologists.) Finally, we tabulated a count for all other specialties not specifically identified above.

(2) We determined the proportion of each specialty group's claims on which each Part B drug appears. Once the claim counts from step (1) were computed, they were divided by the total number of claims submitted by the specialty groups for Part B drugs in an office setting. (Note that the sum over all drugs of these proportions will generally exceed 1.0 because multiple drugs can appear on the same claim.) Table 1 below shows these total claim counts, along with the number of Part B drug line items and total allowed Part B drug charges for each specialty group for drugs administered in an office setting.

TABLE 1.—CLASS & LINE ITEM VOLUME AND ALLOWED CHARGES FOR THE SPECIALTY GROUPS IN 2003

Specialty group	Number of claims	Number of line items	Allowed charges
Oncology	7,311,248	14,628,558	$5,647,268,606
Opthalmology	169,061	178,604	154,720,837
Psychiatry	43,752	55,599	3,626,108
Rheumatology	952,381	1,211,630	404,027,916
All other specialties	12,034,708	15,448,287	1,369,525,241

(3) We then extracted utilization and allowed charge data for each Part B drug in 2004 from BESS. Using BESS, information on utilization (HCPCS units) and total allowed charges for each Part B drug HCPCS code administered in an office setting were extracted. (For codes in the range 90200 through 90799 we retained only those CPT codes for vaccines and immune globulins; the other codes in that range were eliminated because they represent drug administration. We included all HCPCS J-codes. We also included HCPCS Q-codes corresponding to Part B drugs. We also excluded blood product HCPCS P-codes because of the statutory exemption of blood products from the CAP.) The resulting BESS output files were merged to create a single 2004 utilization file.

(4) We then crosswalked 2003 and 2004 Part B drug HCPCS to 2005 HCPCS. We did this in order to account for updates of the HCPCS codes. Specifically, several HCPCS codes from 2003 and 2004 were updated to 2005 codes in the Part B drug utilization data from steps (2) and (3). In most cases, this merely required changing the old HCPCS code to the new code and converting the units of service. However, two drugs required special treatment. In the case of lidocaine (which was formerly J2000, and is now J2001), the unit of service changed from 50 cc to 5 ml, and the NDCs included in the new code suggested a significant change in the mode of administration. In the case of octreotide acetate (which was formerly J2352 and Q4053, and is now J2353 and J2354), a new distinction was made between the depot and non-depot formulations that did not appear, from utilization data and NDC lists, to have been made previously. For these drugs, we summed the allowed charges, and imputed the number of claims to be the maximum of the number of claims for the old HCPCS.

(5) We merged the crosswalked drug utilization data for 2003 and 2004 by the 2005 HCPCS. The data from step (4) for the 2003 and utilization data were merged by the 2005 HCPCS.

(6) We then identified the drugs that we have determined not to include in the CAP drug category at this time. (We have discussed the reasons for not including most of these drugs above.) The types of drugs that are not included in the CAP drug category are:

- Clotting factors and immune globulins.
- Drugs administered through durable medical equipment.
- HCPCS used for erythropoietin administered to ESRD patients.
- HCPCS used for specific drugs administered in hospital outpatient departments and covered by section 1861(s)(2)(B) of the Act (codes Q2001 through Q2022).
- Orally-administered anti-cancer and anti-emetics.
- Orphan drugs that meet the criteria to be single indication orphan drugs for purposes of OPPS, as discussed above.
- Controlled substances on Schedules II, III, IV, and V.
- Tissues (for example, dermal, metabolically active, etc.). (Tissues are not considered drug products, and do not appropriately belong under the category of physician administered drugs that we have devised in response to the comments.)
- Influenza, pneumococcal, hepatitis B, tetanus, and diphtheria vaccines.
- Not otherwise classified (NOC) drugs (HCPCS J3490, J3590, J7199, J7599, J7699, J7799, J9999, and Q0181).
- Leuprolide

(7) We identified drugs to be included in our initial CAP category using the utilization data described above. Specifically, in order to be included in

the category, a drug needed to satisfy at least one of the following conditions:

- Be identified as an oncolytic, chemotherapy adjunct, anti-emetic, hematologic, or have a HCPCS in the J9000 series (except for J9999, which is excluded as a NOC code).
- Appear on more than 0.1 percent of claims for the oncology or all other specialty groups.
- Appear on more than 1 percent of claims for the ophthalmology, psychiatry, or rheumatology specialty groups.
- Have more than $250,000 in allowed charges in office settings in 2004 and be identified as an antibacterial, antifungal, antiparasitic, antidote, or cardiovascular agent.
- Have more than $1 million in allowed charges in office settings in 2004.

In addition to satisfying one of the above conditions, a drug must also satisfy both of the following conditions:

- Not be on the list specified in step (6) above of drugs that are not included in the CAP drug category.
- Have more than $50,000 in allowed charges in office settings in 2004 (another measure designed to avoid including very low volume drugs in this initial category).

We employed the criteria above to ensure that our single drug category would include a broad spectrum of the Part B drugs billed by physicians generally and by various physicians' specialties in particular. Our intent was to provide the physician with a single source for drugs (that is, the approved CAP vendor) that would be able to furnish the majority of drugs used in a practice regardless of the practice specialty or the diversity of prescribing patterns in that practice. Furthermore, we intended to provide the physician with choice and flexibility within groups of drugs that might be used by different specialties for the treatment of various conditions. This list of drugs is intended to accommodate a variety of physician practice patterns and a variety of specialties with the understanding that many drugs, for example, anti-emetics, are used by more than one specialty.

As noted above, we believe that in many cases, there is significant overlap in the types of Part B drugs administered by most physician specialties, including oncology. For this reason, we decided that oncolytics, chemotherapy adjuncts, anti-emetics, hematologics, and drugs having a HCPCS in the J9000 series (except for J9999), should be included in the CAP even if they did not meet the specialty claims percentage thresholds described in step (7) above. We believe that these drugs should be included in the CAP (so long as they meet the baseline claims volume threshold specified above and are not on the list specified in step (6) above). We believe it is necessary to include these drugs, even at lower volumes, because they may often be used in conjunction with one another, both by oncologists and by physicians in many other specialties.

However, for other drugs, we looked at claims volume in the aggregate of all specialties except those identified below to determine a threshold that would allow for a sufficiently sized market for vendors, while at the same time making the CAP a meaningful alternative for most physician specialties. At the same time, in response to specific comments about specialties where there is not significant overlap between small but highly utilized groups of drugs, the drugs that physicians in those specialties use, and drugs commonly used by other physician specialties, we identified psychiatry, ophthalmology, and rheumatology as specialties whose drugs claim threshold should be different. In order to lessen the inventory burden for vendors, we wanted to minimize the number of drugs included in the CAP that are billed in very low volumes, so we have applied a $50,000 minimum threshold for all drugs that otherwise would be included in the CAP (see step (7) above).

We determined separate counts for several specialties, in order to be able to ensure that a broad spectrum of the Part B drugs used by physicians was included in this initial drug category for the CAP. In some cases (oncology), we included a separate count for the specialty because of the significance of drug billing by these physician specialists relative to overall billing for Part B drugs. In other cases (psychiatry, ophthalmology, and rheumatology), we included distinct counts in order to respond adequately to comments specifically recommending the drugs commonly billed by those specialties for inclusion in the program, which, as noted above, are not frequently used by physicians in other specialties. As we have discussed above, we agree with the comment that we should include within this initial stage of the CAP drugs that provide a sufficiently large market for the program to be viable for vendors. For this reason, we decided not to include most very low volume drugs in this initial drug category. However, because overall volume of billing for Part B drugs varies widely from one physician category to another, we determined that the threshold for determining ''low volume'' had to vary somewhat among the specialties that we have separately identified in this analysis. In this context, we have determined that the low volume threshold should be relative to the size of the specialty and the overall volume of billing for Part B drugs by the specialty: The universe of Part B drugs billed by oncologists is roughly comparable to those in all other specialties in the aggregate and is much larger than the universe of Part B drugs billed by ophthalmology, psychiatry, or rheumatology. Specifically, the overall volume of billing for Part B drugs by oncologists is very high, while the overall volume of billing for Part B drugs by psychiatry and ophthalmology is relatively low. The same percentage threshold for these specialties would therefore yield very different numbers of claims for exclusion. We therefore determined that it would be appropriate to establish different percentage thresholds for including drugs billed by these specialties in the CAP. We accordingly set the percentage threshold for the oncology and all other specialty groups at 0.1 percent of claims submitted by the specialty. We set the threshold for ophthalmology, psychiatry, and rheumatology, at 1.0 percent of claims. A low percentage threshold (0.1 percent) for oncology claims (and claims for the other specialty category) is appropriate in relation to the overall high numerical volume of billing by oncologists for Part B drugs: a higher percentage threshold for this specialty would exclude some relatively high volume drugs from the category. Conversely, a similarly low percentage threshold for psychiatric drugs would not be appropriate because it would allow some very low volume drugs into the CAP. A higher percentage threshold in this case is necessary to exclude some very low volume drugs from the CAP. We decided on these specific percentage thresholds after examining various alternative levels (for example, 0.01 percent) and different combinations of levels (for example, 0.1 percent for oncology drugs, 0.01 percent for ophthalmology and psychiatry). After examining a number of alternatives, we determined that these levels strike an appropriate balance: they are high enough to prevent truly low volume drugs from being included in the category, and low enough to incorporate within the category a truly broad spectrum of the Part B drugs commonly billed by physicians. When we considered cutting the list off at a higher threshold (for example, 1.0 percent) for oncology drugs (and the

''other specialty'' category), we realized that numerous commonly billed drugs would have been excluded. Similarly, when we considered a lower threshold (for example, 0.1 percent) for ophthalmology, psychiatry, and rheumatology, we realized that many drugs billed in small numbers would be included.

Finally, we set several other thresholds based on claims volume that we believe would be appropriate for balancing the goal of providing approved CAP vendors with a sufficiently sized market with that of allowing physicians to obtain a broad array of drugs through the CAP. For this reason, we determined that a $250,000 threshold would be appropriate for drugs identified as an antibacterial, antifungal, antiparasitic, antidote, or cardiovascular agents. These drugs are often used by particular specialties like infectious disease or cardiology, but many of these drugs may be used by other specialties, and the $250,000 threshold ensures that only those drugs of this type that are commonly used are included in the CAP. Finally, for the same reasons, we believe that any drug that otherwise meets the criteria for inclusion in the CAP (as specified above), but does not meet one of the other four specific criteria outlined in step (7) above, should be included if the volume of claims for the drug is significant. We have set that threshold at $1 million. The result of performing this methodology is a list of 169 drugs. Table 2 gives the percentage of total allowed charges for Part B drugs for each of the five specialty groups shown in Table 1.

TABLE 2.—PERCENT OF 2003 TOTAL ALLOWED CHARGES ACCOUNTED FOR BY THE CAP BIDDING DRUGS

Oncology	84.92
Ophthalmology	99.97
Psychiatry	46.14*
Rheumatology	99.29
Other specialties	80.57
All non-oncology specialties	86.00
All physicians (in office)	85.20

* **Note:** Our data on drug billing by psychiatrists showed a high proportion (53 percent) of allowed charges for Rho D immune globulin, which is not included in our single drug category for the reasons discussed above. The drugs that we have included represent 97.94 percent of allowed charges for all other drugs commonly used by psychiatrists.

Using these steps, we have identified a list of 169 drugs for inclusion in our single drug category. We show the list of these drugs in Addendum A. These drugs represent a large proportion of the 440 drugs billed incident to physicians' services in our Part B billing data. More importantly, they represent about 85 percent of the charges for all the Part B drugs billed by physicians. We also have revised the definition of ''CAP drug'' in the regulations at § 414.902 to clarify that the provisions of the CAP program apply to drugs that we have included in the drug category.

Comment: Several commenters noted that, in light of the congressional intent to provide physicians with an alternative method for obtaining the Part B drugs that they use, it would be especially appropriate to incorporate into the CAP at an early stage of implementation those drugs that have been identified as posing acquisition problems for physicians under the ASP system.

Response: The methodology that we described above does not specifically account for those drugs. However, we have reviewed the resulting list of 169 drugs against a list that we have maintained of drugs that have been reported to us as posing access problems for physicians under the ASP system. Most of the drugs on that list appear in the drug category that we are establishing for this initial phase of implementing the CAP. These include:

J7050 Normal Saline 250 mL
J9245 Melphalan/Alkeran 50 mg
J2430 Pamidronate
J2920 Methylprednisolone
J2930 Methylprednisolone
J7317 Sodium Hyaluronate
J7320 Hylan G-F 20
J9310 Rituximab
J1750 Iron Dextran 50 mg Injection
J2405 Odansetron 1 mg Injection

To account for the drug category that we are adopting in this interim final rule with comment period, we have revised the proposed regulations at § 414.902 to specify that CAP drugs are those physician-administered drugs or biologicals furnished on or after January 1, 2006 described in section 1842(o)(1)(C) of the Act and supplied by an approved CAP vendor under the CAP as provided in this subpart.

Vendor Implications

We pointed out that the categories established for physicians to select would be the same categories that would be open for bids by potential vendors. Vendors would not be able to submit bids on only some of the HCPCS codes in the category, and physicians would not be able to elect to acquire only some of the HCPCS codes in that category from the approved CAP vendor. Note that in § 414.902 the proposed definition for ''approved vendor'' at § 414.902 has been revised to ''approved CAP vendor'' and clarified to specifically reference 1847B of the Act.

In addition, it is important to keep in mind that HCPCS codes can often describe products represented by multiple National Drug Codes (NDC). For example, the drug cyclophosphamide is manufactured by a number of different pharmaceutical companies and has multiple NDC codes.

In proposed § 414.908(d), we indicated that vendors will not be required to provide every National Drug Code associated with a HCPCS code. Section 1847B(b)(1) of the Act states that ''in the case of a multiple source drug, the Secretary shall conduct such competition among entities for the acquisition of at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area.'' However, we also proposed that vendors be required to provide potential physician participants in the competitive acquisition program the specific NDCs within each HCPCS code that they will be able to provide to the physician. Potential vendors would also need to provide this same information to us as part of the bidding application. This information would be provided to physicians who request it no later than the beginning of the election period during which the physician chooses whether to participate in the CAP and, if so, selects a vendor.

Comment: Many commenters supported our proposal to require vendors to submit bids on at least one drug for each HCPCS code within a category. Many of these commenters urged us to resist any recommendation that vendors be permitted to establish drug formularies by offering drugs from only some of the codes included in a category. Many other commenters expressed opposition to any attempt by the agency to establish a formulary as an element of implementing the CAP. A few commenters representing potential vendors did make such a recommendation. Other commenters recommended that we establish a more stringent standard, such as: requiring that vendors offer at least one drug for each distinctive treatment or therapy represented within a HCPCS code; requiring that vendors be required to offer at least one formulation (that is, at least one NDC) for each single-source drug that falls within the same HCPCS code; or requiring that vendors be required to provide all available FDA-approved drugs within a HCPCS code. Finally, some commenters recommended that information about which specific NDC codes vendors will

be offering be made generally available, perhaps through the CMS Web site, and not merely made available to physicians upon request.

Response: In this interim final rule, we are finalizing our proposal to require vendors to submit bids on at least one drug for each HCPCS code within a category. At the same time, we do not believe that it is advisable or feasible to require vendors to provide all available FDA-approved drugs within a HCPCS code. We are concerned that such a requirement may exclude vendors who are unable to provide even one drug in a category, unduly limiting the number of vendors that would participate in the program. We also do not believe that it is advisable to establish a standard requiring that vendors offer at least one drug for each distinctive treatment or therapy represented within a HCPCS code. Such a provision would be difficult to distinguish from establishing the type of formulary that many commenters opposed. Consistent with the requirement of 1847B(b)(1) of the Act, we have therefore decided to finalize our proposal to require vendors to submit bids on at least one drug for each HCPCS code within a category. We believe that the program will provide a strong incentive for vendors to include a broad selection of drugs within individual codes. It will be difficult for vendors to attract business from physicians under the program if the choice among drugs within specific codes is unduly restrictive. We expect that this incentive will be sufficient to prompt vendors to offer a wide range of drugs, including multiple NDCs within a single drug code, and thus protect physicians' ability to choose the most medically appropriate therapies for their patients. In addition, our decision to include our proposed ''furnish as written'' provision in this interim final rule should provide protection for physicians in those cases when an approved CAP vendor does not offer the specific drug or formulation that is medically necessary for a patient. (See section II.B of this interim final rule.) In addition, in this interim final rule, we are finalizing our proposed policy that vendors will be required to provide to potential physician participants in the CAP the specific NDCs within each HCPCS code that they will be able to provide to the physician. We are not accepting the recommendation that vendors be permitted to establish drug formularies by offering drugs from only some of the codes included in a category. The statute expressly requires that for multiple source drugs, a competition be conducted for the acquisition of at least one drug per billing code within the category. Thus, the statute does not contemplate a formulary. Finally, we agree with the suggestion that the specific NDC codes vendors will be offering be made generally through our Web site. By October 1, 2005, we will make available, on the CAP web page, a directory of the approved CAP vendors and the specific NDC numbers these vendors will be providing.

We also note that we have revised the definition of approved vendor at § 414.902 to read ''approved CAP vendor'' and we have specifically referenced 1847B of the Act.

Comment: A number of commenters asked us to clarify that, if the CAP is phased in by physicians' specialty, physicians of any specialty will still be able to obtain drugs initially included in the program from a CAP vendor.

Response: We stated in the proposed rule (70 FR 10750) that ''if we choose to phase-in the CAP by restricting the program initially to drugs typically administered by members of one specialty, all physicians who administer the drugs selected would still be eligible to elect to obtain these drugs through the CAP and to select a vendor of these drugs. For example, if we choose to phase-in the program initially with drugs typically administered by oncologists, participation in the CAP would not be restricted to oncologists: non-oncologists who prescribe these drugs would still be eligible to elect the CAP and to select a vendor from which to obtain these drugs.'' In this interim final rule, we are establishing one broad category of drugs commonly furnished incident to a physician's services for the initial stage of implementing the program. Physicians of any specialty are eligible to elect the CAP and to select a vendor from which to obtain these drugs. As we refine and expand the program, and expand our single category into multiple drug categories, we will maintain the policy that any physician, regardless of specialty, who administers the drugs in a specific category, may elect to obtain those drugs through the CAP in accordance with the statute and implementing regulations.

Finally, in the proposed rule, we emphasized that, in framing these options, we relied solely on the Secretary's statutory authority under section 1847B(a)(1)(B) of the Act to establish categories of drugs that will be included in the CAP, and to phase-in the program with respect to these categories. Although we did not propose to rely at this time on the Secretary's authority under section 1847B(a)(1)(D) of the Act to exclude competitively biddable drugs and biologicals from the CAP on the grounds that including those drugs and biologicals would not result in significant savings or would have an adverse impact on access to those drugs and biologicals, we proposed to set forth the circumstances for which we may exclude competitively biddable drugs and biologicals (including categories of drugs) from the CAP at § 414.906(b) of our regulations. In this interim final rule, we continue to rely solely on the Secretary's statutory authority under section 1847B(a)(1)(B) of the Act to establish categories of drugs that will be included in the CAP, and to phase-in the program with respect to these categories.

3. Competitive Acquisition Areas

Definition of Competitive Acquisition Areas

Section 1847B(a)(1)(A)(i) of the Act provides that, under the competitive acquisition program (CAP), competitive acquisition areas are established for contract award purposes. Section 1847B(a)(2)(C) of the Act further defines the term ''competitive acquisition area,'' for purposes of the CAP, as ''an appropriate geographic region established by the Secretary.'' Section 1847B(b)(1) of the Act also requires that the Secretary conduct a competition among entities for the acquisition of at least one competitively biddable drug within each billing and payment code within each category of competitively biddable drugs for each competitive acquisition area. Finally, section 1847B(b)(3) of the Act states that the Secretary may limit (but not below two) the number of qualified entities that are awarded contracts for any competitively biddable drug category and competitive acquisition area.

Under this statutory scheme, competitive acquisition areas (that is, the geographic areas the contractor would be responsible for serving) have an important role in the CAP. These areas constitute the geographic boundaries within which entities will compete for contracts to provide competitively biddable drugs.

As explained in the March 4, 2005 proposed rule, the definition of these areas will be a crucial factor in determining—the number of entities that bid for contracts; the number of entities that are ultimately awarded these contracts; the level of savings from the successful bids; and the efficiency with which the system delivers competitively biddable drugs to physicians.

Because the statute grants the Secretary broad discretion in defining competitive acquisition areas under the CAP, we discussed several factors that must be considered in defining competitive acquisition areas for competitively biddable drugs and biologicals, including how promptly physicians need drugs provided to their practices if distribution capacity varies geographically, as well as aspects of vendors and their distribution systems, such as:

- Current geographic service areas;
- Density of distribution centers, distances drugs and biologicals are typically shipped, and costs associated with shipping and handling;
- The relationships between vendors and their suppliers (manufacturers, wholesalers, etc.); and
- State licensing laws that may preclude vendors from operating in a State are to be taken in account. These factors can affect the price of supplying drugs to different regions as well as the size of the market in which vendors are allowed or able to operate.

Section 1847B(a)(1)(B) of the Act specifically requires the Secretary to phase-in the CAP with respect to the categories of drugs and biologicals in the program, in such a manner as the Secretary determines to be appropriate. We believe that this provision, particularly in conjunction with the statutory definition of ''competitive acquisition area'' (''an *appropriate* geographic region *established by the Secretary*'') (emphasis added), provides broad authority for the Secretary to phase-in the CAP with respect to the geographical areas in which the program will be implemented.

In the proposed rule, we identified several basic options for defining the competitive acquisition areas required under the CAP along with possible advantages and disadvantages for these options. The specific options discussed included: establishing a national competitive acquisition area; establishing regional competitive acquisition areas; and establishing statewide competitive acquisition areas.

We requested comments on all the options that we have discussed and also welcomed recommendations of other options for consideration but stated that defining competitive acquisition areas, at least initially, on the basis of a level no smaller than the States is the most feasible approach.

Comment: Many commenters addressed these two related issues: (1) Whether to implement the CAP immediately on a national scale, or to phase-in the program by beginning in one or more smaller areas; and (2) whether to establish a national competitive acquisition area, regional competitive acquisition areas, or statewide competitive acquisition areas on a permanent basis.

Commenters were divided about whether to implement the CAP nationally on January 1, 2006, or to phase-in the program by beginning on a more limited scale. Those commenters in favor of immediate national implementation emphasized congressional intent to establish a national program or the importance of providing physicians immediately with an alternative method for procuring drugs. Commenters in favor of a geographic phase-in argued that the CAP should be tested on a smaller scale in order to ensure that major implementation issues are solved before extending the program nationally. These commenters were divided on how to begin a geographic phase-in. Most of the commenters in favor of a phase-in endorsed beginning on a state or regional level. Some commenters specifically recommended beginning the program on a limited geographic basis in one or more of the most highly populated States, such as California, New York, or Texas. Other commenters recommended implementing the program initially with a few vendors serving a nationwide area.

Some commenters recommended establishing a single, national acquisition area on a permanent basis. Other commenters supported either State-based or regional acquisition areas on a permanent basis. Supporters of State areas emphasized that the licensing requirements operate at the State level, and that State-based areas would permit participation by smaller vendors. Supporters of regional areas pointed to the regional administration of other Medicare programs. Others pointed out that vendors may not bid to provide drugs for some small, low population states if the acquisition areas are established on a statewide basis.

Response: We are persuaded by those commenters who advocated national implementation of the CAP beginning January 1, 2006. We agree with these commenters that it is important to provide an alternative to the ''buy-and-bill'' method of drug acquisition for physicians as widely and quickly as possible. We have therefore decided to implement the program for the broad drug categories that we have previously described on a nationwide basis January 1, 2006.

We also agree with those commenters who recommended initially implementing the program in a single, nationwide competitive acquisition area for several reasons. First, in a single national area, the number of Medicare beneficiaries and physicians is sufficiently large to encourage vendors to participate. In addition, starting with a nationwide competitive acquisition area allows additional time to consider whether smaller, regional competitive acquisition areas should consist of single States or multiple States. Also, implementing the program initially in a single nationwide area would impose less administrative burden on potential bidders than other options, because each applicant would be submitting bids for contracts to cover one geographic area. Finally, implementing a nationwide competitive acquisition area initially allows us to develop and evaluate the administrative structures of the new program in conjunction with the relatively smaller number of vendors that can operate on a national level before extending the program to the larger number of vendors that might operate on a State or regional level, while still providing all physicians the opportunity to participate from the outset. It is important to note that we received 15 responses to our December 13, 2004 Request for Information. All these responders expressed an interest in participating in the CAP. Most of these responders indicated a willingness to provide selected Part B drugs on a nationwide basis. We therefore believe that implementing the CAP initially in a single nationwide competitive acquisition area will allow for an appropriate level of competition among vendors to provide drugs for physicians.

We also agree with those commenters who supported phasing in the CAP. We agree with these commenters that phasing in the CAP would give us the opportunity to test and refine the administrative apparatus with a limited number of vendors before expanding the program to allow larger numbers of vendors to participate. Most of the commenters in favor of a phase-in recommended implementing the program initially on a limited geographic scale, such as one or more States or regions of the country. However, a few commenters supported an alternative phase-in approach that we discussed in the proposed rule. As we stated there, one way to phase-in the program is to begin with the limited number of vendors that can deliver drugs on a nationwide basis: ''the program could be phased in by initially employing a national competitive acquisition area. This would limit participation in the program initially to those vendors that could compete to bid and supply drugs nationally, to the

exclusion of the vendors that could bid and supply drugs on a regional or State basis. Under such a phase-in plan, the definition of competitive acquisition area would ultimately be established on the basis of regions, States, or some other smaller geographic area, which might expand the number of vendors that could bid to participate in the program.''

In this interim final rule, we are establishing a single, national distribution area for the initial stage of the CAP. This national distribution area will embrace the 50 States, the District of Columbia, Puerto Rico, and U.S. territories. In order to participate in this initial stage of the program, vendors will need to be appropriately licensed in all 50 States and the District of Columbia (as well as Puerto Rico and the U.S. territories). It is important that, as we discuss in section 2.C.1 of this interim final rule, vendors submitting bids to participate in the program may employ subcontractors, including vendors that operate on a State-wide or regional basis, to provide for distribution of drugs across the nationwide area that we are establishing. Under this phase-in plan, we expect that the definition of competitive acquisition areas will ultimately be established on the basis of regions, States, or some other smaller geographic area, which we expect to increase the number of vendors that could bid to participate in the program. We will consider how to establish smaller competitive acquisition areas (regional or State-based) as this initial phase of implementation proceeds. We welcome additional comments in response to this interim final rule on how to proceed with the development of smaller competitive acquisition areas for later stages of implementing the program. We anticipate that our final plan for those areas will not only allow smaller, State-based or regional vendors to compete for contracts under the CAP, but also preserve the opportunity for large vendors to participate in the program on a nationwide basis.

B. Operational Aspects of the CAP

1. Statutory Requirements Concerning Claims Processing

Section 1847B(a)(3)(A) of the Act sets forth specific requirements that have a direct impact on the administrative and operational parameters for instituting a CAP. This section of the statute requires the following: (1) Vendors participating in the CAP bill the Medicare program for the drug or biological supplied, and collect any applicable deductibles and coinsurance from the Medicare beneficiary. (For purposes of the preamble the term ''vendor'' means the term ''contractor'' as referred to in the statute.) (2) Any applicable deductible and coinsurance may not be collected unless the drug was administered to the beneficiary. (For purposes of the preamble the term ''drug'' refers to drugs and biologicals.) (3) Medicare can make payments only to the vendor, and these payments are conditioned upon the administration of the drug.

The statute requires the Secretary to provide for a process for adjustments to payments when payment was made for the drugs, but they were not actually administered to the beneficiary. The Secretary is also required to provide a process by which physicians submit information to vendors for purposes of the collection of applicable deductible or coinsurance. Payment may not be made for competitively biddable drugs supplied to a physician who has elected to participate in the CAP unless the vendor supplying the drugs has a contract to provide them in that geographic area and the physician receiving them has elected the vendor to supply that category of drug in that geographic area.

Section 1847B(b)(4)(E) of the Act requires that the vendor supply drugs directly only to the selecting physicians and not directly to individuals, except under circumstances and settings where the individual currently receives drugs in his or her home or another non-physician office setting, as provided by the Secretary. In addition, the vendor may not provide drugs to a physician participating in the CAP unless the physician submits a written order or prescription, and any other data specified by the Secretary, to the vendor.

However, the statute also makes it clear that the physician is not required to submit an order (prescription) for individual treatments of a drug or biological, and that the statute is not intended to change a physician's flexibility to choose whether to write a prescription for a single treatment or a course of treatments. In certain sections of the proposed rule, we used the term ''prescription'' and the term ''order'' interchangeably. Section 1847B of the Act uses the term ''prescription'' but does not define it. For purposes of the CAP, we proposed to interpret the term to include a written order submitted to the vendor.

We also noted that section 1847B(b)(4)(E) of the Act, in requiring that vendors deliver drugs only upon receipt of a ''prescription,'' expressly indicates that the statute does not ''require a physician to submit a prescription for each individual treatment'' or ''change a physician's flexibility in terms of writing a prescription for drugs or biologicals for a single treatment or a course of treatment.'' As we stated in the proposed rule, it is not our intention to restrict the physician's flexibility when ordering drugs from a CAP vendor.

Resupplying Inventory

Section 1847B(b)(5) of the Act requires the Secretary to establish rules under which drugs acquired under the CAP may be used to resupply inventories of these drugs administered by physicians. The statute contains four criteria that must be met in order for the physician to use this provision: the drugs are required immediately; the physician could not have anticipated the need for the drugs; the vendor could not have delivered the drugs in a timely manner; and the drugs were administered in an emergency situation.

Comment: One commenter stated that the statutory requirement to provide for a process of adjustments to payments in cases where payment was made for a drug that was not actually administered to the beneficiary was unnecessary and should be removed or clarified since under the proposed claims processing system payment to the vendor would not be made until administration was verified, unless CMS adopted the partial payment methodology.

Response: We agree with the commenter that generally the claims processing system we are adopting in this interim final rule makes it less likely that we will need to recover payments made in error to vendors for drugs that were not actually administered to the beneficiary, because we will not pay the vendor until the drug administration claim has been processed. However, it is still possible that claims filing and processing errors could occur and that as a result, a vendor could be paid in error. In that event, we will use existing overpayment recovery processes to recover claims payments made in error. Therefore, we are retaining the language at § 414.906(d).

Comment: Some commenters requested that we define the term prescription and/or order in the final rule preamble and regulations. Other commenters stated that because the statute uses the word prescription, CMS does not have the authority to redefine the term to mean an order. Several commenters characterized the drug order process described in the proposed rule as the filling of a prescription for a patient, and stated that only a licensed pharmacist may fill a prescription under State and Federal law. Another

commenter noted that ''prescription'' and ''order'' have very different meanings in the marketplace, with prescription being associated with precise pharmacy rules, and order being more commonly used to describe a distribution system. Some commenters requested that CMS define the program as either a pharmacy program or a distribution program and use consistent language within the regulation. Other commenters felt that there was no doubt that the statute required CMS to define the patient-specific drug order as a prescription and that CMS should consistently describe it as such.

Response: As we stated in the proposed rule, the statute uses the term prescription but does not define it. Further, the process envisioned in the statute contains elements more commonly consistent with orders as well as elements usually associated with prescriptions. We do not believe that the Congress intended us to abide by a rigid definition of a prescription. We note that CAP vendors must comply with State licensing requirements in all cases, and that our definition of prescription as used in the statute is not meant in any way to override those requirements. For purposes of this interim final rule, we will define the CAP drug ordering process as a prescription order and will add a definition of the term to the regulations text at § 414.902. For purposes of the CAP, we define a prescription order as a written order submitted by the physician to the vendor in accordance with the requirements of the CAP. (The discussion of whether CAP requires a drug distributor's license or a pharmacy license is dealt with in more detail in section II C, the CAP contracting process.)

Comment: One commenter believed that it was a violation of physician flexibility to require that in the case of a multiple source drug, vendors supply only one drug within each billing and payment code within each category.

Response: Section 1847B(b)(1) of the Act explicitly states the requirement, and we will implement it as stated in the statute: ''In the case of a multiple source drug, the Secretary shall conduct such competition among entities for the acquisition of at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area.''

Comment: Another commenter believes that CAP vendors should be prohibited from acting differently than the drug distributors or wholesalers with which the physician currently does business. That is, the vendor should be prohibited from exercising the responsibilities of a physician or a pharmacist with regard to drug interactions, appropriate dosing, or other issues such as substituting drugs in the physician's order.

Response: We expect vendors to perform their responsibilities consistent with applicable State law and this interim final rule. To the extent that the vendor is required by State law to include a pharmacist in the CAP process or to act as a pharmacy, the vendor may be required to discuss possible drug interactions or to perform other duties commonly performed by pharmacies. Although the CAP legislation does not require these activities as part of the CAP, neither does it excuse vendors from any applicable requirements under State law.

Comment: Some commenters supported the resupply criteria. Others, including an association of cancer centers, expressed concern about the strict requirements for physician compliance with the criteria for the resupply provision described in section 1847B(b)(5) of the Act and requested that CMS liberalize the provisions.

Response: The four criteria that govern the resupply option are contained in section 1847B(b)(5) of the Act, as specified above. The statute also states that the physician may use drugs and biologicals obtained from a CAP vendor to resupply drugs and biologicals that he or she has taken from his or her own stock to treat the beneficiary if the physician can demonstrate to us that all four of the criteria have been met. Because the criteria and the responsibility to comply with all of them are statutory, we do not have the authority to change them, or to allow that some of them be optional. However, we interpret ''timely manner,'' for purposes of the resupply provisions of the CAP, to mean the ability to meet emergency delivery standards for timely delivery as defined in § 414.902. That is, if the vendor could not have delivered the drugs to the physician to respond to the patient's clinical need for the drug under the emergency delivery process, then the vendor could not have delivered the drug in a timely manner for purposes of the resupply provisions. Further, we interpret the term ''emergency situation,'' for purposes of the resupply provisions of the CAP, to mean a situation that in the physician's clinical judgment requires immediate treatment of the patient. We have made some technical changes to these definitions in § 414.902. (These comments are further addressed in the claims processing/operational overview section that follows).

Comment: Some commenters suggested that in an emergency situation, the physician should be given the option of using the drug replacement option or of billing for the replacement drug using the ASP methodology.

Response: We believe that the Congress created the emergency resupply provision to address situations when a physician participating in the CAP would need immediate access to drugs but would not have the time to obtain them from the vendor. This provision allows a physician to treat the patient in situations that comply with the four criteria specified in the Act, and then obtain replacement drugs from the CAP vendor. This provision specifies that the physician obtain replacement drugs from the CAP vendor and thus does not allow the physician to bill under ASP in this situation.

2. Proposed Claims Processing and Operational Overview

To comply with the statutory requirements described above, in the March 4, 2005 rule, we proposed to implement a claims processing system that would enable selected vendors to bill the Medicare program directly, and to bill the Medicare beneficiary and/or his or her third party payor after verification that the physician has administered the drug. We set forth the proposed requirements for payment under the CAP at § 414.906 of our regulations. For the initial implementation of the CAP, we discussed our plan to designate one Medicare fee-for-service claims processing carrier to process all drug vendors' Medicare claims (and referred to this entity as the designated carrier.) Physicians who elect to participate in the program will continue to bill their local Medicare fee-for-service claims processing carrier for physicians' services.

Comment: One commenter supported CMS' plan to make a single designated carrier responsible for processing drug vendor claims. However, the commenter encouraged CMS to move toward having the Part B carriers process both the physician's claim and the drug vendor's claim at some point. The commenter also suggested that CMS consider aligning the CAP areas with the claims processing jurisdictions that CMS will adopt for the Medicare Administrative Contractors.

Response: We will continue to evaluate the operation of the CAP and will conduct the evaluation in the context of the implementation of Medicare contracting reform.

Roles of the Contractor

We proposed that both the designated carrier and the physician's local carrier would be charged with keeping track of the physician's vendor selection and making sure that the physician is administering drugs provided by the vendor with whom he or she has elected to participate. This process also would involve our central claims processing system.

The March 4, 2005 rule (70 FR 10754) also discussed the proposed operational structure for the CAP and the relationship and responsibilities of the participating CAP physician and approved vendor with respect to the ordering, delivery, and administration of the CAP drug and the payment aspects associated with the CAP drug. A summary of this proposed operational structure follows.

Ordering the CAP Drugs

We proposed that when a physician who has elected to participate in the CAP prepares an order for a drug to be administered to a Medicare beneficiary, the physician would provide basic information about the beneficiary and the beneficiary's third party insurance to the drug vendor. In addition, the physician would check that he or she was planning to use the drug consistent with any local coverage determination policies (LCDs), just as he or she would do now if obtaining a drug under the current payment methodology.

We proposed that the order transmitted between the physician and the drug vendor could occur in a variety of HIPAA-compliant formats, such as by telephone with a follow-up written order.

Comment: Several commenters stated that the drug ordering process outlined in the proposed rule will make it difficult for the physician to treat a patient on the patient's first visit to the office, which will necessitate at least a 1-day delay in treatment. If the patient's condition changes and a different drug or a different amount of the same drug is needed, delays could occur and additional work by the physician's staff to work with the vendor to make the necessary revisions may be necessary. The commenters requested that CMS try to incorporate more flexibility into the drug ordering process.

Response: The CAP drug ordering process must be considered in the context of the statutory requirements of a patient-specific drug ordering process, the requirement that payment to the vendor requires verification that the drug was administered, and the requirement that the vendor bill the Medicare program and the beneficiary or the beneficiary's third party insurance. We have defined delivery timeframes at § 414.902 in such a way that the physician should be able to obtain needed drugs quickly, since the vendor is required to provide routine delivery within two business days, and emergency delivery within one business day. The vendor may be required to ship drugs more quickly if the integrity of the product requires it. If the vendor's routine and emergency delivery processes would not enable the physician to obtain the drug quickly enough for a particular patient, the physician will have the option of obtaining the drug order under the emergency replacement process if the situation complies with the four criteria governing this process specified in the statute. There could be some rare occasions when the physician is unable to obtain a drug to treat a patient at the desired time. In that case, the physician could choose to refer the patient to another health service provider or hospital outpatient department for immediate treatment, or to ask the patient to return to the office for treatment on another day. Physicians may already face this prospect under the buy and bill methodology currently in effect. We hope that these situations will be rare under either the CAP or the ASP system. Physicians who find that the CAP requirements and advantages do not fit the needs of their practice have the option to continue to obtain Part B drugs for their practice under the ASP system rather than electing to participate in the CAP. Note that we have made a technical revision to the proposed definition of designated carrier and local carrier under § 414.902 to specifically reference ''CAP'' rather than ''Part B Competitive Acquisition Program''.

Comment: Some commenters asked for more information on how the carriers would apply coverage policies under the CAP, and whether CMS was planning to change its process for determining if drugs were covered for off-label uses. The Practicing Physicians Advisory Council (PPAC) recommended that CMS require CAP vendors to provide drugs for off-label use when evidence supports such use. In these cases, PPAC suggested that vendors could use established CMS processes for determining medical necessity.

Response: Determinations of medical necessity are made by the Medicare carriers and are not made by suppliers, such as the approved CAP vendor. As we stated in the proposed rule, the local carrier will be responsible for adjudicating the physician's claim for drug administration and checking that the claim is compliant with all local coverage determinations (LCDs). If the local carrier determines that the claim is not compliant with an LCD, the local carrier will deny the physician's claims for administering the drug and send a message to the CMS central claims processing system that the drug vendor's claim for the drug is also not payable. The local carrier will enforce its LCDs because they govern the rules in effect where the drug was administered. The designated carrier's LCDs would not play a role in determining whether the vendor's claim was payable except in its carrier jurisdiction if it is acting as a local carrier in that jurisdiction. It is not our intention to change our policy on the carrier's authority to make decisions about whether a particular medication will be covered. Under the CAP, the local carrier will continue to exercise the same process it currently uses for determining if a drug is payable. Similar to the scenario we have outlined for enforcement of the local carrier's LCDs, we anticipate that the local carrier will review a drug prescribed and make a decision about whether the physician's claim for administering the drug and the vendor's claim for the drug is payable under those circumstances. The local carrier will notify our central claims processing system about its decision, and the vendor's claim will be paid or denied accordingly. If payment for the drug administration claim is denied, the physician will have a responsibility to appeal the denial. As noted in section II.B.3 of this interim final rule, the vendor also may appeal the denial of the drug claim. The vendor also can ask the designated carrier for assistance under the dispute resolution process in making sure the physician's appeal was filed properly or in determining other steps that the vendor can take to resolve the situation. (For a more detailed discussion of this, see the section on dispute resolution at the end of this section.)

Comment: Some commenters requested guidance about how the Comprehensive Error Rate Testing Program (CERT) and the Recovery Audit Contractor Demonstration would apply to the CAP.

Response: We anticipate that the CERT Program will apply to the CAP claims, but the process for doing so has not been determined at this point. The Recovery Audit Contractor (RAC) Demonstration will not apply to the CAP, because there is an explicit exemption in the demonstration for claims that are adjudicated under special processing rules. Claims

processed for drugs provided under the CAP receive special treatment relative to the balance of Part B claims.

Comment: A commenter suggested that the final rule address the steps necessary for a non-CAP physician to refer a patient for treatment to a participating CAP physician.

Response: If a non-participating CAP physician refers a patient to a participating CAP physician, the participating CAP physician will treat the beneficiary as he or she would any other patient, because the decision to participate in the CAP is made at the physician level rather than on a beneficiary-by-beneficiary basis. The participating CAP physician would need to provide the same education about the CAP to the beneficiary referred by the non-participating CAP physician as he or she did for his or her regular patients. If the participating CAP physician needs to provide a drug to the referred patient and the drug is a CAP drug, the drug may be obtained from the approved CAP vendor. If it is medically necessary that the patient receive a specific formulation of a drug not available from the approved CAP vendor, the physician may obtain the drug under the ''Furnish As Written'' provision. Finally, if the drug the patient needs is not one that is included in the CAP category the physician would buy the drug and bill for it under the normal ASP system.

Comment: Several commenters requested guidance about whether the vendor would be able to refuse to ship an order if the vendor believed it was inconsistent with an LCD or if the designated carrier had denied payment for the drug previously for some other reason. Some commenters stated that the vendor should be prevented from substituting its decision making for that of the physician by refusing to ship an ordered drug or changing the dose of a particular drug.

Response: If the vendor believes a drug order is not consistent with an LCD, the vendor may call the physician to discuss the order and try to determine why the physician believes it will be covered under the local carrier's LCD. If the physician declines to change the order, but the vendor still believes the local carrier will not cover the drug, the vendor may ask the beneficiary to sign an Advanced Beneficiary Notice (ABN). Because approved CAP vendors will be Medicare suppliers, they will have the same right to issue ABNs that any other Medicare supplier has. A signed ABN would make the beneficiary liable to pay for the drug if the carrier denied the claim. However, in the event the vendor is not successful in collecting an ABN from the beneficiary, and the physician refuses to change the order, the vendor will still be required to provide the drug to the physician under its contract with us. If the claim for the drug administration is denied, the physician would be required to pursue an appeal of the denial with the local carrier. The vendor also may appeal the denial of the drug claim. If the claim ultimately remains unpaid, the vendor may ask the designated carrier for assistance under the dispute resolution process. (This process is described in more detail in the section on dispute resolution (section II.B.3 of this interim final rule).)

We are requiring the vendor to deliver the drug to ensure that the physician's judgment about the appropriate treatment for the beneficiary is primary in the decision-making process. In addition, the local carrier's coverage determination (rather than the designated carrier's) must apply in the local carrier's jurisdiction so that the same coverage policies are in force in an area regardless of whether a drug is paid for under the CAP or under the ASP system. The only exception to this policy is that if the beneficiary does not pay his or her cost sharing in certain circumstances, the vendor may refuse to ship additional drugs to the participating CAP physician for that beneficiary. For more information on this process, please see the discussion of beneficiary cost sharing later in this section.

Comment: One commenter requested that CMS clarify whether the local carrier may also apply its least costly alternative policy to the claim submitted under the CAP, despite the establishment of pre-determined CAP reimbursement rates.

Response: Least costly alternative policies are established by our contractors. Nothing in this interim final rule is intended to disrupt the longstanding ability of contractors to apply this policy under section 1862(a)(1)(A) of the Act. Section 1862(a)(1)(A) provides that notwithstanding any other provision in the Medicare statute (that is, including section 1847B of the Act), no payment may be made under Part A or Part B for any expenses incurred for items and services that are not reasonable and necessary. Medicare carriers establish local coverage determinations (LCDs), under which coverage for a particular drug is limited to the coverage level for its least costly alternative. If there is an LCD on a particular drug that contains a least costly alternative provision, and the drug is included in the CAP, when the participating CAP physician orders that drug, the drug claim will be paid subject to the LCA policy, rather than the CAP-established price. Both the physician and the drug vendor should be aware of any LCDs that are in effect in a particular jurisdiction. When ordering drugs we ask that the physician be mindful of the fact that the vendor's claim for drug payment will be dependent on the local carrier's coverage policies, including least costly alternative policies. As stated above, under its contract with us, the vendor would need to ship an ordered drug if the vendor believes it will receive a reduced payment because of a carrier payment policy. The vendor may call the physician to discuss the order, but if the physician confirms the order, the vendor must ship it. (The vendor would have the same right to collect an ABN from the beneficiary in this situation, as described elsewhere in this section. In addition, the vendor could appeal the drug claim denial. Further, the vendor may ask the designated carrier for assistance under the dispute resolution process.)

Comment: Some commenters support our proposal that the CAP order may be initiated via a Health Insurance Portability and Accountability Act (HIPAA) compliant phone call or fax with a follow-up written order. The vendor could begin filling the order but wait to finalize shipment until the written order is received. These commenters believe that this process would provide drugs to patients more quickly than if the vendor is required to wait until it has a written order in hand before it begins preparing the order. Additionally, one commenter asked that we clarify that electronic transmission of the drug order between the physician and vendor would be permitted.

Response: We appreciate that commenters supported our proposal. Both the participating CAP physician and the approved CAP vendor will be enrolled Medicare suppliers. As noted elsewhere, the approved CAP vendor will be a covered entity for purposes of the HIPAA rules. If a participating CAP physician meets the criteria under the HIPAA rules, he or she may also be a covered entity. Covered entities must comply with HIPAA privacy and security requirements. Where transmission of protected health information via electronic means would be permitted under the HIPAA privacy and security rules, covered entities may do so. The CAP statute and these implementing regulations are not intended to affect the manner in which HIPAA-compliant communications may occur.

Comment: One commenter requested clarification as to how, if at all,

physicians will be required to incorporate e-prescribing technologies if ordering drugs currently under the Part B program or acquiring drugs through the CAP.

Response: The MMA electronic prescription program provisions apply to the electronic prescription of Medicare Part D drugs for Part D enrolled individuals, not specifically Part B drugs. The MMA provides that not later than one year after the promulgation of final standards for Medicare Part D drugs for Part D enrolled individuals, prescription and certain other related information transmitted electronically can only be transmitted according to the adopted final standards. The Medicare Prescription Drug Benefit final rule (70 FR 4198, January 28, 2005) states that Part D sponsors that participate in the Part D program are required to support and comply with adopted electronic prescription standards. Physicians would not be required to write prescriptions electronically and therefore their participation in Part D electronic prescription drug programs would be voluntary. Those physicians that decide to prescribe Part D drugs electronically, however, would be required to comply with the adopted final standards. We proposed a foundation set of final standards in February 2005 (70 FR 6256, February 4, 2005) and hope to finalize those standards and require compliance by January 2006, when the Medicare Part D prescription drug benefit begins. We will also monitor the program as it develops to determine if some aspects of it could be adapted for use in the CAP drug ordering process.

Content of the CAP Drug Order

We proposed that the physician would transmit the following specific information to the CAP drug vendor from whom he or she has elected to receive drugs. (Abbreviated information could be sent for repeat patients.)

- Date of order
- Beneficiary name
- Physician identifying information: Name, practice location, group practice information (if applicable), PIN and UPIN, Drug name
- Strength
- Quantity ordered
- Dose
- Frequency/instructions
- Anticipated date of administration
- Beneficiary Medicare information/ Health insurance (HIC) number
- Supplementary Insurance information (if applicable)
- Medicaid information (if applicable)
- Shipping address
- Additional Patient Information: date of birth, allergies, Height/Weight/ ICD–9.

We specifically requested comments on this proposed information as well as any additional information that might be necessary.

Comment: We received several comments about the proposed content of the physician's order. Some commenters stated that the proposed items duplicate those submitted on a claim for service and do not reflect the information typically included in a drug order or prescription. *Other* commenters were concerned about compliance with HIPAA guidelines and requested that unnecessary patient-specific information be deleted from the order form. Commenters also stated that the detailed list of order information should be needed only for the initial order for a new patient. They noted that subsequent orders could be greatly abbreviated.

Response: The statute provides that we must establish a process for the sharing of applicable deductible and coinsurance information between the participating CAP physician and the approved CAP vendor. The participating CAP physician is also required to submit a prescription order to the approved CAP vendor to order drugs for an individual patient. The order form information that we proposed in the proposed rule contains information necessary to comply with both of those requirements. It is not possible to link beneficiary-specific information from our claims processing system with the physician's order before the drug vendors compiling the information necessary to prepare the drug order and return it to the physician because it is not possible for a provider to query the system and obtain beneficiary billing information. Allowing suppliers and providers to obtain beneficiary specific information from the Medicare claims processing system could be a violation of beneficiary privacy rules. In addition, the statute specifies that this information will be provided by the physician. The HIPAA guidelines allow the sharing of beneficiary-specific information necessary for treatment purposes. Without needed information, the approved CAP vendor will be prevented from completing the drug order accurately and providing the drug to the participating CAP physician so that the required treatment can be administered to the patient. We are specifying in our regulations that the participating CAP physician will be required to provide the approved CAP vendor complete patient information only for the initial order, or when the information changes (for example, the patient develops a new drug allergy). The approved CAP vendor will specify which information is necessary on a follow-up order.

Comment: One commenter stated that the physician may be uncertain when the patient will be receiving his or her treatment, and thus it may not be possible to determine the anticipated date of treatment with any accuracy. This commenter recommended instead that CMS allow the physician to specify a range of dates when the treatment may be administered.

Response: We agree with the commenter that it may not be feasible for a physician to establish in advance an exact date for drug administration. We will specify that providing the vendor with a range of dates over a 7-day period will be sufficient. We have selected the 7-day timeframe based on our understanding that many of the drugs included in the CAP are used in a treatment regimen that repeats on a weekly basis. The 7-day time period is intended to provide the physician with flexibility to shift the specific date of administration of needed drugs within a specified period without overlapping the next treatment period. When the approved CAP vendor submits its claim for the drug, the vendor will be instructed to include the first day in the 7-day period as the date of service. Because the vendor will not know the actual date the drug is administered before submitting its claim, the date of service will not be used to match the approved CAP vendor's claim with the participating CAP physician's claim. Instead, as described later in this section, a unique number will be used to match the claims.

Comment: Some commenters recommended that CMS eliminate the ''Additional Patient Information'' (date of birth, allergies, height, weight, ICD–9 codes) specified in the potential list of data elements. Information related to height and weight would be used by the physician to determine the dose, and the ICD–9 would be included on the physician's claim form, so the physician would not need to provide it. The commenters stated that this type of information was not typically included in a drug order and that the CAP vendor should not use the information to perform pharmacy functions.

Response: Based on our decisions regarding the approved CAP vendor's ability to break up shipments in appropriate circumstances, our conclusion that approved CAP vendors may directly appeal the denial of their

drug claims, and the fact, with limited exceptions, that approved CAP vendors must ship CAP drugs upon receipt of a prescription order, we believe it is important for approved CAP vendors to have the information specified above. For example, ICD–9 information may help an approved CAP vendor assess whether it should seek to obtain an ABN from the beneficiary. Dosing information will help an approved CAP vendor determine whether it can appropriately split a prescription order into separate shipments. Patient date of birth is required by the Medicare claims processing system and is a required field on the claim form.

Comment: Another commenter noted that because the proposed order form information requested the frequency with which the drug was to be given, the physician was being required to submit a treatment and delivery schedule that would be difficult to comply with for some individuals, such as ''snowbirds'' who obtain their drugs from multiple locations.

Response: The expected frequency of drug administration is needed so that the approved CAP vendor can determine how often the drug will be administered, the amount of drug to ship at one time and the appropriate timing of the shipments. Should the participating CAP physician need to deviate from the anticipated schedule, that can be accommodated. However, if the change in the administration schedule will require the approved CAP vendor to ship more drugs, or ship them on a different schedule, the participating CAP physician will need to inform the approved CAP vendor.

Comment: Another commenter pointed out that a physician may have several practice locations and that it is important that a physician's practice location be included in the information that the physician will provide to the vendor. (Additional elements of this comment are addressed in the section below on shipping.)

Response: A physician's practice location and his or her shipping address are both included as required data elements in the CAP drug order.

Comment: One commenter suggested that the order form should also include beneficiary contact information (phone number, billing address) and credit card information to enable the vendor to collect the beneficiary's coinsurance.

Response: We will add beneficiary's address and phone number to the required list of data elements to enable the approved CAP vendor to mail the bill to the beneficiary and to call him or her should there be an error in mailing to correct the address. The statute requires that we develop a process for the sharing of information between the participating CAP physician and the approved CAP vendor related to the payment of deductible and coinsurance. We have interpreted this to mean beneficiary contact information, Medicare information, and third party insurance information. We will not ask the physician to collect the beneficiary's credit card information and share it with the vendor because it is not information necessary to complete the drug ordering process, nor is it part of any supplemental insurance coverage that the beneficiary may have. Should the beneficiary choose to pay his or her share of the coinsurance via a credit card, he or she can provide that information directly to the approved CAP vendor after receiving a bill.

Comment: One commenter requested that CMS begin using the National Provider Identifier (NPI) as soon as possible, but not later than May 2007 (the implementation date of the NPI).

Response: We plan to adopt the National Provider Identifier for use by the CAP as soon as it is available.

In this interim final rule, we have made revisions to the required list of drug order information. We are adding that ''a range of dates not to exceed 7 days'' may be noted if the physician is uncertain of the specific date the drug will be administered. In addition, we are adding beneficiary's address and phone number; physician's shipping address, the National Provider Identifier, and patient's gender to the list. The information on patient's gender is required for claim submission and was inadvertently omitted from the list in the proposed rule.

The required list of drug order information will be the following:

- Date of order
- Beneficiary's name, address, and phone number
- Physician's identifying information: Name, practice location/shipping address, group practice information (if applicable), PIN and UPIN (NPI when available)
- Drug name
- Strength
- Quantity ordered
- Dose
- Frequency/instructions
- Anticipated date of administration (Range of dates not to exceed 7 days)
- Beneficiary Medicare information/ Health insurance (HIC) number
- Supplementary Insurance info (if applicable)
- Medicaid info (if applicable)
- Additional Patient Information: date of birth, allergies, Height/Weight/ ICD–9 code
- Gender

In the March 4, 2005 rule, we proposed that the participating CAP physician could place an order for a beneficiary's entire course of treatment at one time, but that the approved CAP vendor could split the order in to appropriately spaced shipments. The approved CAP vendor would create a separate prescription order number for each shipment and the physician would track each prescription order number separately and place the appropriate prescription order number(s) on each drug administration claim. The physician would have the ability to modify the course of treatment and submit a separate prescription order as necessary.

Comment: Many commenters supported our proposal that the physician should be able to place one order for the entire course of treatment because it reduces the burden of CAP ordering on both physicians and vendors. However, some commenters supported, while others opposed, our proposal that the vendor, at its discretion, could split the order into different shipments. Those opposed were concerned that some shipments might not arrive timely and needed treatment could be delayed to the beneficiary. Another commenter stated that the vendor should not be allowed to ship more than one visit's drugs at one time, because many physicians' practices will not have the space to store additional inventory.

Response: We plan to implement our proposal and allow the approved CAP vendor to split shipments. We believe the commenters' concerns regarding potential delays in split orders are adequately addressed by the routine and emergency delivery timeframes discussed elsewhere in this interim final rule because the approved CAP vendor will still be required to deliver the initial dose of the drug within two business days for routine delivery or one business day for emergency delivery. Delivery timeframes are discussed in more detail later in this section. We will require that if the approved CAP vendor opts to split shipments, the approved CAP vendor must notify the physician in writing that it is a split shipment and of the schedule for delivering subsequent shipments. We will also require that incremental shipments must arrive at least two business days before they are expected to be administered to a patient (as noted on the prescription order). The two-business-day time period is consistent with the routine delivery timeframe, and should ensure that the physician has sufficient time to obtain

the drugs under the emergency delivery timeframe in the event that they are not delivered within the routine delivery timeframe. In response to the commenters who were concerned that physicians may not have the space to store an entire course of treatment and wanted drugs shipped incrementally, we will allow the physician to specify to the approved CAP vendor whether or not he or she can accommodate larger shipments based on a prescription order for a course of treatment, if the approved CAP vendor desires to do so. The participating CAP physician could also control the amount of drugs that were shipped by ordering smaller quantities of drugs at one time.

Comment: Another commenter requested clarification of whether one prescription order number will be assigned for each patient or whether multiple prescription order numbers will be assigned (that is, one for each drug). These commenters proposed that each drug should have a separate prescription order number, which would include a unique patient identification number. This number should be attached to the drug to decrease the possibility of patient billing errors.

Response: We will require that each dose of a drug must have a separate prescription order number in order to facilitate claim matching and approved CAP vendor payment. The prescription order number will be unique to a dose of a drug to be administered to a particular beneficiary in one setting. It will include an approved CAP vendor specific identification number, the HCPCS code for the drug, and a randomly generated number. The beneficiary information will be provided by the HIC number that will be entered separately on the claim form. Because of privacy concerns we are not making the HIC number part of the prescription order number.

Drug Vendor's Prescription Order Process

In the proposed rule, we specified that the approved CAP vendor would receive the prescription order from the physician, check the physician's CAP eligibility from a list provided by the designated carrier and verify the beneficiary's Medicare eligibility with the designated carrier.

After those checks were completed, the approved CAP vendor would generate a prescription order number that would include the approved CAP vendor's assigned identification number and the drug HCPCS code. The approved CAP vendor would assemble the prescription order and prepare it for shipping. The approved CAP vendor would ship the drug to the participating CAP physician using a delivery method specified by its contract with us.

Comment: One commenter requested additional information on the process that the vendor will use to verify the patient's Medicare eligibility with the designated carrier.

Response: We anticipate that the approved CAP vendor will contact the designated carrier by telephone to verify that the beneficiary has current Part B coverage. As well as being able to verify the beneficiary's coverage the carrier may also know whether another insurer is primary to Medicare.

Comment: One commenter requested clarification on whether the vendor would ship and bill drugs at the HCPCS level or the NDC level. The commenter believes that bidding, ordering and claims processing should all occur at either the NDC level or the HCPCS level.

Response: Drug ordering and claims processing will occur at the HCPCS level. Billing will occur at the HCPCS level, as occurs currently for Part B drugs. The drugs being furnished by the vendor will be identified at the NDC level during the bidding process. We intend for the approved CAP vendors to be able to furnish CAP drugs in a manner that minimizes waste, reshipping and risk of diversion. Noting that section 1847B of the Act states that competition shall occur, for multiple source drugs, for ''at least one competitively biddable drug * * * within each billing and payment code within each category,'' we encourage approved CAP vendors to submit bids in a manner that will provide them with flexibility in terms of providing more than one package size or formulation within a HCPCS code that contains multiple NDCs. The approved CAP vendor will be required to specify the NDCs that it will be providing for a particular HCPCS code for multi-source drugs. This information will be available to the physician when he or she chooses to participate in the CAP and may be used by the physician when selecting an approved CAP vendor.

Comment: Some commenters suggested that CMS develop a contingency plan for use in cases where the CAP runs into ongoing operational challenges that significantly delay drug delivery to oncologists and jeopardizes timely treatment of cancer patients. Under these procedures, commenters recommended that CMS consider permitting physicians to temporarily revert to billing under the ASP system.

Response: Should a drug delivery problem develop with one of our approved CAP vendors, we will work with the approved CAP vendor through the designated carrier's dispute resolution process to promptly restore dependable service. If, despite all of our efforts to resolve the problem, we were to make a decision to terminate an approved CAP vendor for failure to comply with its contractual obligations, we would allow the affected physicians to switch to another approved CAP vendor who could assume the workload. Those physicians would also be given the option to revert to billing under the ASP system for the remainder of the year. In addition in situations where the emergency restocking criteria apply, the physician could use his or her own inventory and get a replacement from the vendor.

Submitting Prescription Order Number

Once a shipment is received from the approved CAP vendor, the participating CAP physician would store the drug until the date of drug administration. When the drug is administered to the beneficiary, the physician or his or her staff will place the prescription order number for each drug administered on the claim form submitted to the regular Part B carrier. Similarly, when the approved CAP vendor bills Medicare for the drug it shipped to the physician, it will place the relevant prescription order number on the claim form submitted to the designated carrier. We note that the electronic version of the Medicare carrier claim form has space for a series of prescription numbers, which we have not used previously for Part B drugs.

In the proposed rule, we stated that vendors and physicians who elect to participate in the CAP will need to be capable of submitting these prescription order numbers to us in their claims processing systems. If physicians and potential vendors are not already billing other payors using prescription numbers, they will need to work with their internal information systems staff or practice management software vendors to make the necessary changes to submit these data elements to Medicare in a manner consistent with HIPAA transaction guidelines for capturing prescription numbers.

Comment: One commenter indicated that to accommodate the new data element, his claims processing software would need to be modified. Another commenter requested that CMS issue billing instructions that instruct physicians regarding the appropriate HIPAA compliant fields on the 837 and CMS 1500 forms to use in submitting the prescription order number on their claims.

Response: As stated in the proposed rule, we are aware that our proposed claims processing system will require some physicians to modify their claims processing software if they do not already have the capability to submit claims with prescription numbers. After publication of the interim final rule, we will issue billing instructions with guidance about the appropriate fields on our electronic and paper claim form to use in billing.

Claims Processing Methodology

Our claims processing methodology will use the prescription order number to match the two claims and authorize payment to the approved CAP vendor. Payment to the approved CAP vendor will be dependent upon the filing of the drug administration claim by the physician, and the physician's claim being approved for payment by our claims processing system.

Comment: Some commenters stated that requiring the physician to put the prescription number on the claim form will complicate the billing process for the physician. In addition, one commenter believes that a separate billing process will be required for drugs billed under the emergency replacement process (discussed below), and that the physician will also require another process for drugs billed under the ''furnish as written'' methodology (discussed below). They suggested that in order to reduce physicians' cost, CMS should simplify the process so that one billing system could be used for all CAP drugs.

Response: We are aware that adding the prescription order number to the claim form will be an additional activity required for physicians who elect to participate in the CAP. Under the CAP program as we are implementing it, the use of the prescription order number is necessary to allow our claims processing system to match the physician's claim for administering the drug with the approved CAP vendor's claim for the drug. The physician's process for billing a drug administration claim for a CAP drug acquired through the regular ordering process and one acquired through the emergency replacement process will be essentially the same, except that the physician will add an additional modifier to the claim form indicating that the drug was acquired under the emergency replacement provision. The modifier is necessary to enable the carrier to identify the replacement claims. For drugs that the participating CAP physician acquires under the ''furnish as written'' process, the physician will bill for the drug and the administration under the ASP system that he or she currently uses. In these situations, the physician will place a modifier on his claim form that will allow him to bill for both the drug and the administration in that circumstance.

''Furnish As Written''

We proposed to allow the physician to obtain a drug under the ASP system in ''furnish as written'' cases when medical necessity requires that a specific formulation of a drug be furnished to the patient and that formulation is not provided by the approved CAP vendor. This situation closely parallels dispense as written (DAW) prescription orders that are used in retail pharmacies or other locations where a prescription is written and the physician wants the pharmacist to fill the prescription with a particular brand of the drug. In cases when the approved CAP vendor does not furnish a specific formulation of a drug or a product defined by the product's NDC number, and the physician has determined that it is medically necessary to use another brand of product within the HCPCS or an NDC that is not being furnished by the approved CAP vendor, the physician could purchase the product for the beneficiary and bill Medicare for it using the ASP system. The physician would be instructed to place a ''furnish as written'' modifier on his or her claim form and bill his or her Medicare carrier for the drug and the administration fee. The modifier would alert the carrier to allow the physician to bill under the ASP system in this case. We proposed that the physician's carrier would, at times, conduct a post payment review of the use of the ''furnish as written'' modifier. If the carrier determined that the physician had not complied with ''furnish as written'' requirements and that a specific NDC or brand name drug was not medically necessary, the carrier could deny the claim for the drug and the administration fee.

We established this method of alternative payment for a competitively biddable drug under proposed § 414.906(c)(2)(ii) of our regulations.

Comment: Commenters were generally in favor of the ''furnish as written'' proposal. However, some commenters who support the ''furnish as written'' provision felt it should be simplified and made easier for physicians to use or that CMS should create other options for the physician to accommodate clinical differences among patients who are on the same treatment regimen. Other commenters were concerned that the ''furnish as written'' option might be overused and subject to gaming by some physicians and manufacturers who were seeking a way to opt out of the CAP when it was financially favorable.

Response: We are implementing the ''furnish as written'' option as described in the proposed rule. The ''furnish as written'' option is intended to be used only occasionally in limited circumstances where a patient's medical condition requires a particular formulation of a drug at the NDC level—it is not intended to be used in routine situations as a means to circumvent the normal CAP ordering process. An example of a situation when the ''furnish as written'' option would be appropriate is where a participating CAP physician is treating a patient with a documented allergy to certain excipients or preservatives who requires a specific formulation of a product that the approved CAP vendor does not furnish as a part of its CAP contract. In this case, documentation of the allergy is a justification to use another product. However, this documentation must be maintained in the patient's medical record. Use of the ''furnish as written'' modifier will permit the physician to bill under the ASP system in this limited circumstance even though the physician has elected to participate in the CAP. Physicians who believe the ''furnish as written'' provision and the emergency replacement provision along with the drugs available through the regular CAP drug ordering process will not meet their patients' clinical needs may choose to continue billing under the ASP system rather than electing to participate in the CAP.

Comment: One commenter requested that CMS provide more guidance on what is meant by the term ''specific formulation.''

Response: A patient known not to respond appropriately to a certain formulation of a product may require a specific formulation of a product that is still within the same HCPCS, but not furnished under the approved CAP vendor's CAP contract because the approved CAP vendor submitted a bid to provide a different NDC within the HCPCS code. Documentation of treatment failure or adverse effects from specific formulations may provide justification to use another product (for example, if an approved CAP vendor was contracted to provide HCPCS code, J9260, which represents the drug Methotrexate Sodium). Several different manufacturers produce this drug, and it may be formulated with or without a preservative. Each product within HCPCS code J9260 has a specific NDC number. If the physician determines that it is medically necessary to administer the preservative-free

methotrexate injection for the patient, but the approved CAP vendor did not offer that product's NDC, the physician would be able to purchase the specific drug for the patient and bill for it under the ASP system by using the ''furnish as written'' modifier.

Comment: Another commenter asked whether the vendor might be able to discontinue providing a drug mid-year if it discovered that the CMS CAP payment amount was not covering its costs. Other commenters asked what would happen if a CAP vendor had trouble obtaining a CAP drug or it became unavailable.

Response: Once a vendor elects to participate in the CAP and decides for a multi-source drug which formulation of the drug (NDC) to provide within a HCPCS code, the approved CAP vendor will not be able to switch NDCs mid-year should the price increase. However, as discussed in further detail in section C.3 below, the statute provides for adjustments to the reimbursement for CAP drugs in certain circumstances in response to changes in the approved CAP vendor's reasonable net acquisition costs.

Mid-year changes will only be allowed should an NDC become unavailable or go through a period of short supply. We expect that the need for substitutions or changes will occur rarely. Although we would like to incorporate flexibility into this process so that an approved CAP vendor may react quickly to substitute an appropriate product, we are concerned that an unrestricted substitution process could have negative consequences. Although many multi-source products can be considered therapeutically equivalent, in some situations, differences in packaging, preservatives, fillers and dissolution rates for powders that require reconstitution may have clinical impact on the beneficiary and work flow impact on those who are preparing and administering the drug. If a vendor is facing a situation where a certain CAP NDC cannot be supplied, but a comparable product can be sent and the approved CAP vendor is willing to accept payment for that product at the CAP rate, the approved CAP vendor must contact the physician's office in order to have the office approve the substitution. This procedure is intended to be used occasionally and is not intended to justify a situation where an approved CAP vendor repeatedly calls a physician to seek approval for a less costly item. If the physician and the approved CAP vendor are unable to resolve short term issues around drug availability and substitution on their own, they may ask the designated carrier's dispute resolution staff for assistance.

In a situation where an item becomes unavailable for an extended period of time (more than 2 weeks), the approved CAP vendor must identify a replacement product or products, obtain CMS approval to do a long-term substitution from the designated carrier's medical director, and notify all physicians who have elected to receive CAP drugs from that approved CAP vendor in writing of the change. Payment for the substituted drug will be at the CAP bid price; the vendor may seek price adjustment at the following annual price adjustment period. Physicians who have elected to participate with that approved CAP vendor will be notified before such a change is made.

We request comments on refinement and alternatives to the short and long term substitution processes.

Comment: Other commenters stated that a physician who uses the ''furnish as written'' methodology to obtain needed drugs for his or her patients may be charged more by a non-CAP wholesaler because its volume has declined because of the physician's participation in the CAP. They propose instead that the physician be reimbursed for his or her actual acquisition costs of the drug instead of paying them under the ASP system.

Response: We do not have the statutory authority to allow physicians to be paid their actual acquisition costs for Part B drugs in this situation. Physicians have the choice of obtaining drugs under the ASP system or of obtaining them from the approved CAP vendor. The occasional need to purchase drugs outside of the CAP and which approved CAP vendor to select will need to be factored into the physician's decision to participate in the program. If an approved CAP vendor provides many of the drugs at the NDC level that a physician routinely uses, the physician should need to rely on the ''furnish as written'' provision rarely.

Comment: Some commenters questioned why the carrier would be conducting a retroactive review of the physician's use of the ''furnish as written'' option, because that would permit the physician to buy and bill the drugs under the ASP system. The commenters asserted that because physicians' ASP claims are not routinely reviewed by the carrier, physicians' use of this provision in the CAP should not be either. Another commenter stated that if the physician's use of the ''furnish as written'' modifier was denied on the basis of post payment review, this could trigger an obligation to appeal on the part of the physician. Some commenters stated that although physicians are accustomed to supporting medical necessity of their orders, historically this has not involved a comparison of clinical appropriateness of one drug within a HCPCS code with that of another.

Response: The statute is clear that for multiple source drugs, the approved CAP vendors are required to supply at least one drug NDC in each HCPCS code. It is also clear that physicians must elect the CAP for an entire drug category. As such, we believe it is appropriate to ensure physicians employ a ''furnish as written'' instruction only when medically necessary. As a result, it is important that physicians document the necessity of a particular formulation of a drug in the medical record. If the physician's use of the ''furnish as written'' option is denied by the local carrier, it will be up to the physician as to whether to appeal because payment to the approved CAP vendor will not be affected.

Comment: Some commenters from physicians' groups and some commenters from potential vendors have expressed an interest in the vendor's providing the needed drug in a ''furnish as written'' situation. Many of the physician commenters suggested that the vendor should be required to provide different formulations of a drug other than the one bid, while some potential vendors have suggested that they be given the option to provide it.

Response: As indicated above, we are implementing the ''furnish as written'' provision described in the proposed rule, but we have moved it as an element to § 414.908(a)(3) as this placement is more appropriate. The CAP statute and section 1861(s)(2)(A) of the Act, as amended by Section 303(i) of the MMA, contemplate that approved CAP vendors can submit claims and be paid for drugs only when they are provided through the CAP. Thus, we do not believe the commenter's proposal to allow the approved CAP vendor to provide the drug under the CAP in ''furnish as written'' situations is feasible.

Timeframes for Routine and Emergency Shipment

Section 1847B (b)(2)(A)(i)(II) of the Act requires that approved CAP vendors have sufficient capacity to acquire and deliver drugs in a timely manner within the geographic area, to deliver drugs in emergency situations, and to ship drugs at least 5 days each week. However, the statute does not provide specific definitions of these timeframes. In addition, as noted previously, the

statute requires that the approved CAP vendor may not provide drugs to a participating CAP physician unless the physician submits a written prescription order to the approved CAP vendor.

We proposed that a CAP prescription order could be initiated by telephone and followed up with a written order. We proposed that the delivery time period would begin when a drug order was received by the approved CAP vendor and would end at the time of delivery to the physician's office or other intended setting. We proposed that routine shipments of drugs furnished under the CAP would occur within a one- to two-business-day time period and that the duration of the delivery time period must not exceed the drug's stability in appropriate shipping containers and packaging. Emergency drug orders would need to be furnished on the next day for orders received by the approved CAP vendor before 3 p.m. (approved CAP vendor's local time). We requested comment on how to define timely delivery for routine and emergency drug shipments and on the feasibility of requiring a shorter duration for routine delivery of CAP drugs and of providing same-day deliveries for orders received for emergency situations.

Comment: Comments on the definition of an appropriate timeframe for deliveries defined a relatively narrow potential timeframe. The shortest recommended timeframes were daily, or up to twice daily deliveries for emergencies, while the longest timeframes were three to five business days. Most comments suggested a one- or two-business-day timeframe for delivery in routine cases and overnight delivery for emergencies. The relatively short turn around time assumed a ''clean'' order—one without patient safety, logistical, or payment problems. One comment suggested category-specific timeframes.

Response: At the program's start, we plan to implement a two-business-day timeframe for routine deliveries and a one business day timeframe for emergency deliveries, except for deliveries to certain U.S. territories in the Pacific, as discussed below. However, these timeframes shall not exceed the drug's stability in appropriate shipping and packaging as defined by manufacturer's labeling, drug compendia, or specialized drug stability references used in the practice of pharmacy or drug distribution. If drug stability necessitates a shorter shipping timeframe, or specialized shipping conditions, the approved CAP vendor must comply with them. For example, some drugs may require insulated packaging and/or cold-packs to prevent exposure to temperature extremes during shipping. Furthermore, we are aware that some drug products are shipped by express carriers in such conditions and are marked ''perishable.''

The delivery timeframe begins when a complete CAP prescription order is transmitted from the participating CAP physician to the approved CAP vendor. The participating CAP physician may begin this process with a phone call to the approved CAP vendor, but must follow-up with a written prescription order within 8 hours for routine deliveries. For emergency deliveries, a telephone order must be immediately followed with a written prescription order. If the participating CAP physician does not meet these deadlines for sending the written prescription order, the emergency or routine delivery timeframes are delayed accordingly until the written prescription order is received. The delivery timeframe ends when the drug is received at the participating CAP physician's office. A written prescription order may be transmitted by FAX, e-mail, or mail, subject to applicable HIPAA privacy and security requirements, and any applicable State pharmacy laws. As specified earlier, all communication between the physician and the approved CAP vendor must be conducted in accordance with applicable HIPAA privacy and security requirements, and with any applicable State pharmacy laws.

The approved CAP vendor is responsible for complying with the timeframes for routine and emergency delivery, as well as with the requirements for appropriate shipping conditions for drugs. If the participating CAP physician is dissatisfied with the vendor's compliance with the shipping timeframes or the manner in which drugs are being shipped, the physician should address the issue by means of the vendor's grievance procedure. If the two parties are unable to resolve the situation to their satisfaction they may ask the designated carrier's dispute resolution staff for assistance.

We believe that the two-business-day period for most routine prescription orders will provide an opportunity to resolve many common problems that can occur with transmitted drug orders, like legibility or poor transmission quality, simple clarification, etc. The two-business-day timeframe also provides a greater window of opportunity for approved CAP vendors and participating CAP physicians who are in different time zones to interact. The intent of the two-business-day timeframe is to balance the cost of shipping with potentially changing clinical requirements of a patient population and the requirement that needed drugs must be available promptly to the physician. The intent of the one-business-day timeframe for emergency deliveries is to accommodate the physician's need for more rapid delivery of drugs in certain clinical situations where the patient's rapidly changing condition requires it with the vendor's ability to ship the drug and have it delivered promptly in a nationwide delivery area. The emergency delivery option is not intended to be used routinely. It should be reserved for those situations when the patient's need for the drug could not have been accommodated under the routine delivery timeframe. At a minimum, under both the routine and emergency delivery timeframes, we expect vendors to accept new prescription orders until at least 5 p.m. (vendor's local time) on business days and we expect physicians to be able to take receipt of deliveries on business days until at least 5 p.m. (physician's local time). For emergency deliveries, we expect that the vendor will make the necessary adjustments in order to be able to prepare the drug for shipping and to deliver it the next business day. We note that the physician and the vendor will each need to be mindful of the time zones within which each are located. CAP participating physicians and approved CAP vendors operating in different time zones will need to be aware of cut-off times for placing orders and coordinate appropriately. We also point out that in some cases, two-business-day shipping may actually require several calendar days of transit during weekends and the commonly observed Federal holidays of New Years, Memorial Day, Independence Day, Labor Day, Thanksgiving, and Christmas. Some degree of coordination between the vendor and the physician's office will be required in those situations, and we stress that the drugs shipped must be packaged in a manner to preserve product integrity during shipping, for example to withstand temperature changes during shipping.

Specific examples appear below.

Example 1: The two-business-day timeframe for routine deliveries means that the physician's office may expect to receive a CAP prescription order on the second business day after it was placed. Therefore, an order received in the approved CAP vendor's office on a Monday by 5 p.m. (Vendor's local time) would arrive in the physician's office no later than Wednesday at 5 p.m. (physician's local time). Orders placed on Friday would arrive no later than

Tuesday. (Note: These orders must comply with the process specified above if the initial prescription order is placed by phone, the follow-up written prescription order must be received within 8 hours for routine deliveries.

Example 2: The one-business-day timeframe for emergency deliveries means that an order received in writing in the approved CAP vendor's office at 1 p.m. (approved CAP vendor's local time) on a Wednesday must be received by the physician in his or her office by 5 p.m. Thursday (physician's local time).

These are minimum standards, and nothing precludes the approved CAP vendor from using faster services and alternative delivery times (for example, Saturday delivery) when these services are available and appropriate. If an approved CAP vendor routinely offers faster shipping services, the approved CAP vendor should inform the physician of their availability.

We believe that the timeframes defined above, are practical and apply to the vast majority of situations that will be experienced at the program's implementation. However we anticipate that there will be occasional situations where a CAP vendor will not be able to furnish a drug to an office because the drug is needed sooner than the available delivery timeframes allow. In these situations, the vendor may elect to use the emergency resupply procedures described later in this section, if the situation complies with the relevant criteria.

The CAP was not designed to supply drugs that would be needed in emergencies such as acute care settings. However, we believe that even with a national program, an approved CAP vendor with multiple distribution points can provide turnaround in less than one to two business days in many situations.

Our discussions above reflect our anticipation that most shipments will occur within the continental United States. However, the initial CAP competitive acquisition area also includes Alaska, Hawaii, and the United States Territories. (We note that the United States territories in which Medicare pays for services are defined in § 400.200 of our regulations as the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.) We believe that shipping to Alaska, Hawaii and the eastern territories (that is, Puerto Rico and the U.S. Virgin Islands) within the timeframes described above is feasible, and we will require the vendor to ship to those areas within the standard routine and emergency timeframes. However, we are concerned that based on available information on shipping costs and delivery time periods, these timeframes may be too narrow for territories in the Pacific (that is, Guam, American Samoa, and the Northern Mariana Islands). Although the CAP drug vendor may be able to meet these timeframes in certain cases, the financial cost of doing so could greatly exceed the vendor's regular delivery costs. Therefore we are setting the standard delivery timeframes for the Pacific Territories, (Guam, American Samoa, and the Northern Mariana Islands) based upon delivery information available from commercial shippers, to be seven business days for routine delivery, and five business days for emergency delivery.

As we gain operational experience with CAP, we would like to explore being able to provide more rapid order turnaround, particularly in urgent situations. We are requesting comments on shortening the routine shipping timeframe to one business day and for requiring shorter shipping timeframes for emergency orders, especially the logistical and cost factors involved for same day or overnight delivery with early morning drop off. We are specifically interested in examples of circumstances when it would apply, who would be responsible for the cost of more rapid shipping methods, how unnecessary express shipping could be avoided, how approved CAP vendors who frequently missed timely delivery deadlines for same-day shipments would be sanctioned, and how those who abuse express shipments by seeking express delivery unnecessarily would be sanctioned. We ask that commenters address whether same day shipping can provide any real benefit to beneficiaries, or if overnight delivery with early morning drop-off is sufficient. We also welcome comment on the practicality of the timeframes set above for the Pacific territories and other areas outside of the continental United States. We seek input on whether the timeframes in general should be adjusted and whether the timeframe for delivery to the Pacific territories are reflective of current delivery timeframes used by other drug distributors shipping to those locations.

Comment: Some commenters stated that the CAP requirements should specify that the physician could return without penalty any drug that arrived in damaged condition or whose integrity the physician believes may have been compromised. The commenters requested that the approved CAP vendor not be allowed to require the physician to seek a remedy from the company that delivered the product.

Response: At the time a shipment of CAP drugs is received at the participating CAP physician's office, we expect that the individual who takes receipt of the order will be responsible for inspecting the external condition of the package(s) and will be given an opportunity not to accept the shipment on the basis of potential compromise of the product's integrity or damage during shipping. This initial inspection is not meant to be a final inspection, and we realize that some types of damage or compromise in integrity may only become apparent after the package is opened and the drug is being readied for use. A physician may return a drug product to the approved CAP vendor at any time if the product's integrity is in question. We recommend that returns of product on the basis of product integrity be coordinated with the approved CAP vendor so that the approved CAP vendor may take appropriate action to follow up on the reason for the breach of integrity. (Delivery requirements are also addressed in section II.C.2 of this interim final rule, ''Bidding Entity Qualifications.'')

Resupply Option for Emergency Situations

We proposed to implement the criteria specified in section 1847B(b)(5) of the Act that governs when in emergency situations, drugs acquired under the CAP could be used to resupply inventories of drugs administered by physicians. The four criteria contained in the Act are: (1) The drugs were required immediately. (2) The physician could not have anticipated the need for the drugs. (3) The approved CAP vendor could not have delivered the drugs in a timely manner. (4) The drugs were administered in an emergency situation. In section II.C.2.a. of this interim final rule, we requested comment on how to define timeframes for timely delivery, for emergency delivery, and for additional criteria we could use to define the replacement process.

We proposed that in emergency situations that met the criteria outlined above, the physician would treat the Medicare beneficiary with a drug from his or her own stock. After administering the drug to the beneficiary, the physician would prepare an order, identifying the drug as an emergency replacement for a drug already administered to the beneficiary. This notation could involve the use of a modifier to a HCPCS code, or another standardized means of incorporating the information into a claim. The approved CAP vendor would prepare the drug order, assign the unique transaction

identification (or prescription) number, and ship the replacement product to the physician. When the drug was received from the approved CAP vendor, the physician would return the drug to his stock. Both the physician and the approved CAP vendor would bill normally for the drug or its administration as applicable. We anticipated that the physician's carrier would, at times, conduct a post payment review of emergency drug replacement in order to determine whether physicians were complying with conditions for emergency drug replacement.

Comment: Some commenters were concerned that neither the statute nor the proposed rule defines ''emergency,'' and encouraged CMS to provide a definition in the final rule. They also questioned whether the definition of emergency would cover situations when the approved CAP vendor failed to deliver a needed drug within specified timeframes. Some commenters proposed that CMS define an emergency to allow any situation the physician felt required immediate attention would meet the criteria.

Response: We believe that the definition of emergency to be used in the emergency replacement provision should be one that enables the physician to use his or her clinical judgment to determine when his or her patient needs immediate treatment. We will define an emergency for purposes of this provision as a situation determined by the physician's clinical judgment to be an unforeseen situation and require prompt action or attention. Should the more expansive definition of the term appear to be causing overuse of this provision, we will consider adopting a more limited interpretation in the future. We will require that physicians ordering drugs under this provision continue to comply with the 14-day prompt filing requirement. The approved CAP vendor will provide a replacement drug from the same HCPCS category that it is providing in the CAP.

In determining whether the patient's need for the drug complies with the emergency replacement criteria, the physician will assess whether all of the criteria are applicable and will document the patient's medical record accordingly. If the approved CAP vendor's emergency delivery timeframe would result in delivery of the drug after the time necessary to meet the patient's clinical need, it shall be considered that the drug could not have been delivered timely. (Refer to the previous section on delivery times for more detail on the definition of routine and emergency deliveries.)

Comment: Another commenter expressed concern about enforcement, especially any documentation requirements for physicians using the emergency resupply provision.

Response: The process for billing for drugs ordered under the emergency resupply provision will be very similar to the regular CAP billing process, with an additional modifier that the physician will add to the claim. The physician will be expected to maintain documentation in the patient's medical record to verify that he or she complied with the criteria governing the resupply provision.

Comment: One commenter suggested that CMS design the CAP ordering process so that the physician could obtain extra doses of CAP drugs from the approved CAP vendor to keep in his or her inventory should the need arise to administer them to Medicare beneficiaries in an emergency situation. This process would be in addition to the process specified under the emergency resupply option.

Response: The statute does not directly address whether an alternative method for emergency drug replacement is permissible. However, it contemplates a beneficiary-specific order, and states that the approved CAP vendor shall not deliver drugs to the physician except upon receipt of the prescription order and such necessary data as may be required by the Secretary to carry out section 1847B of the Act. However, the statute provides for the replacement of drugs taken from a physician's own inventory in an emergency situation where the physician has administered drugs from his or her own stock. In that case, where the emergency resupply criteria are met, the participating CAP physician can replace the drugs that were used from his or her own inventory by means of an order to the approved CAP vendor. Although we recognize the commenters' concerns, we are also concerned about the potential for abuse if a stock of the approved CAP vendor's drugs was placed in physician's offices for use only by CAP patients in very limited circumstances. We believe because of potential program integrity and drug diversion concerns that the emergency replacement provision specified in the statute is the more appropriate way of providing needed drugs to beneficiaries when the patient's clinical condition does not allow time to obtain the drug from the approved CAP vendor.

Delivery of the CAP Drugs

As we specified in the proposed rule under § 414.906(a)(4) of our regulations, approved CAP vendors would deliver drugs directly to physicians in their offices. Although the statute allows us to provide for the shipment of drugs to other settings under certain conditions, we did not propose to implement the CAP in alternative settings at this time.

Comment: A commenter pointed out that a physician may have several practice locations. If the patient should change his or her site of treatment from the one to which the vendor originally shipped the drug, the physician will need an appropriate way of transporting the drugs from one location to another. Some potential vendors expressed concern that drugs could be improperly moved to an alternative location and that, as a result, spoilage and breakage could occur. They expressed concern that since the vendor retains ownership of the drug until it is administered to the beneficiary that they could be held liable if the drug deteriorates and is administered to the beneficiary in substandard condition.

Response: We recognize that a physician or group of physicians may maintain multiple office locations and, as a result, may desire to administer drugs to patients at any one of these multiple locations. Under the CAP, we will require the physician practicing individually, as well as the physician who is practicing as part of a group, to provide the address at which business will be conducted as part of the CAP election process. In the March 4, 2005 rule, we proposed that the vendor provide the ordered drugs to the address that the physician(s) specified on the election form. At this time, it is not a uniform requirement that physicians with multiple practice locations be issued a unique practice identification number (UPIN); therefore, in this interim final rule, we are expanding the reporting information on the election form to allow physicians to provide multiple addresses if they will be administering CAP drugs in multiple locations. We have also revised § 414.908(a)(3)(v) to add the physician's shipping address to the information that the physician will provide to the vendor on the prescription order. In response to the concern expressed by potential vendors about the possible damage to CAP drugs if they are transported by the physician, we will require that physicians must have CAP drugs shipped directly to the location at which they plan to administer them. The physician may not transport CAP drugs from one location to another. We are adding this requirement to the regulations at 414.908(a)(3)(xi). We understand that there may be occasions where a physician may currently transport drugs purchased under the

ASP system in order to administer them to Medicare beneficiaries in their homes. We seek comment on how this could be accommodated under the CAP in a way that addresses the product integrity concerns expressed by the potential vendors.

Storing the CAP Drugs

We proposed that the physician's office staff would receive the CAP drug(s) and store them until the time of administration. Although the statute discusses a patient-specific drug ordering process, it does not address the methods that may be used to store and inventory drugs in an office or clinic setting, or the potential burden associated with storing a patient's CAP drugs separately from other drugs. We believe that less burdensome alternatives to keeping separate inventories exist; however, any alternatives would be required to maintain program integrity and product integrity and to minimize the risk of diversion and medication errors. We do not believe that separate physical storage of CAP drugs is required. However, we proposed that physicians participating in the CAP would be required to maintain a separate electronic or paper inventory for each CAP drug obtained. We requested comment on additional requirements that we should impose on maintaining CAP inventory.

We also proposed that if for some reason the drug could not be administered to the beneficiary on the expected date of administration, the physician would notify the vendor and reach an agreement on how to handle the unused drug, consistent with applicable State and Federal law. The notification would also serve to inform the vendor not to submit a claim for the drug. If the vendor and the physician agreed that the drug could be maintained in the physician's inventory for administration to another Medicare beneficiary at a later time, the physician would generate a new order form at that time. Included in the order would be a notation that the drug was being obtained from the physician's inventory of the vendor's drugs and that the vendor need not ship the drug.

Comment: Some commenters, responding to the suggestion that CAP drugs would not need to be separately physically maintained, indicated that this would not allow the physician's staff to determine visually the amount of stock on hand and for which patient it was intended. Another commenter stated that the physician would actually need three separate inventory areas (for non-CAP drugs, for CAP drugs and for CAP emergency drugs) and doing so would require additional storage space, and could increase the risk of drug administration and claims processing errors.

Response: As we stated in the proposed rule, the physician is required to keep track separately of each CAP drug obtained for each beneficiary. Beyond this requirement, each physician may decide the most feasible way for this to work within the confines of his or her practice. If the physically separate storage of the drugs under CAP works better, then the physician is free to store the CAP drugs separately. If space limitations are an issue or if the separate storage of CAP drugs imposes an additional untenable administrative burden or creates confusion, then the physician is not required to store the CAP drugs separately. The CAP drugs, even if they are not stored separately, must in some way be tracked separately, either electronically or on paper; however, this could be something as simple as an electronic spreadsheet.

Comment: One commenter supported allowing CAP vendors and physicians to enter into contracts that would allow the vendor to receive returns of drugs that were shipped but not administered to the beneficiary. Many commenters expressed safety concerns with returns of unused drugs, especially partly used multi-dose vials. Another commenter addressed the burden of asking the physician to notify the vendor about the change of administration plans and negotiate redirection of the unused drug. Another commenter pointed out that State pharmacy laws may not allow for redirection of unused drugs dispensed for one patient to another; some manufacturers do not allow the return of drugs when they are ordered through a distributor; and there may be potential discrepancies between State law, manufacturers' requirements, and the CAP. One commenter asked whether the vendor could require the physician to retain the drug and attempt to use it on another patient. Another commenter requested that we explain the process that is to be followed if the vendor requests that the physician return the drug, and whether the physician would be responsible for paying the return shipping cost. One commenter stated that communication between the vendor and the physician should be handled electronically when a drug was not administered and that we should implement an electronic system to facilitate this communication. One commenter stated that return on unused drugs should only be allowed when the box has not been opened, and no patient labels are attached. The commenter also stated that 11 States allow for ''reuse'' of unused drugs in very limited circumstances. Typically unused drugs are destroyed by physician or pharmacy staff. The commenter requested that any reference to this possibility be removed to avoid giving the impression that we favored such an option in conflict with State law in many States. The commenter proposed that the vendor be compensated for drugs that are not administered to patients and cannot be billed. Another commenter suggested that we include a statement in the final rule that makes it clear that physicians participating in the CAP would be allowed to use CAP drugs ''only'' for a patient for whom the drugs were dispensed and identified by the beneficiary's Medicare number.

Response: We defer to State law and regulations as well as manufacturers' requirements concerning the disposition of drugs that are not administered or drugs that are left over from an administration. Section 1847B(a)(3)(A)(iii) of the Act states that payment for CAP drugs is conditioned upon the administration of such drugs. Therefore, we do not have the authority to pay for CAP drugs that were not administered to the beneficiary. Please refer to section II.C of this interim final rule for a more complete discussion of our policy on drug wastage and the process for returning unused drugs. Special contracts between the vendor and the physician should not be necessary to provide for the return of unused drugs because the participating CAP physician election agreement and the approved CAP vendor's contract with CMS, as well as the requirements stated in the regulations, address this issue. We are requiring that when a physician does not administer a drug during the time frame specified on the order form, or administers a smaller amount of the drug than was originally ordered, that the physician must contact the vendor to discuss what to do. If it is permissible under state law, the drug is unopened, and both the physician and the vendor are in agreement, the physician may retain the drug for administration to another Medicare beneficiary. However, before the drug could be administered the physician would need to provide the vendor with a new prescription order for the drug, and the vendor would need to supply the physician with a new beneficiary specific prescription order number.

Comment: One commenter inquired whether a physician will be able to use the CAP if he or she is aware that another insurance is primary to Medicare. In addition, commenters asked that we explain what happens if

the physician is not aware, before administering the drug, that another insurance is primary. The commenters also wanted to know if the CAP requirements will be different if the beneficiary has a Medigap policy.

Response: Many beneficiaries have coverage in addition to Medicare. For instance, some beneficiaries have a Medigap policy or another type of supplemental insurance that covers costs that Medicare does not. Some beneficiaries have retiree coverage through a former employer that is secondary to Medicare, and such coverage is, for practical purposes, similar to supplemental coverage because it may cover costs Medicare does not. (See section on beneficiary coinsurance for more detail.) However, many beneficiaries have employer coverage that is primary to Medicare. In this instance, Medicare pays secondary. A beneficiary's additional coverage may have an effect on when or from whom an approved CAP vendor receives payment. However, the requirements under the CAP will not be different. When a beneficiary has supplemental or secondary insurance, the approved CAP vendor may bill such insurance as appropriate (that is, after payment from Medicare). Where Medicare is the secondary payer and not the primary payer for the beneficiary, the vendor would bill the primary insurer first, and bill Medicare second, as appropriate, in accordance with normal Medicare secondary payment rules.

Restricting Physicians to One Vendor

We requested comment on whether we should require that CAP-participating physicians obtain all categories of drugs that a particular approved CAP vendor provides from the vendor, or whether the physician should be allowed to choose the categories of drugs he or she wishes to obtain from the vendor.

Comment: Several commenters supported allowing physicians to choose the categories of drugs they obtain from the CAP. Another commenter suggested that physicians should be required to obtain all drugs for all HCPCS within a designated specialty for their Medicare patients from the CAP vendor to increase billing accuracy, and reduce inventory and paperwork burden. Finally, several commenters suggested that physicians should be allowed to contract with multiple vendors for different categories of drugs.

Response: As indicated earlier in this preamble we are implementing CAP initially with one category that contains all CAP drugs. At a later point we plan to add additional categories of drugs. When there are additional categories from which to choose, physicians will be allowed to select the categories of drugs that they will obtain from the CAP. We will encourage physicians to select vendors in a manner that will minimize the number of vendors used by one practice, in an attempt to reduce potential billing errors and beneficiary confusion. Physicians will be limited to one vendor per category; however, it will be possible to select a different vendor for each category if the physician decides that it best meets his or her needs. Physicians billing under a group billing number will need to reach agreement among themselves on whether to participate in CAP and which vendor to select for each category. [See Section II.D of this interim final rule on physician election for more detailed information on this requirement.]

Administrative Burden

In the proposed rule, we indicated that we did not believe that the clerical and inventory resources associated with participation in the CAP exceed the clerical and inventory resources associated with buying and billing drugs under the ASP system. The payment for clerical and inventory resources associated with buying and billing for drugs under the ASP system is bundled into the drug administration payment under the physician fee schedule. Taking these factors into account, we proposed not to make a separate payment to physicians for the clerical and inventory resources associated with participation in the CAP program.

Comment: Some commenters disagree with our assessment of the clerical and inventory resources associated with participation in the CAP. They believe that the administrative cost of managing inventory would not be eliminated nor reduced proportionally based on drug volume decrease due to the CAP. They added that with the separate ordering process for CAP drugs requiring patient-specific orders, the number of individual orders would be higher with additional delivery times and likely increase waste. One commenter noted that oncologists often use an automated storage and inventory control system that automatically tracks the amount of each drug on hand. Instead of a bulk ordering system, the CAP will require a detailed patient-specific order. The commenters also pointed out that the billing processes would be similar but that the CAP claim form would require the prescription order number for each drug in addition to the HCPCS code. Keeping track of the prescription order number before administering the drug would also be a new activity. One physician also stated that his city requires that he pay tax at the time a drug is administered to a patient, and that he believed the CAP should compensate him for this cost.

Response: Although we agree that a physician may have to make some adjustments in his or her practice in order to comply with the requirements under the CAP, we believe that the relief of the financial burden of purchasing the drugs and billing Medicare for these drugs will be a substantial improvement and benefit for many physicians. Again, as we have stated previously, a physician is free to a significant extent to design his or her practice so that the additional burden of participating under the CAP is as small as possible. CAP is a voluntary program, so if a physician finds it more burdensome, then he or she is under no obligation to participate. Although initially a physician's staff may have to make software changes to recognize the CAP system, this would be a one-time burden. Also, as we have stated previously, separate drug storage is not required—it is a suggested option if such a procedure makes it easier on the physician's practice to track the CAP drugs. Further, in the interest of easing the burden of information exchange to the extent possible, we are requiring at § 414.908(a)(3)(iii) that the physician provide the vendor with patient information for the initial order, or when the patient's information changes (for example, the patient develops a new drug allergy). The vendor would be able to specify which information is necessary on a follow-up order. (We note that some patient specific information such as date of birth and gender are required by the Medicare claims processing system. For additional information refer to Content of the Drug Order earlier in this section.

Drug Administration

We proposed that after administering the drug, the physician would submit a claim to his or her local carrier for drug administration. The claim would include the HCPCS code for the drug administered, the drug administration fee, the prescription code for each drug administered, and the date of service.

The local carrier would adjudicate the claim for drug administration and check that the physician was billing for appropriate drugs from the selected drug vendor, and that the claim was compliant with all local coverage determinations (LCDs). In general, if the physician's claim was inconsistent with an LCD, the local carrier would deny the claim for the drug administration and

would notify our central claims processing system that the drug vendor's claim for the drug would not be paid.

If the claim passes all local carrier edits, the local carrier would forward it to our CMS central claims processing system for additional editing and approval for payment.

We also proposed to require prompt claim filing for the drug administration on the part of physicians who elect to participate in the CAP in order to facilitate the match between the physician claim and the drug vendor claim so that drug administration can be verified. We proposed that in their CAP election agreements, physicians who choose to participate in the CAP would be required to agree to bill their claims within 14 calendar days of the date the drug was administered to the beneficiary, unless extenuating circumstances prevented them from filing the claim. (Statistics obtained from Medicare claims filing data indicated that more than 75 percent of physician's claims are currently filed within 14 days of the date of service.) We requested comment on how we should define the extenuating circumstances that should be considered for exceptions to the 14 calendar day time frame.

Comment: A commenter representing an organization of specialty distributors supported the timely filing of physician claims requirements in the proposed rule; however, the commenter noted that few procedures are proposed to augment physician compliance. The commenter supported development of an enforcement mechanism before the physician's dismissal from the program. Other commenters believe that it is burdensome for a physician to file a claim within 14 days after drug administration. One commenter asked for more detailed information about our data on physician claim filing because the statistics we cited are not reflective of their knowledge of small group practices and solo practitioners. They asserted that requiring CAP physicians to submit their claims within 14 days is too drastic a change from the 365 day current standard, and suggest that the requirement should be changed to 30 days. In response to our request for comment on extenuating circumstances that could be considered for exceptions to the 14 day filing requirement, the commenter stated that extenuating circumstances for claim filing requirements are already defined in Chapter 1 section 70.7 of the Medicare Claims Processing manual and that providers are allowed an extra 120 days in which to file claims in certain situations. They believe the same standards should be applied in the CAP.

Response: Concerning the 14-day requirement on physicians to file claims for drug administrations, we point out that the vendor's payment depends on the physician's administration of the drug that the vendor has already purchased and provided. We believe it is reasonable for the vendor to expect to be paid timely, and it is a benefit to the physician to be paid timely as well. The claim filing data we cited in the proposed rule were based on all physician claims where the place of service was the physician office, so it represented claims filed by all physician practices. Based on physicians' current claims filing practices, we believe that complying with this requirement will not be problematic for most physicians. We expect that physicians will take the requirement into account when they make a decision whether to participate in CAP and that before electing to participate they will have procedures in place that will enable them to meet the requirement on a routine basis if they are not already doing so. The local carrier may grant exceptions on rare occasions when due to extenuating circumstances the physician is unable to submit claims within 14 days. Such requests should not be granted on a routine basis. As physician billing practices increasingly become automated, we believe that this requirement will become less of a burden. We will ask the local carriers to periodically conduct a post payment review of participating CAP physicians' compliance with this requirement. If a vendor notes repeated non-compliance with this requirement on the part of a physician, the vendor may ask the designated carrier to assist in working with the physician to resolve this situation. Failure to comply with this requirement may be a factor taken into consideration in the designated carrier's recommendation to CMS about removing a participating CAP physician from the program.

Comment: One commenter noted that the proposed rule did not address how the patient newly eligible for the Medicare program during a course of treatment would be handled under the CAP. The commenter inquired whether the physician would be required to change the patient's therapy because the vendor might be offering a different NDC of a drug than the physician had been using previously.

Response: A physician that is treating a new Medicare patient is not required to change that patient's course of treatment merely because he or she may be participating in the CAP if the ''furnish as written'' conditions are met. If a patient becomes eligible for Medicare and the treating physician is participating in the CAP, and a particular formulation of a patient's drug is not available through the CAP, but is medically necessary, then the physician may obtain the drug through the ''furnish as written'' methodology and bill the local carrier for the drug under the ASP system.

Comment: Several commenters suggested that the CAP vendors and physicians should be able to enter into contracts or agreements that would allow them to work out details of doing business under the CAP such as how to handle drugs that were ordered and shipped but not administered. Other commenters proposed that we allow vendors and physicians to enter into contracts that would increase vendor financial incentives to participate in the CAP while at the same time reducing the physician's administrative burden. As an example, the commenter suggested allowing the vendor to bill for both the administration fee on behalf of the physician and the drug itself. In addition, another commenter asked if there are any restrictions concerning a physician using a CAP vendor for non-Medicare patients. Specifically, the commenter inquired whether a participating CAP physician could have an ancillary agreement with the approved CAP vendor to obtain drugs for his or her non-Medicare patients.

Response: This interim final rule does not prohibit approved CAP vendors and physicians from entering into a contract or agreement governing their arrangements for the provision of CAP drugs or other items or services. However, parties to such arrangements must ensure that the arrangements do not violate the physician self-referral (''Stark'') prohibition (section 1877 of the Act), the Federal anti-kickback statute (section 1128B(b) of the Act), or any other Federal or State law or regulation governing billing or claims submission. For example, an agreement under which the approved CAP vendor provides billing services to a physician must comply with the Stark law, anti-kickback statute, and Medicare rules regarding billing agents (§ 447.10). On the other hand, an approved CAP vendor may not contract to furnish drugs at below market rates to a physician or a group for their private pay patients in exchange for the physician's or group's CAP business. For additional information on the Stark and anti-kickback statutes, parties may wish to consult the CMS and OIG Web sites.

Payment to Vendor

After shipping the drug to the physician, we proposed that the drug vendor could file a claim for the drug with the designated carrier no sooner than the expected date of administration. The claim form would contain the prescription number for each drug administered to the beneficiary on one calendar day, the unique provider identifier (UPIN) or (NPI when available) for the physician to whom the drug was supplied, and the expected date of service. The designated carrier would submit the claim to the central claims processing system after the claim had passed all edits. The central claims processing system would match the physician claim with the vendor claim using the prescription number.

As required by the statute, we proposed that the vendor would not be allowed to bill the beneficiary or his or her third party insurance, or both, for any applicable deductible and coinsurance until the Medicare carrier had verified that the physician administered the drug to the beneficiary, and final payment was made by the Medicare program. Proof that the drug was administered to the beneficiary would be established by the physician's claim being matched with the drug vendor's claim in the Medicare central claims processing system. After the two claims were matched, the claims processing system would notify the designated carrier to issue final payment to the vendor. We proposed that issuance of final payment by the Medicare program would serve as notification to the vendor that drug administration had been verified and that the vendor could proceed with billing the beneficiary or his or her third party insurance.

Comment: A specialty distributors association commented that every day that a vendor must wait for payment from Medicare and the beneficiary or his or her third party insurance represents additional working capital invested in the program by the CAP vendor and added inefficiencies to the Medicare program. Vendors may experience at least a 2-month delay in payment from the time the drug is shipped to the physician and payment is received from the Medicare program. The commenter stated that CAP vendors will not be able to assume the level of financial risk that was described in the proposed rule. They proposed a series of steps that we could take in the final rule to attempt to lessen the degree of risk that CAP vendors will assume. These include: Establishing a pre-review process to certify the medical necessity of a drug before the CAP vendor sends the order to the physician, creating risk corridors similar to those being used in the Part D program so that the vendor and CMS are sharing in the risks and benefits of the program, and implementing a process so that the CAP vendor could collect coinsurance from the beneficiary at the time the drug is administered. Commenters also expressed concern about the potential for low profit margins and delayed payment that exist in the CAP and suggested that we should provide additional financial safeguards for CAP vendors.

Response: Following is a response to the commenters' proposed suggestions about how to lessen the degree of risk that vendors will face in the CAP:

(1) Medicare contractors do not generally provide advance approval of potential claims. As stated previously both the participating CAP physician and the approved CAP vendor are expected to familiarize themselves with LCDs, NCDs, and other Medicare rules that may affect claims payment. If an approved CAP vendor encounters a circumstance where it believes that a prescription order is inconsistent with any of these things, the approved CAP vendor may work with the physician to amend the order. If the physician declines to change the order, but the approved CAP vendor believes the drug claim will not be paid by Medicare, the approved CAP vendor may issue an ABN to the beneficiary. If for some reason the vendor is unable to obtain a signed ABN from the beneficiary, the vendor still will have a responsibility under its CAP contract to ship the drug to the physician. (The only exception to this requirement is in the case of the beneficiary's failure to meet his or her obligation to pay deductible or coinsurance. This provision is described in more detail in the discussion of beneficiary coinsurance later in this section.)

We will include in the CAP contract a requirement that the vendor ship the drug in most situations because we believe that under the CAP program as it is being implemented, it would be inappropriate for the approved CAP vendor to interfere in the participating CAP physician's clinical decision making. If the payment for the drug is ultimately denied, then the physician will be required to appeal the drug administration claim denial. The approved CAP vendor may also appeal to the local carrier in accordance with the discussion of administrative appeals below in the dispute resolution section.

(2) We do not have the statutory authority under section 1847B of the Act to create risk corridors.

(3) We have designed the CAP payment system so that the vendor may bill the beneficiary and or his or her third party insurance when payment for the drug has been made by the CMS claims processing system. In order to ensure that this process happens as soon as possible, we are imposing a 14-day claim submission requirement on the physician. We have implemented this requirement because the statute requires that applicable deductible and coinsurance may not be collected unless the drug was administered to the beneficiary. Currently, we have no way of verifying drug administration other than by the matching of the physician's claim for drug administration with the vendor's claim for the drug. We seek comment on other ways that administration could be verified earlier in the process that minimize the burden on the approved CAP vendor, the participating CAP physician, and the beneficiary.

Partial Payment

Although we noted in the March 4, 2005 rule that we were not proposing to implement a system for partial claims payment, we requested comments on compelling reasons for making such a payment. We also sought comment on whether there are demonstrable, compelling reasons why we should consider making a partial payment to the vendor in cases where the drug administration claim is not received by our claims processing system within 28 calendar days of the anticipated date of administration and what the appropriate percentage of the partial payment should be.

We briefly described how such a partial payment methodology might work, if we decided to implement such an option. After the designated carrier made the partial payment, our claims processing system would continue to attempt to match the physician claim and the vendor claim for 90 days. We would not pay interest on interim payments. If a match of the two claims occurred, the vendor would receive Medicare payment for the remaining amount of money due on the claim. If no match between the two claims was made within 90 days, recovery of the amount already paid by Medicare would occur using normal Medicare overpayment recovery processes. After the Medicare program made the final payment, the vendor would be allowed to bill the beneficiary or the beneficiary's third party insurance, or both.

Comment: Some commenters supported partial payment of the vendor's claim at the time the drug is shipped to the physician, and 20 percent was suggested as an appropriate amount. Another commenter strongly opposed partial payment for the vendor because neither physicians nor pharmacies nor DME suppliers have ever received partial payment. The commenter expressed concern that the beneficiary would receive a bill on the partial payment.

Response: After further consideration of this issue, we will finalize the proposal to pay only when both the vendor claim for the drug and the physician's claim for administering the drug have been matched in the claims processing system. We believe that this is a more straightforward process and that it is a process that will assist in preserving the Medicare trust fund because it will not involve payment recovery if a claim is denied or a physician does not administer the drug.

Beneficiary Coinsurance

Comment: Some commenters stated that having the vendor collect the coinsurance adds further ''bureaucracy'' to patient care and introduces a middleman between the doctor/patient relationship.

Response: As stated in the proposed rule, the statute specifically requires that the vendors participating in the CAP collect any applicable deductible and coinsurance from the beneficiary. Therefore, we do not have any latitude in determining who collects the coinsurance.

Comment: A few commenters questioned our proposal to prohibit the vendor from billing for coinsurance until final payment of claim, stating this would be a significant change from current practice. The commenters believe delayed billing would increase risk of bad debt and increase collection-related efforts and costs and potentially risk solvency of the vendor and viability of program.

Response: We understand the concerns raised by the commenters; however, the statute specifies that the collection of any applicable deductible or coinsurance cannot occur until the drug is administered and that the vendor is responsible for billing the beneficiary for cost sharing. We note that Medicare allows for the collection of coinsurance at the time a service is delivered, however since the approved CAP vendor is not present at the time the drug is administered the vendor is unable to bill the beneficiary at that time. We agree that the delay in billing could increase the incidence of beneficiaries who are unable to meet their coinsurance obligations; however we note that (as explained in more detail below) approximately 80 percent of beneficiaries have supplemental insurance coverage which covers their Part B coinsurance. In order to help ensure more prompt payment to the vendor, we are requiring that the participating CAP physician must submit the claim for drug administration within 14 calendar days of the date of administration. In addition, the existing CMS coordination of benefits process provides for the automatic crossover of many Medicare beneficiaries' claims to their supplemental insurance provider after Medicare has paid its portion of the claim. For beneficiaries with supplemental insurance, their coinsurance obligation is usually met through the automatic coordination of benefit process, instead of requiring the beneficiary to pay the coinsurance at the time of service. We are currently consolidating the claims crossover process, on a national basis, to introduce standardization and efficiencies in a national crossover process that will automatically cross claims over to supplemental insurers/payers, including Medigap plans, employer retiree supplemental plans, TRICARE, and State Medicaid Agencies, for their use in calculating their financial liability after Medicare. Under this consolidated crossover process, supplemental insurers/payers will execute a national Coordination of Benefits Agreement with a single CMS contractor, the national Coordination of Benefits Contractor (COBC), for purposes of receiving Medicare crossover claims. We believe that the majority of supplemental insurers/payers will participate in the national consolidated crossover process due to the consistencies and efficiencies that result from a standard national process. Standardization of the crossover process thereby decreases the likelihood that beneficiaries' claims will not be crossed over.

Comment: Commenters raised concerns about the requirement that the approved CAP vendor collect the coinsurance for the drug from the beneficiary with respect to the following three major areas:

- *Effect on beneficiaries.* Under the current system, the physician often works with the beneficiary and social agencies to obtain payment, or in appropriate circumstances these costs may be born by the physician practice in cases of financial hardship as bad debt. Commenters expressed concern that vendors may use overly aggressive collection techniques, or no longer provide drugs for patients who are too far in arrears.
- *Effect on approved CAP vendors.* The inability of approved CAP vendors to collect coinsurance from beneficiaries could pose a major financial hardship to vendors. Collection of coinsurance may also be exacerbated due to the time delay between the dates of treatment and payment, as well as the approved CAP vendor's lack of a direct personal relationship with patients.
- *Clinical issues.* Failure to provide the drug due to nonpayment of coinsurance by the beneficiary may endanger patients and expose physicians to liability issues. Commenters stated that regardless of the patient/vendor dispute, this does not involve physician services, and failure of the vendor to provide the required drug could affect the physician's plan of treatment for the beneficiary.

Commenters recommended that the vendor should not be able to drop the physician from the CAP or withhold the shipping of the drugs due to nonpayment of the coinsurance.

Additionally, commenters suggested vendors be required to have in place procedures for assessing indigence and waiving coinsurance when a non-Medicaid-eligible beneficiary's income, assets, and medical expenses meet certain pre-established criteria. Ideally, these procedures should incorporate the assistance of social workers trained to explore all payment options and assistance programs available to the individual. The commenters recommended that assessment of these procedures should be part of our vendor evaluation process. If it is determined that vendors can refuse to deliver drugs because of coinsurance issues, commenters believe this must be made clear to physicians when they sign up for the CAP. As an alternative, other commenters recommended that when this occurs, physicians should be able to obtain drugs through the ASP system or be able to opt out of the CAP immediately. One commenter suggested that this option should also be available if the beneficiary's secondary insurance denies the claim.

The Practicing Physicians Advisory Council (PPAC) expressed similar concerns about the collection of coinsurance and recommended that we require selected CAP vendors be willing to advance credit for drugs to patients who are not able to pay the coinsurance.

Other commenters recommended that the final rule allow CAP vendors to refuse to distribute products to patients who have a prior history of failing to fulfill coinsurance obligations. This

would eliminate a significant amount of financial risk and uncertainty for vendors.

Response: We appreciate the commenters' concerns, and we address these concerns as outlined below:

• *Effect on beneficiaries.* With respect to commenters' concerns about the impact of the CAP on beneficiaries, the purpose of the CAP is to provide an alternative to physicians for obtaining Medicare Part B drugs and is not intended to have a negative impact on patient care. However, as part of their enrollment in Medicare, beneficiaries are obligated to pay the Part B deductible and coinsurance amounts, and this cost-sharing assists in controlling the over utilization of services. Information from the 2003 Medicare Current Beneficiary Survey shows that approximately 80 percent of fee-for service Medicare enrollees report that they have supplemental coverage that covers their Part B coinsurance obligations. Although we are uncertain of the level of coverage provided by these plans, we believe this supplemental coverage provides significant financial protection to many beneficiaries. However, we understand that there will be instances where a beneficiary may have difficulty in meeting the deductible or coinsurance payment. When this occurs under the current payment system, the physician often helps the beneficiary in finding assistance to meet this obligation or might choose not to pursue collection of the cost-sharing if the physician has made a good faith determination of financial need or reasonable collection efforts have failed.

In order to address these concerns, we are modifying the program requirements at § 414.914(g) to include a provision requiring vendors to provide information on sources of cost-sharing assistance available to beneficiaries on request. It is important to note that routine waiver of deductibles and coinsurance can violate the Federal anti-kickback statute, as well as the civil prohibition on offering inducements to beneficiaries at section 1128A(a)(5) of the Act. However, cost-sharing waivers are permitted under certain conditions for beneficiaries who are experiencing financial hardship. The assistance offered by the vendor must take the form of one of the following: a referral to a bona fide and independent charitable organization, implementation of a reasonable payment plan, and/or a full or partial waiver of the cost-sharing amount based on the individual financial need of the patient, provided that the waiver meets all of the requirements of paragraph (1) of 42 CFR 1003.101 (Definition of ''Remuneration''). The availability of waivers may not be advertised or be made as part of a solicitation; however, vendors may inform beneficiaries generally of the various categories of assistance noted in the preceding sentence. In no event may the vendor include or make any statements or representations that promise or guarantee that beneficiaries will receive cost-sharing waivers. We will evaluate the procedures that applicant vendors propose to implement to make cost-sharing assistance referrals as part of the approved CAP vendor application review process.

• *Effect on approved CAP vendors.* With respect to concerns about the potential impact on the approved CAP vendors, we will not require an approved CAP vendor to continue to provide CAP drugs for beneficiaries who do not pay their deductible or coinsurance. As noted previously, under the CAP contract, we are requiring vendors to ship ordered drugs to physicians in most situations. However, in the case of a beneficiary who fails to satisfy his or her cost-sharing obligations for CAP drugs ordered by a particular participating CAP physician, we will allow the vendor to refuse to make further shipments to that physician for that beneficiary in accordance with the provisions outlined below. The vendor may refuse to ship drugs to a physician for a beneficiary who has not met his or her coinsurance obligations, when the conditions outlined below are met, until the earlier of the end of the calendar year or the beneficiary's past due balance is paid in full. We will require that after receiving final payment by Medicare, the vendor must first bill any applicable supplemental insurance policy that the beneficiary may have. If there is a balance due after payment by the supplemental insurer, or if the beneficiary has no supplemental insurance, the vendor may proceed with billing the beneficiary.

As discussed previously, consistent with the requirements of section 1128A(a)(5) of the Act and § 414.914(g), at the time of billing, the vendor may inform the beneficiary generally of the types of cost-sharing assistance that may be available. If the beneficiary is unable to pay the coinsurance or deductible, he or she may request assistance from the vendor as described above. The vendor has an obligation to provide the information requested, and to take one of the actions specified in § 414.914(g). However, if the beneficiary has not requested financial assistance and if after a period of 45 days from the postmark date of the approved CAP vendor's bill to the beneficiary, the beneficiary's coinsurance obligation remains unpaid, the vendor may refuse to make further shipments of drugs to the physician for that beneficiary. We note that these provisions assume that the vendor bills the beneficiary after payment is received from Medicare and his or her supplemental insurance provider (if applicable.)

If the beneficiary requests cost-sharing assistance and the vendor refers the beneficiary to a bona fide independent charitable organization for assistance or offers a payment plan, the vendor must wait an additional 15 days from the postmark date of the approved CAP vendor's response to the beneficiary's request for cost-sharing assistance. If at the end of the 15-day time period the vendor has not received a cost-sharing payment (either from the charitable organization or from the beneficiary under the payment plan), the vendor may refuse to ship additional drugs to the physician on behalf of that beneficiary. Further, if the approved CAP vendor implements a reasonable payment plan, the vendor must continue to ship CAP drugs for the beneficiary, so long as the beneficiary remains in compliance with the payment plan.

Finally, if the vendor waives the cost-sharing in accordance with section 1128A(I)(6)(A) of the Act, 42 CFR § 1003.101, and § 414.914(g)(3) of these regulations, the vendor may not refuse to ship CAP drugs for the beneficiary. In instances where a beneficiary has failed to meet his or her obligation to pay coinsurance or deductible for a drug and the vendor has refused to continue providing the drug, we will permit the participating CAP physician to opt out of that drug category for CAP. Note that for the initial implementation of the CAP, there is only one CAP drug category. Thus, a physician exercising this option will be opting out of the entire CAP program until the next opportunity to elect to participate. We are amending the regulations at § 414.908(a)(5) to include this provision. We seek comment on additional provisions that we should use to define these processes to protect the vendor and the beneficiary.

• *Clinical issues.* With respect to concerns raised that the inability of a beneficiary to make the coinsurance payment should not affect treatment, we believe the modifications we are making to require the vendor to provide information on sources available to a beneficiary who may be in need of assistance with his or her coinsurance payment as well as allowing the

physician to opt out of the CAP will assist in ensuring that the treatment is not affected.

Comment: One commenter questioned what is required from physicians for patients with Medigap or another type of supplemental insurance coverage.

Response: A high percentage of Medicare beneficiaries carry supplemental insurance such as a Medigap policy to cover deductible and coinsurance amounts, and the physician will provide this insurance information to the approved CAP vendor. The specific information that the physician must provide is discussed earlier in this section.

Comment: Another commenter requested that we implement processes to assist vendors in collecting beneficiary coinsurance, especially if the patient is deceased.

Response: We do not believe special provisions need to be made in this rule for beneficiaries who are deceased. If a beneficiary has died after receiving the CAP drug, but before he or she could pay the coinsurance amount to the vendor, the designated carrier would still process the approved CAP vendor's drug claim in accordance with the normal procedures outlined in these regulations, and the approved CAP vendor could bill the beneficiary's estate or the beneficiary's alternative insurance in accordance with CAP requirements. However, we would welcome further comments on this issue.

Comment: Commenters questioned whether vendors would be expected to bill Medicaid for coinsurance and deductible after billing Medicare in the case of dual eligible beneficiaries and the consequences to the beneficiary if Medicaid did not pay the coinsurance. Another commenter recommended that we require any vendors awarded the contracts to provide this prescription benefit with a coinsurance structure no higher than Medicaid.

Response: The CAP is an alternative to the current system for paying for Medicare Part B drugs. Because the coinsurance is a part of the Medicare total payment amount, we cannot establish a limit for this amount based on another payment system (that is, Medicaid). We have no authority to set coinsurance at anything other than 20 percent of the Medicare rate. If a beneficiary has supplemental insurance, the approved CAP vendor will bill the insurance provided by the beneficiary for the coinsurance amount. Medicaid payment rates and policies for dual eligibles will vary by State.

Comment: One commenter recommended that we establish a policy to reimburse vendors for part of the bad debt they experience when they are unable to collect in full the coinsurance and deductibles, similar to provisions for certain other providers. Alternatively, the commenters believe we should adjust the bid limit to take this issue into account.

Response: The bad debt policy referred to by the commenter is established by statute and regulations for specific provider types and is not applicable to the CAP program. We do not agree with the suggestion that we should adjust the proposed bid limit to account for the possibility that vendors will be unable to collect all coinsurance. Although the Medicare statute and regulations provide specific provisions to recognize and account for bad debt in the context of payments to hospitals and certain other provider types, there is no such provision in relation to the CAP. We therefore lack authority to provide for explicit recognition of bad debt in the mechanisms for bidding and determining payment amounts under the CAP.

Comment: One commenter stated that the CAP could result in beneficiaries returning to the physician's office more often and thus double the coinsurance amount. For example, a beneficiary undergoing chemotherapy may see the physician and have his or her laboratory results checked one day and, based on changes to the prescription, the physician will have to order a new drug and the beneficiary will have to return on another day to receive the drug.

Response: The statute and these regulations provide for situations in which a drug is needed immediately. If the criteria outlined in § 414.906(e) are met, the participating CAP physician can submit a prescription order to the approved CAP vendor to obtain a replacement for a drug from his own stock that was used to treat the beneficiary. The participating CAP physician is always free to do what is best for the beneficiary, but under CAP payment rules, payment is made for the CAP drug only when it is ordered from the vendor or the resupply or ''furnish as written'' criteria are met.

3. Dispute Resolution

Section 1847B of the Act is generally silent with regard to the treatment of disputes surrounding the delivery of drugs and the denial of drug claims. However, section 1847B(b)(2)(A)(ii)(II) of the Act does contain a reference to a grievance process which is included among the quality and service requirements expected of vendors.

As explained in the March 4, 2005 proposed rule, we gave substantial consideration to the applicability of the Medicare Part B administrative appeals process found at § 405.801 *et seq.* We believe the traditional Part B appeals process continues to be the appropriate dispute resolution process for beneficiaries and participating CAP physicians seeking review of drug administration claims that have been denied by the local carrier for any of the reasons described in § 405.803(a). Those reasons include the following: (1) Services were not a covered benefit; (2) The deductible was not met; (3) No evidence of acceptable payment; (4) Charges for services were unreasonable; and (5) Services furnished were not reasonable and necessary.

We also outlined reasons that we believed disputes raised by the approved CAP vendor regarding the nonpayment of a drug claim by the designated carrier cannot be adjudicated by application of the traditional Part B appeals process. First, the designated carrier's denial is based on the lack of a unique prescription ID number match in the central claims processing system. This reason does not meet any of the appeal criteria in § 405.803(a). Second, given the ministerial aspect of the designated carrier's prescription number matching task, an informal process focused on getting the underlying participating CAP physician's drug administration claim properly filed and adjudicated is a more effective remedy. Finally, we believed application of the proposed progressive alternative dispute resolution process described in the proposed rule represents a better use of program administration resources.

We encourage participating CAP physicians, beneficiaries, approved CAP vendors and the designated carrier to use informal communication to resolve service-related administration issues that occur in a delivery and payment system of this complexity. However, we recognized certain disputes will require the intervention of a neutral third party and established a proposed dispute resolution process § 414.916 which is summarized as follows.

a. Resolution of Vendor's Claim Denial

The participating CAP physician has control of the claim filed with the local carrier for drug administration services. In the proposed rule, we stated that the approved CAP vendor would not be a party to the appeal a physician may file if his or her drug administration claim is denied. We based this statement on the fact that the approved CAP vendor would possess little of the evidence required to substantiate the medical necessity requirements for administration of the drug. However, we

wish to clarify that the approved CAP vendor may appeal as a Medicare supplier under the Part B appeals rules at 42 CFR Part 405 and the online Medicare Claims Processing Manual, Chapter 29, §§ 20 and 60.4. Because the local carrier's initial determination regarding the drug administration claim is determinative of the CAP vendor's drug claim, we interpret that initial determination to be an initial determination regarding payment of the CAP vendor's drug claim for purposes of the Part B appeals regulations at 42 CFR 405. Thus, the CAP vendor is a party to any redetermination of the drug administration claim by the local carrier. In addition, any appeal from an initial determination regarding a claim for payment of a drug by the designated carrier should be filed with the local carrier. It is the local carrier, rather than the designated carrier, that possesses all information necessary to adjudicate an appeal from a denial of a claim for payment of a CAP drug. This information includes local coverage decisions, medical necessity determinations, and information regarding payment of drug administration claims. Thus, all parties, including the CAP vendor, will have 120 days from the date of receipt of an initial determination by the designated carrier regarding a claim for payment of a drug in which to file a request for a redetermination of that claim with the local carrier.

Accordingly, we have expanded the participating CAP physician's participation obligations to include support of the approved CAP vendor's appeal with documentation and written statements. Please see the comments and responses below.

The approved CAP vendor's drug product claim may be denied by the designated carrier if the participating CAP physician's drug administration claim is denied. In that event, the approved CAP vendor can not bill Medicare for the cost of a drug and can not bill the beneficiary for the appropriate deductible or coinsurance.

The approved CAP vendor will track its business with the individual participating CAP physicians who order drugs. We proposed that when an approved CAP vendor is not paid and the total dollar amount of the approved CAP vendor's loss exceeds an acceptable threshold, then the approved CAP vendor may ask the designated carrier to counsel the participating CAP physician on his or her obligation under the CAP election agreement to file a clean claim and pursue an administrative appeal in accordance with his or her CAP election agreement. We outlined the particulars of the proposed participating CAP physician's CAP election agreement in § 414.908(a)(3) of our regulations and we requested comment on the appropriate amount for the CAP vendor's loss threshold.

If problems persist, we proposed that the approved CAP vendor may request the designated carrier to review the situation and potentially recommend a suspension of the participating CAP physician's CAP election agreement. The designated carrier would gather and review the relevant facts, and make a recommendation to us on whether the physician has been filing his or her CAP administration claims in accordance with the requirements for CAP participation. We would review the recommendation of the designated carrier and, if necessary, gather additional information before deciding whether to suspend the participating CAP physician's election to participate in the CAP.

We proposed the suspension would last for a period not to exceed the end of the following CAP election cycle. Inasmuch as participating CAP physicians can elect to enroll every year for a 12-month period commencing in January, the suspension would end on one or another December thirty-first. We are clarifying that the participating CAP physician could enroll again a year from the next January first. Upon consideration of the situation where the participating CAP physician is suspended in the early months of the year, we have determined that the suspension may prove to be unnecessarily long. Accordingly, we have determined that a suspension commencing before October 1 will conclude on December 31 of the same year. A suspension commencing on or after October 1 will conclude on December 31 of the next year. A suspension of less than 2 months would not have a meaningful impact. We indicated that the physician would be able to appeal our initial decision through the process articulated in proposed § 414.916.

Comment: Comments on the appropriate loss threshold that an approved CAP vendor would have to bear before requesting suspension of the participating CAP physician were varied. The potential vendor community indicated that it would prefer to have authority to exclude participating CAP physicians unilaterally. Physician commenters indicated that they would like a well-defined threshold with a high dollar and occurrence level.

Response: Regardless of whether a physician is participating in CAP, our primary concern is the welfare of the beneficiary and the implications of repeated drug administrations that are not in accordance with Medicare coverage policy. Our existing medical review safeguards and provider education efforts are as applicable to drug administration when the drug is provided by the approved CAP vendor as when it is purchased by the participating CAP physician. These existing mechanisms help ensure that our beneficiaries are receiving medically reasonable and necessary services and, as a consequence, will help ensure that the approved CAP vendors are able to be paid for drugs shipped to physicians. We also note that physicians, as a condition of participation in CAP, will have agreed to the claims, appeals filing, and CAP assignment requirements described in section II.D.1, ''Physician Election,'' of this interim final rule. This will also help to ensure that the approved CAP vendors are able to be paid for drugs shipped to physicians.

We emphasize that we believe many of the issues of concern raised by the potential vendors can either be resolved through cooperative interaction between the approved CAP vendor and the participating CAP physician or the dispute resolution efforts of the designated carrier without using the formal process for removal of physician from the CAP program. However, we recognize the need for such a process in the event the above efforts are unsuccessful just as we recognize the need to be able remove an approved CAP vendor from the CAP program if necessary.

We believe each CAP drug claim denial will require individual analysis to determine the cause. That review focuses on the depth of consideration the participating CAP physician gave to the pertinent Medicare coverage policy. If it turns out the physician knowingly ordered and administered a drug that is not covered, and the physician did not file a claim, or filed a frivolous claim to create the appearance of appropriate consideration of the coverage requirements, then the approved CAP vendor's request to initiate a suspension investigation may be well founded. Approved CAP vendors can not be expected to have no recourse in the event they are routinely shipping drugs for which they do not receive payment. However, participating CAP physicians should not be removed from the CAP program lightly. We think the ability of the approved CAP vendor to raise these issues to an independent party, the designated carrier, for investigation and a recommendation to us, provides a fair opportunity for the participating CAP

physician and the approved CAP vendor to submit evidence in support of continued participation in CAP or removal from the program. Our review of the recommendation adds another impartial step to the determination of whether to remove the participating CAP physician from the program. If we determine that the participating CAP physician should be removed from the CAP program, the ability of the participating CAP physician to request reconsideration and the potential for the involvement of an impartial hearing officer provides yet another level of safeguard against the improper removal of a physician from the CAP program. However, to take into account the legitimate business needs of the approved CAP vendor once a determination by us has been made that the participating CAP physician should have his or her CAP participation agreement suspended, the physician will be able to obtain drugs and bill for them under the ASP payment system until a final reconsideration determination is made. In response to comments, we have removed the last sentence of § 414.916(b)(3) which indicated a participating CAP physician could select another approved CAP vendor while a reconsideration was pending. The ability of the Director of the Center for Medicare Management to provide a final reconsideration of the matter is yet a potential fourth level of safeguard in this process. We believe this process strikes an appropriate balance between providing swift recourse for approved CAP vendors and the desire for a fixed threshold.

Given the impartial nature of the process for removing physicians from the CAP, and after consideration of all the related comments, we believe that institution of a fixed threshold would run counter to the desired outcome. We seek to have participating CAP physicians give careful consideration to Medicare coverage policy before ordering drugs. There will be cases when the cost of the denied drug is high, but the participating CAP physician researched and considered the applicable coverage policy as carefully as possible. Conversely, there will be cases where the cost of the denied drug is relatively low, but coverage was denied because the participating CAP physician did not consider whether the applicable coverage policy would support payment for the drug and its administration under the circumstances of the specific case. The approved drug vendor must be able to address a participating CAP physician who flouts coverage policy before a drug with a relatively high cost is denied. We will monitor the data trends carefully and may reexamine our dispute resolution process as we gain more experience under the CAP. Our final process is codified in § 414.916(b).

Comment: Some potential physicians commented and questioned the legal authority for the designated contractor to function in this capacity. One commented that the designated carrier is not qualified to make the recommendation discussed in § 414.916(b)(2)(i) because the recommendation amounts to a legal determination, and the regulation states no qualification for the individual designated carrier employee who develops that recommendation.

Response: As we noted in the proposed rule, section 1847B of the Act is generally silent with regard to the treatment of disputes surrounding the delivery of drugs and the denial of drug claims. However, section 1847B(b)(2)(A)(ii)(II) of the Act does contain reference to a grievance process which is included among the quality and service requirements expected of vendors. We believe that section 1847B(b)(2)(A)(ii)(II) of the Act, at a minimum, provides authority for this function of the designated contractor.

We have a longstanding history of working with contractors such as carriers and fiscal intermediaries, that employ individuals to make recommendations with respect to various operational and policy issues related to the administration of the Medicare program. The designated carrier will meet all of the qualifications that are applicable to our administrative contractors generally.

Specialty carriers perform a variety of functions to support programs that deliver benefits in a new or unique manner. As an example, the Durable Medical Equipment Competitive Acquisition demonstration carrier performed an alternative dispute resolution function similar to the function the designated carrier will perform here.

Therefore, we believe that both the designated carrier and its employees will be qualified to undertake the activities called for in this regulation.

Comment: Some commenters questioned the impartiality of the designated carrier and indicated a preference for the local carrier.

Response: We note that the designated carrier is not making the removal determination, but only providing a recommendation to us. The designated carrier has been selected from the pool of existing Part B carriers though the process used to select Title XVIII contractors. We will closely monitor the designated carrier's dispute resolution function with Government oversight staff experienced with other contractors that perform dispute resolution functions in the Medicare program.

Although we believe either the designated carrier or local carrier would function impartially, the designated carrier will have the most familiarity with the CAP program and there are administrative efficiencies that can be realized from consolidating this function. However, because the local carrier will possess valuable information to add to the process, the designated carrier will work closely with the local carrier as appropriate before making a recommendation.

Comment: Some potential physician commenters questioned the qualifications and impartiality of the hearing officer.

Response: We find the Director of the CMS Center for Medicare Management, the Center with oversight responsibility for the CAP program, to be abundantly qualified to make an appropriate unbiased selection of a hearing officer.

Comment: One commenter encouraged CMS to inform the participating CAP physician community that claims should be submitted timely and in compliance with local medical policies. This commenter suggested that CMS supply approved CAP vendors with coverage determination information prior to delivery of the drug and shift the financial risk to the participating CAP physician. The commenter also suggested that CMS regularly post the CAP claim denial rates of participating CAP physicians on a Web site in an effort to encourage participating CAP physicians to meet their obligation to file claims and appeals.

Response: As described earlier, the participating CAP physicians' claims and appeals filing expectations are described in section II.D.1, ''Physician Election,'' of this interim final rule. Approved CAP vendors should consult with the local carrier Web sites to familiarize themselves with LCDs. They should also review NCDs posted on the our Web site.

We do not believe it is appropriate to publish the names and claim denial rates of participating CAP physicians because approved CAP vendors will not have the authority to refuse to service participating CAP physicians who select them.

Comment: One commenter asked us to create a more meaningful way for the approved CAP vendor to appeal the local carrier's denial of the drug administration claim.

Response: As noted above, we have clarified that the approved CAP vendor has an independent right to appeal claims under existing Part B appeals rules. To assist approved CAP vendors in exercising these rights, we are including a new obligation in the participating CAP physician's CAP election agreement. The participating CAP physician must reasonably cooperate with the approved CAP vendor if the vendor chooses to appeal the local carrier's denial. Reasonable cooperation may include providing the approved CAP vendor with access to or copies of medical records, as appropriate, and written statements.

Comment: Several commenters were concerned that the process for determining whether a participating CAP physician should be removed from the CAP program would allow approved CAP vendors to pressure participating CAP physicians to alter their prescribing pattern and to intrude unacceptably on the participating CAP physician's clinical decision making.

Response: Please note the approved CAP vendor will be required under the terms of its CAP contract to ship the drug ordered by a participating CAP physician in most cases. The designated contractor will closely monitor the activities of approved CAP vendors and complaints from participating CAP physicians to ensure that no such inappropriate intrusion on physician clinical decision making occurs. Participating CAP physicians may address concerns of this type through the participating CAP physician/approved CAP vendor dispute resolution process described below and in § 414.917.

Comment: Several commenters suggested that, during the designated carrier's investigation into the participating CAP physician's compliance with his or her CAP election agreement, the designated carrier should be explicitly required to gather information from the participating CAP physician.

Response: The designated carrier will gather necessary information from the local carrier, the participating CAP physician and the approved CAP vendor. Section 414.916(b)(2)(ii) has been adjusted to explicitly include the physician among the sources of information the designated carrier must query during the investigation.

Comment: A commenter from a physician association believed that the participating CAP physician should be allowed to submit additional material to the record during the phase described in § 414.916(b)(3) when CMS makes a determination whether to suspend the participating CAP physician's CAP participation agreement.

Response: We agree. Section 414.916(b)(3) has been adjusted to require us to gather additional material from the participating CAP physician as appropriate.

Comment: Several commenters have suggested emphatically that CMS drop from the final rule the requirement that suspended physicians' names be published in the **Federal Register**. These commenters also requested that the final rule make clear that suspension of a CAP election agreement for denial of claims does not result in the physician becoming listed on the exclusion list under section 1128 of the Act.

Response: A suspension of a participating CAP physician's CAP election agreement or a termination of an approved CAP vendor's contract with us does not result per se in either party being excluded from participation in any Federal health care program. Such a decision only precludes the physician or vendor from participation in the CAP. Whether a participating CAP physician or vendor is excluded from all Federal health care programs under section 1128, 1128A, or any other exclusionary authority given to the Secretary under the Act, shall be based on a determination made by the Office of Inspector General of HHS, not by CMS through the § 414.916 or § 414.917 processes. We agree with the commenters' recommendation that we refrain from publishing the names of suspended physicians in the **Federal Register**, and this requirement has been removed.

Comment: One potential vendor suggested that vendors should not be required to enroll or re-enroll physicians who had been suspended from CAP at the conclusion of the suspension period.

Response: Physicians whose period of suspension from the CAP program has ended will be allowed to elect to participate in the CAP as described above, and could potentially select the same vendor that generated the suspension request. Section 1847B(a)(1)(A)(ii) of the Act states that each physician is given the opportunity annually to elect to obtain drugs under the CAP.

b. Resolution of Physicians' Drug Quality and Service Complaints

The proposed rule discussed how the participating CAP physician would use the approved CAP vendor's grievance process for drug quality or approved CAP vendor service issues and turn to the designated carrier for assistance in developing solutions. Based on comments from physicians, we have added § 414.917. This new section sets forth a process culminating in termination of the approved CAP vendor's contract for serious quality or service issues. It is described below in the responses to comments.

Comment: Several commenters suggested that CMS make approved CAP vendors indemnify participating CAP physicians for legal defense costs connected with ''adverse drug events'' when the participating CAP physician is ultimately exonerated.

Response: Individual participating CAP physicians and approved CAP vendors can seek legal advice from someone competent to provide such advice regarding the product liability laws and other laws applicable to financial liability associated with adverse drug events. We believe that addressing these complex issues is beyond the scope of this rule.

Comment: Several commenters requested that the final rule include a more definitive process for participating CAP physicians to employ for the resolution of service and drug quality issues. They requested a process that would include suspension of the vendor's right to participate in the CAP program.

Response: Issues connected with drug quality and approved CAP vendor service will be given a top priority. Both the approved CAP vendor and the designated carrier will be required to have qualified staff available to address drug quality and service complaints upon their receipt. Egregious drug safety issues should be brought to the designated carrier right away. For instance, evidence of counterfeit drugs would generate an immediate referral to the appropriate Federal, State, and local authorities, including the Department of Health and Human Services, Office of the Inspector General. The ultimate sanction for service and quality issues is suspension and/or termination of the approved CAP vendor's contract upon exhaustion of the reconsideration process set forth in § 414.917. This process is very similar to the process for removing participating CAP physicians, which is described above and in § 414.916.

When a participating CAP physician is dissatisfied with the drug quality or drug delivery performance of an approved CAP vendor, we expect the participating CAP physician to make a meaningful effort to resolve the issue with the approved CAP vendor informally, and then to use the approved CAP vendor's grievance procedure. The next step is to ask for

the designated carrier's assistance in developing a solution with cooperation from both parties. Failing resolution there, the participating CAP physician may ask the designated carrier to recommend to CMS that the approved CAP vendor's contract be suspended. CMS will act on that recommendation after gathering any necessary, additional information from the participating CAP physician and approved CAP vendor. The vendor may appeal our initial decision through the process articulated in § 414.917.

In response to these comments, we also believe that the process set forth in § 414.917 is the appropriate means for approved CAP vendors to seek a review of our suspension or termination of its CAP contract under § 414.914(a). We are specifying that this process will be available to approved CAP vendors who are dissatisfied with our determination to suspend or terminate the CAP contract for default. While the approved CAP vendor's appeal of our decision is pending, the approved CAP vendor's participation in the CAP would be suspended. We seek further comment about this issue.

In summary, § 414.916 and § 414.917 present several dispute resolution processes to treat program challenges experienced by beneficiaries, participating CAP physicians, and approved CAP vendors. The framework of the process for treating the approved CAP vendor's request to suspend the participating CAP physician's CAP election agreement has been changed in these ways:

- The participating CAP physician may now offer information to the designated carrier as it develops its recommendation on whether CMS should suspend the participating CAP physician's CAP election agreement;
- The participating CAP physician may now offer information to CMS as it makes its decision on whether to suspend the participating CAP physician's CAP election agreement; and
- CMS will not publish in the **Federal Register** the names of physicians whose CAP participation agreements have been suspended.

Section 414.917 has been added to create a process for termination of a vendor's CAP contract upon the request of a physician when service and quality issues cannot be resolved cooperatively.

We will ensure beneficiaries are educated on the avenues available to them to dispute billing issues. Approved CAP vendors may use the advance beneficiary notice (ABN) process if the approved CAP vendor reasonably expects its drug claims may be denied.

c. Resolution of Beneficiary Billing Issues

In the proposed rule, we specified that the beneficiary would receive a medical summary notice (MSN) from the local carrier indicating whether the physician's drug administration claim has been paid or denied. If the drug administration claim has been denied, the MSN would reflect a message instructing the beneficiary that no deductible or coinsurance may be collected for the drug. If the beneficiary receives a bill for coinsurance from the vendor, the beneficiary may participate in the approved CAP vendor's grievance process to request correction of the approved CAP vendor's file. If the beneficiary is dissatisfied with the result of the approved CAP vendor's grievance process, the beneficiary may request intervention from the designated carrier. The designated carrier would first investigate the facts and then facilitate correction to the appropriate claim record and beneficiary file. If the approved CAP vendor requires targeted education on the subject of beneficiary billing, the designated carrier would initiate that effort.

Comment: Several commenters requested that CMS require every CAP MSN to include standard language clearly explaining the beneficiary grievance process and make clear that the CAP physician is not involved with billing for drug coinsurance amounts.

Response: We share the commenters' concern that beneficiaries should be provided with complete and timely information about the approved CAP vendor's grievance process. We support the commenters' interest in giving the beneficiary notice that the participating CAP physician is independent from the approved CAP vendor. We will consider these comments as the educational materials are finalized. All beneficiary education materials are focus-group tested to be certain they are understandable and communicate the intended message. We will require approved CAP vendors to provide participating CAP physicians with information on how beneficiaries, and participating CAP physicians, can each use their respective grievance processes when the approved vendors send introductory materials to the participating CAP physicians each autumn. It is unlikely the Medicare summary notice will be used to communicate about the beneficiary grievance process because there will exist no billing dispute until the approved CAP vendor actually bills the beneficiary. Information on the beneficiary grievance process will be more appropriately included with any bill the approved vendor may send to the beneficiary. We also will require all participating CAP physicians to distribute the CMS developed fact sheet to beneficiaries in the participating CAP physician's office. The fact sheet presents a good medium for distribution of information on the beneficiary grievance process, and information about the participating CAP physician's independence from the approved vendor.

Comment: Several commenters have requested that we describe whether and how an approved CAP vendor could deliver an ABN to a beneficiary.

Response: An ABN is the standard mechanism for advising beneficiaries of the cost of items and/or services for which they will be financially responsible. Generally, an ABN informs the beneficiary that, even though the service being delivered may be covered by Medicare in some situations, the issuer has reason to believe Medicare coverage policy will not support payment under the circumstances of the present case. For instance, an approved CAP vendor may reach the conclusion that the drug it is providing to the participating CAP physician for administration to the beneficiary would not be reasonable and necessary—and therefore will not be paid for by Medicare—after reviewing data on the prescription order and having follow-up communication with the participating CAP physician. The approved CAP vendor may request the participating CAP physician to deliver an ABN. If the participating CAP physician agrees to do so, then the physician will describe on the ABN both the administration services and the drug product, together with the estimated cost for each that the beneficiary must pay if he or she receives the drug.

If the participating CAP physician will not deliver an ABN on behalf of the requesting approved CAP vendor, then the approved CAP vendor may issue an ABN directly to the beneficiary before the item(s) or service(s) is received. For instructions and forms connected with ABNs, please visit this Web site: *http//www.cms.hhs.gov/medicare/bni.*

C. CAP Contracting Process

1. Quality and Product Integrity Aspects

Sections 1847B(b)(2), 1847B(b)(3), and 1847B(b)(4) of the Act address the issue of quality under the competitive acquisition process at both the product and approved CAP vendor level. We proposed to use the bid evaluation

process to ensure that these quality aspects are met.

a. Information To Assess and Ensure Quality

Sections 1847B(b)(2) and 1847B(b)(3) of the Act specifically require that approved CAP vendors meet financial and quality of care requirements aimed at assuring the stability and safety of the CAP program. Section 1847B(b)(2)(A) of the Act requires that approved CAP vendors have sufficient capacity to acquire and deliver drugs in a timely manner within the geographic area, to deliver drugs in emergency situations, and to ship drugs at least 5 days each week. This section also requires that approved CAP vendors meet quality, service, financial performance, and solvency standards, which include having procedures for dispute resolution with physicians and beneficiaries regarding product shipment, and having an appeals process for the resolution of disputes. We proposed that CMS be allowed to suspend or terminate an approved CAP vendor's contract if the vendor falls out of compliance with any of these quality requirements. Section 1847B(b)(2)(B) of the Act states that the Secretary may refuse to award a contract, and may terminate a contract if the entity's license to distribute drugs (including controlled substances) has been suspended or revoked, or if the entity is excluded from participation in the Medicare or other Federal health care program under section 1128 or 1128A of the Act. In the proposed rule, we stated this requirement is enforced through the routine provider enrollment form monitoring process. We also specified that section 1847B(b)(3)(C) of the Act states that the ability to ensure product integrity must be included in the criteria for awarding approved CAP vendor contracts.

In the March 4, 2005 proposed rule, we stated that at a minimum, we wanted to define a set of overall financial and quality standards to ensure that reputable and experienced vendors are chosen to participate in the CAP. We believe that physicians would be reluctant to participate in the CAP if they had little confidence that the CAP vendors would be reliable and provide quality CAP products. We also stated that approved CAP vendors would be required to provide quality products in a timely manner.

Section 1847B(b)(4)(C) of the Act specifies that any contractor selected for this program ''shall (i) acquire all drugs and biological products it distributes directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer; and (ii) comply with any product integrity safeguards as may be determined to be appropriate by the Secretary.'' We proposed to include this requirement in the contracts signed between CMS and approved CAP vendors who are providing drugs or biologicals under this section. We solicited comments on what records or other evidence bidders would be required to furnish and approved CAP vendors would be required to maintain during the contract period.

Comment: Several commenters raised issues related to product integrity and vendors' distribution systems (for example, shipping and storage procedures). In addition, many commenters, including physicians, potential vendors, and a mix of other affected groups, associated high quality with appropriate access to care, avoiding delays in therapy, and beneficiary safety. Commenters did not perceive new or additional product integrity requirements as desirable, but requested that we provide a more specific description of product integrity and other quality requirements. One commenter noted that the criteria for assessing the adequacy of retail pharmacy networks under Tricare and the Part D rule (68 FR 4194) that will be implemented in 2006 exist and that these guidelines could be used to evaluate CAP vendors.

Response: The approved CAP vendors' ability to accurately furnish drug products in a timely manner will be vital to this program's success. Assessment of the bidding entity's ability to perform similar drug distribution tasks and the entity's financial status will occur through the Medicare Provider enrollment process and through a separate CAP Vendor Application. This form was made available for public comment and is pending OMB approval.

In an effort to ensure that the CAP provides high quality service and to protect the integrity of drugs furnished under the CAP, we proposed that the approved CAP vendor be a Medicare provider or supplier, and we proposed additional and more specific requirements on licensing, product integrity, and contract agreements. We plan to implement these requirements in this interim final rule. The proposed regulation and corresponding changes to sections § 414.908(b) and § 414.914(f) of the proposed regulation reflect these requirements. The Provider Enrollment and Vendor Application form process will collect the detailed information that will be used to assess a potential CAP vendor's capacity to acquire drugs, and the ability to provide quality products and service, timely and accurate shipping, use of a compliance plan, history of past experience, and evidence of appropriate State licensure. We believe that the requirements described above will not be improved by incorporating additional criteria intended to assess retail pharmacy networks because CAP vendors are expected to operate differently than retail pharmacy networks. In addition, we have determined that the CAP vendors will be considered suppliers for Medicare purposes.

Comment: Several commenters stated that in order to attract physician participation, quality requirements should be stringent, and approved CAP vendors should be held to very high standards for quality and performance. These commenters agreed that measures, up to and including contract termination, were appropriate means of dealing with failure to adhere to a contractual agreement. One commenter also requested that we clarify the procedure physicians should follow to obtain CAP drugs when an approved CAP vendor is terminated from the program.

Response: As mentioned earlier, entities seeking a contract to furnish CAP drugs will be required to submit detailed information that will be used during the bid evaluation. Ongoing quality assessment will be conducted in a variety of ways, including routine Medicare provider enrollment monitoring, carrier statistics, and complaint monitoring. Approved CAP vendors are also expected to maintain appropriate licensure to furnish CAP drugs in the States in which they are supplying drugs and to maintain status as a Medicare supplier through the contract's period of performance.

During the contract's period of performance, compliance with these standards, as well as such other terms and conditions as we may specify consistent with section 1847B of the Act, will be a contractual requirement. The contract between CMS and an approved CAP vendor shall provide for contract termination for patterns of poor performance, single serious breaches of contract, or failure to comply with applicable laws and regulations. Methods to improve vendor performance and to resolve disputes between parties are discussed in the dispute resolution section of this interim final rule in section II.B.3. We note that the process described in § 414.917 for reconsidering the termination of a CAP vendor's approved status applies not only in cases where the termination was the result of a drug

service or quality issue brought to our attention by a participating CAP physician, but also in cases where we suspend the CAP contract for noncompliance or terminate the CAP contract for cause under § 414.914(a). We believe that this process will provide approved CAP vendors with an adequate process to contest our decision to suspend or terminate the contract. As noted above, pending the final determination under § 414.917, the approved CAP vendor's contract is suspended. Finally, we note that we consider the termination of the approved CAP contract to be separate and distinct from any determination with respect to the approved CAP vendor's status as a Medicare supplier. Therefore, the provisions of 42 CFR part 498 would not apply in the case of the termination of a CAP contract.

Comment: One commenter stated that the statutory requirement to make payments to the vendor meant that vendors would not be permitted to subcontract with a local or State licensed pharmacy, because the pharmacy could not be reimbursed directly. The commenter believes that this would mean that an approved CAP vendor would be required to obtain a license in each State, and the overall cost of the program would be increased.

Response: We do not agree that the statutory requirement that states payments be made directly to the approved CAP vendor would preclude the vendor from subcontracting with another drug distributor or pharmacy. A vendor could subcontract with another entity as long as that entity met all of our approved CAP vendor requirements and the subcontracting arrangement was divulged in the vendor's CAP application. A subcontractor's qualifications, including its history, structure, ownership and measures used to ensure product integrity must be described on the application and will be reviewed during the bidding process. The applicant is also required to certify that other aspects of a subcontractor's operation are in compliance with licensing requirements, Federal and State requirements, including compliance with all applicable fraud and abuse requirements, and that key personnel have not been excluded from participation in various Federal and State health care programs, including Medicare. It is the approved CAP vendor's responsibility to determine that subcontractors remain compliant with these standards. We intend that subcontractors or other entities associated with furnishing CAP drugs under an approved CAP vendor's contract maintain the same standards as the approved CAP vendor for the role that they play in furnishing CAP drugs. Section 414.914(f)(9) of the regulation states subcontractors' requirements.

The approved CAP vendor and the subcontracted entity would need to make arrangements between themselves, so that even if the subcontractor handled the billing in a particular area, it would still be acting as an agent of the vendor and identify itself as acting on the vendor's behalf. Medicare will only make payment to the vendor, and the vendor is responsible for payment to the subcontractor. Payment from the vendor to the subcontractor shall be consistent with all applicable laws, including all fraud and abuse laws such as the physician self-referral (''Stark'') prohibition (section 1877 of the Act) and the Federal anti-kickback statute (section 1128B(b) of the Act).

Comment: Several comments stated that proven capacity, including specific experience with Part B injectable drugs, was a desirable quality for a vendor. One commenter stated that evidence of Pharmacy licensing would be a sufficient measure as an alternative to the requirement for 3-years of experience furnishing Medicare Part B drugs. Among commenters who discussed a specific timeframe associated with furnishing Part B drug injectable drugs, 3 years was generally acceptable, but some commenters suggested that experience with the drugs in a category would be a better marker. One commenter asked if our 3-year requirement for ''furnishing'' Part B injectable drugs meant furnishing drugs that would be used by physicians for their Medicare beneficiaries under the ASP system, specialty pharmacy, and distribution experience. One commenter also stated that the ability to ship on an immediate basis was highly desirable. Other commenters stated that 3 years of experience furnishing Part B injectables did not measure services expected in a pharmacy dispensing model, and its restrictive nature could decrease competition. Another commenter specifically recommended that we ask for references that could describe the entity's customer service.

Response: Although pharmacy licensing may indicate some vendors' ability to meet certain standards and may be required in some States, we believe that 3 years' experience in furnishing Medicare Part B drugs serves to demonstrate the approved CAP vendors' commitment to maintaining an infrastructure required to acquire, store, and handle these drugs, to ship them in a timely manner, and also demonstrates familiarity with these products at the organizational level.

Information supplied during the provider enrollment process and from the Vendor Application Form addresses the comments above. Although this process does not specifically ask for references, the process collects and checks similar information, including licensure, financial stability, and business affiliations. In response to these comments, we plan to amend the Vendor Application form to include a request for references from businesses or organizations to which the bidding entity has supplied significant volumes of Medicare Part B injectables.

Comment: Several commenters raised issues regarding licensure and its relationship to quality. Although some comments supported the inclusion of pharmacists in the CAP order process, others pointed out that the involvement of additional professionals may not guarantee product integrity.

Response: The issue of licensing is discussed elsewhere in this IFC. We do not seek to pre-empt State law, but we also recognize that licensing requirements may not always guarantee quality. Approved CAP vendors will be required to have and maintain licensure that is required by the State(s) in which they furnish drugs under the CAP. This licensing requirement and additional quality requirements included in the vendor application process and ultimately in the approved CAP vendor's contract are intended to ensure that the CAP provides the highest quality services.

b. Product Integrity

Section 1847B(b)(3)(C) of the Act states that the Secretary must consider the ability of the applicant to ensure product integrity. We proposed that the evaluation include, but not be limited to, the applicants' ability to assure that products are not adulterated, misbranded, spoiled, contaminated, expired, or counterfeit. We stated that at a minimum, all drugs and biologics used in this program must be licensed under section 351 of the Public Health Service Act or approved under section 505 of the Federal Food, Drug, and Cosmetic Act. We also indicated approved CAP vendors would also be required to comply with sections 501 and 502 of the Federal Food, Drug, and Cosmetic Act concerning adulteration and misbranding. We note drug products furnished under CAP are expected to comply with FDA requirements including current good manufacturing practices (See 501(a)(2)(B) of the Federal Food Drug and Cosmetic Act; 21 CFR Parts 210 and 211 for finished pharmaceuticals).

Additionally, we proposed that applicants would be required to employ trained personnel, have appropriate physical facilities, and use adequate security measures to assure that processing, handling, storage, and shipment of drugs and biologicals are adequate to maintain product integrity. Because Federal statutory and regulatory requirements are designed to meet the standards in the paragraph above, we also proposed to require that all applicants comply with State licensing requirements and be in full compliance with any State or Federal requirements for wholesale distributors of drugs or biologics in States where they furnish drugs for the CAP.

Although we did not propose to require applicants to employ measures beyond those required for licensure and regulatory compliance, we believe the measures set a minimum standard, and we requested that applicants discuss any additional measures they have taken to assure product integrity. We suggested that applicants review the report on counterfeit drugs issued by the Food and Drug Administration (FDA), ''Combating Counterfeit Drugs,'' available on the FDA Web site *http://www.fda.gov/counterfeit*. We proposed that applicants describe measures taken to ensure drug product integrity on the CAP vendor application. We provided examples of additional measures that posed minimal burden, but enhance the ability to detect adulterated, misbranded or counterfeit drugs that included the following:

- Complying with the ''Recommended Guidelines for Pharmaceutical Distribution System Integrity'' developed by the Healthcare Distribution Management Association, available at *http://www.healthcaredistribution.org*.
- Cooperating with Federal and State authorities in their investigations of suspected counterfeit drugs.
- Establishing mechanisms to obtain timely information about suspected counterfeits in the marketplace and to educate their employees on how to identify them.
- Notifying appropriate State and Federal authorities within 5 business days of any suspected counterfeit products discovered by the wholesaler.

Comment: A number of commenters agreed that vendors must demonstrate commitment to furnishing products that were not adulterated, misbranded, spoiled, contaminated, expired, or otherwise counterfeit. Commenters also supported CMS' overall approach to maintaining product integrity and vendor contract requirements that include the statutory requirement for acquiring CAP drugs directly from the manufacturer or from a distributor who has acquired the drug from a manufacturer. One commenter also suggested that we require approved CAP vendors to be in compliance with the Prescription Drug Marketing Act (PDMA) in addition to State and other Federal requirements.

Response: The CAP vendor application process, the maintenance of appropriate licensure and Medicare supplier status form the framework for protecting product integrity. We believe that these requirements address the qualifications of personnel who may be handling the drugs as well. The FDA, not CMS, is the agency that is charged with enforcing the PDMA, however approved CAP vendors are still subject to the PDMA's requirements, including the prohibition on the sale of drug samples. Vendors should consult with the FDA for further guidance on the PDMA.

Comment: Another commenter stated that distributors and vendors that participated in the CAP supply chain could verify a product's origin and avoid use of a paper pedigree (a document that tracks the product's origin) by including simple language with shipping materials. The language would verify that CAP drugs were obtained directly from the manufacturer or from a distributor that acquired them from the manufacturer. This commenter also noted that a ''paper pedigree'' system was burdensome and subject to forgery or other types of failure, and that practical electronic pedigrees are a future solution that is 2 to 4 years away.

Response: The statute does not exempt CAP vendors from PDMA requirements, therefore a CAP vendor who makes a wholesale distribution of prescription drugs for which it is not an authorized distributor is required to pass on a pedigree that complies with PDMA and current regulations (see U.S.C. 353(e)(1)(A). Since some CAP drug shipments may not be classified as drug distribution, we also require a distributor who ships to an approved CAP vendor or an approved CAP vendor who ships to a physician's office to include language with shipping material stating that the drug was acquired directly from the manufacturer or that the vendor possesses verification that the drug was acquired directly from the manufacturer and has been acquired in a manner that is consistent with statutory requirements. The approved CAP vendor or the distributor must also be able to immediately furnish evidence to support that information if requested by CMS, its contractors, law enforcement, the designated carrier, or a physician's office. We have modified the regulation text at § 414.906(a)(4) and § 414.914(c)(1) to reflect the comments above.

Comment: Some commenters expressed concern that physicians could not vouch for the quality of products that were opened by the vendor for repackaging, for mixing the drug with other drugs or injectable fluids (admixture), or for removing a part of the contents in order to supply the exact dose for a beneficiary. Therefore, these commenters recommended that vendors deliver their products in the same form in which they are received from the manufacturer, without opening packaging or containers, mixing or reconstituting vials, or repackaging. Specific points of concern included the capabilities of individuals who mix the drug, as well as shipping conditions, storage and stability.

Response: CAP is not intended to require approved CAP vendors to perform pharmacy admixture services, (for example, to furnish reconstituted or otherwise mixed drugs repackaged in IV bags, syringes, or other containers that are ready to be administered to a patient) when furnishing CAP drugs. Admixture services for injectable drugs require specialized staff, training, and equipment, and these services are subject to standards such as United States Pharmacopoeia Chapter 797, Pharmaceutical Compounding—Sterile Preparations. These requirements have significant impact on drug shipping, storage, and stability requirements as well as system cost and complexity. Approved CAP vendors are to ship CAP drugs in unopened manufacturer's packaging. Packages containing multiple individual units of one drug (like vial trays) may be split into quantities that are appropriate for a beneficiary's shipment, but individual vials must be unopened and any packaging surrounding the individual vial must be left intact.

Comment: One commenter mentioned that because approved CAP vendors would obtain drugs directly from the manufacturer or from a distributor who had obtained the drugs directly from the manufacturer, the Healthcare Distribution Management Association (HDMA) Recommended Guidelines for Pharmaceutical Distribution System Integrity would not apply. The guidelines were not intended to be applied to relationships between distributors and manufacturers. Instead, they had been developed for situations when a distributor was planning to buy drug products from another distributor, or to establish trading partner agreements. Because the document was

a guideline, the commenter urged CMS to allow vendors to use the guidelines to fit the individual vendor's circumstances.

Response: The HDMA Guidelines were being used as an example of measures that could be used or adapted in order to decrease risk of product integrity. We did not propose to require applicants to employ further measures beyond those required for licensure and regulatory compliance. However, we would like bidders to be aware of specific additional measures, such as the HDMA Guidelines, that may be used to protect product integrity.

Comment: One commenter stated that a formal compliance program to ensure adherence to drug storage and handling requirements should be required of vendors and distributors, and that this information should be a part of the bid.

Response: We believe that the vendor application process we proposed will adequately assess a bidding entity's compliance plan. The vendor application form specifically requires the applicant to submit a compliance plan that describes written policies, procedures, and standards of conduct articulating the organization's commitment to abide by all applicable Federal and State standards; the designation of a compliance officer and compliance committee accountable to senior management. The compliance plan is also required to establish effective training and education of the compliance officer, organization employees, contractors, agents, and directors; effective lines of communication between the compliance officer and organization employees, contractors, agents and directors and members of the compliance committee; disciplinary standards; procedures for internal monitoring and auditing; and procedures for ensuring prompt response to detected offenses and development of corrective action initiatives, relating to the applicant's contract as an approved CAP vendor.

In the application and under our regulation at § 414.914(c)(6)), we also recommend that applicants' compliance plans include provisions that require the reporting of fraud and abuse to the appropriate government authority. Approved CAP vendors that self-report violations will continue to receive the benefits of voluntary self-reporting found in the False Claims Act and Federal sentencing guidelines.

As we mentioned elsewhere, in order to monitor approved CAP vendor quality, we plan to include routine Medicare provider enrollment monitoring, carrier statistics, and complaint monitoring. Vendors are also expected to maintain appropriate licensure to furnish CAP drugs in the States in which they are supplying drugs.

Comment: For quality standards other than product integrity, two commenters suggested that we use the DMEPOS Supplier Manual as a guideline.

Response: The CAP does not encompass DME drugs and is intended to furnish medications to a physician's office. Therefore, we do not believe that the DMEPOS quality standards are an exact match for the CAP. However, we do note that our focus on product integrity, accurate delivery and other vendor qualifications, including enrollment as a Medicare supplier are similar to the DMEPOS standards.

Comment: Several comments questioned how the effects of shipping on product integrity would be addressed and were especially concerned with breakage, damage, and delays. One commenter asked who would bear the cost burden of shipping a damaged drug or a drug whose integrity was in question, and whether replacement would be offered. Another suggested that approved CAP vendors be responsible for maintaining records of product integrity from the time that the vendor received the product until it reached the physician's office, including situations where a third party shipper transported the drug to the physician's office.

Response: Approved CAP vendors are required to ship drugs in a manner that will protect product integrity and a manner that is consistent with the definitions of the CAP delivery time frames, contractual obligations under the CAP, and drug stability requirements. Approved CAP vendors are also responsible for keeping records of how and when a specific drug order was shipped to the physician's office. Finally, vendors are financially responsible for the shipping costs associated with the return of drugs, and the approved CAP vendor retains title to the drug until it is administered. However, as noted above, other issues regarding product liability laws and other laws applicable to financial liability associated with adverse drug events are beyond the scope of this rule.

Comment: Commenters suggested that we provide specific guidance on how to manage drug waste and returns.

Response: Although a variety of situations may create quantities of unused drugs at the place of administration, we believe the unused CAP drugs will come in 3 forms: an unopened vial (and/or vial package) as shipped by the approved CAP vendor, an opened vial (that may or may not be reconstituted or partly used), and a drug that has been removed from a vial or package and is in a syringe, IV bag, or other device or container used for drug administration. Unused quantities of a drug may increase the risk of waste, fraud and abuse, and attempts to use the excess drug may violate pharmacy law and may compromise product integrity. We expect that approved CAP vendors will furnish drugs in a manner that will minimize unused drug. We also expect that physicians and approved CAP vendors will both make an effort to label, ship, and store drugs in a manner that will allow the legal reuse of an unopened and intact container of a drug. Returns of unused products through a distribution system may be acceptable, however many States prohibit reusing drugs that have been dispensed by a pharmacy (For further information, see FDA CPG 460.300). We are aware of situations when an approved CAP vendor may label a vendor-supplied outer container for prescriptions to keep the actual manufacturer's packaging intact and unlabelled. We further expect approved CAP vendors to offer and ship units of a drug that match the beneficiary's dosing requirements and HCPCS billing amount as closely as practical. In this way, a degree of waste will be prevented. Specific details, including how waste, returns, and their cost burden are handled, will depend on State law and regulation as well as the individual situations. Approved CAP vendors should establish policies on these issues (making sure that they comply with applicable laws and regulations) and make the policies available for physicians to review during the election period and through the CAP contract's period of performance.

Approved CAP vendors will furnish drugs to physician's offices in unopened vials. However, in situations where a drug is dosed by body weight or body surface area, the amount of drug in vials may not match the patient's actual dose, and the vendor will be forced to ship excess drug. In certain States, pharmacy law may prevent the use of excess CAP drug for another beneficiary if the order must be labeled as a prescription.

The return process is guided by the following:

- Federal Law and guidelines (such as the FDA's CPG 460.300), State law, Medicare requirements (such as the Claims Processing Manual), drug stability, and appropriate standards (such as United States Pharmacopoeia Chapter 797, Pharmaceutical Compounding—Sterile Preparations) will be used to determine how extra

drug product may be used for subsequent dosing on the same beneficiary or for use on another beneficiary.

• If excess drug product remaining in a vial shipped by an authorized CAP vendor must be returned, the approved CAP vendor is expected to accept excess drugs for disposal and is expected to pay for shipping. The physician is responsible for appropriately packing the drug. Consolidating shipping into larger and less frequent packages by the physician would be encouraged. We do not intend for this requirement to be used as a vehicle for routine disposal of empty or nearly empty vials, disposal of any drug product not shipped by an authorized CAP vendor, or disposal of drug mixed in IV bags, syringes, associated needles and tubing, or other devices used in the administration of the drug product to a beneficiary.

• The vendor bills Medicare only for the amount of drug administered to the beneficiary and the beneficiary's coinsurance amount will be calculated from the quantity of drug that is administered. Since the CAP statute authorizes us to pay the approved CAP vendor only upon administration of the drug, any discarded drug (or drug that is considered waste) will not be eligible for payment. We have modified the proposed regulation at § 414.906(a)(5).

The CAP dispute resolution process will be available to resolve any associated disputes. This process is described in the interim final rule at section II.B.3.

Comment: Commenters also cited ''brown-bagging'' (that is, having a beneficiary pick up a drug at a pharmacy and bring it to the physician's office for administration) as a potential threat to product integrity as well as an inconvenience for the beneficiary.

Response: We agree that the practice of brown bagging may jeopardize product integrity by potentially subjecting the drug to unknown storage conditions and exposing the drug to diversion. Brown bagging may also create a further burden on the beneficiary by requiring additional time and travel to obtain the drug product and then requiring appropriate storage of the drug. Section 1847B(b)(4)(E) of the Act indicates that drugs furnished under the CAP must usually be shipped directly to the physicians. The CAP is being implemented in a manner consistent with section 1847B(b)(4)(E) of the Act; therefore, we do not expect ''brown bagging'' to occur.

c. Financial Performance and Solvency Standards

Section 1847B(b)(2) of the Act discusses the financial performance and solvency standards we must develop for entities that seek to become approved CAP vendors. We proposed to fold integrity and internal control aspects of fiscal responsibility into this analysis.

In the March 4, 2005 proposed rule, we stated that while licensure by the State to distribute drugs may assess some degree of financial responsibility, we believe the focus and depth of financial capability evaluations associated with licensure might vary across States. To assess bidders' financial solvency in a consistent manner with appropriate scrutiny and minimal burden on the bidders, we proposed using criteria from the Federal Acquisition Regulation (FAR) Section 9.104 and following standards for ''responsible contractors'' as a baseline standard. The FAR standards also contain nonfinancial components that address areas such as integrity, performance, and ethics. In addition, we sought to add standards that would demonstrate the following:

Overall Capitalization and Financial Capability and Working Capital

We proposed that bidders furnish a copy of their most recent year's audited financial statements. Specific items, such as net worth, could be used in the evaluation process. We requested comments on the potential validity of specific financial indicators for this process and whether or not specific thresholds would be applicable. We also requested comment on this overall requirement from potential bidders, such as group purchasing organizations Group Purchasing Organizations (GPOs), who do not routinely take possession of drug products.

We proposed to review the audited financial statements to determine if the bidder has adequate working capital to meet contractual obligations. Ratios of current assets to current liabilities, total liabilities to net worth, and cash or cash equivalents to current liabilities are commonly used to assess financial capability (see the form at FAR 53.301–1407). Given the 3-year contract duration, we requested comments regarding the appropriateness of these tests, and thresholds to apply for the ratios.

Comment: Several commenters noted that financial standards in the proposed rule were not clearly defined. One commenter agreed that financial capability standards were important, but cautioned against setting standards that could unfairly or inadvertently exclude bidders due to insufficient capitalization, while another suggested that credit worthiness be evaluated in cases where a bidder was seeking to expand operations by participating as an approved CAP vendor. Other commenters suggested that vendors have significant financial stability to withstand the potential risk of participating in CAP and that debt to capital ratio be included in the evaluation because the commenter considered financial ratio to be particularly useful in assessing a prospective vendor's financial stability.

Response: In the proposed rule we stated that we sought to define a set of overall financial standards that would ensure that reputable and experienced vendors are chosen to participate in the CAP. As noted by several commenters, the proposed rule was intended to provide us with a framework to which we could add details based on public comment.

Financial data supplied by the bidders is intended to demonstrate that the entity is capitalized, generating sales volume, and is not operating at a loss. We also plan to use several simple financial ratios from Standard Form (SF) 1407, Preaward Survey of Prospective Contractor Financial Capability (see FAR 53.301–1407) to determine whether a contractor has financial resources to perform a contract. We expect bidders to have a current ratio (current assets : current liability) of >1. However, many bidders are expected to have significant inventory, particularly if they are engaged in drug distribution activities. We will also apply the quick ratio (also known as the acid test ratio, that is, current assets minus inventory : current liability). Comparison of the current and quick ratios also gives a sense of the relative amount of inventory that an entity may possess The debt to equity ratio (total liability : net worth) is intended to gain a sense of the role that creditors have in financing the entity's operations. These ratios will be used to help assess whether the vendor can meet obligations to deliver CAP drugs on receipt of a prescription order. More specific financial information, such as audited annual financial statements, will be used to confirm the general findings above.

Bidding entities could be a diverse group that could include single organizations or groups. The entities could have a variety of backgrounds including drug distribution, specialty pharmacy, or group purchasing. Therefore, in an effort to minimize the risk of having an absolute threshold disqualify a potentially capable bidder,

we are avoiding using absolute thresholds when possible. Instead, we plan to compare data, especially the financial ratios, and use the data to rank bidders relative to one another. We will rank the bidders on four basic financial categories: Financial ratios, profitability, capitalization, and total sales. These rankings would then be used along with quality information provided during the bidding process and bid prices to select vendors who will be offered a contract to furnish drugs under CAP. A lower financial ranking will not be an absolute reason for exclusion from the bidding process, but will be one of several factors being evaluated.

Comment: One commenter stated that requiring bidders to have Medicare sales account for less than half of their total predicted sales volume for the upcoming year would demonstrate an entity's scale and would limit the entity's dependence on Medicare as a means to ensure financial viability.

Response: Although we believe that experience with Medicare Part B injectable drugs is necessary for a vendor, we do not believe that it would be appropriate for us to set a limit in the manner the commenter suggests because it could interfere with the vendor's business planning and may have the effect of excluding qualified bidders.

Comment: Group Purchasing Organizations (GPOs) and similar entities who do not routinely take possession of drug products were invited to comment on the assessment of a bidder's financial capability. However, we received one comment from a GPO expressing concern about the significant financial risk of long-term receivables and low margins, but GPOs did not comment specifically on proposed financial indicators.

Response: We will use the financial evaluation process outlined earlier. By statute, payment for drugs furnished under CAP is conditioned upon the administration of a drug to the beneficiary. This limits how soon a vendor can be paid. We believe that establishment of operations and the opportunity for periodic price adjustments will create an opportunity for the vendors to achieve financial stability while participating in the CAP.

Comment: Several commenters agreed with deriving financial and solvency standards from the FAR. Commenters also suggested that FAR business integrity and conflict of interest standards be adopted. Finally, commenters requested details on how ongoing compliance would be monitored, which parameters would have to be reported, and penalties for failing to report standards or missing the standards.

Response: The proposed rule mentions using FAR Section 9.104 as a baseline for evaluating a prospective contractor. We also adapted a form (FAR 53.301–1407) used for the preaward financial evaluation of a contractor for use in the Vendor Application. However, the FAR does not contain specific financial solvency standards.

We did not propose a competition strictly based on FAR, nor do we plan on implementing CAP in this manner in this interim final rule. Business integrity, conflict of interest, compliance, and penalties are discussed in section 2.B.2 of this interim final rule.

Record of Integrity

We proposed that the bidders supply us with applicable information on whether any of the bidder's Board of Directors, employees, affiliated companies, or subcontractors—

- Know they are under investigation by any State, Federal, or Local Government agency related to a fraud issue; and
- Have escrowed money in anticipation of, or entered into a settlement agreement or corporate integrity agreement with any State or Federal Government agency related to a fraud issue.

We also proposed that bidders provide a conflict of interest mitigation plan to address financial relationships the bidder may have with manufacturers of drugs or biologicals in the CAP.

We received no comments on this topic. Therefore, we will finalize these requirements as proposed. The vendor application process, which includes enrollment as a Medicare Supplier and the completion of the Vendor Application and Bid Form will provide information related to a record of integrity. Bidders will also be required to submit a conflict of interest mitigation plan as described above during the vendor application process. Conflict of interest and mitigation strategies are described in section II.2.C.3. in this interim final rule.

Internal Control

We proposed to review information relating to the establishment and effectiveness of the bidder's internal control system designed to provide reasonable assurance of financial and compliance objectives. We provided examples of information that we might review as evidence of the design and effectiveness of a bidder's internal control system.

We proposed to set forth these requirements in regulations at proposed § 414.908.We received no comments about internal financial control. Therefore, we will finalize these requirements as proposed.

Deemed Compliance

In the proposed rule, we noted that some vendor applicants may already be subject to financial oversight by one or more State or Federal regulators. The vendor applicant's current financial reporting may satisfy one or more of the above requirements. We proposed to request documentation of this parallel oversight together with contact information for the regulator. We would contact the regulator to inquire as to the vendor applicant's status and we may deem certain portions of the above requirements ''met'' at our discretion. We received no comments on this topic.

Therefore, we will finalize these requirements as proposed.

2. Bidding Entity Qualifications

a. Quality and Financial Information—Vendor Application

In the March 4, 2005 proposed rule, we stated that the vendor would be responsible for completing and meeting all criteria on both the Vendor Application Form and the Provider/Supplier Enrollment Application (Form CMS 855B) (for the purpose of completing these applications, vendors will be considered suppliers) by the established deadlines in order to be considered as a potential vendor under the CAP. For example, if a vendor has been excluded from participation in a Federal health program, or has been convicted of a fraud-related crime, the vendor must record that on the form 855B. We would treat these admissions from vendors in the same manner as we do for other suppliers. Both a draft copy of the Vendor Application Form and the Provider/Supplier Enrollment Application (Form CMS 855B) are available on the CMS Web site at the following address: *http://www.cms.hhs.gov/providers/drugs/*). Both forms are needed to cover all required vendor qualifications.

In the proposed rule, we stated that we would require that the vendor be prepared to offer complete information in four major areas and complete a certification statement. The vendor's business experience would be required to be within the United States. In addition, we proposed to require that prospective vendor provide on the Vendor Application Form, a complete list of drugs that the vendor would

intend to bid by National Drug Code (NDC) number.

Management and Operations

We proposed to require that the vendor attest that adequate administrative arrangements are in place to ensure effective operations, such as but not limited to, policies that assure that business is conducted in the best interest of the customer, maintenance of fidelity bonds, and insurance policies to cover losses. General identifying information would also be required such as business name, address, taxpayer identification number, contacts representing the organization, and a description of the organization's structure. In addition, we proposed that each subcontractor, subsidiary, or business affiliate that is used by the vendor under the CAP would be required to provide the same information.

Experience and Capabilities

In the proposed rule we stated that the approved CAP vendor would be required to:

- Maintain the operation of a grievance process so that physician, beneficiary, and beneficiary caregiver complaints can be addressed;
- Provide a prompt response to any inquiry as outlined in the vendor application form;
- Maintain business hours on weekdays and weekends with staff available to provide customer assistance for the disabled, including the hearing impaired, and to Spanish speaking inquirers; and
- Provide toll free emergency assistance when the call center is closed.

We emphasized that customer service is a primary consideration, especially the ability to respond on an emergency basis to participating CAP physicians. In addition, we stated that a working telephone customer service number be submitted for verification during the bid evaluation process.

Section 1847B(b)(2)(A)(i)(II) of the Act gives some guidance regarding timeframes for routine and emergency shipment; however, the statute does not provide specific definitions of these timeframes. Therefore, we requested comment on how to define timely delivery for routine and emergency drug shipments. For the purposes of this discussion, we proposed that the delivery time period would begin when a drug order is received by the vendor and would end at the time of delivery to the participating CAP physician's office or other intended setting. We proposed that routine shipments of drugs furnished under the CAP would occur within a 1 to 2 business day time period. However, the duration of the delivery time period must not exceed the drug's stability in appropriate shipping containers and packaging. We requested comments on the feasibility of requiring a shorter duration for routine delivery of CAP drugs. This discussion is included in section II.B. of this interim final rule, ''Operational Aspects of the CAP.''

We proposed to require that approved CAP vendors maintain a formal mechanism for responding to complaints from participating CAP physicians, beneficiaries, and their caregivers (if applicable). In the proposed rule, we stated that evidence of this mechanism, in the form of any complaint resolution manuals, agendas, and minutes from complaint resolution committee meetings, or other evidence of complaints being resolved would be submitted as part of the bid application.

In addition to providing an audited financial statement as an attachment, we proposed that the vendor be required to present a standardized summary of financial information on the collection form. We also proposed that the vendor must have been in the business of furnishing Part B injectable drugs for at least 3 years, and specifically requested comment on whether the requirement of 3 tax reporting years of experience would prevent newer vendors with sufficient experience and resources from being included in the program. We also proposed that the vendor would be prepared to offer and substantiate the drug volume managed (in dollars and units) for the immediate previous calendar year and provide specific personnel statistics such as the number of staff assigned to various activities, and its policy-making organizational structure within the United States.

Finally, because selected approved CAP vendors would be considered a covered entity under the HIPAA Administrative Simplification Rules, to the extent that they conduct any of the standard HIPAA transactions electronically, these approved CAP vendors would be required to comply with the Administrative Simplification rules, including the Privacy Rule.

Comment: Some commenters were concerned with our proposed requirement for a vendor to have been in business for 3 years as one of the thresholds for participation in the CAP. These commenters argue that there is no correlation between business longevity and quality of care.

Response: The statute directs us to select among qualified bidders based on, among other things, past experience in the distribution of drugs and biologicals. We believe that it is reasonable to expect a vendor who seeks to participate in the CAP to have been in the business of furnishing Part B injectable drugs for at least 3 years because that will provide us with an appropriate amount of information to assess the applicant's past experience. We believe that requiring a potential vendor to prove 3 years of experience would allow us to evaluate their ability to use resources appropriately based on their past performance. Vendors with less than 3 years of experience would not be in a position to demonstrate any kind of a track record that could be reviewed so that we could be assured of their ability to perform effectively and in an acceptable manner under the CAP. Finally, a vendor who meets all the criteria except that it has not yet been in the business of furnishing Part B injectable drugs for the required 3-year threshold is free to participate in the CAP once it has met the 3-year requirement.

Comment: Commenters suggested that submitted bid information provided by the vendor should be kept confidential and protected from public disclosure.

Response: As we mentioned in the proposed rule, we will follow HIPAA standards to protect privacy. All cost information will be confidential and not made available for public display. In accordance with section 1927(b)(3) of the Act, bid prices will be kept confidential.

Comment: Commenters suggested that CMS collect additional information on the vendor's application forms.

Response: We believe that the vendor information submitted on the Form 855B (the Medicare fee-for-service physician/supplier enrollment form) and the vendor application forms is sufficient.

Licensure

We proposed that the vendor would be required to maintain an appropriate license in each State in which the drug vendor seeks to operate under the CAP. We also proposed to require that the vendor certify that any subcontractor or subsidiary also maintains a license that complies with State regulations in every applicable State.

Comment: Several commenters believed that we should require a vendor to be licensed to operate a pharmacy as well as to be a licensed wholesaler in the States in which the vendor seeks to do business under the CAP. These commenters stated that the drug dispensing duties of a vendor naturally require the experience and

expertise of a pharmacist, rather than a general wholesaler.

Response: We believe that vendors must operate as distributors in order to participate in the CAP, and we recognize that a natural outgrowth of participating in this program may be that those distributors also will need to be licensed as a pharmacy. Regardless, either the vendor, its sub-contractor under the CAP, or both, must be licensed appropriately by each State to conduct its operations under the CAP. Therefore, a vendor under the CAP would be required to be licensed as a pharmacy as well as a distributor if a State requires it. Because our initial competitive acquisition area is nationwide, appropriate licensure in all States would be required. We note that by its terms, nothing in section 1847B of the Act shall be construed as waiving applicable State requirements relating to the licensing of pharmacies.

Business Integrity

In the proposed rule, we stated that the vendor would be responsible for identifying and disclosing business relationships and conflicts of interest as well as potential conflicts of interest with other organizations. We also stated that the vendor would be required to answer questions and provide information about fraud investigations, settlement agreements, and Federal government exclusions.

Comment: We received several comments supporting our strong requirements related to vendor qualifications, including management and operations standards, operation of a grievance process, experience, HIPAA compliance, licensure, and business integrity. Commenters believe that the requirements were necessary to ensure that only qualified entities were selected as CAP vendors.

Response: In evaluating whether to award a CAP vendor contract or renew an approved CAP vendor contract, CMS will take into account a bidder's record of corporate integrity and performance and will review the bidder's internal integrity measures, which include at a minimum, a compliance plan to prevent fraud, waste and abuse. We appreciate comments in support of our approach to review these criteria as part of our selection and renewal process. As a result, we are retaining our requirements for potential vendors under the CAP. Additionally, in response to comments we are including language at § 414.908(c) that permits CMS to refuse to award or terminate a contract based on a potential CAP vendor's past violations or misconduct related to the marketing, distribution, or handling of drugs. This requirement will strengthen CMS' efforts to ensure that entities granted the ability to provide Medicare products or services have a record of corporate integrity and performance that reflects the provision of scrupulous products and services.

Certification

We proposed that the vendor be prepared to certify that all the information in the Vendor Application Form is true, accurate, and complete and to certify to any other requirements as specified by us. Failure to provide correct and updated information when it becomes available, if it affects the information provided on the Vendor Application Form, may be cause for termination of the vendor's contract under the CAP. We believe that it is vital to certify that the information provided is accurate. We received no comments on this issue, so, as a result, we are finalizing that requirement in this rule. In addition, we provide further direction for vendor and subcontractor conduct in the next two sections (Fraud and Abuse as well as Conflicts of Interest).

b. Specific Information Relating to Prevention of Fraud and Abuse

Section 1847B(b)(4)(D)(ii) of the Act requires that the approved CAP vendor comply with all applicable provisions relating to the prevention of fraud and abuse. This includes compliance with applicable guidelines of the Department of Justice (DOJ) and the Office of the Inspector General (OIG) of the DHHS.

In accordance with this statutory authority, we proposed that each approved CAP vendor develop and maintain a compliance plan to control program fraud, waste, and abuse, that includes at a minimum, the requirements proposed at § 414.914(c) of our regulations. These requirements already apply to many of the entities participating in the Medicare program, such as prescription drug plans administering the prescription drug benefit and Medicare Advantage organizations. In addition, the OIG has recommended these minimum elements in published guidance.

We stated in our proposed rule that a compliance plan should contain policies and procedures that control program fraud, waste and abuse. In developing written policies, procedures, and standards of conduct for detecting and preventing waste, fraud and abuse, we stated that approved CAP vendors should consult a variety of sources including applicable statutes and regulations and compliance guidance issued by CMS, our contractors, Program Safeguard Contractors (PSCs), and the OIG. We provided some recommended sources for relevant information. Approved CAP vendor compliance plans must be submitted with the CAP applications, and must be available to us and our contractors for periodic reviews.

We also proposed that approved CAP vendors and entities that they contract with establish effective training and education programs related to fraud, waste and abuse that address pertinent laws related to fraud and abuse including the physician self-referral (''Stark'') prohibition (section 1877 of the Act) and the Federal Anti-Kickback statute (section 1128B(b) of the Act), and the False Claims Act (31 U.S.C. 3729–3733). In addition, we proposed that approved CAP vendors and entities that they contract with be trained on detecting and preventing common fraudulent schemes in the pharmaceutical industry, as identified by CMS, the OIG, and/or the DOJ and provided examples of some common fraudulent or abusive problems within the pharmaceutical industry.

To ensure successful internal monitoring and auditing of fraud, waste, and abuse under Part B, we proposed that approved CAP vendors should regularly monitor and audit their processes and procedures to ensure that they are in fact taking the steps necessary to comply with all Federal and State regulations and to mitigate the potential for waste, fraud, and abuse within their organizations. Establishing procedures to ensure prompt responses to potential fraud violations is an important element in an effective fraud and abuse plan. Approved CAP vendors are responsible for monitoring and identifying potentially fraudulent or abusive activity. We further stated that after an approved CAP vendor has determined that any misconduct has violated or may violate criminal, civil or administrative law, the approved CAP vendor should report the existence of the misconduct to OIG or other appropriate government authority within a reasonable period, but no later than 60 days after the determination that a violation may have occurred. Self-reporting of fraud and abuse is a critical element to an effective compliance plan, and approved CAP vendors are strongly encouraged to alert CMS, the PSCs, the OIG, or law enforcement of any potential fraud or misconduct relating to the CAP. We investigate all cases referred as potentially fraudulent and then refer them to the appropriate law enforcement agency as warranted. Likewise, we expect that the approved CAP vendors would fully cooperate in

any investigations related to fraud identified in a particular approved CAP vendor's organization.

We are aware that there are many possible approaches to developing an effective compliance plan. Therefore, we requested comments on the scope and implementation of an effective compliance plan.

Comment: There were some operational comments regarding the opportunity for fraud, waste and abuse. One commenter pointed out that when a drug product sent to a physicians' office is unused and returned to the approved CAP vendor, this transaction could allow for the opportunity for fraud and drug spoilage. Because CAP drugs are kept in a separate inventory, a commenter asked if inventory errors would be subject to prosecution for fraud and abuse.

Response: We discuss the design of the inventory and return process in section II.B.2 of this interim final rule and the product integrity requirement in section II.C.1 of this interim final rule. We believe these processes, along with the fraud, waste and abuse provisions outlined above provide a framework for ensuring the integrity of the product delivery process. We note that the return of a product must be in accordance with applicable State and Federal laws. The approved CAP vendor is responsible for providing appropriate drug product delivery to the participating CAP physician's office that preserves that drug's integrity. The participating CAP physician is responsible for not accepting delivery of a drug product damaged during shipment or whose integrity the participating CAP physician believes was compromised. It is also the responsibility of the participating CAP physician to store appropriately an accepted product delivery to ensure its continued integrity.

Typically, there must be intent to commit fraud in order for the government to subject a physician or approved CAP vendor to prosecution for fraud and abuse. Minor inventory errors normally would not subject a participating CAP physician or approved CAP vendor to prosecution for fraud and abuse. Approved CAP vendors and participating CAP physicians each are responsible for complying with all laws and regulations applicable to them that govern the receipt, storage, and return of drug products. Participating CAP Physicians and approved CAP vendors may be held accountable for failing to adhere to any applicable requirements. We will investigate all cases brought to our attention as potentially fraudulent and then, if warranted, refer them to the appropriate law enforcement agency.

c. Conflicts of Interest

Section 1847B(b)(4)(D)(i)of the Act requires that approved CAP vendors participating in the CAP comply with a code of conduct, specified or recognized by the Secretary. The statute authorizes us to require approved CAP vendors to establish a code of conduct related to conflicts of interest in bidding and performance.

In the March 4, 2005 proposed rule, we stated that a code of conduct should function much like a constitution, that is, it should be a document that details the fundamental principles, values, and framework for action within an organization. We proposed that the code of conduct for approved CAP vendors articulate the approved CAP vendor's expectations of commitment to compliance by management, employees, and agents, and summarize the broad ethical and legal principles under which the company must operate.

Avoiding conflicts of interest and the appearance of these conflicts is critical to the operations of the CAP. In accordance with our statutory authority under the Act, we proposed to require that each approved CAP vendor establish and follow a code of conduct that addresses its policies and procedures for identifying and resolving any conflict of interest. We stated that a conflict of interest may occur where an approved CAP vendor, its representative, or contractor provides a product or service for a Medicare participating CAP physician or beneficiary and the approved CAP vendor, representative or contractor has a relationship with another person, entity, product or service that impairs or appears to impair the approved CAP vendor's or contractor's objectivity to provide the Medicare-covered product or service. Situations that compromise or appear to compromise an approved CAP vendor's ability to avoid self-dealing when providing a Medicare product or service create a conflict of interest and must be resolved. Approved CAP vendors should take steps to identify and mitigate any conflict of interest that may arise in the provision of a product or service for a Medicare participating CAP physician or beneficiary.

We indicated the code of conduct should communicate the need for all management, board of directors, employees, and agents to comply with the approved CAP vendor's code of conduct and policies and procedures for addressing and resolving conflicts of interest. It also should reflect the approved CAP vendor's commitment to detect and resolve any conflict of interest. The code of conduct should establish procedures for determining whether or not a conflict exists, and if so, how the conflict will be resolved. We proposed that the code of conduct address issues such as whether or not the offer or acceptance of some remuneration to or from an approved CAP vendor, physician, beneficiary, or manufacturer would diminish, or appear to diminish, the objectivity of professional judgment; or whether or not certain transactions raise patient safety or quality of care concerns.

In addition, throughout the solicitation of CAP contracts, we proposed that approved CAP vendors comply with the requirements of the FAR organizational conflict of interest guidance, found under 48 CFR Subpart 9.5, and the requirements and standards contained in each individual contract awarded to perform functions under section 1847B of the Act. Consistent with FAR 9.507–2, in making awards to approved CAP vendors, we proposed that each contract contain a conflict of interest clause specific to the approved CAP vendor for inclusion in the contract.

We proposed fairly general conflict of interest requirements because we believe that individual contracts may be a better venue to address specific conflicts of interest. However, we solicited comments regarding what may or may not constitute a conflict of interest in the CAP program and how such conflicts might be identified and mitigated.

We proposed to set forth our conflict of interest policies and procedures in regulations at proposed § 414.912.

Comment: One commenter suggested that CMS require full disclosure of an approved CAP vendor's corporate relationships during the bidding process and take steps to prevent monopolization by any one company within the bidding or contract award stages of the CAP program. This includes adopting language that requires corporate-structure disclosure and specifically prohibits approved CAP vendor subsidiaries from bidding against their parent company or other subsidiaries with the same parent company. The commenter suggested that CMS revise the language of § 414.908(e), ''Multiple contracts for a category and area,'' § 414.910(a) on the bidding process, and elsewhere, to reflect this bidding and contract award restriction. Another commenter suggested that the final rule address situations in which a company affiliated with a potential approved CAP vendor

manages a physician or medical/nurse practice. In these cases the physician may have no effective choice of an approved CAP vendor and non-affiliate vendors may not have a meaningful opportunity to compete for the business of the practice. The commenter recommended that the final rule include explicit conflict of interest standards to guard against preferential selection and treatment of potential approved CAP vendors that are affiliated with physician and medical/nursing practice management companies.

Response: The proposed rule stated that the approved CAP vendor's code of conduct should communicate the need for all management, board of directors, employees, and agents to comply with the approved CAP vendor's code of conduct and policies and procedures for addressing and resolving conflicts of interest. Also, consistent with FAR 9.507–2, in making awards to approved CAP vendors, each contract will contain a conflict of interest clause specific to the approved CAP vendor for inclusion in the contract. We believe this will identify potential conflicts of interest pertaining to participation in the CAP. Approved CAP vendors that are affiliated with a medical practice management company do not create a per se conflict of interest. However, these relationships should be entered into carefully and monitored closely for the appearances of a conflict of interest. There are a minimum of two and a maximum of five approved CAP vendors in each category in a given CAP area. In the optimal situation, there will be five approved CAP vendors for a given drug category, and where a conflict of interest is obvious between one approved CAP vendor and a physician's practice, the physician's practice would have up to four other approved CAP vendors to choose from, and should choose one of those other approved CAP vendors accordingly. Based on the comments received and data analysis discussed elsewhere in this interim final rule with comment period, there will be one extensive CAP category of drugs covering one single national area including all States, the District of Columbia, and the U.S. Territories. If there are only two approved CAP vendors for a given drug category and there is a potential conflict of interest, the physician's practice has two options to consider. The physician's practice can choose to receive drug products under the CAP program from the approved CAP vendor with which it does not have a conflict, or the physician's practice can choose not to participate in the CAP program.

Medical and utilization review activities currently utilized by carriers and CMS Program Integrity contractors will be applied to the provision of drug products through the CAP program. These efforts will help to ensure the medical necessity of the drugs provided and to monitor for inappropriate utilization that may stem from improper preferential selection.

Comment: Some commenters were concerned that the creation of formularies could have the appearance of conflicts of interest if their purpose was to steer market share toward one drug in a category over another in response to contracting discounts and rebates. Commenters believed this could occur if physicians are required to acquire drugs within categories as defined by the approved CAP vendor, and the approved CAP vendor offers only a limited selection of the possible drugs.

Another commenter suggested that CMS prohibit approved CAP vendors from offering physicians financial incentives to stock preferred drugs specifically for ''re-supply'' under the CAP. This will help prevent approved CAPs from enforcing preferred status in the CAP by controlling which agents a physician keeps in-stock (for example, for their commercially insured patients).

Response: We believe that the code of conduct should address issues such as acceptance of remuneration to or from an approved CAP vendor, participating CAP physician, beneficiary, or manufacturer that would diminish, or appear to diminish, the objectivity of professional judgment; or whether or not certain transactions raise patient safety or quality of care concerns. Section II.A.2 of this interim final rule describes the development of the drug category. The drug category was intended to be a list of HCPCS codes for the Part B drugs and biologicals on which a potential CAP vendor may bid. It does not constitute a drug formulary. We do not expect there to be creation of a drug formulary. As discussed above, there will be one extensive CAP drug category. It will include many of the HCPCS for drugs commonly used by physicians' offices, but not all of them. Also, as discussed before, an NDC number represents a specific drug manufacturer's product formulation and package size for its drug product. Currently there may be more than one NDC number associated with a HCPCS code if the drug is multi-source, is available in multiple package sizes, or if the drug is available in different formulations. A participating CAP physician, who has elected a CAP vendor from whom he or she wishes to order drugs, may find it medically necessary to require a specific drug represented by a specific NDC within a given HCPCS code. If the CAP vendor has contracted to provide a drug within that HCPCS code but not the specific NDC that the participating CAP physician requires, then the participating CAP physician may obtain the drug through the ''Furnish As Written'' option discussed in section II.B.2 of this interim final rule. If the participating CAP physician needs to obtain a drug identified by a HCPCS code that is not available from the CAP vendor, the participating CAP physician may continue to obtain the drug through the normal ASP system.

In response to the re-supply comment, section II.B.1 of this interim final rule describes the conditions under which a drug administered from the participating CAP physician's supply may be replaced with a CAP drug. These occurrences are expected to be few and only in the event of an emergency. The utilization of this option will be monitored to detect patterns of abuse through carrier and CMS Program Integrity contractor oversight.

Comment: A commenter commended CMS on the thorough code of conduct language. The commenter stated that they currently have an objective third party that monitors and prevents conflicts, and assures some equity within the market.

Response: We believe the commenter is indicating that it has a process in place to monitor for and prevent conflicts in the healthcare market. The commenter seems to indicate that this function should now be the responsibility of the CAP. The CAP is only a small part of the healthcare market. Approved CAP vendors are ultimately responsible for monitoring and preventing conflicts of interest related to only their participation in the CAP. Our contracts with approved CAP vendors will require that approved CAP vendors adhere to a code of conduct that establishes policies and procedures for recognizing and resolving conflicts of interest. We will also continue to apply the medical and utilization review activities currently used by carriers and CMS Program Integrity contractors to the provision of drugs through the CAP. These monitoring efforts will help to ensure the medical necessity of the drugs provided and to monitor for inappropriate utilization that may stem from conflicts of interest. If an undisclosed conflict is discovered through one of our various reviews, such as a Program Safeguard Contractor audit, we will raise the issue with our

Contracting department and inform law enforcement where appropriate.

Physicians, suppliers, and approved CAP vendors should be aware that we expect all entities with whom we do business to continue to comply with all applicable conflict of interest rules, including the Stark law and Anti-Kickback Statute. We also hope that all entities involved in the CAP will continue to take whatever measures they believe necessary to assure the prevention of conflicts of interest.

Comment: Commenters recommended that CMS prohibit approved CAP vendors from using, sharing or selling patient information for any purpose other than that which is strictly related to fulfilling CAP orders.

Response: An approved CAP vendor is a HIPAA covered entity and is subject to the HIPAA Privacy Rule that governs the use and disclosure of protected health information. As covered entities, approved CAP vendors also are subject to the HIPAA Security Rule.

Record Retention

As in other regulations that apply to entities that retain records of their dealings with the Medicare program, we believe approved CAP vendors should be held to reasonable record retention standards. We seek additional comment on whether these requirements should be further explicated in the final CAP regulation.

After reviewing the comments, we are finalizing § 414.912 with amendments to the content of the code of conduct which is submitted as part of the application process.

3. CAP Bidding Process—Evaluation and Selection

a. Evaluating Bid Prices by the Composite Bid Price

In the March 4, 2005 proposed rule we stated that in selecting vendors, the statute requires consideration of both price and non-price (for example, quality of service and financial qualifications) aspects of the bid. We also stated that technical and financial criteria for selecting CAP vendors would be used to determine which bidders will be awarded contracts to furnish drugs under the CAP. Our ultimate choice of an appropriate evaluation process will take into account the final policies concerning the drug categories, the geographic areas for the program, and comments on our proposed evaluation process. We proposed a basic approach to the evaluation and bidding selection process and encouraged comments on this proposal and recommendations for alternative approaches.

Comment: Several commenters suggested that CMS continue to provide interested parties with opportunities for learning more about the CAP. One commenter specifically suggested that a pre-bid conference be held for potential CAP vendors in order to provide potential bidders with detailed information that bidders could then use to calculate their bid prices.

Response: We agree that communicating information about the CAP bidding process (as well as other aspects of CAP) is necessary. Therefore, we plan to use several methods to communicate bidding requirements, update existing information, provide clarification, and answer questions. While we may not have time to host a formal pre-bid conference, these methods may include a public conference call with potential vendors. We also may hold an open door forum. We will also provide updates to the CAP Web site, and other channels.

Comment: One comment asked for clarification about whether the vendor could provide services to manufacturers for fees and whether this payment would influence ASP calculations.

Response: Bona fide service fees that are paid by a manufacturer to an entity, that represent fair market value for an actual service provided by the entity, and that are not passed on in whole or in part to a client or customer of an entity, are not included in the calculation of ASP because these fees would not ultimately affect the price realized by the manufacturer. ''Bona fide service fees'' means expenses that are for an itemized service actually performed by an entity on behalf of the manufacturer that would have generally been paid for by the manufacturer at the same rate had these services been performed by other entities.

In the discussion of our proposal for the bidding process as set forth in § 414.910, we assumed that we were conducting competitive bidding for some number of distinct drug categories. We also assumed that bidders with relatively large (including national) distribution networks might also want to submit bids for multiple acquisition areas (depending upon the area definitions that we adopted in the final rule). We stated that these bidders would be permitted either to submit the same bid price for all areas in which they wish to compete, or to submit separate bid prices for each acquisition area. The procedure for evaluating the price component of the bids (and setting payment rates) would be the same regardless of the method for defining the categories of drugs (HCPCS) adopted in the final rule. Section 1847B(c)(6) of the Act requires that the submitted bid price include all costs related to the delivery of the drug to the selecting physician, and the costs of dispensing (including shipping) the drug and management fees. Costs related to the administration of the drug or wastage, spillage, or spoilage may not be included in the submitted bid. We proposed to specify these requirements at § 414.910 of the regulations.

As discussed in the proposed rule, the purpose of requiring vendors to bid for all drugs in a category would be to identify a set of vendors that can supply the range of drugs in that category at an appropriate overall cost. Because a vendor may have different discounts that it can negotiate for a drug, a vendor may be able to bid a lower price for one drug, but not for another drug within a category. We sought to identify a selection process that, in the aggregate, could provide drugs at reasonable cost to the program while maintaining the required quality standards.

We therefore proposed to employ a ''composite bid,'' constructed from the bid prices for the individual drugs in the CAP category, in the process of selecting bidders for the CAP. The composite bid would be constructed by weighting each HCPCS bid by the HCPCS code's share of volume (measured in HCPCS units) of drugs in a particular drug category during the prior year. Within each CAP category, the drug weights would sum to one. Based on data availability, the volume data used for bids in the first CAP bidding cycle (for supplying drugs starting January 1, 2006) would be from 2004 because bidding is anticipated to occur in mid-2005. (We noted that we had not developed a method to weight drugs introduced during and after 2004, but invited public comment on methods for consideration.) The calculated composite bid would equal the average price per HCPCS unit for drugs in that category. In this way, the composite bid would be proportional to the expected cost to the program of acquiring drugs from that vendor (based on the assumption that the 2004 volume in each HCPCS category is roughly proportional to volume in 2006). If one vendor has a lower composite bid than another, it will also have a lower expected cost of supplying all drugs in the particular CAP category.

The statute requires consideration of price and non-price (for example, quality of service and financial qualifications) aspects of the bid. In order to implement this requirement, we proposed a two-step bidder selection process:

• First, all bidders must meet certain quality and financial thresholds.

• Second, winning bidders would be selected from those that meet the quality and financial thresholds based on the composite bids.

We considered several basic methods for evaluating the composite bids. From these alternatives, we proposed a method that bases the selection of winning bidders on a predetermined threshold. Specifically, we proposed that we would select, from all those bidders that meet the quality and financial thresholds, up to the five lowest bidders for a drug category within each area. However, we would not select any bid for the category that is higher than 106 percent of the weighted ASP for the drugs in that category. We believe that limiting the maximum bid price that we would accept is consistent with Congressional intent that the CAP promote savings.

We proposed this method for selecting bids because it is straightforward and relatively easy to implement. In addition, rejecting composite bids that exceed the payment level under the new ASP payment methodology is consistent with one major purpose of the new competitive acquisition system, since it creates the possibility of realizing savings to the Medicare program. We believe this method was preferable to other options and provided a discussion of an alternative method that could have been used. This would have been to accept any composite bid for a drug category that is less than 106 percent of the weighted ASP for the drugs in that category. Under this alternative method, it would be possible for every bidder to submit a bid price just below ASP plus 6 percent, in the confidence that the bid would be accepted. This alternative method would thus limit the potential for savings to the program, compared to the bidding process that we proposed. Under the process that we proposed, bidders retain an incentive to submit the best bid price that is possible for them. Restricting the number of bids that might be accepted provides for more competition in the bidding process than accepting all bidders under a designated threshold. Thus, we proposed to accept up to five composite bids, for a category of drugs, but we proposed not to accept any bid that exceeds a composite bid threshold of 106 percent of ASP. We would compute the composite bids, and the 106 percent composite bid threshold, in the manner described in the example we provided in the proposed rule (70 FR 10763).

We requested comments on this proposed process, as well as recommendations for alternative approaches.

Comment: Several commenters expressed general agreement with our proposal to employ a composite bid to compare bids. However, a number of commenters objected to our proposal not to accept any bid for a category that is higher than 106 percent of the weighted ASP of the drugs in a category. Some of these commenters expressed concern that such a limit would discourage vendors from bidding, and result in too few vendors participating in the program. Some commenters pointed out that the ASP system itself is new, and that it remains to be determined whether it provides adequate reimbursement. Some commenters pointed out that the statute itself does not require a ceiling. Some commenters also expressed concern that the methodology would result in a ''race to the bottom,'' as potential vendors elect to bid only on drugs that can be offered at a savings to the Medicare program. Other commenters recommended that we impose no ceiling on the level of acceptable composite bids; others advocated a higher ceiling (120 percent of ASP). One commenter suggested that the ceiling be waived if it was necessary to do so in order to approve at least 3 bidders in any competitive acquisition area. Still other commenters recommended the adoption of methods such as risk corridors to protect vendors against unexpected losses in the early stages of the program and simultaneously allow the program to share in any savings that may be realized from the CAP. One commenter asked for confirmation that the bidding threshold should be established on the basis of ASP prices in effect during the quarter in which the bids are generated. A few commenters suggested not announcing the composite bid threshold.

Response: Although the statute does not specifically require adopting a ceiling on acceptable bids, we believe that doing so is appropriate, as well as consistent with the statute. Indeed, one major purpose of the CAP is to create the possibility of realizing savings to the Medicare program. This is one reason why the statute gives the Secretary the authority (which we are not specifically exercising with respect to our determination of which competitively biddable drugs are included in the current drug category) to exclude from the CAP drugs that are not likely to result in significant savings (see section 1847B(a)(1)(D). The bid ceiling that we proposed ensures that the CAP will be no more costly to the Medicare program than the alternative method of paying for drugs at 106 percent of ASP. This ceiling is thus consistent with the possibility of realizing savings to the Medicare program. It would also serve to maintain a level of parity between the two systems, preventing a situation in which significant payment differentials might skew incentives and choices. We are therefore finalizing that provision in this interim final rule. We are not adopting some of the alternatives recommended by some commenters (for example, no ceiling, a higher ceiling, waiver of ceiling under certain circumstances) because the recommendations would not preserve the possibility of realizing some savings to the Medicare program. We are not adopting the recommendation for establishing risk corridors because we do not believe that such a provision would be consistent with the statute. Section 1847B(d)(1) of the Act specifically requires that the Secretary establish a ''single payment amount for each competitively biddable drug'' in an area. We do not believe that the composite bid methodology we are adopting will lead to a ''race to the bottom,'' in which vendors bid only on drugs that will yield savings to the Medicare program. In the first place, we are requiring potential vendors to bid on all the drugs in the broad category of Part B physician drugs that we are establishing for this initial stage of implementing the CAP. Vendors will not be able to choose among the HCPCS codes included in the drug category. In addition, the methodology that we are adopting does not require that the bid for each drug be at or below the level of 106 percent of ASP. Rather, it requires only that weighted average of the bids for all drugs in the category will be less than or equal to 106 percent of the weighted average of the ASPs for all the drugs in a category. Under this methodology, potential vendors can bid more than 106 percent of ASP for some drugs in the broad, single category that we are establishing. In order to meet the threshold requirement, bidders will only have to bid below 106 percent of ASP on enough drugs in our large single drug category to produce composite bids at or below 106 percent of the weighted average of the ASPs for all the drugs in a category. We believe that it is reasonable to expect that potential vendors will be able to realize sufficient efficiency in obtaining and delivering Part B drugs commonly administered incident to a physician's service to produce a composite bid at or below this threshold.

Finally, we are confirming that the composite bid ceiling will be

determined on the basis of ASP prices in effect during the quarter in which the bids are generated. Specifically, we will determine the threshold (106 percent of the weighted ASP for the drugs included in our single drug category) on the basis of the ASP prices in effect at the time of the bidding, which will be conducted during the second quarter of calendar year 2005. Potential vendors will be able to find the ASP pricing file on our Web site at *http://www.cms.hhs.gov/providers/drugs/asp.asp.* We will provide potential vendors with the ceiling in time for consideration in developing bids. Vendors will also be able to compute the ceiling from the weighting factors in Addendum A of this interim final rule with comment period and the ASP prices in effect for the second quarter of calendar year 2005.

We also note that we have revised § 414.910(b) of our proposed regulations to clarify that the amount of a bid for any CAP drug must be uniform for all portions of a specific competitive acquisition area.

Comment: Several commenters expressed concern about the lag in the utilization data that would be employed in weighting the bid prices under the composite bid methodology. Even the most recent available utilization data may not reflect utilization patterns in the payment year, creating a potential vulnerability for vendors if physicians increase their utilization of more costly drugs.

Response: We will always employ the most recent available utilization data to compute the weights that will be employed in computing composite bids. In this interim final rule, we are employing utilization data from FY 2003 and FY 2004 for this purpose. (We describe the utilization data used to construct the weights in section II.A.2 of this interim final rule. We display the weights that we computed on the basis of these data in our table of the drugs that we are including in our single drug category. See Addendum A of this interim final rule with comment period.) At the same time, we do not believe that the composite bid methodology creates the vulnerability described by the commenters. It is important to keep in mind that while it is necessary to employ a prior year's utilization data in the computation and evaluation of composite bids, the composite bids themselves do not determine the single payment price for each drug. Rather, as we describe below in section 3.b. of this interim final rule, the single price for a drug is a function of the bids submitted for that drug by the winning bidders: specifically, we are setting the single price for each drug at the median of the bids of the winning bidders for that drug. The utilization data will play a role in determining acceptable composite bids (those composite bids that are no greater than 106 percent of the weighted average of the ASPs for all the drugs in the category) and the winning bids (up to the five lowest composite bids below the threshold in our nationwide competitive acquisition area, from qualified applicants). However, once the winning bidders have been determined, only those bidders' specific bids for each HCPCS code are used to set the single price. Utilization data from a prior year has no effect on the single price for any drug under this methodology.

Comment: Several commenters recommended that, in order to provide greater choice among vendors, we should accept all bidders with composite bids at or below 106 percent of the weighted average of the ASPs for all the drugs in a category. These commenters therefore requested that we drop our proposal to accept up to the five lowest bids.

Response: As we discussed in the proposed rule (70 FR 10763), we had considered this alternative to our proposal that we accept the five lowest bids in any area with composite bids at or below 106 percent of the weighted average of the ASPs for all drugs in the category. We stated in that discussion that one alternative to the method we proposed is simply to accept any composite bid for a drug category that is less than 106 percent of the weighted ASP for the drugs in that category. Under this method, it would be possible for every bidder to submit a bid price just below ASP plus 6 percent, in the confidence that the bid would be accepted. This method would thus limit the potential for savings to the program, compared to the bidding process that we proposed. Under the process that we proposed, bidders retain an incentive to submit the best bid price that is possible for them. Thus, restricting the number of bidders that might be accepted provides for more competition in the bidding process than accepting all bidders under a designated threshold. We continue to find this rationale persuasive. Therefore, in order to promote competition among vendors and the possibility of realizing some savings for the Medicare program, we are finalizing our proposal to select, from all those bidders that meet the quality and financial thresholds, up to the five lowest bids for a drug category in our nationwide competitive acquisition area. However, we would not select any bid that is higher than 106 percent of the weighted ASP for the drugs in our single drug category.

Comment: One comment suggested that the vendor be allowed to include costs of spoilage and breakage in the bid. Another commenter suggested that vendors be paid for patient and provider education, counseling and compliance checks.

Response: The costs that a bidding entity may include in their bid price are described in section 1847B(c)(6) of the Act. The statute requires that the submitted bid price include ''all costs related to the delivery of the drug or biological to the selecting physician'' and ''the costs of dispensing (including shipping) of such drug or biological and management fees.'' The statute specifically prohibits including ''any costs related to the administration of the drug or biological, or wastage, spillage, or spoilage.'' We therefore do not have the statutory authority to allow inclusion of costs for spoilage and breakage in the bid. We also do not have the authority to provide separate payment to vendors for patient and provider education, counseling, and compliance checks.

Comment: One comment stated that the method for determining the bid price for multiple source drugs was not clear and suggested that it should be the same method that is used for single source drugs. Another comment suggested that using a pre-MMA fee schedule as the threshold was more appropriate.

Response: We assume that the commenter is referring to the drug prices established under the AWP methodology in effect prior to the MMA. We do not believe that employing the prices determined under that methodology as a benchmark would be appropriate, because Congress has specifically replaced that methodology with the ASP system for most Part B drugs. Under the composite bidding methodology that we have adopted, bidders must submit bid prices for each HCPCS code included in our broad category of drugs. As we note in section A.2 of this rule, HCPCS codes can often describe products represented by multiple National Drug Codes (NDCs). We are requiring vendors to submit bids for each HCPCS code within a category, and to provide at least one drug within each code. Vendors will also be required to provide potential physician participants in the competitive acquisition program the specific NDCs within each HCPCS code that they will be able to provide to the physician. In constructing their bids for each code, vendors will need to take into account

which specific drug(s) they intend to provide within that code. In constructing their bids, it will also be important for potential vendors to consider whether the drug or drugs within a specific code are multiple source or single source, and the prices at which they may be able to obtain these drugs from the respective manufacturers. However, it is neither necessary nor advisable for us to prescribe the manner in which vendors should take these considerations into account in developing the bid price for each specific code. Rather, we believe that the CAP will function most efficiently in this respect if bidders have the flexibility to construct their bids in the light of their own business goals and cost analysis within the statutory and regulatory parameters (that bid prices may not include any costs related to wastage, spillage, or spoilage).

As discussed above, our method for computing composite bids requires us to weigh the bids for the specific drugs in our single drug category. We proposed to employ volume data, specifically each HCPCS code's share of volume (measured in HCPCS units) for the prior year. In the proposed rule, we invited public comment on methods for weighting drugs introduced during and after 2004 within the composite bidding methodology (70 FR 10762).

Comment: Many commenters urged us to provide for inclusion of newer drugs within the drug categories that we adopt. Commenters did not offer specific proposals for developing weights for these drugs in order to provide for considering them with the composite bidding methodology. Commenters generally suggested using the new ASP system as a basis of bidding and payment for these drugs within the CAP, or allowing for payment based on a vendor's actual costs for acquiring these drugs.

Response: We agree with the commenters that it is important to include newer drugs within the CAP as quickly as possible. In the case of drugs that have been introduced during and after 2003 (but in time for consideration in developing this interim final rule), we have decided upon the following methodology. We have developed a list of drugs that have been introduced during and after 2003 and that are appropriate for inclusion within the established category of Part B drugs that are commonly administered incident to a physician's services. We have included in this list only those drugs that meet a minimum threshold in allowed charges ($50,000) in our billing data from the first quarter of CY 2005. The drugs on this list include important new therapies such as risperidone. The complete list of these drugs is shown in Addendum B of this interim final rule with comment period. We will require that prospective vendors include bids for these drugs in their submissions and provide these drugs to physicians who elect to participate in the CAP. However, we will not incorporate the bids for these drugs into the composite bid methodology, because we lack sufficient utilization data to compute appropriate weights for these drugs. Instead, we will consider these bids separately from, but parallel to, evaluation of the composite bid for the other drugs for which we have adequate utilization data. Specifically, we will require bidders to submit a separate bid for each drug in the list. We will also impose a ceiling on acceptable bids. As in the case of the composite bids, that ceiling will be tied to the ASP payment methodology. Specifically, we will not accept any bid for a new drug that is higher than 106 percent of the ASP for that drug (as determined at the time when the bidding begins, which will be the second quarter of calendar year 2005). Vendors will be able to locate the appropriate prices for that quarter on our Web site at *http://www.cms.hhs.gov/providers/drugs/asp.asp.* In order to be selected as a CAP vendor, a bidder must submit acceptable bids on each of the new drugs listed in Addendum B of this interim final rule with comment period.

In order to be selected as a vendor, then, a bidder must meet three conditions. First, a bidder must submit a composite bid on the single drug category that is less than or equal to the 106 percent of the weighted ASP for the drugs in that category (based on the ASP prices in effect during the second quarter of CY 2005, during which the bidding will begin). Second, a bidder must submit one of the five lowest bids for the single drug category in our nationwide competitive acquisition area. Third, a bidder must also submit acceptable bids on each of the new drugs listed in Addendum B of this interim final rule with comment period. An acceptable bid on one of these new drugs is less than or equal to 106 percent of the ASP for that drug (as determined at the time of the bidding, which will begin during the second quarter of CY 2005).

In this interim final rule, we are therefore finalizing our proposal to employ a ''composite bid,'' constructed from the bid prices for the individual drugs in the CAP category, in the process of selected bidders for the CAP. The composite bid will be constructed by weighting each HCPCS bid by the HCPCS code's share of volume (measured in HCPCS units) of drugs in our single drug category during the prior year. Within the single category, the drug weights will thus sum to one. Based on data availability, the volume data used for bids in the first CAP bidding cycle (for supplying drugs starting January 1, 2006) will from FY 2004. The calculated composite bid will be equal to the average price per HCPCS unit for drugs in that category. In this way, the composite bid will be proportional to the expected cost to the program of acquiring drugs from that vendor (based on the assumption that the 2004 volume is roughly proportional to volume in 2006). If one vendor has a lower composite bid than another, it will also have a lower expected cost of supplying all drugs in the CAP category. Also, as a point of clarification, although it will not impact the initial implementation of CAP since it is one area, we are revising § 414.910 to clarify in the case of multiple areas, entities can bid on one or more areas.

To illustrate how the composite bid will be calculated, we are providing the following example. Suppose that there are four drugs in a CAP drug category (Drug A, Drug B, Drug C, and Drug D). The first column of Table 3 below provides the total volume (HCPCS units) of these drugs administered in 2004 for this hypothetical drug category.

TABLE 3.—EXAMPLE DRUG VOLUMES AND RELATIVE VOLUMES, 2004

Drug	Total HCPCS units	Relative volume
Drug A	1,452,472	0.3520
Drug B	988,586	0.2395
Drug C	1,671,567	0.4050
Drug D	14,302	0.0035
Total	4,126,927	1.0000

Three drugs (Drugs A, B, and C) have volumes (total HCPCS units) much greater than that of the fourth (Drug D). The second column of Table 3 gives the relative volumes, computed by dividing the volumes of the individual components of this CAP category by the total volume of HCPCS units for drugs in this category. These relative volumes are the weights used to construct the composite bids.

The computation of the composite bids for these four bidders is shown in Table 4. The composite bid for Bidder 1 is computed as the weighted sum of the bids for the four drugs: ($520 × 0.3520) + ($400 × 0.2395) + ($135 × 0.4050) + ($4,780 × 0.0035), which is equal to $350.25. The composite bids for the other three bidders are computed similarly.

TABLE 4.—EXAMPLE COMPOSITE BID COMPUTATION

Drug	Weight	Bidder 1	Bidder 2	Bidder 3	Bidder 4	Low bidder
Drug A	0.3520	$520	$530	$550	$530	1
Drug B	0.2395	400	410	380	390	3
Drug C	0.4050	135	105	135	120	2
Drug D	0.0035	4,780	4,830	4,430	4,800	3
Composite Bid	.....	$350.25	$344.19	$354.79	$345.37	2

As Table 4 illustrates, it is possible for a bidder to submit the lowest bid on more individual drugs than other bidders (such as, Bidder 3 has submitted the lowest bids for Drug B and Drug D), but have the highest composite bid. This is because Bidder 3 submitted relatively high bids for Drug A and Drug C, which have the largest volumes (in HCPCS units). Also note that although Bidder 4 did not submit the lowest bid for any of the four drugs, its composite bid is the second lowest.

As we have discussed above, we have decided to adopt a method that bases the selection of winning bidders on applying a predetermined ceiling on the composite bid. Specifically, under the method we are adopting, we will select, from all those bidders that meet the quality and financial thresholds, up to the five lowest bidders for the single drug category in our nationwide competitive acquisition area. However, we will not select any bid for the category that is higher than 106 percent of the weighted ASP for the drugs in that category. As we have also discussed, we believe that limiting the maximum bid price we would accept is consistent with Congressional intent that the CAP promote savings.

As an example of this computation, suppose that the ASPs for four drugs in the composite bid example above (see Table 4) are as follows: $516 for Drug A, $376 for Drug B, $111 for Drug C, and $4,831 for Drug D. Using the relative weights in Table 4, we would compute the composite bid threshold as $1.06 \times (\$516 \times 0.3520 + \$376 \times 0.2395 + \$111 \times 0.4050 + \$4,831 \times 0.0035)$, which is equal to $353.56. In this example, three bidders (Bidder 1, 2 and 4) would be selected as CAP vendors. (See Table 5.)

TABLE 5.—EXAMPLE: PROPOSED COMPOSITE BID SELECTION METHOD

Drug	Weight	Bidder 1	Bidder 2	Bidder 3	Bidder 4	Bids selected
Drug A	0.3520	$520	$530	$550	$530	.....
Drug B	0.2395	400	410	380	390	.....
Drug C	0.4050	135	105	135	120	.....
Drug D	0.0035	4,780	4,830	4,430	4,800	.....
Composite Bid	.....	$350.25	$344.19	$354.79	$345.37	.....
Maximum Bid	.....	$353.56	$353.56	$353.56	$353.56	1, 2, 4

b. Determining the Single Price for a Category of Drugs

Once the winning bidders have been identified, section 1847B(d)(1) of the Act requires that a single price must be determined for each drug in a competitive acquisition area, ''based on bids submitted and accepted.'' We considered a number of options for determining this single price on the basis of the accepted bid prices. In the proposed rule at § 414.906(c)(1), (which describes the computation of the payment amount), we proposed to establish a single price for each drug in a competitive acquisition area, based on the median bid of the winning bidders if there is an odd number of vendors (3 or 5). If there are four vendors, we will employ the median through averaging of the bids of the second and third highest bidders on each drug to set the price for the drugs. If only two bidders are selected, we would use the median, in this case also the average, of the two bids for the drug to set the price for that drug. [Note the mean (or average) is the median of the two middle bids or the straight average if there are only two bids.] The qualified vendors would be made aware of the established price set for the CAP drugs before he or she signs the contract to be an approved vendor.

We proposed to employ the median bid for several reasons. First, this method is straightforward and relatively easy to implement. The median bid is an obvious statistical method to determine a single price based on using the information provided by bids, as required by the statute. In addition, this method could realize some savings to the Medicare program: Unless the bids for a given drug of all selected bidders are at or above the level of the maximum allowable bid (106 percent of ASP), this method for determining the single price would yield savings to the program.

In cases where there are four winning bidders for a drug category in an area, we proposed to employ the average of the bids of the second and third highest bidders on each drug to set the price for the drug. If there are only two bidders, we would use the average of the two bids for the drug to set the price for that drug. We noted that the qualified vendors would be made aware of the established price set for the CAP drugs before they sign the contract to be an approved vendor. As we stated in the proposed rule (70 FR 10763), qualified vendors will be made aware of the established price set for the CAP drugs before he or she signs the contract to be an approved vendor.

We requested comments on our proposed approach for determining the price of the drug under the CAP and any alternative approaches that might be utilized.

Comment: One commenter suggested that vendor-specific payment be considered, but also acknowledged that this would require a change to the statute. Some commenters also recommended that we pay each vendor the actual bid amount rather than pay a median of the bids of all the winning vendors.

Response: We agree with the commenter who acknowledged that statutory change would be necessary to adopt vendor-specific payment. The statute specifically requires establishment of a ''single payment amount for each competitively biddable

drug or biological'' in an area (section 1847B((d)(1) of the Act). It is not possible to establish a single price for each drug in the nationwide competitive acquisition area and simultaneously to provide for vendor-specific payment. Because paying each vendor the actual bid amount would essentially establish a vendor-specific payment, that method also is not permitted by the statute.

Comment: One commenter expressed concern that one expensive and heavily utilized HCPCS code in a category could have a significant impact on the entire category's price.

Response: We do not believe that our proposed method for using bids to determine single prices for drugs will lead to this result. In particular, we did not propose establishing a price for an entire category. Rather, we proposed using the bids, for each specific HCPCS code, of the successful bidders to set the price for the drug. In addition, we proposed that the single price for a drug would be the median of those bids (or in the cases of even numbers of accepted bidders, averages of the bids, as previously described). The weighting of heavily utilized drugs will thus have an effect on the calculation of composite bids and the determination of successful bids. However, our decision to establish one large category with a large number of HCPCS codes will minimize the effect of any one drug or one manufacturer on the composite bids as a whole. In addition, using the median to determine the single price limits the effects of any one highly expensive drug in a HCPCS code on the determination of the single price for that code.

Comment: Several comments asked us to confirm which ASP quarter would be used to evaluate bid prices. Some commenters also requested that we provide some allowance for price increases from that quarter until the contract period during which the single drug prices would be in effect. One commenter suggested using the Producer Price Index for this purpose. Other commenters suggested tying single price updates to changes in ASP prices.

Response: As we discussed in section 3.a above, the composite bid ceiling will be determined on the basis of ASP prices in effect during the quarter in which the bids are generated. Specifically, we will determine the threshold (106 percent of the weighted ASP for the drugs included in our single drug category) on the basis of the ASP prices in effect at the time when the bidding begins, which will be during the second quarter of calendar year 2005.

We agree with the commenters that adopting some mechanism for updating prices from the period in which bidding begins (the second quarter of calendar year 2005) to the period in which the single prices will actually be in effect (calendar year 2006) is appropriate. We also agree with the suggestion of some commenters that the most appropriate mechanism for doing so is to employ the changes in the Producer Price Index (PPI) for prescription preparations over the same period. Therefore, in this interim final rule, we are providing that the single price for each drug (HCPCS code) will be initially determined on the basis of the median of the bids submitted during the second quarter of calendar year 2005 for that drug. The price of each drug will then be updated to the mid-point of calendar year 2006 (five quarter increase) PPI for prescription preparations. The PPI for prescription preparations is released monthly by the Bureau of Labor Statistics, and reflects price changes at the wholesale or manufacturer stage. By comparison, the Consumer Price Index (CPI) reflects price changes at the retail stage. Because the CAP drugs are purchased direct from the manufacturer or wholesaler, this is an appropriate price index to use. In addition, the PPI for prescription drugs is the measure used in various market baskets that update Medicare payments to hospitals, physicians, skilled nursing facilities and home health agencies. We will be using the most up to date forecast data available from Global Insight Inc. at the time of contract award to determine the PPI. We feel that the use of an independent forecast, in this case from Global Insight, Inc. is superior to using the National Health Expenditure Projections for drug prices (which is the CPI for prescription drugs) and is consistent with the methodology used in projecting market basket increases in Medicare prospective payment systems.

Currently, we do not believe there has been enough experience with the ASP payment methodology to update the bids based on growth in the ASP. We are only in the second quarter of using ASP as a payment, and we do not have enough data to make reliable projections in growth. However, we will continue to analyze the ASP data and will revisit this issue in the future. We welcome comments on this method of updating the single drugs prices to the payment year, and will consider those comments as we develop and refine the CAP.

Under our approach of updating to the mid-point of 2006, it is also important to note that the CAP prices may be somewhat higher than the ASP prices during the first half of calendar year 2006. We have chosen to update to the mid-point of the year to most accurately reflect the increase in prices that will occur over the course of the year. ASP prices are updated on a quarterly basis so there is no need to make projections under that payment system. On balance and over the entire year, CAP and ASP prices should be equivalent. We welcome comments on this method of updating the single drugs prices to the payment year, and will consider those comments as we develop and refine the CAP in subsequent regulations.

Section 1847B(d)(2) of the Act requires the Secretary to ''establish rules regarding the use * * * of the alternative payment amount provided under section 1847A of the Act'' for payment of a new drug or biological under the CAP. Section 1847A of the Act establishes the average sales price methodology for most drugs paid under Part B of the Medicare program. Section 1847A(c)(4) of the Act further provides alternatives for the Secretary to determine the amount payable for new drugs during an initial period. In accordance with the requirement at section 1847B(d)(2) of the Act, we proposed to apply the payment amount that we establish under section 1847A of the Act in the case of any drug or biological for which we determine that—(1) the drug or biological is properly assigned to a category established under the CAP; and (2) issuance of a new HCPCS code is required for the drug or biological. We also stated we would employ the payment amount determined in accordance with the methodology provided under section 1847A(c)(4) of the Act until the next annual update of the single price amounts.

Comment: Many commenters asked us to clarify whether and how we would pay for new drugs. Many of these commenters recommended that vendors be required to provide new drugs, so that beneficiaries will have access through the CAP to the most recent therapies available. These commenters variously recommended that vendors be reimbursed at the ASP price or at cost for providing these new drugs. Alternatively, some commenters asked us to clarify that physicians who elect to obtain their drugs through a CAP vendor may still obtain drugs that are not available through the vendor, such as new drugs or drugs not included in the drug category provided under the CAP contract, from other sources and receive payment under the ASP system. Another comment recommended that new drugs be added to CAP no later than 2 quarters after introduction.

Response: It is important to distinguish two categories of new drugs in relation to the CAP. The first category consists of drugs that have been released in the period just prior to the bidding in a given year, have been assigned codes, and have established prices under the ASP system. In these cases, we sometimes do not have sufficient data on volume to include these drugs in the composite bidding methodology. As we discuss in section 3.a above, we have decided to include a select list of drugs that have been introduced during and after 2004 within the single drug category that we are adopting. We will also require that prospective vendors include bids for these drugs in their submissions and provide these drugs to physicians who elect to participate in the CAP. However, we will not incorporate the bids for these drugs into the composite bid methodology, but rather consider these bids separately, imposing a ceiling tied to the ASP payment methodology on acceptable bids. That is, the bids for each drug on the list must not exceed the payment level determined under section 1847A of the Act.

The second category of new drugs consists of those that are introduced too late even to be incorporated under this special methodology. These drugs may have been introduced prior to the bidding period, but too late to obtain HCPCS codes and/or ASP prices. Other such new drugs may not be introduced until after the bidding period, even in the second or third years of the vendor contracts under the CAP. We agree with the commenters that it is important to provide beneficiaries with access to these drugs as quickly and effectively as possible. However, we do not agree that it is appropriate, especially during the initial stages of implementing the CAP, to impose a requirement on vendors to include all new drugs introduced too late to be taken into consideration during the bidding period. Such a requirement may impose unpredictable, and sometimes difficult or impossible, burdens on some vendors. Vendors may not be able to make the acquisition arrangements necessary to obtain some new drugs, or at least to obtain them at a reasonable price. It would also be difficult to develop the administrative mechanisms necessary to identify new drugs that should be included within the CAP, to advise vendors that they must begin providing specific new drugs, to monitor vendor compliance, and to enforce these requirements (where necessary) in a timely fashion. Therefore, we are not adopting such a requirement at this time. It is important to note that physicians who have elected to participate in CAP are expected to order all of the CAP drugs they use through the CAP vendor except when a CAP physician is utilizing the ''furnish as written'' exception. If a physician obtains a CAP drug elsewhere, the drug will not be covered. When a participating CAP physician is purchasing a drug under the ''furnish as written'' exception or is purchasing a drug that is not available under the CAP, he or she can receive payment for those drugs through the ASP system and would be expected to bill Medicare directly for the drugs. At the same time, we certainly encourage vendors to add such new drugs as they are introduced. We are therefore adopting the mechanism we proposed in order to make it possible for vendors to do so. In accordance with the requirement at section 1847B(d)(2) of the Act and § 414.906(c)(2), we will apply the payment amount that we establish under section 1847A of the Act in the case of any drug or biological for which we determine that—(1) The drug or biological would be properly assigned to the single drug category that we are establishing for this initial stage of implementation under the CAP; and (2) issuance of a new HCPCS code is required for the drug or biological and will revise the regulation at § 414.906(c)(2) to ensure that it is explicit. We will provide for payment to CAP vendors for these new drugs at the time of the next quarterly update after the drug receives a code. Vendors may contact CMS in order to propose adding a new drug to their approved list. If we determine that the new drug is appropriate for inclusion on the approved CAP vendor's approved list, we will approve the vendor's request to add the drug under the CAP contract and provide for payment at the next quarterly update. The new drug will be considered a CAP drug for purposes of the CAP program, and the coverage rules described above will apply (that is, the physician must obtain the drug from the approved CAP vendor in order for payment to be made for the drug, unless the ''furnish as written'' exception applies). We will not formally revise the CAP categories in order to accommodate vendor requests to add new drugs, since such additions will not be mandatory. If there are any further annual updates during the period of a vendor's contract after we initially provide for payment of a new drug that the vendor is providing, we will employ the mechanism for annual updates of single price amounts that we describe below.

Section 1847B(b)(4)(B) of the Act provides that contracts for the acquisition of competitively biddable drugs under the CAP must be for a period of 3 years. Therefore, it is necessary to determine some mechanism for setting the single price for each category of drugs in the second and third years of this 3-year contract. We proposed to employ the mechanisms provided under section 1847B(c)(7) of the Act for this purpose. Specifically, that section requires that each contract must provide for disclosure to the Secretary of the vendor's ''reasonable, net acquisition costs'' on a regular basis (not more often than quarterly). It further requires that contracts must provide for ''appropriate price adjustments over the period of the contract to reflect significant increases or decreases in a vendor's reasonable, net acquisition costs, as so disclosed.'' Therefore we proposed at § 414.906(c)(1) to update the CAP prices for each drug in a category in year 2 and year 3 based on the vendor's ''reasonable, net acquisition costs'' for that category as determined by CMS based, in part, on information disclosed to the Secretary and limited by the weighted payment amount established under 1847A of the Act across all drugs in that category.

Section 1847B(c)(7) of the Act gives the Secretary the discretion to establish an appropriate schedule for the CAP vendor's disclosure of this cost information to us, provided that disclosure is not required more frequently than quarterly. We proposed to require that each vendor disclose to the Secretary its reasonable, net acquisition costs for the drugs covered under the contract annually during the period of its contract. Annual disclosure imposes the minimal burden on vendors consistent with employing this provision to determine the single price for drugs in the second and third years of a contract. More frequent disclosure (for example, quarterly) is, of course, also consistent with this purpose. We anticipate that the annual disclosure would be required in or around October of each year, to provide sufficient time to determine what, if any, update in drug prices would be appropriate for the following year. We invited comments regarding an appropriate disclosure schedule under section 1847B(c)(7) of the Act for this purpose.

Comment: Several commenters stated that yearly cost disclosure and price adjustments would be sufficient. One commenter favored yearly adjustment because more frequent adjustment may cause vendors to leave the program if rates are not adjusted in their favor.

Many other commenters recommended more frequent reporting and updates. Some of these commenters recommended a biannual process, but most preferred quarterly updates. Some comments acknowledged that more frequent acquisition cost reporting could be a burden for vendors, but many commenters noted that increasing the frequency of acquisition cost reporting and price adjustments would provide for greater consistency between CAP and ASP systems, minimize the payment difference between CAP and ASP, and would be less financially risky for vendors.

Response: We appreciate the concerns of the commenters who recommended more frequent (biannual or quarterly) updates. However, we continue to believe that annual reporting and payment updates provide the most appropriate balance between vendor and CMS administrative burden and paying for CAP drugs based upon the most timely data, at least during this initial stage of implementing the CAP. Specifically, we remain concerned that more frequent updates would also require more frequent reporting. We are reluctant to impose the burden of semiannual or quarterly reporting at this time. When the administrative mechanisms of the CAP are operational and vendors have more experience under the program, we will consider whether more frequent reporting would be appropriate.

We proposed the following methodology for developing an appropriate adjustment on the basis of the net reasonable cost information disclosed by vendors. We would employ the net reasonable cost information disclosed by each vendor to determine whether the vendor has experienced significant increases or decreases in the reasonable, net acquisition costs across a category of drugs. For this purpose, we stated that we were considering establishing a threshold percentage change in these costs, to determine whether the changes warrant computing an adjustment to the single prices for the drugs in that category. If the change in the costs reported by a particular vendor meet this threshold, we would use a two-step process to recompute the single price for each drug in that class. First, we would adjust the bid price that the vendor originally submitted by the percentage change indicated in the information that the vendor disclosed. Next, we would recompute the single price for the drug as the median of these adjusted bid prices. We noted that this mechanism would apply in the case of any significant change in reasonable, net acquisition costs, whether those changes reflect increase or decreases in costs. It is therefore possible that the single price for a drug could decrease in the second or third year of a contract where, for example, acquisition costs for the drug have decreased because of the introduction of a generic equivalent.

Comment: A number of commenters recommended that we apply no threshold test in determining whether price adjustments should occur. One commenter supported using a rolling 12 month ASP as the basis of price adjustments in order to smooth out the influence of price spikes. Another comment recommended that price changes from manufacturers should be automatically reflected in an update. Comments asked for more specific information about how the threshold would be calculated, specifically, which quarter's data would be used to calculate an adjustment, noting that the ''lag'' period between the time of adjustment and the time that financial information was collected should be minimal.

Response: We agree with the commenters who recommended that we not employ a threshold for determining whether a change in costs warranted an update in the single prices for drugs. Rather, we will adopt the mechanism that we described in the proposed rule without applying any threshold. Specifically, we will employ the net reasonable cost information disclosed by each vendor to determine whether the vendor has experienced changes in the reasonable, net acquisition costs for the drugs included in our single category of drugs. If there is a change in the costs reported by a particular vendor, we would use a two-step process to recompute the single price for each drug in the single drug category. First, we would adjust the bid price that the vendor originally submitted by the percentage change indicated in the information that the vendor disclosed. Next, we would recompute the single price for the drug as the median of all of these adjusted bid prices. We would then notify all of the vendors of the single price that we would be paying for the particular drugs in the following year. As we noted in the notice of proposed rulemaking, this mechanism would apply in the case of any change in reasonable, net acquisition costs, whether those changes reflect increase or decreases in costs. It is therefore possible that the single price for a drug could decrease in the second or third year of a contract where, for example, acquisition costs for the drug have decreased because of the introduction of a generic equivalent. It is also possible that one vendor would report large increases while the other vendors report price decreases or vice versa. In this situation, we would follow the same two step process for updating the single price. As noted in the proposed rule, we will limit the annual update by the weighted payment amount established under section 1847A of the Act across all drugs in the category. We will require submission of net reasonable cost information by each vendor at the beginning of the fourth quarter in each year of the contract, in order to provide sufficient time to determine any update in drug prices for the following calendar year. We believe that this reporting deadline reduces the inevitable lag between the reporting of financial information and the time of adjustment to an acceptable, minimal level.

We indicated in the proposed rule that we would consider ''reasonable, net acquisition costs'' to be those costs actually incurred by the vendor that are necessary and proper for acquiring the drugs that the vendor is obligated to provide under a CAP contract. Actual acquisition costs are net of all discounts and rebates provided by the vendor's own suppliers. We would require full disclosure of the vendor's acquisition costs for drugs included in the CAP contract. We proposed that this disclosure would reflect the vendor's purchases of these drugs from all manufacturers, and the total number of units purchased from each manufacturer. The vendor would be required to submit full documentation reflecting actual purchase prices. This documentation would include all records reflecting discounts that result in a reduction of actual cost to the vendor. (Such discounts would include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, rebates, refunds, and other price concessions regardless of when they are recognized.)

Comment: One commenter recommended that all costs related to drug delivery and dispensing be included in the report and that all factors be considered in determining the price adjustment. Other commenters stated that only CAP program prices be used in the price determination. Another commenter stated that prompt pay discounts should be excluded for the net acquisition cost, since the discount actually occurs as a term of financing.

Response: We do not agree with the recommendation to exclude prompt pay discounts from the determination of reasonable, net acquisition costs for purposes of Section 1847B(c)(7) of the Act. It is not obvious to us that this

discount occurs exclusively as a term of financing, nor that it should be excluded from consideration even if that is the case. We do not see how prompt pay discounts are any different from other types of price concessions and why they would need to be treated differently for purposes of the CAP. We are interested in learning more about how these discounts are arranged and whether they are indeed different from other price concessions and discount arrangements. We appreciate the comment that only CAP program prices be used in the determination of whether acquisition costs have increased. However, we are concerned that it may be administratively difficult for approved CAP vendors to distinguish their acquisition costs for provision of drugs under the CAP program from acquisition costs for drugs generally. We are therefore not adopting the recommendation at this time. Finally, we cannot adopt the recommendation that all costs related to drug delivery and dispensing be included in the report. Section 1847B(c)(7) of the Act provides only for the disclosure of contractor's ''reasonable, net acquisition costs'' to the Secretary, and for basing price adjustments under the CAP on ''significant increases or decreases'' in those costs. Therefore, only net acquisition costs that meet these criteria may be included. We would also note that we are not adopting any specific definition of ''significant'' at this time. In this initial stage of the program, we will treat all cost increases and decreases as significant.

Comment: Two commenters expressed concern about whether price information could be made exempt from Freedom of Information Act requests and suggested that vendors certify the accuracy of CAP drug price information in a manner similar to ASP pricing certification. Another commenter mentioned confidentiality provisions of the Trade Secrets Act. These commenters requested details about how confidentiality of manufacturer's pricing information would be handled. Two commenters stated that the pricing information is proprietary and should be treated as such. Several comments noted that price data provided to CMS should be afforded the same protection as ASP data and data submitted to Medicaid.

Response: Section 1847B(a)(1)(C) of the Act provides that, in implementing the CAP, the Secretary may waive provisions of the Federal Acquisition Regulation (FAR), ''other than provisions relating to the confidentiality of information.'' The confidentiality provisions of the FAR thus apply to the data submitted by bidders and vendors under the CAP. Generally, the FAR requires contractors and bidders to clearly mark all information they seek to protect, and generally, a bidder's confidential business strategies and unit prices are protected as confidential. However, what is confidential for FAR purposes may not necessarily be protected under the provisions of the Freedom of Information Act (FOIA). In the event that CMS receives a FOIA request for pricing information, the CMS FOIA officer will process the request in accordance with 5 U.S.C 552 and 5 CFR part 5, and determine whether any of the FOIA's exemptions to mandatory disclosure may apply to protect the information. In addition, under section 1847B(c)(5) of the Act, the Medicaid drug rebate confidentiality provisions of section 1927(b)(3)(D)of the Act apply to periods during which a bid is submitted with respect to a CAP drug in the same manner as it applies to information disclosed under the Medicaid drug rebate statute. We also require that vendors certify the accuracy of their CAP drug pricing information on the vendor application form.

We also proposed to make more frequent adjustments (but not more often than quarterly) in three cases: introduction of a new drug, expiration of a drug patent, or a material shortage that results in a significant price increase for a drug. We may restrict the circumstances in which we would make adjustments to account for shortages to those in which the Secretary has declared a public health emergency under section 319 of the Public Health Service Act. We invited comments on this approach.

Comment: We received no comments addressing our specific proposal for more frequent updates in these cases. However, several commenters asked for clarification about the obligations of vendors when a drug offered under the CAP becomes unavailable (such as in the case of a recall). Some of these commenters recommended that the vendor be allowed to add a new drug to its list to replace or complement the drug that is no longer available. One commenter recommended that vendors should be allowed to remove drugs from the list of CAP drugs only when it is necessary to address safety concerns or when the drug has been removed from the market.

Response: We agree with the recommendation that vendors should be allowed to remove drugs from their lists in cases of withdrawals from the market. We also agree that vendors should be allowed to replace such drugs where it is possible to do so. Therefore, we are providing in § 414.906(c)(1)(iv) of this interim final rule with comment period that, in cases where drugs are withdrawn from the market, vendors may substitute another drug if one is available (for example, another drug within a HCPCS code that contains multiple NDCs). In order to make such substitutions more feasible for vendors, we will also expand our proposal for more frequent updates (restricted in the proposed rule to introduction of a new drug, expiration of a drug patent, or a material shortage) to include this case. This mechanism will not, of course, be available if no replacement (another available NDC within the HCPCS) is available. Until we have the opportunity to update the drug price, we will pay for these substitutions at the price previously established for the drug code.

Comment: Many commenters also requested clarification about whether the prices determined under CAP will be taken into account in computing the average sales price (ASP) under section 1847A of the statute. Most of these commenters recommended exclusion of CAP prices from the ASP calculation. Some of these commenters pointed out that inclusion of CAP prices in the ASP computation may discourage manufacturers from offering price concessions to CAP vendors. A congressional commenter supported exclusion of CAP prices from the ASP computation, stating that it was the intent of Congress that these two programs should not interact, and that prices developed under the CAP should not be incorporated into ASP calculations. Another commenter noted, however, that section 1847A(c)(2) of the Act contains a specific list of sales that are exempt from the ASP calculation, and sales to vendors operating under CAP are not included on that list. This commenter therefore contended that manufacturer prices offered under the CAP must be included in ASP calculations.

Response: We do not believe that we have the statutory authority to exclude prices determined under the CAP from the computation of ASP under section 1847A of the Act. Section 1847A(c)(2) of the Act contains a specific list of sales that are exempt from the ASP calculation, and sales to vendors operating under CAP are not included on that list. Prices offered under the CAP must therefore be included in ASP calculations.

In this interim final rule, we are therefore establishing the following policies and procedures for establishing single prices for drugs under the CAP, and updating those prices as

appropriate. Once the winning bidders have been identified, section 1847B(d)(1) of the Act requires that a single price must be determined for each drug in a competitive acquisition area, ''based on bids submitted and accepted.'' Consistent with that requirement, we calculate a single price, for each drug in a competitive acquisition area, based on the median of the bids for that drug submitted by the winning bidders. (In case there are four winning bidders, we will employ the average of the bids of the second and third highest bidders on each drug to set the median price for the drug. If there are only two winning bidders, we would use the average of the two bids for the drug to set the median price for that drug.)

We will also update the single prices from the period in which bidding is conducted (the second quarter of calendar year 2005) to the period in which the single prices will actually be in effect (calendar year 2006). Specifically, the price of each drug will be updated to the mid-point of calendar year 2006 on the basis of projecting the overall change in PPI prices for prescription preparations.

Section 1847B(d)(2) of the Act requires the Secretary to ''establish rules regarding the use ''of the alternative payment amount provided under section 1847A of the Act'' for payment of a new drug or biological under the CAP. Section 1847A of the Act establishes the average sales price methodology for most drugs paid under Part B of the Medicare program. In accordance with this requirement and as established in § 414.906(c)(2), we will apply the payment amount that we establish under section 1847A of the Act in the case of any drug or biological for which we determine that—(1) the drug or biological is properly assigned to a category established under the CAP; and (2) issuance of a new HCPCS code is required for the drug or biological. We are encouraging vendors to add such drugs that are introduced too late to be incorporated into the bidding process to the lists of the drugs provided under CAP. However, due to systems limitations during this initial stage of the CAP, we will only be able to provide for payment to CAP vendors at the time of the next quarterly update of the CAP prices. If there are any further annual updates during the period of a vendor's contract after we initially provide for payment of a new drug that the vendor is providing, we would employ the mechanism for annual updates of single price amounts that we describe below. As noted above, participating CAP physicians are expected to order all of the CAP drugs they use through the CAP vendor except when the ''furnish as written'' exception applies. If a physician obtains a CAP drug elsewhere, the drug will not be covered. When a participating CAP physician is purchasing a drug under the ''furnish as written'' exception or is purchasing a drug that is not available under the CAP, he or she can bill for those drugs under the ASP system.

Section 1847B(b)(4)(B) of the Act provides that contracts for the acquisition of competitively biddable drugs under the CAP must be for a period of 3 years. Therefore, it is necessary to determine some mechanism for setting the single price for each category of drugs in the second and third years of this 3-year contract. We will employ the mechanisms provided under section 1847B(c)(7) of the Act for this purpose. Specifically, that section requires that each contract must provide for disclosure to the Secretary of the vendor's ''reasonable, net acquisition costs'' on a regular basis (not more often than quarterly). It further requires that contracts must provide for ''appropriate price adjustments over the period of the contract to reflect significant increases or decreases in a vendor's reasonable, net acquisition costs, as so disclosed.''

In this interim final rule, we are providing in § 414.906(c)that we will employ the net reasonable cost information disclosed by each vendor to determine whether the vendor has experienced changes in the reasonable, net acquisition costs for the drugs included in our single category of drugs. Such disclosure will be required annually, at the beginning of the fourth quarter of each calendar year of the contract. If there is a change in the costs reported by a particular vendor, we will use a two-step process to recompute the single price for each drug in the single category for all vendors. First, we will adjust the bid price that the vendor originally submitted by the percentage change indicated in the information that the vendor disclosed. Next, we would recompute the single price for the drug as the median of these adjusted bid prices. This mechanism would apply in the case of any change in reasonable, net acquisition costs, whether those changes reflect increase or decreases in costs.

We will also make more frequent adjustments (but not more often than quarterly) in four cases: introduction of a new drug, expiration of a drug patent, substitution of a drug for a drug withdrawn from the market, or a material shortage that results in a significant price increase for a drug.

4. Contract Requirements

Section 1847B(b)(4) of the Act discusses items to be incorporated in the contract entered into with an approved CAP vendor. These include the following:

- The length of the contract.
- Assurance of the integrity of the drug distribution system.
- A pledge to comply with code of conduct and fraud and abuse rules.
- Assurance that drugs are only supplied directly to CAP physicians, with limited exceptions, upon receipt of a prescription and other necessary data.

We set forth the contract terms between CMS and the approved CAP vendor as well as approved CAP vendor responsibilities in proposed § 414.914.

Comment: A potential vendor commented that a vendor should be allowed to withdraw from the CAP at any time upon a showing of financial hardship or if the vendor can demonstrate it cannot acquire product directly from the manufacturer for less than the reimbursed amount.

Response: We appreciate the potential vendor's comment on the duration of the approved CAP vendor's contract. Given the statutory requirement that the term of the contracts are for 3 years, we are specifying at § 414.914(a)(2) that an approved CAP vendor may terminate the contract in the absence of a contract violation, if the approved CAP vendor provides notice to us by June 30 for an effective date of termination of December 31 of the same year. We believe that to allow for a mid-year termination, except where we terminate the contract as provided in § 414.914(a) or § 414.917, including in cases of quality problems, would be unnecessarily disruptive to services being provided and to the operation of the CAP.

Contract terms between CMS and the approved CAP vendor, as well as approved CAP vendor responsibilities, will be addressed at § 414.914 as proposed; however, modifications have been made to incorporate revisions based on issues discussed elsewhere in this preamble.

5. Judicial Review

Provisions of section 1847(B)(g) of the Act concerning administrative and judicial review are set forth in regulations at proposed § 414.920. This section of the Act specifies aspects of the CAP that are not subject to administrative or judicial review.

We received no specific comments on requirements proposed under § 414.920 concerning administrative and judicial reviews, so we are finalizing this section as proposed.

D. Implementation of the CAP

1. Participating CAP Physician Election Process

Section 1847B(a)(1)(A) of the Act specifies that each physician be given the opportunity annually to elect to participate in the CAP. Physicians who do not elect to participate in the CAP would continue to buy the drugs they provide to beneficiaries incident to a physician's service and bill the Medicare program for them under section 1847A of the Act, the ASP system.

Section 1847B(a)(5)(A) of the Act requires that we develop a process that physicians who wish to participate in the CAP may use on an annual basis to select the approved CAP vendor from whom they wish to obtain the categories of drugs they wish to obtain under the CAP program. The statute also requires that we coordinate the physician's election to participate in the CAP with the Medicare Participating Physician Process described in section 1842(h) of the Act. To inform physicians about the choices of drugs and approved CAP vendors available to them under the CAP, we are required to post a directory on our Web site or to make such a directory available to interested physicians on an ongoing basis.

In the proposed rule, we specified that physicians who elect to participate in the CAP would remain in the program for at least 1 calendar year. As described in more detail later in this section, physicians who elect to participate in the CAP would be required to complete a CAP election agreement. By completing this participating CAP physician election agreement, the participating CAP physician would select the approved CAP vendor that he or she would use under the CAP and would agree to the participating CAP physician requirements. As described in further detail in this section and the regulations, a participating CAP physician agrees to—

- Share information with the approved CAP vendor to facilitate the collection of applicable deductible and coinsurance.
- Promptly file drug administration claims.
- Timely and appropriately pursue claims that are denied because of medical necessity issues.
- Accept assignment for CAP drug administration claims.
- Notify the approved CAP vendor when a drug is not administered.
- Agree to comply with emergency drug replacement rules.
- Agree to requirements for using the ''furnish as written'' provision.
- Maintain an inventory for each CAP drug he or she obtains.
- Provide support to the approved CAP vendor on an administrative appeal of the drug administration claim denial. Such support may include medical records and written statements.

If we find it necessary, we could suspend the physician's election to participate in the CAP if the participating CAP physician fails to abide by the participating CAP physician election agreement.

We proposed to initiate an annual participating CAP physician election process and modeled this proposed process after the existing Medicare Participating Physician Process to the extent possible. In addition, we communicated information to physicians about the upcoming CAP through the fact sheet that accompanied the 2005 Participating Physician Mailing, and proposed to continue to use that vehicle to communicate information about CAP to physicians in future years. However, we noted that the annual physician participation election process for accepting assignment runs from November 14 to December 31 of each year. Waiting until December 31 to receive information about physicians' CAP election choices would not provide sufficient time for us and our claims processing contractors to record information about participating CAP physicians and their approved CAP vendor selections, update claims processing files, perform testing, and inform approved CAP vendors so that we are ready to pay CAP claims on January 1, 2006. For this 3-year contract cycle for the approved CAP vendors, there will be one drug category. In the future, as more CAP drug categories are developed, the collection of information on the selection of the approved CAP vendor and drug category will be more complicated. In addition, a deadline of December 31 would not allow sufficient time for approved CAP vendors to meet the operational timeframe of January 1. Therefore, we proposed that the participating CAP physician election process would run from October 1 to November 15 of each calendar year. We proposed that participating CAP physicians who intend to continue into subsequent years may signal that preference by executing an abbreviated participating CAP physician election agreement. The abbreviated agreement would be used to indicate a preference to change approved CAP vendors or, as applicable, drug categories from year to year. We proposed that a physician who has elected to participate in the CAP would select an approved CAP vendor outside the annual election process if the previously selected approved CAP vendor's contract is terminated, or if the participating CAP physician leaves the group practice that had selected the given approved CAP vendor or relocates to another competitive area once multiple CAP competitive areas are developed. We proposed to set forth the exceptions to the annual selection process at § 414.908(a)(2) of our regulations.

We requested comments on the potential options available to affected participating CAP physicians when an approved CAP vendor's contract is terminated during the middle of the CAP year. The proposed participating CAP physician options included leaving the CAP or selecting another approved CAP vendor as presented in the proposed participating CAP physician election agreement for the physician to participate in the CAP.

Comment: One commenter expressed concern that for this first year in 2005 participating CAP physician election agreements must be postmarked by November 15 but that the carrier is not expected to be ready to pay claims until January 1, 2006. This meant that the earlier a physician elects CAP and acquires drugs from CAP, the longer the physician will wait for reimbursement for drug administration. The commenter expressed concern that the time lag would be more than 3 months for those who elect early. The commenter suggested that we permit physicians to complete the participating CAP physician election process, with the agreement effective as of January 1, 2006, and allow them to use the ASP system until then.

Response: Although the participating CAP physician election period ends on November 15, 2005, the CAP does not begin until January 1, 2006. Physicians who elect to participate in the CAP are to continue to use the ASP system through December 31, 2005. On January 1, 2006, physicians who have elected to participate in the CAP should order drugs from the approved CAP vendor they have selected. The early selection process is necessary so that the local carrier and the designated carrier can begin system testing to be ready to pay claims. This is consistent with the statute, which requires that the CAP be phased in beginning in 2006.

Comment: Commenters opposed the election period of October 1 to November 15 for physicians to elect to participate in the CAP. They asserted that this deadline would confuse physicians because it is different from

the Medicare participation agreement timeline. They proposed that the deadline coincide with the participation agreement election period (November 14 through December 31) and that although notification of enrollment may occur after December 31, physicians could bill for drugs under the ASP system until the vendor had processed and acknowledged approval of the physician application. A commenter suggested that we should provide vendor notification of selection by a physician.

Response: We believe that an election period that is earlier than the participating physician enrollment process is necessary to allow both the approved CAP vendors and us to prepare for the CAP and to be ready to ship drugs and pay claims on January 1, 2006. Waiting until December 31 to receive information about physicians' CAP election choices will not provide sufficient time for the approved CAP vendors to acquire the necessary volume of drugs and make introductions with participating CAP physicians who have selected them in order to meet the operational timeframe of January 1, 2006. Further, waiting until December 31 will not allow for us and our claims processing contractors to record information about participating CAP physicians and their selected approved CAP vendor, update the Web site with CAP information, update the claims processing files, perform testing, and inform approved CAP vendors so that we are ready to pay CAP claims on January 1, 2006. For this 3-year contract for the approved CAP vendors, there will be one drug category. In the future, as more CAP drug categories are developed, the collection of information on the election of the approved CAP vendor and drug category will be more complicated.

Comment: Several commenters asserted that physicians should have the ability to elect into the system more than once per year. Commenters suggested election options that ranged from the ability to disenroll or switch vendors at any time, to the adoption of a transition period ranging anywhere from 3 to 24 months during which there would be greater flexibility to opt in or out of the CAP. Commenters were concerned that the 1-year enrollment period would commit them to a poor performing vendor with no recourse available to them. In particular, commenters were concerned with the quality of the products, timely delivery of drugs, overall performance of the vendor, and the physician's financial situation if he or she chooses the CAP versus the ASP system. Other commenters asserted that although the statute does provide for an annual election, nothing in the statute requires or supports the use of a ''lock-in'' period. Still other commenters requested that we provide more flexibility within the CAP enrollment period to be able to evaluate the impact on a practice's financial situation by being able to asses the most current ASP payment rates, published quarterly, and then determining whether to elect to participate in the CAP.

Response: Section 1847B(a)(1)(A)(ii) and section 1847B(a)(5)(A)(ii) of the Act require that each physician be given the opportunity annually to elect to obtain drugs and biologicals through the CAP and to select an approved CAP vendor. Furthermore, section 1847B(a)(5)(A)(i) of the Act allows for selection of another approved CAP vendor more frequently than annually in exigent circumstances as defined by CMS. As discussed above, we proposed that a participating CAP physician would select an approved CAP vendor outside the annual election process if the previously selected approved CAP vendor's contract is terminated, or if the participating CAP physician leaves the group practice that had selected the given approved CAP vendor, or the participating CAP physician relocates to another competitive area (once multiple CAP competitive areas are developed). Physicians will need to carefully consider their options because the CAP election agreement will be binding for 1 calendar year. We proposed to set forth the exceptions to the annual selection process at § 414.908(a)(2) of our regulations.

It is typical for Government and private sector programs to operate on a 1-year basis. However, we have built in safeguards in the CAP that participating CAP physicians may use in addressing operational issues that arise in addition to communicating their program issues to their local carrier. These include the dispute resolution option that participating CAP physicians may use to address operational and quality issues (see section II.B.3 of this interim final rule on dispute resolution). If approved CAP vendor quality issues cannot be resolved, we may terminate the approved CAP vendor's contract. The participating CAP physician would then have the option to elect a new approved CAP vendor mid-cycle. We also believe that by the time physicians are given the option to elect the CAP, they will have had almost 1 year of experience in the ASP system and will be able to choose which option is best for their practice. However, in response to comments, we have modified § 414.908(a)(2), to allow a participating CAP physician to either select an approved CAP vendor outside of the annual selection process or opt out of the CAP for the remainder of the annual selection period when one of the conditions specified in § 414.908(a)(2) is met.

Comment: Commenters urged us to assure physicians that vendors will be required to accept all physicians who elect to participate in the CAP. A few commenters also requested assurance that vendors not be allowed to terminate the ''contract'' with a physician because the beneficiaries are not making their coinsurance payments.

Response: As noted above in section II.B.2 of this preamble, this interim final rule does not prohibit CAP vendors and physicians from entering into a contract or agreement governing their arrangements for the provision of CAP drugs or other items or services. However, we will not require contracts between participating CAP physicians and the approved CAP vendor they select. Instead, there will be 3-year contracts between CMS and the approved CAP vendors, and participating CAP physicians will sign annual participating CAP physician election agreements with CMS. Discussed elsewhere in this interim final rule are the criteria for the selection of the approved CAP vendor and the content of the approved CAP vendor contracts. We will include a provision in the approved CAP vendor contract that requires an approved CAP vendor to accept all physicians who elect to participate in the annual CAP election process. In addition, the contract will specify that approved CAP vendors may not unilaterally drop participating CAP physicians. Rather, the approved CAP vendor may ask the designated carrier to intervene under the dispute resolution process described elsewhere in this preamble.

As noted above, in addition to the 3-year approved CAP vendor contract there will be an initial participating CAP physician election agreement, and an abbreviated participating CAP physician agreement for subsequent years, that participating CAP physicians will sign to notify us of their intent to elect the CAP and agree to the terms and conditions of the CAP participation. We are clarifying the definition of the participating CAP physician election agreement at § 414.902 to codify that participating CAP physicians must sign this agreement to notify us of their participation in CAP and to agree to the terms and conditions of CAP participation as set forth in these regulations.

A physician may elect to participate in the CAP independently of his or her

choice to participate in Medicare. Participation in Medicare is not a requirement for participation in the CAP. However, as noted below, all participating CAP physicians must be enrolled in Medicare.

Participating CAP physicians will select the approved CAP vendor to provide them with drugs for their Medicare patients on an annual basis. We previously described the circumstances, listed in § 414.908(a)(2), under which a physician who has elected to participate in the CAP would select an approved CAP vendor outside the annual election process. In addition to those circumstances, for the specific circumstance that the beneficiary does not pay their coinsurance, we will allow a participating CAP physician the opportunity to opt out of that drug category; and while there is only one drug category for CAP, the participating CAP physician would be allowed to opt-out of the CAP altogether. The opt-out would be effective until the next election cycle begins at which time the physician can elect a new approved CAP vendor, that same approved CAP vendor or leave CAP. We are amending our regulations at § 414.908 to include this provision.

Comment: Commenters questioned whether information for the CAP election would be available timely. One commenter stated that targeting to complete the following steps by Fall 2005 appeared to be an unrealistic timeframe: Bidding and finalizing vendors, having materials sent to physicians, notifying beneficiaries, and allowing physicians time to evaluate the specific NDCs. Another commenter would like to see the list of approved CAP vendors within a sufficient amount of time to be able to make a decision on whether to select a CAP vendor or the ASP system.

Response: We stated in the proposed rule that we would prepare a posting on our Web site approximately on October 1, describing the approved CAP vendors we have selected for CAP, their categories of drugs, and the geographic areas within which they would operate. We stated that we would publicize the participating CAP physician election information on our Web site via our physicians' listservs, and through our Medicare fee-for-service contractors' Web sites and newsletters. We would also coordinate with physician specialty organizations to inform their members that the participating CAP physician election information is available.

We agree that this is an ambitious timeline and intend to provide timely communication about the CAP. The CAP fact sheet is scheduled for completion this summer so that the carriers can disseminate it to their physicians by September 1, 2005. Before October 1 2005, there will be an education campaign to inform physicians about the CAP Web site and the election process. By October 1, 2005, we will make available, on our Web site, information on the CAP, a directory of the approved CAP vendors and the specific NDC numbers the approved CAP vendors will be providing, and the participating CAP physician election agreement forms. We will continue to update the approved CAP vendor directory on our Web site or make the directory available to interested physicians on an ongoing basis, as required under the statute.

Physicians will be asked to access the participating CAP physician election agreement on our Web site and determine whether they would like to elect to participate in the program. They will have 6 weeks in which to evaluate the information, download and complete the election forms and mail them to their carrier. Physicians who elect to participate will be asked to download, complete, and sign the CAP election agreement. The participating CAP physician election agreement will require that they select the approved CAP vendor(s) in their area from which they would like to obtain drugs and the categories of drugs they wish to obtain through the program when multiple categories of drugs become available. For this 3-year contract-cycle with the approved CAP vendor, there will only be one category of drugs.

Physicians will be instructed to return the completed participating CAP physician election agreement to their local carrier. The participating CAP physician election agreement must be postmarked by November 15. The local carrier will note the physician's decision to participate in the CAP, and the approved CAP vendor and categories of drugs selected when multiple categories of drugs become available. The local carrier will forward information from the participating CAP physician election agreement to the CAP designated carrier. The designated carrier will compile a master list of all participating CAP physicians' approved CAP vendor and drug category selections. In addition, the designated carrier will notify each approved CAP vendor of the participating CAP physicians who have elected to enroll with that approved CAP vendor.

Comment: One commenter urged us to modify the proposed § 414.908(a)(2)(ii) to remove the example of ''physician relocates to another competitive area'' as an exigent circumstance that would permit a physician to choose another vendor. The commenter believes that it would not be necessary for a nationally based acquisition area program.

Response: For a nationally based approved CAP vendor, it would not be necessary for a relocating participating CAP physician to choose another approved CAP vendor. This would be the case for this first round of competitive acquisition. In the future, when we create other competitive acquisition areas, we believe participating CAP physicians who are relocating to another competitive acquisition area will need to be able to select a different approved CAP vendor. Therefore, we retain this provision in the regulation.

Comment: Commenters suggested that if a vendor leaves the program mid-year, the physician should have the option to either leave the program or choose another vendor. In particular, one commenter suggested that physicians might choose to be in the CAP based on the specific brand-name drugs a vendor would supply. In that case, the commenter believes, if that vendor leaves the program mid-cycle, the physician should be given the option to choose another vendor or return to the ASP system. However, another commenter indicated that because physicians are accustomed to changing suppliers on a frequent basis, it should not be problematic for them to select a different CAP vendor.

Response: We previously described the circumstances, listed in § 414.908(a)(2), under which a physician who has elected to participate in the CAP would select an approved CAP vendor outside the annual election process. These were if the selected approved CAP vendor's contract is terminated, or if the participating CAP physician leaves the group practice that had selected the given approved CAP vendor, or the participating CAP physician relocates to another competitive acquisition area, once multiple CAP competitive areas are developed, or other exigent circumstances defined by CMS. However, under these specific circumstances, the participating CAP physician may also opt out of CAP. We have revised the regulation accordingly.

Requirements for Group Practices

We specified in the proposed rule that, consistent with the Medicare Participating Physician Process, if members of a group practice elect to participate in the CAP, the entire practice would participate. Physician groups that elect to participate in the

CAP would be paid for drug administration based on the group PIN number that they place on their claim. We proposed that when a physician bills as a member of a group using the group PIN, he or she must follow the group's election to participate or not to participate in the CAP. However, we also proposed that if a group practice physician maintains a separate solo practice, he or she could make a different determination to participate or not to participate in the CAP with respect to the solo practice if using his or her individual PIN.

Comment: Commenters asserted that requiring a single CAP election for an entire physician group practice is contrary to the statute. Some of these commenters suggested that we allow physicians that practice in groups to elect to participate in CAP on an individual or on a specialty basis. This flexibility would allow a specialty having difficulty obtaining its drugs to elect CAP while not affecting another specialty within the same group that is satisfied with ''buy and bill.'' The commenters asserted that, without such flexibility multi-specialty groups may break up into separate practices. Alternatively, the commenters suggested that physicians might provide care at other sites operated by the group, thereby potentially decreasing patient access to care in order to comply with the group election provision.

In contrast, other commenters supported the recommendation that all physicians in a group practice who enroll in the CAP program under the group number must adhere to the participation decision of the group because it simplifies the need to enroll all group practice physicians in the CAP program. One commenter requested that the group CAP election apply across group and private practice affiliations. They recommended that we require group practices to submit both group and individual unique provider identification number (UPIN) numbers upon application to avoid the possibility of allowing physicians to ''cherry pick'' medications to administer in their private practice, thereby requiring approved CAP vendors to supply a disproportionate share of the unprofitable drugs. Another commenter asserted that there is a possibility that a group practice may channel different purchases through different physicians, allowing the group to choose on a per drug basis whether to use the CAP or the ASP system. The commenter suggested that to avoid such abuses, group practices (including any entities controlled by a group practice) should be required to choose, as a group, to participate in the CAP and that physicians who are part of the group practice should not be permitted to bill separately for drugs covered under the CAP.

A commenter requested that we clarify whether an individual physician in a group practice would be allowed to enroll in the CAP program under his or her own individual number; in particular, the commenter questioned whether the group would be held accountable to the individual's decision. Commenters asserted that it would be the individual physician's choice to participate in the CAP and it should not be attributed to the whole group, unless the business as a whole enrolls the entire group under its number in the program.

Response: We do not believe that CAP elections on a group basis violate the statutory provision requiring each physician to be given an opportunity to elect to obtain drugs under the CAP program. The statute requires us to coordinate the selection of the approved CAP vendor with agreements entered into under section 1842(h) of the Act (agreements to become a Medicare participating physician). The participating physician enrollment process coordinates the participation election of, and claims processing for, physicians, including those who work in one or more group practices. Consistent with the rules for Medicare participation agreements under section 1842(h) of the Act, CAP elections are linked to the billing number under which an individual physician bills. Accordingly, if a physician in a group practice chooses to bill for his or her professional services through a billing number assigned to a group, he or she has chosen to delegate the CAP election to the group. If a physician practices in a group that has elected to participate in CAP, but the physician wants to ''buy and bill,'' the physician may avoid participating in CAP by billing all of his or her professional services under his or her own billing number instead of under a billing number assigned to the group (this would require the physician to revoke his or her reassignment agreement with the group in accordance with applicable Medicare procedures). Thus, a physician in a group practice may not participate in the two payment systems (ASP and CAP) at the same time in the same practice. However, if a physician renders professional services in more than one group practice (or in a group practice and in a separate solo practice), the CAP elections of the different groups or practices need not be the same. We believe that our interpretation will preserve each physicians' choice while simplifying the election process, assuring that election into the CAP is correctly identified for billing purposes, and minimizing the potential for program abuse.

With respect to the comment that the group CAP election apply across group and private practice affiliations, we believe the commenter is recommending not allowing a physician in a group and a solo practice in another location separately to determine whether to participate in the CAP. In the proposed rule, we noted that if a physician has a solo practice in another location, he or she will be able to make a separate determination about whether to participate in the CAP. To assist the approved CAP vendor in identifying for which practice a physician has elected CAP, we will be requiring collecting on the participating CAP physician election form the participating CAP physician's UPIN and the PIN or Group PIN, or both, for each practice that has elected the CAP. We believe this information will avert the unethical practices that were of concern to the commenter.

Comment: Some commenters stated that groups whose physicians cannot agree on whether to elect CAP participation will dissolve or break up. The commenters asserted that the dissolution or breakup of group practices had implications under the physician self-referral prohibition (also known as the ''Stark law'') in section 1877 of the Act. Specifically, the commenter feared that groups suffering a partial breakaway of group members might be unable to satisfy the ''substantially all test'' under the Stark definition of a ''group practice'' (§ 411.352), which in turn would jeopardize the group's ability to rely on the Stark exception for in-office ancillary services.

Response: We think it is unlikely that CAP will cause a significant number of group practices to dissolve because a group physician may still ''buy and bill,'' even though the group has elected to participate in CAP, as long as the physician bills all of his or her professional services rendered to group patients under his or her own individual PIN. Moreover, we believe that physicians choose to practice in a group for many reasons having nothing to do with whether or not a vendor furnishes a particular item or service to patients served by the group (for example, the ability to share overhead costs, coverage duties, and expertise).

Under the ''substantially all test'' referenced by the commenter, substantially all of the patient care services of the physicians who are members of the group must be furnished

through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group. We see no reason why the resignation of one or more physician members of a group would cause the remaining group members to be unable to satisfy the ''substantially all test.'' On the other hand, depending on the circumstances, it is possible that the decision of some group members to bill individually and not through a number assigned to the group could cause the group to fail the ''substantially all test.'' Accordingly, physicians and their group practices will have to consider the Stark law implications of their CAP elections and exercise their choice in a manner that will ensure compliance with Stark.

CAP Election Agreement

Consistent with the Medicare participating physician enrollment process, we will give physicians who are newly enrolled in Medicare 90 days in which to decide to elect to participate in the CAP. We will provide information about the CAP when they enroll in Medicare and will be instructed how to find the election information and forms on our Web site. If they elect to participate in the CAP, they will download the participating CAP physician election agreement and submit it to their Medicare carrier.

The final election process is summarized as follows:

(1) We will prepare a posting on our Web site approximately on October 1, describing the approved CAP vendors, the categories of drugs they will be providing, and the geographic areas within which each approved CAP vendor will operate.

(2) We will publicize the availability of the participating CAP physician election information on our Web site via our physicians' listservs, and our Medicare fee-for-service contractors' Web sites and newsletters. We will also coordinate with physician specialty organizations to enlist their assistance in informing their members that the physician election information is available.

(3) Physicians will be asked to access the participating CAP physician election agreement on our Web site and determine whether they would like to elect to participate in the program.

(4) Physicians who elect to participate will be asked to download, complete and sign the participating CAP physician election agreement. The participating CAP physician election agreement will require that they select the approved CAP vendor(s) in their area from which they would like to obtain drugs and the categories of drugs they wish to obtain through the program (when multiple categories of drugs become available). For this 3-year contract-cycle with the approved CAP vendors, there will only be one category of drugs.

(5) Physicians will be instructed to return the completed participating CAP physician election agreement to their local carrier. The participating CAP physician election agreement must be postmarked by November 15 for participation in the CAP beginning January 1 of the following year.

(6) The local carrier will note the physician's decision to participate in the CAP, and the approved CAP vendor and categories of drugs selected (when multiple categories of drugs become available). For this 3-year contract-cycle with the approved CAP vendor, there will only be one category of drugs.

(7) The local carrier will forward information from the CAP election agreement to the CAP designated carrier.

(8) The designated carrier will compile a master list of all participating CAP physicians' approved CAP vendor and drug category selections. In addition, the designated carrier will notify each approved CAP vendor of the participating CAP physicians who have selected that approved CAP vendor.

(9) After the necessary claims processing files are prepared, the local carrier and the designated carrier will begin system testing to be ready to pay claims by January 1, 2006.

The requirements concerning a physician's election to participate in the CAP are set forth in § 414.908(a).

Comment: Commenters requested clarification as to whether a physician must participate in Medicare in order to participate in the CAP.

Response: We believe that the commenter is asking if the physician must agree to accept assignment for all Medicare covered services, not if a physician must be enrolled in the Medicare program. A physician is required to be enrolled into the Medicare program as a supplier in order to receive a Medicare billing number. Physicians who participate in Medicare must accept assignment, but non-participating physicians are not required to accept assignment. A physician can be in the CAP and have a CAP election agreement if he or she is enrolled in the Medicare program, but is not required to be a Medicare participating physician who has elected to accept assignment of all Medicare covered services. However, as we have implemented the CAP, participating CAP physicians must appeal drug administration claim denials. Therefore, non-participating physicians who elect to join the CAP will need to accept assignment for CAP drug administration claims on a case-by-case basis in order to be in compliance with their CAP election agreements. We are revising the definition of participating CAP physician to address this issue at § 414.902.

Toward the end of each calendar year (generally in November), all Medicare carriers have an open enrollment period. Also toward the end of each calendar year (generally in October), we will be making available to physicians the option to participate in the CAP. As noted above, a physician who is newly enrolled in Medicare will have the opportunity to elect to join the CAP.

Comment: One commenter requested that we clarify whether physicians will be penalized if they do not elect to participate in the CAP in the first year. Another commenter requested that we clarify the definition of ''new physician'' for the purposes of the CAP program and the triggering event for the 90 days notification timeline.

Response: We will not penalize physicians if they choose not to participate in the CAP in the first year. If a physician chooses not to enroll the first year, there will be an annual process for physicians to participate in CAP, and the physician may enroll during the next available period. However, if the reason for not electing to participate in the first year of the CAP was that the physician was newly enrolled in Medicare, he or she may elect to participate within 90 days of his or her billing number activation, and his or her initial CAP election agreement will continue through December 31 of the calendar year. The date that the billing number is activated is the triggering event of the 90-day election time-period. This is consistent with the process for new physicians to choose to participate in Medicare and accept assignment.

We will finalize the requirements at § 414.908 with modification. At § 414.908(a)(2), we set forth the exceptions to the annual selection process. At § 414.908(a)(5), we amend the provision to include the option for a physician to opt out of that drug category; and while there is only one drug category for CAP, the physician would be allowed to opt-out of the CAP altogether for the remainder of the year. At § 414.902, we are clarifying the definition of the participating CAP physician election agreement.

2. Vendor or Physician Education

To ensure that vendors and physicians have timely access to accurate Medicare program information regarding the CAP, in the proposed rule, we indicated we would instruct the CAP designated carrier to use various communication channels at the local and national levels to disseminate information about the CAP and assist vendors and physicians in understanding the Medicare program's operations, policy, and billing and administration procedures regarding the CAP. The CAP designated carrier would be instructed to use data analyses in tailoring its outreach and educational efforts for vendors and physicians regarding identified areas of confusion about the CAP. Additionally, we specified that the CAP designated carrier would be instructed to use mass media, as well as educational and outreach products, services, forums, and partnerships in an effort to disseminate information about, and provide assistance regarding, the CAP to the vendor and healthcare practitioner communities. The fundamental goal of our outreach and education requirements of the CAP designated carrier would be to ensure that those who provide services to beneficiaries receive the information they need to understand the Medicare program so that it is administered appropriately and billed correctly. As such, we would be involved in oversight of, and partnership with, the CAP designated carrier's vendor and physician outreach and educational program regarding the CAP.

Comment: Commenters were supportive of our proposal to utilize numerous outreach and educational activities to disseminate information about the CAP and emphasized that education is paramount to successful implementation of the CAP program. Commenters also stressed that information provided by the CAP designated carrier must be correct and timely and that CMS stay actively involved in the process.

Response: We also believe that education will be vital to the success of the CAP and will be ensuring that the CAP designated contractor fulfills the responsibility of providing timely and accurate information on the CAP.

As proposed we will have the CAP designated carrier utilize a variety of communication channels at the local and national levels to disseminate information about the CAP and assist approved CAP vendors and physicians in understanding this new program.

3. Beneficiary Education

The CAP will have an impact on beneficiaries who receive physician-administered drugs. As discussed in the March 4, 2005 proposed rule, if a physician elects to participate in the CAP, beneficiaries receiving services from this physician would receive a separate medical summary notice (MSN) from the designated carrier that processes invoices for the approved CAP vendor as well as a bill from the approved CAP vendor for the coinsurance of the drug. This could cause confusion for the beneficiary because he or she would only know that the drugs were administered by a physician. In addition, because the activity of the approved CAP vendor would be transparent to the beneficiaries, they may question why they are receiving a bill from an unknown entity.

To educate beneficiaries in a proactive fashion, we proposed to develop a beneficiary-focused fact sheet and to update existing related educational materials to reflect these changes. The fact sheet would be available for physicians who elect to participate in the CAP to provide to beneficiaries at the time of service. It would explain the CAP and its impact on the beneficiary. We would also make this fact sheet available at 1–800–MEDICARE, as well as on the *http://www.medicare.gov* Web site. Although we did not propose to require participating CAP physicians to provide beneficiaries with the fact sheet, we requested comments on the administrative burden associated with this activity. In addition, although we did not propose to require any additional options for specific outreach, we requested comments on other mechanisms that might be used to inform the beneficiary of services provided as part of the CAP and the burden that would be associated with this mechanism.

We also proposed to provide information about the CAP in the 2006 versions of the Medicare & You handbook and Your Medicare Benefits. The handbook is mailed annually to each beneficiary household. Your Medicare Benefits is available upon request at 1–800–MEDICARE, as well as on the *http://www.medicare.gov* Web site. We also proposed to provide information to the 1–800–MEDICARE helpline so that operators can answer CAP-related questions. The *http://www.medicare.gov* Web site would also have consumer-friendly information available about the CAP.

Comment: Several commenters were pleased with the proposals to create and distribute material on CAP to educate stakeholders while one commenter believed that a fact sheet was not sufficient. Some commenters indicated that the physician should be required to provide information about the CAP to the beneficiary. However, one commenter stated that proactive communication for services that they may never receive will increase costs to CMS and physicians for a program not applicable to all beneficiaries, while another commenter recommended the fact sheet be developed as a template with sections that could be customized by each CAP physician so information relevant to a specific beneficiary could be added (for example, CAP drugs being procured, name of vendor).

Other commenters opposed a mandate to require physicians to distribute outreach materials to beneficiaries. One of these commenters stated it was not the physician's responsibility to make this information available to their patients, while another stated practice management systems cannot easily identify patients who are participating in a subprogram of an individual health insurance product. Other commenters, while agreeing this information is important, believed that this information should come from CMS and added that the physician and the CAP vendor should not be required to educate the beneficiary directly as this is outside their role.

One commenter also encouraged us to have the CAP vendors supply fact sheets or introductory letters to the CAP physicians who contract with them that the physician can provide to beneficiaries.

Response: We agree that the education of the stakeholders in the CAP is extremely important and we will be providing information on the CAP as discussed in the proposed rule. Because we are aware that the CAP may not impact all beneficiaries, we will not provide specific information on the CAP to all Medicare beneficiaries. However, we will provide some general information about the CAP in the Medicare & You booklet so that beneficiaries will be aware of this program. Although a few commenters recommended that the participating CAP physician should not be required to provide a fact sheet to beneficiaries, we believe that it is important that beneficiaries understand that their physician has elected to participate in the CAP and what this will mean to the beneficiary. Therefore, we will require the physician to provide the fact sheet developed by us during the beneficiary's

first visit to the office subsequent to the physician enrolling in the CAP.

This fact sheet detailing the CAP program in plain language will also be available to beneficiaries via 1–800–MEDICARE (1–800–633–4227) and *http://www.medicare.gov*. When distributing the fact sheet, physicians may include additional information specific to the beneficiary. We believe that this approach will allow the participating CAP physician to address the specific needs of the beneficiary and minimize the burden on the participating CAP physician. As commenters suggested, we will also encourage the approved CAP vendors to provide introductory information about themselves and the CAP program that could be shared with beneficiaries. As discussed in section II.B.3 of this interim final rule, we will also have the approved CAP vendor include information on the beneficiary grievance process with any bill that is sent to the beneficiary. As a final point, as part of the vendor application process, we have stated that customer service is of primary importance and approved CAP vendors must demonstrate the ability to respond to inquiries on both weekdays and weekends.

Because we recognize the impact the CAP will have on Medicare beneficiaries, we will use a multi-tiered educational approach to provide information that will increase beneficiary awareness of the issues related to the CAP. The outreach efforts will include the following:

- A plain language fact sheet to be distributed by participating CAP physicians and available upon request via 1–800–MEDICARE (1–800–633–4227) and *http://www.medicare.gov.*
- New language in the existing Medicare & You and Your Medicare Benefits booklets. The Medicare & You booklet is mailed each fall to every beneficiary household. Your Medicare Benefits is available through 1–800–MEDICARE (1–800–633–4227) and *http://www.medicare.gov*.
- CAP related scripts for the customer service representatives at 1–800–MEDICARE (1–800–633–4227).
- Frequently asked questions and answers in consumer friendly language regarding the CAP available at *http://www.medicare.gov* on the Web.

III. Provisions of the Interim Final Rule

[If you choose to comment on issues in this section, please include the caption ''Provisions to the Interim Final Rule'' at the beginning of your comments.]

For the most part, this interim final rule incorporates the provisions of the March 4, 2005 proposed rule. Those provisions of this interim final rule that differ from the proposed rule follow.

Under § 414.902, we are revising our definitions section to revise current definitions set forth in the proposed rule and to add new definitions:

We are making a conforming change to revise ''approved vendor'' to read ''approved CAP vendor.'' In § 414.902, we are also making a technical clarifying revision to the definition of an ''approved CAP vendor'' to specify that this vendor is one that has been approved by CMS to participate in the CAP program under ''1847B of the Act'' to avoid confusion with the competitive acquisition program for DME provided for under section 1847 of the Act. We are also revising the definition of ''participating CAP physician'' to clarify that physicians who do not participate in Medicare but elect to participate in the CAP agree to accept assignment for CAP drug administration services.

We are adding a definition of ''CAP drug'' to mean a physician-administered drug or biological furnished on or after January 1, 2006 described in section 1842(o)(1)(C) of the Act and supplied by an approved CAP vendor under the CAP as provided in this subpart.

- Under § 414.902, we are adding the definition of emergency delivery to mean the delivery of a CAP drug within one business day in appropriate shipping and packaging, in all areas of the United States and its territories, with the exception of the Pacific Territories. In the Pacific Territories, emergency delivery means delivery of a CAP drug within 5 business days in appropriate shipping and packaging. We are also adding that this timeframe may be reduced if product stability requires it, meaning that the manufacturer's labeling instructions, drug compendia, or specialized drug stability references indicate that a shorter delivery timeframe is necessary to avoid adversely affecting the product's integrity, safety, or efficacy.
- We are adding the definition of an emergency situation to mean an unforeseen occurrence or situation determined by the participating CAP physician, in his or her clinical judgment, to require prompt action or attention for the purposes of permitting the participating CAP physician to use a drug from his or her own stock, if the other requirements for the CAP under § 414.906 are met.
- We are adding a definition ''Pacific territories'' to mean, for purposes of the CAP, American Samoa, Guam, or the Northern Mariana Islands.
- We are making a conforming change to revise ''CAP election agreement'' to read ''Participating CAP physician election agreement.'' In addition, we are revising the definition to clarify that this is an agreement the physician signs to notify CMS of the physician's election to participate in the CAP and to agree to the terms and conditions of CAP participation as set forth in our regulations.
- We are adding a definition for prescription order. We are defining a prescription order as a written order submitted by the participating CAP physician to the approved CAP vendor that meets the requirements of part 414, subpart K.
- Under § 414.902, we are adding the definition of routine delivery to mean the delivery of a drug within 2 business days in appropriate shipping and packaging, in all areas of the United States and its territories, with the exception of the Pacific Territories. In the Pacific Territories, routine delivery of drug means delivery of a CAP drug within 7 business days in appropriate shipping and packaging. This timeframe will be reduced if product stability requires it, meaning that the manufacturer's labeling instructions, drug compendia, or specialized drug stability references indicate that a shorter delivery timeframe is necessary to avoid adversely affecting the product's integrity, safety, or efficacy.
- Under § 414.902, we are adding the definition of ''timely delivery'' to mean the delivery of a CAP drug within the defined routine and emergency delivery timeframes. Compliance with timely delivery standards is also a factor for evaluation of potential and approved CAP vendors.
- We are also making additional conforming changes to terms under our definitions section to include revising ''competitive area'' to read ''competitive acquisition area.''

We are revising § 414.906(a)(4) to specify that when the approved CAP vendor delivers the drugs directly to the participating CAP physician, the drugs must be in unopened vials or other original container as supplied by the manufacturer or from a distributor that has acquired the products directly from the manufacturer, and the shipping material must include language stating that the drug was acquired in a manner that is consistent with statutory requirements. In addition, we are providing the process that the approved CAP vendor must follow if the approved CAP vendor opts to split shipments. We are revising § 414.906(a)(5) to specify that the approved CAP vendor bills Medicare only for the amount of the drug that the participating CAP physician has administered to the patient, and the beneficiary's

coinsurance will be calculated from the quantity of the drugs that is administered.

We are making revisions under § 414.906(c)(1) to clarify the payment methodology for CAP drugs.

We are making revisions under § 414.906(c)(2) regarding those circumstances under which the alternative payment amount established under section 1847A of the Act may be used to establish payment for a competitively biddable drug. At § 414.906(c)(2)(i) and (ii), we are clarifying that this alternative payment amount may be allowed if the drug is properly assigned to a category established under the CAP and if a HCPCS code must be established for the drug.

We are adding § 414.906(f) to specify the process the approved CAP vendor must follow if the approved CAP vendor substitutes a CAP drug.

We are revising § 414.908(a)(2) to clarify that under certain circumstances, the participating CAP physician not only has the option to choose another approved CAP vendor outside of the annual selection process but also the option to ''opt out'' of the CAP for the remainder of the annual selection period. The circumstances may include when the approved CAP vendor ceases to participate in the CAP; the participating CAP physician leaves a group practice participating in CAP; the participating CAP physician relocates to another competitive acquisition area; or other exigent circumstances defined by CMS.

We are revising § 414.908(a)(3)(iii) to specify that the participating CAP physician will submit a ''prescription order'' to the approved CAP vendor with complete patient information for the initial orders or when the information changes. In addition, we are specifying how and when abbreviated information may be used and we are also adding that the participating CAP physician may initiate the prescription orders by telephone with a follow-up written order within a specified period of time.

We are revising § 414.908(a)(3)(v) to set forth the specific information that the participating CAP physician must provide to the approved CAP vendor to facilitate collection of applicable deductible and coinsurance (except where applicable State pharmacy law prohibits it).

We are adding new § 414.908(a)(3)(vi) to specify that the participating CAP physician must also notify the approved CAP vendor when a drug is not administered, or when he or she administers a smaller amount of the drug than was originally ordered. The participating CAP physician and the approved CAP vendor will agree on how to handle the unused CAP drug. We outlined the procedures the participating CAP physician follows if an agreement is reached for this physician to maintain the CAP drug in his or her inventory to be administered later.

We are adding new § 414.908(a)(3)(x) to state that the physician participating in the CAP agrees not to transport CAP drugs from one practice location (place of service) to another location.

We are adding new § 414.908(a)(3)(xi) to specify that the physician participating in the CAP agrees to provide the CMS-developed CAP fact sheet to beneficiaries.

We are adding a new § 414.908(a)(3)(xii) to specify that the participating CAP physician may receive payment under the ASP system when medical necessity requires a certain brand or formulation of a drug that the approved CAP vendor has not been contracted to furnish under the CAP.

We are adding a new § 414.908(a)(5) to set forth the opt out provision for participating CAP physicians that is in addition to the circumstances described under § 414.908(a)(2). We specify that if the approved CAP vendor refuses to ship to the participating CAP physician because the conditions of § 414.914 have been met, the physician can withdraw from CAP for the remainder of the year immediately upon notice to us and the approved CAP vendor.

We are revising § 414.908(b)(1)(i) to specify that competing bidders and vendors will submit the bid prices ''using the OMB Approved Vendor Application and Bid Form'' for competitively biddable drugs within the category and competitive acquisition area.

Under § 414.908(b)(1), we specify the criteria we use to select an approved bidder. We are adding additional criteria. We are revising § 414.908(b)(1)(iii) to add that the potential vendor's ''grievance process'' is considered when we select a bidder. We are also adding a new § 414.908(b)(1)(ix) to include that the approved CAP vendor must maintain appropriate licensure to supply CAP drugs in States in which the approved CAP vendor supplies the drugs as well as new § 414.908(b)(1)(x) to indicate that the approved CAP vendor must provide cost-sharing assistance. We are redesignating proposed § 414.908(b)(1)(ix) as § 414.908(b)(1)(xi) with minor editorial revisions.

At § 414.908(c)(3), we are adding language indicating that CMS may refuse to award a contract or terminate an approved CAP vendor contract for past violations or misconduct related to the pricing, marketing, distribution, or handling of drugs provided incident to a physician's service.

At § 414.914(a), we are making revisions to clarify that the term of the contract between the approved CAP vendor and us is 3 years, ''unless terminated or suspended earlier as provided in this section or § 414.917.'' At § 414.914(c)(1), we describe the elements of the approved CAP vendor's compliance plan. We indicated in the proposed rule that the approved CAP vendor must comply with all applicable Federal and State laws, regulations, and guidance and we have added that this also includes, but is not limited to, compliance with the Prescription Drug Marketing Act, the physician self-referral (''Stark'') prohibition, the Anti-Kickback statute, and the False Claims Act.

Under 414.914(f)(2), we are clarifying that the approved CAP vendor must have arrangements for shipment at least 5 ''weekdays'' each week of CAP drugs under the contact.

Under § 414.914(f)(7), we are clarifying that the terms of the contract for the approved CAP vendor must also specify that the approved CAP vendor comply with all ''applicable Federal and State laws, regulations, and guidance'' related to the prevention of fraud and abuse.

- Under § 414.914, we are adding additional conditions under the terms of the contract between the approved CAP vendor and us under new § 414.914(f)(8), (f)(9), (f)(10), and (f)(11).

We are adding a new § 414.914(g) to include additional vendor requirements under the contract. These terms specify that the approved CAP vendor must provide appropriate assistance to patients experiencing financial difficulty in paying their cost-sharing amounts through any one or all of the following:

- Referral to a bona fide and independent charitable organization.
- Implementation of a reasonable payment plan.
- A full or partial waiver of the cost-sharing amount after determining in good faith that the individual is in financial need or the failure of reasonable collection efforts, provided that the waiver meets all of the requirements of section 1128A(i)(6)(A) of the Act and the corresponding regulations at paragraph (1) of the definition of ''Remuneration'' in § 1003.101 of this title. The availability

of waivers may not be advertised or be made as part of a solicitation. Approved CAP vendors may inform beneficiaries that they generally make available the categories of assistance described in paragraphs (g)(1), (g)(2), and (g)(3) of this section. In no event may the approved CAP vendor include or make any statements or representations that promise or guarantee that beneficiaries will receive cost-sharing waivers.

We are adding a new § 414.914(h) to specify the procedures that the approved CAP vendor must comply with before it may refuse to make further shipment of CAP drugs to a participating CAP physician on behalf of a specific beneficiary.

We are revising the heading of § 414.916 to read ''Dispute resolution process for vendors and beneficiaries.''

Under § 414.916, regarding the responsibilities of the designated carrier, we are removing paragraph (b)(2)(i) under this section that stated that the designated carrier will investigate and make a recommendation to us on whether the participating CAP physician has been meeting the claims and appeals obligations in his or her CAP election agreement. We are also redesignating paragraphs (b)(2)(ii) and (b)(2)(iii) as paragraphs (b)(2)(i) and (b)(2)(ii), respectively.

Upon receiving the designated carrier's recommendation, we will make a determination regarding suspension of the participating CAP physician's election agreement. Specifically, we are revising § 414.916(b)(3) to clarify the suspension period for participating CAP physicians. We are adding that a suspension commencing before October 1 will conclude on December 31 of the same year. A suspension commencing on or after October 1 will conclude on December 31 of the next year. We are removing the last sentence in § 414.916(b)(3), which indicated a participating CAP physician could select another approved CAP vendor while a reconsideration was pending.

Under § 414.916(c)(8) regarding the findings of the hearing officer, we are clarifying that if the hearing officer decides to conduct an in-person or telephone hearing, the hearing officer will send a hearing notice to the participating CAP physician ''within 10 days of receipt of the hearing request.''

Under § 414.916(c)(9), we are clarifying our language regarding the final reconsideration determination. Under § 414.916(c)(9)(i) we are clarifying that if the decision is favorable to the participating CAP physician, the participating CAP physician may resume participation in the CAP. We are also adding that the hearing officer and the CMS official may review decisions that are favorable or unfavorable to the participating CAP physician. Under § 414.916(c)(9)(iv), we are clarifying that if our decision is unfavorable to the participating CAP physician, the participating CAP physician's CAP election agreement is terminated.

We are removing proposed § 414.916(d) that stated the following: ''The approved CAP vendor treats quality and service issues through its grievance process. If the approved CAP vendor does not resolve a quality issue to the participating CAP physician's satisfaction, the participating CAP physician may escalate the matter to the designated carrier. The designated carrier attempts to develop solutions that satisfy program requirements and the needs of both the participating CAP physician and the approved CAP vendor.'' This language has been incorporated into new § 414.917. We are also redesignating the proposed paragraph (e) as new (d) under this section.

We are adding a new § 414.917 to set forth the process and responsibilities for the dispute resolution for participating CAP physicians and for suspension or termination of an approved CAP vendor's CAP contract. We believe that moving this language to a separate section more clearly presents the process and the responsibilities of the particular parties.

Under the dispute resolution process set forth under § 414.916 and § 414.917, we are adding that the designated carrier will include in its recommendation to us, ''numbered findings of fact'' when it makes a recommendation whether the participating CAP physician has been filing his or her drug administration claims in accordance with the requirements of physician participation in the CAP.

In addition, we are making editorial and technical revisions as well as necessary conforming changes.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Waiver of Delayed Effective Date

[If you choose to comment on issues in this section, please include the caption ''Waiver of Delayed Effective Date'' at the beginning of your comments.]

We also ordinarily provide a 60-day delay in the effective date of the provisions of a rule in accordance with the Administrative Procedure Act (APA) (5 U.S.C. 553(d), which requires a 30-day delayed effective date, and the Congressional Review Act (5 U.S.C. 801(a)(3), which requires a 60-day delayed effective date for major rules. However, we can waive the delay in effective date if the Secretary finds, for good cause, that such delay is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons in the rule issued. 5 U.S.C. 553(d)(3); 5 U.S.C. 808(2).

The Secretary finds that good cause exists to implement the requirements related to the selection process for approved CAP vendors immediately upon publication in the **Federal Register**. Under section 1847B of the Act, we are required to phase in the CAP beginning in 2006. In addition, section 1847B(a)(5)(A)(ii) of the Act requires that the physicians' annual selection of approved CAP vendors be coordinated with the Medicare participating physician described in the (PARDOC) process under section 1842(h) of the Act, which occurs in November and December each year. To comply with that statutory mandate, it will be necessary for us to have contracts in place with approved CAP vendors in time to give physicians a meaningful opportunity to review and select an available approved CAP vendor in their competitive acquisition areas. If contracts with vendors are not in place by that time, the next available physician selection period would be at the end of 2006 for a CAP implementation date of January 1, 2007. Such a delay would not be consistent with the statutory mandate that the CAP be phased-in beginning in 2006. Therefore, the Secretary has determined that it would be impractical and contrary to the public interest to delay the effective date of the provisions that apply to the vendor application and bidding process would be impracticable and contrary to the public interest. An effective date of July 6, 2005, for the requirements related to the selection process for approved CAP vendors will ensure that the selection of approved CAP vendors can proceed and will afford the approved CAP vendors needed time to prepare for the enrollment of physicians and education

of beneficiaries concerning the CAP program.

We note that only the provisions associated with the selection process for approved CAP vendors will be implemented within 60 days of the date of publication of this rule. There will be at least 60 days between publication of this rule and the implementation of other provisions of this rule, including the provisions related to physician selection and operation of the CAP program.

For all these reasons, we believe that a 60-day delay in the effective date of the provisions that apply to the vendor application and bidding process would be impracticable and contrary to the public interest. We therefore find good cause for waiving the 60-day delay in the effective date for the requirements related to the selection process for approved CAP vendors.

VI. Collection of Information Requirements

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:

Competitive acquisition program as the basis for payment (§ 414.906). A physician who elects to participate in the program and has selected an approved CAP vendor, must provide information to the approved CAP vendor to facilitate collection of applicable deductible and coinsurance as described in § 414.906(a)(2).

The burden associated with this requirement is the time and effort necessary for the participating CAP physician to provide the information to the approved CAP vendor to facilitate collection of applicable deductible and coinsurance.

We estimate the burden to be approximately 29167 hours. We believe there will be 500,000 claims and it will take five minutes for the initial claim per beneficiary and three minutes for subsequent beneficiary claims. The collection of information for the initial claim is estimated to take five minutes and subsequent claims will take approximately three minutes. We estimate 25 percent of claims to be initial and 75 percent to be subsequent.

Competitive acquisition program (§ 414.908). A physician is provided an application process for the selection of an approved CAP vendor on an annual basis. The CAP election agreement will facilitate physician enrollment and designation of their approved CAP vendor and agreement to abide by the CAP program requirements.

In addition, physicians participating in the CAP must elect to use an approved CAP vendor for the drug category area as discussed in § 414.904(a)(1); submit a written order or prescription to the approved CAP vendor; not receive payment for the competitively biddable drug except as described in § 414.906(c)(2)(ii); provide information to the approved CAP vendor to facilitate collection of applicable deductible and coinsurance as described in § 414.906(a)(3); notify the approved CAP vendor when a drug is not administered; maintain a separate electronic or paper inventory for each CAP drug obtained; agree to file the Medicare claim when the drug is administered.

The revised burden associated with this requirement is the time and effort necessary for the participating CAP physician to provide and/or maintain the information required as discussed above. We revised our original estimate to reflect new estimates on how many physicians may participate in CAP and the time required to fill out the most current revision of the Physician election form. For these burden purposes, we estimate that there will be 10,000 physicians who fill out an application and it will take the physician 2 hours to complete the application. Therefore, the burden estimate is 20,000 hours.

Bidding process (§ 414.910). Vendors may bid to furnish competitively biddable drugs in all areas of the United States, or a specific region that meets the requirements of this section.

The burden associated with these requirements is the time and effort necessary to submit the bid application, supporting documentation, and maintain necessary documentation demonstrating that the requirements set forth in the contract have been or will be met.

We currently estimate that it will require 12 bid applicants 40 hours each to meet the bidding and contract requirements. This revised estimate is based on data from the CAP RFI that concluded in January and the policies outlined in this IFC. The estimate of hours required for one bidder to meet this burden is unchanged.

Terms of contract (§ 414.914). The terms of the contract between CMS and the approved CAP vendor will be for a term of 3 years. During the contract period the approved CAP vendor must disclosure to CMS or its agent, the approved CAP vendor's reasonable, net acquisition costs for a specified period of time, on at least an annual basis.

The burden associated with these requirements is the time and effort necessary for the approved CAP vendor to submit to CMS or its agent, the approved CAP vendor's reasonable, net acquisition costs for a specified period of time, at least on an annual basis.

We estimate that it will require each of the five vendors 8 hours on an annual basis to submit the necessary information, for total annual burden of 8 hours per vendor. The estimate was revised to reflect a maximum of five approved CAP vendors for one national area.

Dispute resolution for vendors and beneficiaries. Dispute resolution (§ 414.916). Cases of an approved CAP vendor's dissatisfaction with denied drug claims are resolved through a voluntary alternative dispute resolution process.

The dispute resolution process may involve the gathering of information, however, since the requirements set forth in this section are in accordance with administrative action, audit, or investigation, the requirements of this section are exempt from the PRA as stipulated under 5 CFR 1320.4(a)(2).

Dispute resolution and process for suspension or termination of an approved CAP vendor (§ 414.917). If a participating CAP physician finds an approved CAP vendor's service, or the quality of a CAP drug to be dissatisfactory, then the participating CAP physician may treat the issue first through the approved CAP vendor's grievance process, and second through an alternative dispute resolution process administered by the designated carrier and CMS. In addition, if CMS suspends or terminates an approved CAP vendor's CAP contract for cause, the approved CAP vendor may request a reconsideration of this decision.

This process may involve the gathering of information, however, since the requirements set forth in this section are in accordance with administrative action, audit, or investigation, the requirements of this section are exempt from the PRA as stipulated under 5 CFR 1320.4(a)(2).

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn: Jim Wickliffe, CMS–1325–IFC, Room C5–13–28, 7500 Security Boulevard, Baltimore, MD 21244–1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Christopher Martin, CMS Desk Officer, CMS–1325–P, Christopher *Martin@omb.eop.gov*. Fax (202) 395–6974.

Comments Related to the Collection of Information Requirements

Comment: One commenter suggested that CMS revise its estimate for completing the physician application for CAP election to reflect the additional time it will take for physicians to evaluate the CAP.

Response: While we understand this concern, paperwork burden estimates generally do not include the time necessary to evaluate or consider taking a specific action. Paperwork burden estimates generally the time to complete the information collection, including the time to review instructions, search existing data resources, gather the needed data, and complete and review the information collection. Accordingly, CMS is not adopting this recommendation.

Comment: Several commenters recommended that CMS closely monitor physician clerical and inventory resources associated with the CAP during the initial years of the program, and if appropriate, consider making additional payment to physicians to cover the administrative costs associated with CAP.

Response: CMS will monitor the impact of the CAP program on physicians, patients, and on Part B drug prices closely. CMS will monitor its implementation approach and, if necessary, make adjustments to ensure patient access and reduce the administrative costs for providers.

VII. Regulatory Impact Analysis

[If you choose to comment on issues in this section, please include the caption ''Regulatory Impact Analysis'' at the beginning of your comments.]

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.

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 (that is, a final rule that would have an annual effect on the economy of $100 million or more in any 1 year, or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities).

We indicated in the March 4, 2005 proposed rule that we were considering this to be a major rule, but at that time we had not yet defined geographic area(s) and category(ies) of CAP drugs. Based on the establishment of the CAP initially as a national program with one drug category, we continue to believe that this rule is a major rule, and we anticipate more than $100 million will pass through the CAP payment system in 2006. Therefore, we have prepared a regulatory impact analysis (RIA). However, as previously discussed in the preamble, certain sections of this rule will be effective immediately. Specifically, the provisions related to the vendor bidding process will not be subject to the 60-day delay in effective date applicable to major rules under the Congressional Review Act (5 U.S.C. 801 *et seq.*) because of the need to meet the statutory requirement to coordinate the physicians' election to participate in the CAP with the Medicare Participating Physician Process described in section 1842(h) of the Act. We can only meet this statutory requirement if the delay in effective date for these particular portions of the rule are waived. We note that although the vendor bidding process will begin immediately, vendors will not be required to sign contracts with Medicare until after the effective date of all of the provisions of this rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. 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 less than $6 million to $29 million in any 1 year. We prepare an initial or final regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason the action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities. Individuals and States are not included in the definition of a small entity. For the reasons described in the section on ''Anticipated Effects,'' we certify that this rule will not have a significant economic impact on a substantial number of small entities.

For purposes of the RFA, physicians and non-physician practitioners are considered small businesses if they generate revenues of $8.5 million or less. Approximately 96 percent of physicians in private practice are considered to be small entities. There are in excess of 20,000 physicians and other practitioners that receive Medicare payment for drugs. These physicians are more concentrated in the specialties of oncology, urology, and rheumatology. Of the physicians in these specialties, approximately 40 percent are in oncology and 45 percent in urology.

The impact of this interim final rule on an individual physician is dependent on the drugs they provide to Medicare beneficiaries and whether these drugs are included in the category of ''incident to'' drugs identified in the preamble for competitive acquisition and whether the physician chooses to obtain drugs administered to Medicare beneficiaries through the CAP.

In addition, this interim final rule will have a potential impact on entities, either existing or formed specifically for this purpose, that are involved in the dispensing or distribution of drugs. This aspect was dependent on our determination of the particular category/categories of drugs to be included in the CAP and the geographic areas in which

it is to take place. It also depends on the ability of potential vendors to successfully compete and receive approval as a vendor under the CAP. As previously discussed, the CAP will be a national program, and an approved CAP vendor must be able to furnish all the drugs in the established CAP category of drugs.

Comment: At least one commenter believed that the initial regulatory flexibility analysis was not sufficient to allow small vendors sufficient notice that the CAP could have an impact on them.

Response: We believe that small businesses received ample notice that this rule could have an impact on them. We provided detailed explanations of the options for the areas and categories in the preamble to the proposed rule, and indicated that the impact on small entities would depend on how those choices played out. We received more than 500 comments from a variety of sources, including potential CAP vendors and individual physicians. We believe that all possibly affected entities, including small vendors, had an opportunity to comment.

Also, section 1102(b) of the Social Security Act requires us to prepare an initial and final regulatory flexibility analysis if a rule has 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. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We have determined that this interim final rule will have no significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule that mandates expenditures in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 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. We have examined this interim final rule in accordance with Executive Order 13132 and UMRA and have determined that this regulation will have no consequential effect on the rights, roles, or responsibilities of State, local, or tribal governments, or impose direct costs on State, local, or tribal governments. Nor does the rule mandate direct costs on the private sector.

Comment: Several commenters believe that, should CMS include oncologists and oncology drugs in the CAP, more Medicare beneficiaries will require hospital treatment due to delayed access to necessary drugs for their treatment programs and this will potentially impact small hospitals.

Response: Based on the comments received and the results of our data analysis, we will be including certain oncology drugs in the CAP, and we anticipate that some oncologists may elect to participate in the CAP. However, participation under the CAP is voluntary, and we would not expect these physicians to participate if this would result in adverse consequences for their Medicare beneficiary patients. Moreover, we believe that we have built into the program various safeguards that will preserve beneficiary access and prevent treatment delays or unnecessary hospital referrals, as discussed elsewhere in the preamble: For example, the provisions related to ''furnish as written'' and the resupply of inventories for drugs administered in an emergency situation will help ensure that Medicare beneficiaries will receive their treatments timely within their physicians' offices. Finally, the likely effects on physicians and Medicare beneficiary patients are discussed at greater length in the discussion of ''Anticipated Effects'' below.

B. Anticipated Effects

We have prepared the following analysis related to the assessment requirements. It explains the rationale for, and purposes of, the rule, details the costs and benefits of the rule, analyzes alternatives, and presents the measures we are using to minimize the burden on small entities. As indicated elsewhere in this rule, this program provides an alternative to the method that physicians currently use to obtain and pay for certain Medicare drugs in response to the requirements of section 1847B of the Act. The provisions of this rule discuss how this option will be offered to physicians. The CAP process is an alternative payment system for Part B drugs and biologicals. This rule does not impose reporting, recordkeeping, and other compliance requirements except as described in sections II.B, II.C and II.D. of the preamble. We are not aware of any relevant Federal rules that duplicate, overlap, or conflict with this rule.

Comment: Several commenters expressed concern that there would be a significant administrative as well as a financial impact on physicians. These commenters claimed that physicians who elect to participate in the CAP will not be appropriately compensated for additional costs such as maintaining separate drug storage for CAP medications, hiring additional personnel to order and keep track of CAP medications, and the additional time required to adequately track the actual drug administrations.

Response: Although we recognize that electing to participate in the CAP imposes certain new burdens on physicians who choose to participate, we believe these are offset by the decrease in burden associated with no longer having to buy most Part B drugs and bill the Medicare program for them. The administrative payment burdens that are relieved or reduced include collecting the applicable deductible and coinsurance from the beneficiary or other supplemental insurer and the time and cost of assuming legal ownership of the drugs covered under the CAP. As the physician does not assume legal ownership of the drug under the CAP (ownership remains with the approved CAP vendor), this removes the burden of negotiating with drug suppliers for the best price. Further, it is possible that the time and effort involved in generating the drug in a quantity other than that in which it was received also could be removed from the physician. Receiving drugs in the proper administration dosage, where possible, saves the physician time and effort. We note that the CAP is an option offered to physicians who believe that it is a viable alternative to the buy and bill system, especially when dealing with extremely expensive drugs. Physicians who believe the CAP burden would be too onerous for their practice always will have the option of electing not to participate in the CAP and continue to be paid under the ASP payment system for the medically necessary drugs that they obtain and administer under Medicare. We remain committed to working with members of the health care community to assist them in identifying the most appropriate payment scenarios for providers as well as the highest quality of care for beneficiaries.

Comment: Several commenters were concerned that if CMS selected a national geographic area, then approved CAP vendors who participate in the CAP would be asked to handle business on a national level. Small vendors who want to operate under the CAP in a specific area for a small number of local physicians believe that in such an event, they will have been excluded from the CAP out of hand.

Response: Initially, we believe that, in order to get the program started, the CAP needs to be administered on a national level. Most of the comments we received indicated that small vendors were not limited geographically but, instead, by drug specialty. The CAP requirements are in place to facilitate access to care for Medicare beneficiaries and to maintain quality of care in the treatment programs of these beneficiaries. However, that does not mean that larger vendors cannot contract with smaller vendors under the CAP to provide drugs to smaller geographic areas of the country or specific physicians, as long as all other criteria can be met by the sub-contracted vendor. Furthermore, there is nothing that precludes a relatively small firm from providing services on a national basis. In this way, every qualified vendor has the opportunity to participate, even though it may not be in a direct way. In the future, we will establish additional or alternative competitive acquisition areas and drug categories and solicit comments on those additions or alternatives, as necessary.

The effect of this interim final rule on an individual physician will be dependent on the drugs he or she provides to Medicare beneficiaries and whether the drugs he or she furnishes are included in the category of drugs considered for the CAP. For example, a physician may (1) determine the cost associated with acquiring drugs through the competitive acquisition program; (2) determine the cost associated with acquiring drugs through traditional means and billing Medicare under the ASP payment system methodology; and (3) determine whether there is a cost savings to them associated with either program. Different outcomes may result from these calculations depending on the drug mix, overhead cost, and Medicare beneficiary patient mix.

A physician who elects to participate in the program would obtain all of his or her Medicare-related drugs included in the category through an approved CAP vendor. The approved CAP vendor will collect applicable deductibles and coinsurance from the beneficiary. Under this option, the participating CAP physician will never take legal ownership of the drug and will eliminate the cost associated with collecting deductibles and coinsurance. Because the drug remains the property of the approved CAP vendor until the time of administration, the participating CAP physician also may be able to reduce the cost associated with storage and individual drug supplier negotiations. The CAP may also save participating CAP physicians money because they will not be in the drug purchasing and procurement business and will not have to collect coinsurance for those drugs from beneficiaries.

Comment: Several commenters were concerned about increased drug waste by physicians who participate in the CAP because, in their view, the physician will not be able to return the unused drug to the approved CAP vendor or to use the drug when a beneficiary's treatment plan changes on short notice. These commenters further cited problems with redirecting these unused medications to alternative beneficiaries due to State regulations in some instances.

Response: If it becomes apparent that there is a problem with excessive waste under the CAP, then we will examine ways to specifically address the issue. One question would concern whether some types of physician practices may be affected because drugs they use are more prone to wastage for particular reasons, or if waste is more of a random problem that would lead us to deal with the issue on an individual basis.

This rule also establishes rules whereby drugs administered by the participating CAP physician in emergency situations that were not originally acquired through a Medicare-approved CAP vendor may be resupplied through the Medicare-approved CAP vendor, as described elsewhere in the preamble.

C. Impact of Establishment of a Competitive Acquisition Program

The purpose of the CAP program is to potentially achieve budgetary savings to Medicare and beneficiaries through a competitive bidding approach to determining Medicare payment rates for selected drugs and to provide physicians with an alternative way to obtain these selected drugs that they use for treating their Medicare beneficiaries in their offices. We have estimated the impact of the costs of furnishing or administering drugs through the CAP on the Medicare program and expect it to be negligible, at least during the beginning until participating CAP physicians, approved CAP vendors and CMS gain more experience with the program. During the first year, we anticipate no significant additional cost savings or increases associated with the CAP, particularly relative to the ASP payment system. The CAP program will provide alternatives to physicians who do not wish to be in the drug purchasing and coinsurance collection business. We will further refine theses impacts as participating CAP physicians, approved CAP vendors, and CMS gain experience with this new program.

D. Alternatives Considered

As we developed the CAP, we considered whether to break the country into smaller geographic regional or State areas as opposed to one national competitive acquisitions area (the 50 United States, the District of Columbia and the U.S. territories). We also considered whether to include all drugs available under the CAP in one category as opposed to breaking the drugs out into different categories such as oncology drugs, non-oncology drugs, and crossover drugs. We also considered variations of these options such as breaking down the drug categories at the national level versus offering one drug category at the regional or State level. In reference to these options, we did not receive any comments about administering the CAP in specific regions of the country or specific States or any data to support such a conclusion. As we stated earlier in this section, vendors who wish to be approved CAP vendors and who also wish to operate in certain States, regions, or areas of the country, as opposed to nationally, are free to seek out vendors who plan to participate in the CAP at the national level to see whether their services can be used at the sub-contractor level. We do not intend to direct such an arrangement other than to reiterate that our criteria for participation in the CAP must be met by any and all potential approved CAP vendors; however, we encourage this communication between potential CAP vendors as we believe that it will enhance the opportunities for approved CAP vendors as well as participating CAP physicians under the CAP.

We also considered whether or not to split drugs into more than one category as well as several options for defining drug categories across a wide spectrum of physician Part B drugs, as described in the preamble. Commenters on the proposed rule were divided about whether to employ broadly defined or narrowly defined categories of drugs. We are persuaded that more broadly defined categories would better serve the purposes of the program, at least in the initial stage. This approach would make it more feasible for participating CAP physicians to obtain all, or almost all, of their Part B drugs from one approved CAP vendor. We expect that the approved CAP vendors participating on a nationwide scale will be able to provide the broad spectrum of drugs without appreciably more difficulty, if any, than narrower sets of drugs. In accordance with the statute, we will

develop more narrowly defined categories if it seems advisable at a later stage.

In this interim final rule, based on the comments and our data analysis, we are implementing the CAP with one extensive category as it provides the most expansive category of drugs and it is the most simple in terms of operationalization. We believe that this option will encourage the highest number of approved CAP vendors to participate under the CAP due to the potential for larger market share and the opportunity for smaller vendors to contract with the larger vendors. We also believe that this option will encourage the highest number of physicians to participate under the CAP due to the potential for acquiring a large portion of the drugs administered to their Medicare beneficiaries from a single approved CAP vendor.

However, we will monitor the program carefully, assessing all the issues discussed above, and make appropriate program adjustments if these seem warranted. We welcome input on any and all issues.

E. Impact on Beneficiaries

We have estimated the potential changes in beneficiary coinsurance for drugs and related changes in beneficiary Part B premium payments resulting from the implementation of the CAP for Part B drugs. We do not expect, during the first year of the program, that there will be an appreciable difference to the beneficiaries if their drugs were to be administered by a physician participating in the CAP or purchasing them and being reimbursed for them within the ASP payment system. At least initially, until approved CAP vendors, participating CAP physicians, and CMS gain more experience with this new program, we do not anticipate there would be any significant additional costs or savings to a beneficiary whose physician participates in the CAP. The CAP should be largely transparent to the beneficiary population. The only change should be the entity that bills the beneficiary for the coinsurance.

We do not believe that beneficiaries would experience drug access issues as a result of implementation of the CAP. However, we intend to monitor beneficiary access closely and may propose additional changes to our payment system in the future, if necessary.

We intend to develop educational material to distribute to beneficiaries, such as pamphlets and a discussion in The *Medicare & You Handbook*, to help explain the CAP and the changes they will see on their Medicare summary notices. Specifically, under the CAP, beneficiaries will now pay their coinsurance and deductibles to their approved CAP vendor instead of the administering participating CAP physician.

Comment: Several commenters believed that beneficiary access to a drug or drugs associated with the beneficiary's specific treatment program will be compromised under the CAP, resulting in multiple trips to the physician's office by not only the beneficiary, but the beneficiary's family members, for a single treatment. Also, these commenters believe that the beneficiary's condition may be compromised and, in fact, may decline, resulting in a hospital admission, because treatment was delayed in these circumstances. The commenters stated that, often, a beneficiary's treatment program is altered on short notice. A participating CAP physician that stocked his or her own drugs would, presumably, be able to accommodate these treatment changes onsite, rather than having to plan a subsequent visit while an alternative drug prescription order is filled.

Response: We appreciate the concerns of these commenters, and we will monitor beneficiary access under the CAP. We believe that the construct of the CAP will enhance beneficiary access in several ways. The participating CAP physician will have access to a category of drugs that he or she can order to meet the beneficiary's needs. If the approved CAP vendor does not offer a particular drug that is medically necessary for a beneficiary's treatment plan, then the participating CAP physician may use the ''furnish as written'' option and access the specific drug through this channel. Further, if a beneficiary presents in a condition that requires the participating CAP physician to alter his or her treatment plan, and the participating CAP physician determines it is an emergency, and the other criteria under the resupply provision are met such as, that the need is unanticipated and the vendor cannot provide the drug in time, then the participating CAP physician could immediately administer a drug out of his or her own stock and then order a replacement from the approved CAP vendor. Although we cannot say that a situation would never occur wherein a beneficiary would need a drug that is not immediately available, this could also occur under the current ASP payment system.

Comment: Some commenters pointed out that beneficiaries may be disadvantaged if an approved CAP vendor cannot react expeditiously when new drugs are introduced or patents expire due to the restrictions of the CAP. An approved CAP vendor is limited to offering drugs within a certain category while the participating CAP physician can act outside the CAP for drugs that are different or new.

Response: We appreciate the fact that new drugs may become available through the FDA drug or biological approval process, or alternatively that previously approved drugs may be discontinued on an ongoing basis. New drugs may be included in the CAP once they are assigned a permanent HCPCS code, as described elsewhere in this preamble. If a new drug or biological is not offered by the participating CAP physician's approved CAP vendor, participating CAP physician can purchase it and bill for it through the ASP payment system.

A drug approved by the FDA as a generic for an existing drug with a HCPCS code may not be available within the CAP because for multiple source drugs, the approved CAP vendor is required to provide only one NDC within a HCPCS code (although the approved CAP vendor is free to bid to provide multiple NDCs within a HCPCS code). If a participating CAP physician finds it medically necessary to prescribe a new drug that is within an existing HCPCS code in the CAP drug category, but that his or her selected approved CAP vendor has not contracted to provide, he or she can obtain it and bill for it under the ASP payment system using the ''furnish as written'' provision.

Comment: A large number of commenters involved in the mental health arena stated that the inclusion of psychiatric drugs under the CAP would enable more patients in need of valuable mental health medications to have access to them, especially in rural areas, and, as a result, bring new psychiatric therapies into wider use. In the view of these commenters, the current ASP payment system presents them with barriers to care for their patients because of the administrative burden of locating new mental health therapies and then billing Medicare and tracking the claims, which often are only partly paid. If psychiatric drugs were included as an available category, then this burden would be removed.

Response: We appreciate the positive response from the mental health community for the CAP. We are working to ensure the availability of the most effective treatments to enable at-risk individuals to live productive lives in the least restrictive environments. As previously stated, several mental health

drugs are included in the drug category we have established for the CAP.

Comment: Several commenters believe that Medicare beneficiaries will have a difficult time understanding why they receive two statements (one from the participating CAP physician for the administration of the drug and one from the approved CAP vendor for the coinsurance and deductible payments) about each episode of treatment.

Response: We have built extensive educational tools into the CAP for beneficiaries, as described elsewhere in the preamble. Beneficiaries will receive information on the implementation of the CAP and how it will affect them and what they see as far as Medicare billing is concerned. They will also be provided with access to a help line for the questions about their bills as well as written information that they can reference. Of course, regardless of which option they select, we would expect most participating CAP physicians to explain to their Medicare beneficiaries the process by which they will be billed.

Comment: Some commenters were concerned that beneficiaries who were financially burdened would be adversely affected by the CAP because they would be removed from dealing directly with their physicians in working out payment options for their deductibles and copayments because the approved CAP vendor would be responsible for billing the beneficiaries for these items.

Response: Beneficiaries are legally responsible for paying their coinsurance, and providers, including participating CAP physicians and other suppliers such as the approved CAP vendors, are required to make an effort to collect it. We address above in this preamble measures that the approved CAP vendor may take to address this issue. We encourage beneficiaries to talk to the approved CAP vendor in these circumstances and encourage the approved CAP vendor to provide beneficiaries information about patient assistance programs. Again, we will be monitoring beneficiary access under the CAP. In addition, approximately 80 percent of Medicare beneficiaries have some type of supplemental coverage for Part B that will pay their deductible and coinsurance amounts either in whole or in part.

F. Conclusion

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in this preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 1. 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)).

Subpart K—Payment for Drugs and Biologicals Under Part B

■ 2. Revise the heading of subpart K to read as set forth above.

■ 3. Amend § 414.900 by—

■ A. Revising the section heading.

■ B. Revising paragraph (a).

■ C. Revising paragraph (b)(3)(ii).

The revisions read as follows:

§ 414.900 Basis and scope.

(a) This subpart implements sections 1842(o), 1847A, and 1847B of the Act and outlines two payment methodologies applicable to drugs and biologicals covered under Medicare Part B that are not paid on a cost or prospective payment system basis.

(b) * * *

(3) * * *

(ii) Pneumococcal and Hepatitis B vaccines.

* * * * *

■ 4. Amend § 414.902 by republishing the introductory text to the section and adding the definitions of ''Approved CAP vendor,'' ''Bid,'' ''CAP drug,'' ''Competitive acquisition area,'' ''Competitive acquisition program,'' ''Designated carrier,'' ''Emergency delivery,'' ''Emergency situation,'' ''Local carrier,'' ''Pacific Territories,'' ''Participating CAP physician,'' ''Participating CAP physician election agreement,'' ''Prescription order,'' ''Routine delivery,'' and ''Timely delivery.''

§ 414.902 Definitions.

As used in this subpart, unless the context indicates otherwise—

Approved CAP vendor means an entity that has been awarded a contract by CMS to participate in the competitive acquisition program under 1847B of the Act.

Bid means an offer to furnish a CAP drug within a category of CAP drugs in a competitive acquisition area for a particular price and time period.

CAP drug means a physician-administered drug or biological furnished on or after January 1, 2006 described in section 1842(o)(1)(C) of the Act and supplied by an approved CAP vendor under the CAP as provided in this subpart.

Competitive acquisition area means a geographic area established by the Secretary for purposes of implementing the CAP required by section 1847B of the Act.

Competitive acquisition program (CAP) means a program as defined under section 1847B of the Act.

Designated carrier means an entity assigned by CMS to process and pay claims for drugs and biologicals under the CAP.

* * * * *

Emergency delivery means delivery of a CAP drug within one business day in appropriate shipping and packaging, in all areas of the United States and its territories, with the exception of the Pacific Territories. In the Pacific Territories, emergency delivery means delivery of a CAP drug within 5 business days in appropriate shipping and packaging. In each case, this timeframe shall be reduced if product stability requires it, meaning that the manufacturer's labeling instructions, drug compendia, or specialized drug stability references indicate that a shorter delivery timeframe is necessary to avoid adversely affecting the product's integrity, safety, or efficacy.

Emergency situation means, for the purposes of the CAP, an unforeseen occurrence or situation determined by the participating CAP physician, in his or her clinical judgment, to require prompt action or attention for purposes of permitting the participating CAP physician to use a drug from his or her own stock, if the other requirements of § 414.906(e) are met.

Local carrier means an entity assigned by CMS to process and pay claims for administration of drugs and biologicals under the CAP.

* * * * *

Pacific Territories means, for purposes of the CAP, American Samoa, Guam, or the Northern Mariana Islands.

Participating CAP physician means a physician electing to participate in the CAP, as described in this subpart. The participating CAP physician must complete and sign the participating CAP physician election agreement. Physicians who do not participate in Medicare but who elect to participate in the CAP must agree to accept assignment for CAP drug administration claims.

Participating CAP physician election agreement means the agreement that the physician signs to notify CMS of the physician's election to participate in the CAP and to agree to the terms and conditions of CAP participation as set forth in this subpart.

Prescription order means a written order submitted by the participating CAP physician to the approved CAP vendor that meets the requirements of this subpart.

Routine delivery means delivery of a drug within 2 business days in appropriate shipping and packaging in all areas of the United States and its territories, with the exception of the Pacific Territories. In the Pacific Territories, routine delivery of drug means delivery of a CAP drug within 7 business days in appropriate shipping and packaging. In each case, this timeframe will be reduced if product stability requires it, meaning that the manufacturer's labeling instructions, drug compendia, or specialized drug stability references indicate that a shorter delivery timeframe is necessary to avoid adversely affecting the product's integrity, safety, or efficacy.

* * * * *

Timely delivery means delivery of a CAP drug within the defined routine and emergency delivery timeframes. Compliance with timely delivery standards is also a factor for evaluation of potential and approved CAP vendors.

* * * * *

■ 5. Amend § 414.904 by revising the section heading to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

■ 6. Add § 414.906 to read as follows:

§ 414.906 Competitive acquisition program as the basis for payment.

(a) *Program payment.* Beginning in 2006, as an alternative to payment under § 414.904, payment for a CAP drug may be made through the CAP if the following occurs:

(1) The CAP drug is supplied under the CAP by an approved CAP vendor as specified in § 414.908(b).

(2) The claim for the prescribed drug is submitted by the approved CAP vendor that supplied the drug, and payment is made only to that vendor.

(3) The approved CAP vendor collects applicable deductible and coinsurance with respect to the drug furnished under the CAP only after the drug is administered to the beneficiary.

(4) The approved CAP vendor delivers CAP drugs directly to the participating CAP physician in unopened vials or other original containers as supplied by the manufacturer or from a distributor that has acquired the products directly from the manufacturer and includes language with the shipping material stating that the drug was acquired in a manner consistent with all statutory requirements. If the approved CAP vendor opts to split shipments, the participating CAP physician must be notified in writing which can be included with the initial shipment, and each incremental shipment must arrive at least 2 business days before the anticipated date of administration.

(5) The approved CAP vendor bills Medicare only for the amount of the drug administered to the patient, and the beneficiary's coinsurance will be calculated from the quantity of drug that is administered.

(b) *Exceptions to competitive acquisition.* Specific CAP drugs, including a category of these drugs, may be excluded from the CAP if the application of competitive bidding to these drugs—

(1) Is not likely to result in significant savings; or

(2) Is likely to have an adverse impact on access to those drugs.

(c) *Computation of payment amount.* (1) Except as specified in paragraph (c)(2) of this section, payment for CAP drugs is based on bids submitted, as a result of the bidding process as described in § 414.910. Based on these bids, a single payment amount for each CAP drug in the competitive acquisition area is determined on the basis of the bids submitted and accepted and updated from the bidding period to the payment year. This single payment amount is then updated on an annual basis based on the approved CAP vendor's reasonable net acquisition costs for that category as determined by CMS based, in part, on information disclosed to CMS and limited by the weighted payment amount established under section 1847A of the Act across all drugs in that category. Adjustment to the payment amounts may be made more often than annually, but no more often than quarterly, in any of the following cases:

(i) Introduction of new drugs.

(ii) Expiration of a drug patent or availability of a generic drug.

(iii) Material shortage that results in a significant price increase for the drug.

(iv) Withdrawal of a drug from the market.

(2) The alternative payment amount established under section 1847A of the Act may be used to establish payment for a CAP drug if—

(i) The drug is properly assigned to a category established under the CAP; and

(ii) It is a drug for which a HCPCS code must be established.

(d) *Adjustments.* There is an established process for adjustments to payments to account for drugs that were billed, but which were not administered.

(e) *Resupply of participating CAP physician drug inventory.* A participating CAP physician may acquire drugs under the CAP to resupply his or her private inventory if all of the following requirements are met:

(1) The drugs were required immediately.

(2) The participating CAP physician could not have anticipated the need for the drugs.

(3) The approved CAP vendor could not have delivered the drugs in a timely manner. For purposes of this section, timely manner means delivery within the emergency delivery timeframe, as defined in § 414.902.

(4) The participating CAP physician administered the drugs in an emergency situation, as defined in § 414.902.

(f) *Substitution of CAP drugs.* An approved CAP vendor may agree to furnish more than one CAP drug (defined at the NDC level) for a HCPCS code. Payment is based on a bid price defined by the HCPCS code and the unit of measure for the HCPCS code. Substitution of a different NDC within the HCPCS code for the NDC currently furnished by the approved CAP vendor can occur in the following situations:

(1) On an occasional basis, if the approved CAP vendor is willing to accept the payment amount that was established for the original NDC within a HCPCS code under the CAP, and the participating CAP physician approves the substitution; or

(2) For an extended period of time (more than 2 weeks), if the approved CAP vendor identifies the replacement product, the designated carrier's medical director approves the long-term substitution on behalf of CMS, and all participating CAP physicians who have selected the approved CAP vendor are notified of the change. In the case of such long-term substitution, payment is based on the price established in accordance with § 414.906(c).

■ 7. Add § 414.908 to read as follows:

§ 414.908 Competitive acquisition program.

(a) Participating CAP *physician selection of an approved CAP vendor.* (1) CMS provides the participating CAP physician with a process for the selection of an approved CAP vendor on an annual basis, with exceptions as specified in § 414.908(a)(2).

Participating CAP physicians will also receive information about the CAP in the enrollment process for Medicare participation set forth in section 1842(h) of the Act.

(2) A participating CAP physician may select an approved CAP vendor outside the annual selection process or opt out of the CAP for the remainder of the annual selection period when—

(i) The selected approved CAP vendor ceases participation in the CAP;

(ii) The physician leaves a group practice participating in CAP;

(iii) The participating CAP physician relocates to another competitive acquisition area; or

(iv) For other exigent circumstances defined by CMS.

(3) The physician participating in the CAP—

(i) Elects to use an approved CAP vendor for the drug category and area as set forth in § 414.908(b);

(ii) Completes and signs the CAP election agreement;

(iii) Submits a written prescription order to the approved CAP vendor with complete patient information for patients new to the approved CAP vendor or when information changes. Abbreviated information may be sent on all subsequent orders for a patient for which the approved CAP vendor has previously received complete information and that has no changes to the original information. Prescription orders may be initiated by telephone, with a follow-up written order provided within 8 hours for routine deliveries and immediately for emergency deliveries;

(iv) Does not receive payment for the CAP drug;

(v) Except where applicable State pharmacy law prohibits it, provides the following information to the approved CAP vendor to facilitate collection of applicable deductible and coinsurance as described in § 414.906(a)(3):

(A) Date of order.

(B) Beneficiary name, address, and phone number.

(C) Physician identifying information:

Name, practice location/shipping address, group practice information (if applicable), PIN, and UPIN.

(D) Drug name.

(E) Strength.

(F) Quantity ordered.

(G) Dose.

(H) Frequency/instructions.

(I) Anticipated date of administration.

(J) Beneficiary Medicare information/Health insurance (HIC) number.

(K) Supplementary insurance information (if applicable).

(L) Medicaid information (if applicable).

(M) Additional patient information: date of birth, allergies, height/weight, ICD–9.

(vi) Notifies the approved CAP vendor when a drug is not administered or a smaller amount was administered than was originally ordered. The participating CAP physician and the approved CAP vendor agree on how to handle the unused CAP drug. If it is agreed that the participating CAP physician will maintain the CAP drug in his inventory for administration at a later date, the participating CAP physician submits a new prescription order at that time. This prescription order specifies that the CAP drug is being obtained from the participating CAP physician's CAP inventory and shipment should not occur;

(vii) Maintains a separate electronic or paper inventory for each CAP drug obtained;

(viii) Agrees to file the Medicare claim within 14 calendar days of the date of drug administration;

(ix) Agrees to submit an appeal accompanied by all required documentation (such as medical records or a certification) necessary to support payment if the participating CAP physician's drug administration claim for a CAP drug is denied;

(x) Agrees not to transport CAP drugs from one practice location (place of service) to another location;

(xi) Agrees to provide the CMS-developed CAP fact sheet to beneficiaries; and

(xii) May receive payment under the ASP system when medical necessity requires a certain brand or formulation of a drug that the approved CAP vendor has not been contracted to furnish under the CAP.

(4) Physician group practices. If a physician group practice using a group billing number(s) elects to participate in the CAP, all physicians in the group are considered to be participating CAP physicians when using the group's billing number(s).

(5) *Additional opt out provision.* In addition to the circumstances listed in § 414.908(a)(2), if the approved CAP vendor refuses to ship to the participating CAP physician because the conditions of § 414.914(h) have been met, the physician can withdraw from CAP for the remainder of the year immediately upon notice to CMS and the approved CAP vendor.

(b) *Program requirements.* (1) CMS selects approved CAP vendors through a competition among entities based on the following:

(i) Submission of the bid prices using the OMB-approved Vendor Application and Bid Form for CAP drugs within the category and competitive acquisition area that—

(A) Places the vendor among the qualified bidders with the lowest five composite bids; and

(B) Does not exceed the weighted payment amount established under section 1847A of the Act across all drugs in that category.

(ii) Ability to ensure product integrity.

(iii) Customer service/Grievance process.

(iv) At least 3 years experience in furnishing Part B injectable drugs.

(v) Financial performance and solvency.

(vi) Record of integrity and the implementation of internal integrity measures.

(vii) Internal financial controls.

(viii) Acquisition of all CAP drugs directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer.

(ix) Maintenance of appropriate licensure to supply CAP drugs in States in which they are supplying CAP drugs.

(x) Cost-sharing assistance as described in § 414.914(g).

(xi) Other factors as determined by CMS.

(2) Approved CAP vendors must also meet the contract requirements under § 414.914.

(c) *Additional considerations.* CMS may refuse to award a contract or terminate an approved CAP vendor contract based upon the following:

(1) Suspension or revocation by the Federal or State government of the entity's license for distribution of drugs, including controlled substances.

(2) Exclusion of the entity under section 1128 of the Act from participation in Medicare or other Federal health care programs. These considerations are in addition to CMS' ability to terminate the approved CAP vendor for cause as specified in § 414.914(a).

(3) Past violations or misconduct related to the pricing, marketing, distribution, or handling of drugs provided incident to a physician's service.

(d) *Multiple source drugs.* In the case of multiple source drugs, there must be a competition among entities for the acquisition of at least one CAP drug within each billing and payment code within each category for each competitive acquisition area.

(e) *Multiple contracts for a category and area.* The number of bidding qualified entities that are awarded a contract for a given category and area may be limited to no fewer than two.

■ 8. Add § 414.910 to read as follows:

§ 414.910 Bidding process.

(a) Entities may bid to furnish CAP drugs in all competitive acquisition areas of the United States, or one or more specific competitive acquisition areas.

(b) The amount of the bid for any CAP drug for a specific competitive acquisition area must be uniform for all portions of that competitive acquisition area.

(c) A submitted bid price must include the following:

(1) All costs related to the delivery of the drug to the participating CAP physician.

(2) The costs of dispensing (including shipping) of the drug and management fees. The costs related to the administration of the drug or wastage, spillage, or spoilage may not be included.

■ 9. Add § 414.912 to read as follows:

§ 414.912 Conflicts of interest.

(a) Approved CAP vendors and applicants that bid to participate in the CAP are subject to the following:

(1) The conflict of interest standards and requirements of the Federal Acquisition Regulation (FAR) organizational conflict of interest guidance, found under FAR subpart 9.5.

(2) Those requirements and standards contained in each individual contract awarded to perform functions under section 1847B of the Act.

(b) *Post-award conflicts of interest.* Approved CAP vendors must have a code of conduct that establishes policies and procedures for recognizing and resolving conflicts of interest between the approved CAP vendor and any entity, including the Federal Government, with whom it does business. The code of conduct which is submitted as part of the application must—

(1) State the need for management, employees, contractors, and agents to comply with the approved CAP vendor's code of conduct, and policies and procedures for conflicts of interest; and

(2) State the approved CAP vendor's expectations for management, employees, contractors, and agents to comply with the approved CAP vendor's code of conduct, and policies and procedures for detecting, preventing, and resolving conflicts of interest.

■ 10. Add § 414.914 to read as follows:

§ 414.914 Terms of contract.

(a) The contract between CMS and the approved CAP vendor will be for a term of 3 years, unless terminated or suspended earlier as provided in this section or provided in § 414.917. The contract may be terminated—

(1) By CMS for default if the approved CAP vendor violates any term of the contract; or

(2) In the absence of a contract violation, by either CMS or the approved CAP vendor, if the terminating party notifies the other party by June 30 for an effective date of termination of December 31 of that year.

(b) The contract will provide for a code of conduct for the approved CAP vendor that includes standards relating to conflicts of interest standards as set forth at § 414.912.

(c) The approved CAP vendor will have and implement a compliance plan that contains policies and procedures that control program fraud, waste, and abuse, and consists of the following minimum elements:

(1) Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State laws, regulations, and guidance, including, but not limited to, the Prescription Drug Marketing Act (PDMA), the physician self-referral (''Stark'') prohibition, the Anti-Kickback statute and the False Claims Act.

(2) The designation of a compliance officer and compliance committee accountable to senior management.

(3) Effective training and education of the compliance officer and organization employees, contractors, agents, and directors.

(4) Enforcement of standards through well publicized disciplinary guidelines.

(5) Procedures for effective internal monitoring and auditing.

(6) Procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as an approved CAP vendor.

(i) If the approved CAP vendor discovers evidence of misconduct related to payment or delivery of drugs or biologicals under the contract, it will conduct a timely and reasonable inquiry into that conduct.

(ii) The approved CAP vendor will conduct appropriate corrective actions including, but not limited to, repayment of overpayments and disciplinary actions against responsible individuals, in response to potential violations referenced at paragraph (c)(6)(i) of this section.

(7) Procedures to voluntarily self-report potential fraud or misconduct related to the CAP to the appropriate government agency.

(d) The contract must provide for disclosure of the approved CAP vendor's reasonable, net acquisition costs for a specified period of time, not to exceed quarterly.

(e) The contract must provide for appropriate adjustments as described in § 414.906(c)(1).

(f) Under the terms of the contract, the approved CAP vendor must also—

(1) Have sufficient arrangements to acquire and deliver CAP drugs within the category in the competitive acquisition area specified by the contract;

(2) Have arrangements in effect for shipment at least 5 weekdays each week of CAP drugs under the contract, including the ability to comply with the routine and emergency delivery timeframes defined in § 414.902;

(3) Have procedures in place to address and resolve complaints of participating CAP physicians and individuals and inquiries regarding shipment of CAP drugs;

(4) Have a grievance and appeals process for dispute resolution;

(5) Meet applicable licensure requirements in each State in which it supplies drugs under the CAP;

(6) Be enrolled in Medicare as a participating supplier;

(7) Comply with all applicable Federal and State laws, regulations and guidance related to the prevention of fraud and abuse;

(8) Supply CAP drugs upon receipt of a prescription order to all participating CAP physicians who have selected the approved CAP vendor, except when the conditions of § 414.914(h) are met;

(9) Ensure that subcontractors who are involved in providing services under the approved CAP contractor's CAP contract meet all requirements and comply with all laws and regulations relating to the services they provide under the CAP program. Notwithstanding any relationship the CAP vendor may have with any subcontractor, the approved CAP vendor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS;

(10) Comply with product integrity and record keeping requirements including but not limited to drug acquisition, handling, storage, shipping, drug waste, and return processes; and

(11) Comply with such other terms and conditions as CMS may specify in the CAP contract consistent with section 1847B of the Act.

(g) Under the terms of the contract, the approved CAP vendor must provide assistance to beneficiaries experiencing financial difficulty in paying their cost-sharing amounts through any one or all of the following:

(1) Referral to a bona fide and independent charitable organization.

(2) Implementation of a reasonable payment plan.

(3) A full or partial waiver of the cost-sharing amount after determining in good faith that the individual is in financial need or the failure of reasonable collection efforts, provided that the waiver meets all of the requirements of section 1128A(i)(6)(A) of the Act and the corresponding regulations at paragraph (1) of the definition of ''Remuneration'' in § 1003.101 of this title. The availability of waivers may not be advertised or be made as part of a solicitation. Approved CAP vendors may inform beneficiaries that they generally make available the categories of assistance described in paragraphs (g)(1), (g)(2), and (g)(3) of this section. In no event may the approved CAP vendor include or make any statements or representations that promise or guarantee that beneficiaries will receive cost-sharing waivers.

(h) The approved CAP vendor must comply with the following procedures before it may refuse to make further shipments of CAP drugs to a participating CAP physician on behalf of a beneficiary:

(1) Subsequent to receipt of final payment by Medicare, the approved CAP vendor must bill any applicable supplemental insurance policies.

(2) If after that action is taken, a balance remains, or if there is no supplemental insurance, the approved CAP vendor may bill the beneficiary.

(3) At the time of billing, the approved CAP vendor may inform the beneficiary of any types of cost-sharing assistance that may be available consistent with the requirements of section 1128A(a)(5) of the Act and § 414.914(g).

(4) If the beneficiary demonstrates a financial need, the approved CAP vendor must follow the conditions outlined in paragraph (g) of this section.

(5) If after 45 days from the postmark date of the approved CAP vendor's bill to the beneficiary, the beneficiary's cost sharing obligation remains unpaid, the approved CAP vendor may refuse further shipments to the participating CAP physician for that beneficiary; however, if the beneficiary has requested cost-sharing assistance within the 45-day period, the provisions of paragraph (6), (7), or (8), as applicable, apply.

(6) If the approved CAP vendor implements a reasonable payment plan, as specified in § 414.914(g)(2), the approved CAP vendor must continue to ship CAP drugs for the beneficiary, as long as the beneficiary remains in compliance with the payment plan and makes an initial payment under the plan within 15 days after the postmark date of the approved CAP vendor's written notice to the beneficiary offering the payment plan.

(7) If the approved CAP vendor has waived the cost-sharing obligations in accordance with section 1128A of the Act and § 414.914(g)(3), the approved CAP vendor may not refuse to ship drugs for that beneficiary.

(8) If the approved CAP vendor refers the beneficiary to a bona fide and independent charity in accordance with § 414.914(g)(1), the approved CAP vendor may refuse to ship drugs if the past due balance is not paid 15 days after the postmark date of the approved CAP vendor's written notice to the beneficiary containing the referral for cost-sharing assistance.

(9) The approved CAP vendor may refuse to make further shipments to that participating CAP physician on behalf of the beneficiary for the lesser of the end of the calendar year or until the beneficiary's balance is paid in full.

■ 11–12. § 414.916 to read as follows:

§ 414.916 Dispute resolution for vendors and beneficiaries.

(a) *General rule.* Cases of an approved CAP vendor's dissatisfaction with denied drug claims are resolved through a voluntary alternative dispute resolution process delivered by the designated carrier, and a reconsideration process provided by CMS.

(b) *Dispute resolution.* (1) When an approved CAP vendor is not paid on claims submitted to the designated carrier, the vendor may appeal to the designated carrier to counsel the responsible participating CAP physician on his or her agreement to file a clean claim and pursue an administrative appeal in accordance with subpart H of part 405 of this chapter. If problems persist, the approved CAP vendor may ask the designated carrier to—

(i) Review the participating CAP physician's performance; and

(ii) Potentially recommend to CMS that CMS suspend the participating CAP physician's CAP election agreement.

(2) The designated carrier—

(i) Gathers information from the local carrier, the participating CAP physician, the beneficiary, and the approved CAP vendor; and

(ii) Makes a recommendation to CMS on whether the participating CAP physician has been filing his or her CAP drug administration claims in accordance with the requirements for physician participation in the CAP as set forth in § 414.908(a)(3). The recommendation will include numbered findings of fact.

(3) CMS will review the recommendation of the designated carrier and gather relevant additional information from the participating CAP physician before deciding whether to suspend the participating CAP physician's CAP election agreement. A suspension commencing before October 1 will conclude on December 31 of the same year. A suspension commencing on or after October 1 will conclude on December 31 of the next year.

(4) The participating CAP physician may appeal that suspension by requesting a reconsideration of CMS' decision. The reconsideration will address whether the participating CAP physician's denied claims and appeals were the result of the participating CAP physician's failure to participate in accordance with the requirements of § 414.908(a)(3).

(c) *Reconsideration.* (1) *Right to reconsideration.* A participating CAP physician dissatisfied with a determination that his or her CAP election agreement has been suspended by CMS is entitled to a reconsideration as provided in this subpart.

(2) *Eligibility for reconsideration.* CMS reconsiders any determination to suspend a participating CAP physician's election agreement if the participating CAP physician files a written request for reconsideration in accordance with paragraphs (c)(3) and (c)(4) of this section.

(3) *Manner and timing of request for reconsideration.* A participating CAP physician who is dissatisfied with a CMS decision to suspend his or her CAP election agreement may request a reconsideration of the decision by filing a request with CMS. The request must be filed within 30 days of receipt of the CMS decision letter notifying the participating CAP physician of CMS' decision to suspend his or her CAP election agreement. From the date of receipt of the decision letter until the day the reconsideration determination is final, the ASP payment methodology under section 1847A of the Act applies to the physician.

(4) *Content of request.* The request for reconsideration must specify—

(i) The findings or issues with which the participating CAP physician disagrees;

(ii) The reasons for the disagreement;

(iii) A recital of the facts and law supporting the participating CAP physician's position;

(iv) Any supporting documentation; and

(v) Any supporting statements from approved CAP vendors, local carriers, or beneficiaries.

(5) *Withdrawal of request for reconsideration.* A participating CAP physician may withdraw his or her request for reconsideration at any time before the issuance of a reconsideration determination.

(6) *Discretionary informal hearing.* In response to a request for reconsideration, CMS may, at its discretion, provide the participating CAP physician the opportunity for an informal hearing that—

(i) Is conducted by a hearing officer appointed by the director of the CMS Center for Medicare Management or his or her designee; and

(ii) Provides the participating CAP physician the opportunity to present, by telephone or in person, evidence to rebut CMS' decision to suspend or terminate a participating CAP physician's CAP election agreement.

(7) *Informal hearing procedures.* (i) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The informal reconsideration hearing will be conducted in accordance with the following procedures:

(A) The hearing is open to CMS and the participating CAP physician requesting the reconsideration, including—

(*1*) Authorized representatives;

(*2*) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts);

(*3*) Representatives from the local carrier;

(*4*) Representatives from the approved CAP vendor; and

(*5*) Legal counsel.

(B) The hearing is conducted by the hearing officer who receives relevant testimony;

(C) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissible under the rules of evidence applied in Federal courts;

(D) Either party may call witnesses from among those individuals specified in paragraph (c)(7)(ii)(A) of this section; and

(E) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(8) *Hearing officer's findings.* (i) Within 30 days of the hearing officer's receipt of the hearing request, the hearing officer presents the findings and recommendations to the participating CAP physician who requested the reconsideration. If the hearing officer decides to conduct an in-person or telephone hearing, the hearing officer will send a hearing notice to the participating CAP physician within 10 days of receipt of the hearing request, and the findings and recommendations are due to the participating CAP physician within 30 days of the hearing's conclusion.

(ii) The written report of the hearing officer includes separate numbered findings of fact and the legal conclusions of the hearing officer.

(9) *Final reconsideration determination.* (i) The hearing officer's decision is final unless the director of the CMS Center for Medicare Management or his or her designee chooses to review that decision within 30 days. If the decision is favorable to the participating CAP physician, then the participating CAP physician may resume his or her participation in CAP. The hearing officer and the CMS official may review decisions that are favorable or unfavorable to the participating CAP physician.

(ii) The CMS official may accept, reject, or modify the hearing officer's findings.

(iii) If the CMS official reviews the hearing officer's decision, the CMS official issues a final reconsideration determination to the participating CAP physician on the basis of the hearing officer's findings and recommendations and other relevant information.

(iv) The reconsideration determination of the CMS official is final. If the final decision is unfavorable to the participating CAP physician, then the participating CAP physician's CAP election agreement is terminated.

(d) The approved CAP vendor may not charge the beneficiary for the full drug coinsurance amount if the designated contractor did not pay the approved CAP vendor in full, unless a properly executed advance beneficiary notice is in place. When a beneficiary receives an inappropriate coinsurance bill, the beneficiary may participate in the approved CAP vendor's grievance process to request correction of the approved CAP vendor's file. If the beneficiary is dissatisfied with the result of the approved CAP vendor's grievance process, the beneficiary may request intervention from the designated carrier. This is in addition to, rather than in place of, any other beneficiary appeal rights. The designated carrier will first investigate the facts and then facilitate correction to the appropriate claim record and beneficiary file.

■ 13. Add § 414.917 to read as follows:

§ 414.917 Dispute resolution and process for suspension or termination of approved CAP contract.

(a) *General rule.* If a participating CAP physician finds an approved CAP vendor's service, or the quality of a CAP drug supplied by the approved CAP vendor to be unsatisfactory, then the physician may address the issue first through the approved CAP vendor's grievance process, and second through an alternative dispute resolution process administered by the designated carrier and CMS. If CMS suspends an approved CAP vendor's CAP contract for noncompliance or terminates the CAP contract in accordance with § 414.914(a), the approved CAP vendor may request a reconsideration in accordance with paragraph (c) of this section.

(b) *Dispute resolution.* (1) When a participating CAP physician is dissatisfied with an approved CAP vendor's service or the quality of a CAP drug supplied by the approved CAP vendor, then the participating CAP physician may use the approved CAP vendor's grievance process. If the service or quality issues are not resolved through the grievance process to the physician's satisfaction, then the participating CAP physician may ask the designated carrier to—

(i) Review the approved CAP vendor's performance; and

(ii) Potentially recommend termination of the approved CAP vendor's CAP contract.

(2) *Responsibility of the designated carrier.* The designated carrier—

(i) Gathers information from the local carrier, the participating CAP physician, the beneficiary, and the approved CAP vendor; and

(ii) Makes a recommendation to CMS on whether the approved CAP vendor has been meeting the service and quality obligations of its CAP contract. This recommendation will include numbered findings of fact.

(3) CMS will review the recommendation of the designated carrier and, gather relevant additional information from the approved CAP vendor, the participating CAP physician, the local carrier, and the beneficiary before deciding whether to terminate the approved CAP vendor's CAP contract.

(4) The approved CAP vendor may appeal that termination by requesting a reconsideration. A determination must be made as to whether the approved CAP vendor has been meeting the service and quality obligations of its CAP contract.

(c) *Reconsideration.* (1) *Right to reconsideration.* An approved CAP

vendor dissatisfied with a determination that its CAP contract has been suspended or terminated by CMS is entitled to a reconsideration as provided in this subpart.

(2) *Eligibility for reconsideration.* CMS will reconsider any determination to suspend or terminate an approved CAP vendor's contract if the approved CAP vendor files a written request for reconsideration in accordance with paragraphs (c)(3) and (c)(4) of this section.

(3) *Manner and timing of request for reconsideration.* An approved CAP vendor that is dissatisfied with a CMS decision to suspend or terminate its CAP contract may request a reconsideration of the decision by filing a request with CMS. The request must be filed within 30 days of receipt of the CMS decision letter notifying the approved CAP vendor of the suspension or termination of its CAP contract.

(4) *Content of request.* The request for reconsideration must specify—

(i) The findings or issues with which the approved CAP vendor disagrees;

(ii) The reasons for the disagreement;

(iii) A recital of the facts and law supporting the approved CAP vendor's position;

(iv) Any supporting documentation; and

(v) Any supporting statements from participating CAP physicians, the local carrier, or beneficiaries.

(5) *Withdrawal of request for reconsideration.* An approved CAP vendor may withdraw its request for reconsideration at any time before the issuance of a reconsideration determination.

(6) *Discretionary informal hearing.* In response to a request for reconsideration, CMS may, at its discretion, provide the approved CAP vendor the opportunity for an informal hearing that—

(i) Is conducted by a hearing officer appointed by the Director of the CMS Center for Medicare Management or his or her designee; and

(ii) Provides the approved CAP vendor the opportunity to present, by telephone or in person, evidence to rebut CMS' decision to suspend or terminate the approved CAP vendor's CAP contract.

(7) *Informal hearing procedures.* (i) CMS will provide written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The informal reconsideration hearing will be conducted in accordance with the following procedures:

(A) The hearing is open to CMS and the approved CAP vendor requesting the reconsideration, including—

(*1*) Authorized representatives;

(*2*) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts);

(*3*) Representatives from the local carriers and the designated carrier;

(*4*) The participating CAP physician who requested the suspension, if any; and

(*5*) Legal counsel.

(B) The hearing will be conducted by the hearing officer, who will receive relevant testimony;

(C) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissible under the rules of evidence applied in Federal courts;

(D) Either party may call witnesses from among those individuals specified in the paragraph (c)(7)(ii)(A) of this section; and

(E) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(8) *Hearing officer's findings.* (i) Within 30 days of the hearing officer's receipt of the hearing request, the hearing officer will present the findings and recommendations to the approved CAP vendor that requested the reconsideration. If the hearing officer conducts a hearing in person or by phone, the hearing officer will send a hearing notice to the approved CAP vendor within 10 days of receipt of the hearing request, and the findings and recommendations are due to the approved CAP vendor within 30 days from of the hearing's conclusion.

(ii) The written report of the hearing officer will include separate numbered findings of fact and the legal conclusions of the hearing officer.

(9) *Final reconsideration determination.* (i) The hearing officer's decision is final unless the Director of the CMS Center for Medicare Management or his or her designee (CMS official) chooses to review that decision within 30 days. If the decision is favorable to the approved CAP vendor, then the approved CAP vendor may resume participation in CAP. The hearing officer and the CMS official may review decisions that are favorable or unfavorable to the approved CAP vendor.

(ii) The CMS official may accept, reject, or modify the hearing officer's findings.

(iii) If the CMS official reviews the hearing officer's decision, the CMS official will issue a final reconsideration determination to the approved CAP vendor on the basis of the hearing officer's findings and recommendations and other relevant information.

(iv) The reconsideration determination of the CMS official is final.

■ 14. Add § 414.918 to read as follows:

§ 414.918 Assignment.

Payment for a CAP drug may be made only on an assignment-related basis.

■ 15. Add § 414.920 to read as follows:

§ 414.920 Judicial review.

The following areas under the CAP are not subject to administrative or judicial review:

(a) The establishment of payment amounts.

(b) The awarding of vendor contracts.

(c) The establishment of competitive acquisition areas.

(d) The selection of CAP drugs.

(e) The bidding structure.

(f) The number of vendors selected.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 9, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: June 23, 2005.

Michael O. Leavitt,

Secretary.

ADDENDUM A.—SINGLE DRUG CATEGORY LIST

HCPCS	Long description
J0150	INJECTION, ADENOSINE FOR THERAPEUTIC USE, 6 MG.
J0152	INJECTION, ADENOSINE FOR DIAGNOSTIC USE, 30 MG.
J0170	INJECTION, ADRENALIN, EPINEPHRINE, 1 ML AMPULE.
J0207	INJECTION, AMIFOSTINE, 500 MG.
J0215	INJECTION, ALEFACEPT, 0.5 MG.
J0280	INJECTION, AMINOPHYLLIN, 250 MG.

ADDENDUM A.—SINGLE DRUG CATEGORY LIST—Continued

HCPCS	Long description
J0290	INJECTION, AMPICILLIN SODIUM, 500 MG.
J0475	INJECTION, BACLOFEN, 10 MG.
J0540	INJECTION, PENICILLIN G BENZATHINE AND PENICILLIN G PROCAINE, 1,200,000 UNITS.
J0550	INJECTION, PENICILLIN G BENZATHINE AND PENICILLIN G PROCAINE, 2,400,000 UNITS.
J0570	INJECTION, PENICILLIN G BENZATHINE, 1,200,000 UNITS.
J0585	BOTULINUM TOXIN TYPE A, PER UNIT.
J0587	BOTULINUM TOXIN TYPE B, PER 100 UNITS.
J0600	INJECTION, EDETATE CALCIUM DISODIUM, 1000 MG.
J0637	INJECTION, CASPOFUNGIN ACETATE, 5 MG.
J0640	INJECTION, LEUCOVORIN CALCIUM, PER 50 MG.
J0670	INJECTION, MEPIVACAINE HYDROCHLORIDE, PER 10 ML.
J0690	INJECTION, CEFAZOLIN SODIUM, 500 MG.
J0692	INJECTION, CEFEPIME HYDROCHLORIDE, 500 MG.
J0696	INJECTION, CEFTRIAXONE SODIUM, PER 250 MG.
J0698	INJECTION, CEFOTAXIME SODIUM, PER GM.
J0702	INJECTION, BETAMETHASONE ACETATE & BETAMETHASONE SODIUM PHOSPHATE, PER 3 MG.
J0704	INJECTION, BETAMETHASONE SODIUM PHOSPHATE, PER 4 MG.
J0735	INJECTION, CLONIDINE HYDROCHLORIDE, 1 MG.
J0800	INJECTION, CORTICOTROPIN, 40 UNITS.
J0880	INJECTION, DARBEPOETIN ALFA, 5 MCG.
J0895	INJECTION, DEFEROXAMINE MESYLATE, 500 MG.
J1000	INJECTION, DEPO-ESTRADIOL CYPIONATE, 5 MG.
J1020	INJECTION, METHYLPREDNISOLONE ACETATE, 20 MG.
J1030	INJECTION, METHYLPREDNISOLONE ACETATE, 40 MG.
J1040	INJECTION, METHYLPREDNISOLONE ACETATE, 80 MG.
J1051	INJECTION, MEDROXYPROGESTERONE ACETATE, 50 MG.
J1094	INJECTION, DEXAMETHASONE ACETATE, 1 MG.
J1100	INJECTION, DEXAMETHASONE SODIUM PHOSPHATE, 1MG.
J1190	INJECTION, DEXRAZOXANE HYDROCHLORIDE, PER 250 MG.
J1200	INJECTION, DIPHENHYDRAMINE HCL, 50 MG.
J1212	INJECTION, DMSO, DIMETHYL SULFOXIDE, 50%, 50 ML.
J1245	INJECTION, DIPYRIDAMOLE, PER 10 MG.
J1250	INJECTION, DOBUTAMINE HYDROCHLORIDE, PER 250 MG.
J1260	INJECTION, DOLASETRON MESYLATE, 10 MG.
J1335	INJECTION, ERTAPENEM SODIUM, 500 MG.
J1440	INJECTION, FILGRASTIM (G-CSF), 300 MCG.
J1441	INJECTION, FILGRASTIM (G-CSF), 480 MCG.
J1450	INJECTION, FLUCONAZOLE, 200 MG.
J1580	INJECTION, GARAMYCIN, GENTAMICIN, 80 MG.
J1600	INJECTION, GOLD SODIUM THIOMALATE, 50 MG.
J1626	INJECTION, GRANISETRON HYDROCHLORIDE, 100 MCG.
J1631	INJECTION, HALOPERIDOL DECANOATE, PER 50 MG.
J1642	INJECTION, HEPARIN SODIUM, (HEPARIN LOCK FLUSH), PER 10 UNITS.
J1644	INJECTION, HEPARIN SODIUM, PER 1000 UNITS.
J1645	INJECTION, DALTEPARIN SODIUM, PER 2500 IU.
J1650	INJECTION, ENOXAPARIN SODIUM, 10 MG.
J1655	INJECTION, TINZAPARIN SODIUM, 1000 IU.
J1710	INJECTION, HYDROCORTISONE SODIUM PHOSPHATE, 50 MG.
J1720	INJECTION, HYDROCORTISONE SODIUM SUCCINATE, 100 MG.
J1745	INJECTION, INFLIXIMAB, 10 MG.
J1750	INJECTION, IRON DEXTRAN, 50 MG.
J1756	INJECTION, IRON SUCROSE, 1 MG.
J1885	INJECTION, KETOROLAC TROMETHAMI.NE, PER 15 MG.
J1940	INJECTION, FUROSEMIDE, 20 MG.
J1956	INJECTION, LEVOFLOXACIN, 250 MG.
J2001	INJECTION, LIDOCAINE HCL FOR INTRAVENOUS INFUSION, 10 MG.
J2010	INJECTION, LINCOMYCIN HCL, 300 MG.
J2150	INJECTION, MANNITOL, 25% IN 50 ML.
J2260	INJECTION, MILRINONE LACTATE, 5 MG.
J2300	INJECTION, NALBUPHINE HYDROCHLORIDE, PER 10 MG.
J2324	INJECTION, NESIRITIDE, 0.25 MG.
J2353	INJECTION, OCTREOTIDE, DEPOT FORM FOR INTRAMUSCULAR INJECTION, 1 MG.
J2354	INJECTION, OCTREOTIDE, NON-DEPOT SUBCUTANEOUS OR INTRAVENOUS INJECTION, 25 MCG.
J2405	INJECTION, ONDANSETRON HYDROCHLORIDE, PER 1 MG.
J2430	INJECTION, PAMIDRONATE DISODIUM, PER 30 MG.
J2505	INJECTION, PEGFILGRASTIM, 6 MG.
J2550	INJECTION, PROMETHAZINE HCL, 50 MG.
J2680	INJECTION, FLUPHENAZINE DECANOATE, 25 MG.
J2765	INJECTION, METOCLOPRAMIDE HCL, 10 MG.
J2780	INJECTION, RANITIDINE HYDROCHLORIDE, 25 MG.
J2820	INJECTION, SARGRAMOSTIM (GM-CSF), 50 MCG.
J2912	INJECTION, SODIUM CHLORIDE, 0.9%, PER 2 ML.

ADDENDUM A.—SINGLE DRUG CATEGORY LIST—Continued

HCPCS	Long description
J2916	INJECTION, SODIUM FERRIC GLUCONATE COMPLEX IN SUCROSE INJECTION, 12.5 MG.
J2920	INJECTION, METHYLPREDNISOLONE SODIUM SUCCINATE, 40 MG.
J2930	INJECTION, METHYLPREDNISOLONE SODIUM SUCCINATE, 125 MG.
J2997	INJECTION, ALTEPLASE RECOMBINANT, 1 MG.
J3260	INJECTION, TOBRAMYCIN SULFATE, 80 MG.
J3301	INJECTION, TRIAMCINOLONE ACETONIDE, PER 10 MG.
J3302	INJECTION, TRIAMCINOLONE DIACETATE, PER 5 MG.
J3303	INJECTION, TRIAMCINOLONE HEXACETONIDE, PER 5 MG.
J3315	INJECTION, TRIPTORELIN PAMOATE, 3.75 MG.
J3370	INJECTION, VANCOMYCIN HCL, 500 MG.
J3396	INJECTION, VERTEPORFIN, 0.1 MG.
J3410	INJECTION, HYDROXYZINE HCL, 25 MG.
J3420	INJECTION, VITAMIN B–12 CYANOCOBALAMIN, UP TO 1000 MCG.
J3475	INJECTION, MAGNESIUM SULFATE, PER 500 MG.
J3480	INJECTION, POTASSIUM CHLORIDE, PER 2 MEQ.
J3487	INJECTION, ZOLEDRONIC ACID, 1 MG.
J7030	INFUSION, NORMAL SALINE SOLUTION, 1000 CC.
J7040	INFUSION, NORMAL SALINE SOLUTION, STERILE (500 ML=1 UNIT).
J7042	5% DEXTROSE/NORMAL SALINE (500 ML = 1 UNIT).
J7050	INFUSION, NORMAL SALINE SOLUTION , 250 CC.
J7051	STERILE SALINE OR WATER, 5 CC.
J7060	5% DEXTROSE/WATER (500 ML = 1 UNIT).
J7070	INFUSION, D5W, 1000 CC.
J7120	RINGERS LACTATE INFUSION, 1000 CC.
J7317	SODIUM HYALURONATE, PER 20 TO 25 MG DOSE FOR INTRA-ARTICULAR INJECTION.
J7320	HYLAN G-F 20, 16 MG, FOR INTRA ARTICULAR INJECTION.
J9000	DOXORUBICIN HCL, 10 MG.
J9001	DOXORUBICIN HYDROCHLORIDE, ALL LIPID FORMULATIONS, 10 MG.
J9031	BCG (INTRAVESICAL) PER INSTILLATION.
J9040	BLEOMYCIN SULFATE, 15 UNITS.
J9045	CARBOPLATIN, 50 MG.
J9050	CARMUSTINE, 100 MG.
J9060	CISPLATIN, POWDER OR S0LUTION, PER 10 MG.
J9062	CISPLATIN, 50 MG.
J9065	INJECTION, CLADRIBINE, PER 1 MG.
J9070	CYCLOPHOSPHAMIDE, 100 MG.
J9080	CYCLOPHOSPHAMIDE, 200 MG.
J9090	CYCLOPHOSPHAMIDE, 500 MG.
J9091	CYCLOPHOSPHAMIDE, 1.0 GRAM.
J9092	CYCLOPHOSPHAMIDE, 2.0 GRAM.
J9093	CYCLOPHOSPHAMIDE, LYOPHILIZED, 100 MG.
J9094	CYCLOPHOSPHAMIDE, LYOPHILIZED, 200 MG.
J9095	CYCLOPHOSPHAMIDE, LYOPHILIZED, 500 MG.
J9096	CYCLOPHOSPHAMIDE, LYOPHILIZED, 1.0 GRAM.
J9097	CYCLOPHOSPHAMIDE, LYOPHILIZED, 2.0 GRAM.
J9098	CYTARABINE LIPOSOME, 10 MG.
J9100	CYTARABINE, 100 MG.
J9110	CYTARABINE, 500 MG.
J9130	DACARBAZINE, 100 MG.
J9140	DACARBAZINE, 200 MG.
J9150	DAUNORUBICIN, 10 MG.
J9170	DOCETAXEL, 20 MG.
J9178	INJECTION, EPIRUBICIN HCL, 2 MG.
J9181	ETOPOSIDE, 10 MG.
J9182	ETOPOSIDE, 100 MG.
J9185	FLUDARABINE PHOSPHATE, 50 MG.
J9190	FLUOROURACIL, 500 MG.
J9200	FLOXURIDINE, 500 MG.
J9201	GEMCITABINE HCL, 200 MG.
J9202	GOSERELIN ACETATE IMPLANT, PER 3.6 MG.
J9206	IRINOTECAN, 20 MG.
J9208	IFOSFAMIDE, 1 GM.
J9209	MESNA, 200 MG.
J9211	IDARUBICIN HYDROCHLORIDE, 5 MG.
J9213	INTERFERON, ALFA–2A, RECOMBINANT, 3 MILLION UNITS.
J9214	INTERFERON, ALFA–2B, RECOMBINANT, 1 MILLION UNITS.
J9219	LEUPROLIDE ACETATE IMPLANT, 65 MG.
J9245	INJECTION, MELPHALAN HYDROCHLORIDE, 50 MG.
J9250	METHOTREXATE SODIUM, 5 MG .
J9260	METHOTREXATE SODIUM, 50 MG.
J9263	INJECTION, OXALIPLATIN, 0.5 MG.
J9265	PACLITAXEL, 30 MG.

ADDENDUM A.—SINGLE DRUG CATEGORY LIST—Continued

HCPCS	Long description
J9268	PENTOSTATIN, PER 10 MG.
J9280	MITOMYCIN, 5 MG.
J9290	MITOMYCIN, 20 MG.
J9291	MITOMYCIN, 40 MG.
J9293	INJECTION, MITOXANTRONE HYDROCHLORIDE, PER 5 MG.
J9310	RITUXIMAB, 100 MG.
J9320	STREPTOZOCIN, 1 GM.
J9340	THIOTEPA, 15 MG .
J9350	TOPOTECAN, 4 MG.
J9355	TRASTUZUMAB, 10 MG.
J9360	VINBLASTINE SULFATE, 1 MG.
J9370	VINCRISTINE SULFATE, 1 MG.
J9375	VINCRISTINE SULFATE, 2 MG.
J9390	VINORELBINE TARTRATE, PER 10 MG.
J9395	INJECTION, FULVESTRANT, 25 MG.
J9600	PORFIMER SODIUM, 75 MG.
Q0136	INJECTION, EPOETIN ALPHA, (FOR NON ESRD USE), PER 1000 UNITS.
Q0137	INJECTION, DARBEPOETIN ALFA, 1 MCG (NON-ESRD USE).
Q3025	INJECTION, INTERFERON BETA–1A, 11 MCG FOR INTRAMUSCULAR USE.

ADDENDUM B.—NEW DRUGS FOR CAP BIDDING FOR 2006

Code	2005 Description
J0128	Abarelix injection.
J0180	Agalsidase beta injection.
J0878	Daptomycin injection.
J1931	Laronidase injection.
J2357	Omalizumab injection.
J2469	Palonosetron HCl.
J2794	Risperidone, long acting.
J7518	Mycophenolic acid.
J9035	Bevacizumab injection.
J9041	Bortezomib injection.
J9055	Cetuximab injection.
J9305	Pemetrexed injection.

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