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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–1325–P]

RIN 0938–AN58

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement 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. We are seeking comments on which of the proposed approaches we should use to implement the competitive acquisition program as well as the criteria and standards that should be applied in the selection and enrollment of vendors.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on April 26, 2005.

ADDRESSES: In commenting, please refer to file code CMS–1325–P. 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–P, P.O. Box 8010, Baltimore, MD 21244–8010.

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 Praela, (410) 786–6508.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–1325–P 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. CMS posts all electronic comments received before the close of the comment period on its public website 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 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.

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

Alphabetical List of Acronyms Appearing in the Proposed Rule

ASP—Average sales price.

AWP—Average wholesale price.
 BBA—Balanced Budget Act of 1997, Public Law 105–33.
 CAP—Competitive Acquisition Program.
 CFR—Code of Federal Regulations.
 CMS—Centers for Medicare & Medicaid Services (formerly Health Care Financing Administration).
 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.
 OPPTS—Outpatient prospective payment system.
 PIN—Provider identification number.
 PSCs—Program Safeguard Contractors.
 RFA—Regulatory Flexibility Act (September 19, 1980, Public Law 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 proposed rule, 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

These are injectable or intravenous drugs that are administered incident to a physician’s service (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 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 coverage to drugs that are not usually self-administered. Examples include injectable prostate cancer drugs (such as lupron acetate for depot suspension, goserelin acetate implant), 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 used to treat rheumatoid arthritis, and rituximab used to treat non-Hodgkin’s lymphoma.

2. Durable Medical Equipment (DME) Drugs

These are drugs that 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 drug payment methodology for all or some of the Medicare covered drugs they furnish include: physicians, 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 proposed 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. History of the Current Payment System

In the June 5, 1991 physician fee schedule proposed rule (56 FR 25792), we proposed that the drug payment limit be based on 85 percent of the national average wholesale price (AWP) of the drug. For very high volume drugs, we proposed that the drug payment limits be based on the lesser of the 85 percent of the AWP or the estimated acquisition cost (EAC) of the drugs. Based on comments received, the 1992 physician fee schedule final rule established a payment limit based on the lower of 100 percent of AWP or the EAC. However, the EAC proved to be unworkable and was never implemented. Various legislative proposals were submitted to move away from payment based on 100 percent of AWP, including changing the percentage of AWP to a lower amount. In 1997, the Congress amended the Act to limit payment for drugs not paid on a cost or prospective payment basis to the lower of the actual charge or 95 percent of AWP (section 1842(o)(1) of the Act as added by section 4556 of the Balanced Budget Act of 1997 (BBA 1997) (Pub. L. 105–33)).

Numerous reports by the General Accounting Office (GAO), and the Office of Inspector General (OIG), as well as data collected by the Department of Justice (DOJ), indicated that 95 percent of list AWP reflected in published compendia is significantly higher than the prices that drug manufacturers, wholesalers, physician supply houses, specialty pharmacies, and similar entities actually charge to physicians and other suppliers purchasing these drugs.

C. Revised Drug Payment Methodology

Based on these numerous reports conducted by the OIG and the GAO as well as the data collected by the DOJ

that identified the well-documented flaws in the AWP drug payment system, significant changes were made to the manner in which Medicare Part B pays for covered drugs.

The MMA revised the drug payment methodology 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.

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 all the manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter (excluding certain sales exempted by statute) and the total number of units of the drug sold by the manufacturer in that same quarter, 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.

D. 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 competitively biddable Part B covered drugs under the ASP drug payment methodology. 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 proposed rule.

The competitive acquisition program 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 and that drug coinsurance can represent large amounts for a beneficiary and physician. The competitive acquisition program eliminates the need for physicians to collect coinsurance on CAP drugs from Medicare beneficiaries.

II. Provisions of the Proposed Rule

A. Policy for the CAP

1. General Overview of the CAP

[If you choose to comment on issues in this section, please include the caption "Overview of the CAP" at the beginning of your comments.]

Implementation

To implement the CAP, we need to complete a number of activities prior to 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 and described elsewhere in this proposed rule.

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".

Activities Prior to the Issuance of This Proposed Rule

Subsequent to the enactment of the MMA, we initiated the following activities to enable us to implement the statutory provisions of section 1847B of the Act:

—We awarded a contract to Research Triangle Institute (RTI) to obtain information and develop alternatives regarding the implementation of a drug and biological competitive bidding program. As part of this contract, RTI consulted with groups representing beneficiaries, physicians and suppliers, drug suppliers, and drug manufacturers to obtain input on the implementation of this MMA provision.

—We conducted a Special Open Door Listening Session on April 1, 2004, to gather additional input, and to allow interested parties to hear and be heard by other members of the healthcare industry.

—We established an electronic mailbox, MMA303DDrugBid@cms.hhs.gov, for interested parties to submit comments on the CAP program prior to the issuance of this proposed rule.

—We issued a Request for Information (RFI) on December 13, 2004. The purpose of this RFI was to assess the public's interest in bidding on contracts to supply drugs and biologicals for the CAP. In reply to the RFI, we received 15 responses expressing an interest to participate in the CAP. Most responders indicated a willingness to provide selected Part B drugs on a national basis. Responders also provided information regarding the types of drugs they would be most interested in providing within the selected jurisdictions. Four responders indicated a willingness to provide nearly all the drugs listed on the RFI.

In the specialty areas of oncology, hematology, internal medicine, infectious disease, urology, rheumatology, and obstetrics/gynecology, several responders indicated a willingness to provide the most costly and the most frequently used drugs in these areas. In addition, some responders indicated an interest in providing drugs or biologicals in the areas of oncology, hematology, pulmonary, and neurology.

Regulations

We propose to codify the requirements and provisions for the CAP in regulations at 42 CFR Part 414, Subpart K. We propose to revise the heading for subpart K to read "Payment for Drugs and Biologicals under Part B". We also propose to 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 are proposing to revise existing § 414.900, which sets forth the basis and scope for subpart K, to provide that the regulations in this subpart implement sections 1847A and 1847B of the Act. In the examples of drugs at § 414.900, we propose to revise paragraph (b)(ii) to clarify that the hepatitis vaccine referred to in this paragraph is the hepatitis "B" vaccine. Under this subpart, we propose to add new § 414.906 through § 414.920 to address requirements with respect to payment under the CAP. We also are revising § 414.902 to add definitions pertaining to the new CAP addressed in new § 414.906 through § 414.920.

2. Categories of Drugs To Be Included Under the CAP

[If you choose to comment on issues in this section, please include the caption "Categories of Drugs to be Included under the CAP" at the beginning of your comments.]

Section 1847B of the Act describes a program that will permit physicians to elect to obtain drugs from contractors 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, the mechanisms described in the statute include the following:

- 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 section 1847B 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 vendor 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 submission of information that will be used by the vendor 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 vendors.

- 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 such drugs and biologicals—

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

(2) Is likely to have an adverse impact on access to such 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." 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 in the CAP 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. There may be an alternative reading of the statute, under which the CAP is properly restricted to drugs administered incident to a

physician's service. We welcome comments on this issue.

Using our authority to establish drug categories and to phase in the CAP as appropriate, we could include in the CAP all drugs administered by physicians, or, for an initial period, only drugs that are usually administered by one or more physician specialties (for example, oncology or rheumatology). The CAP could be phased in with respect to categories of drugs in any number of ways. A phase-in could, for example, begin with drugs that are usually administered by oncologists, and later be extended to include all drugs administered by physicians. Given our concerns about the clear direction of the statute that the election to participate in this program rests with physicians, 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 recognize that the statute provides a potentially broader definition of "competitively biddable drugs and biologicals" in section 1847B(a)(2)(A) of the Act. Therefore, we are soliciting 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.

We propose to set forth the definition for "competitively biddable drugs" and other terms relevant to the CAP in regulations under revised § 414.902.

Below we discuss the merits of these options for the drug categories to be included within the CAP. We also discuss our proposed approach to phasing in the program with respect to drug categories. We invite comments on all these options and on all aspects of our proposal. We welcome alternative suggestions for our consideration for the final rule.

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, inclusion of all drugs furnished incident to a physician's service would be important to provide an alternative to physicians who did not want to be in the drug purchasing business and did not want to have to collect coinsurance on drugs. It may also provide more opportunity for realizing savings to the program than some other options.

Phasing in CAP Drugs by Physician Specialty

As we have discussed above, it may be advisable 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. In fact, drugs that are typically furnished incident to an oncologist's service represent the largest portion of expenditures for physician-administered drugs under Medicare, followed by drugs typically furnished incident to a urologist's service, a rheumatologist's service, a gynecologist's service, an infectious disease specialist's service, and a primary care physician's service. Drugs typically administered by other physician specialties represent smaller portions of physician-administered drugs. We therefore believe that the basic phase-in decision with respect to drugs administered in physician offices is 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. We discuss each of these options below.

Begin with Drugs Used by a Single Physician Specialty: Oncology

Under this approach, we would initially implement the CAP for a limited set of drugs that are typically administered by oncologists. Drugs typically administered by other specialties would be included over the next few years of the program.

The advantage of this approach is that during the phase-in we could focus our implementation efforts on one specialty with a more homogeneous set of concerns and issues. Also, by limiting the target drugs to those typically administered by oncologists, the required physician education process would be streamlined and potentially more effective. In addition, oncologists use a high proportion of the physician-administered drugs that could be included under the CAP. By initiating a phase-in with drugs that are typically administered by oncologists, we could thus begin to realize much of the benefit that is possible under the CAP. Therefore, we believe that it would be reasonable to include drugs typically

administered by oncologists in the early stages of implementing the CAP.

A potential disadvantage of singling out drugs typically administered by one physician specialty for the initial stages of phasing in the CAP is that the scope of the CAP in the early years may be too narrow for us to effectively identify issues or concerns for specialties that typically administer drugs not initially included. In addition, the CAP would not initially provide an alternative for physicians in other specialties. We welcome comments from oncologists and others about the merits of beginning the phase-in of the CAP with drugs typically administered by oncologists.

Begin with Specialties That Use Fewer Part B-Covered Drugs

An alternative phase-in approach would be to choose a limited set of drugs that are typically administered by one or more physician specialties that use Part B-drugs less intensively. Focusing on Part B drugs typically administered by physicians in these specialties would limit the scope of the initial implementation, and allow operational issues to be addressed more gradually. This more limited scope would allow us to identify lessons and issues before phasing in larger drug classes (such as drugs typically administered by oncologists) at a later time. The disadvantage of this approach, however, is that such a limited scope may also restrict the potential benefits of the CAP, especially potential savings to the Medicare program and potential benefits to physicians in other specialties who do not want to be in the drug procurement and drug coinsurance collection business and who would prefer to obtain drugs that they typically administer under the CAP. The restricted scope of this approach might not elicit a response from potential bidders if they believe that the potential market is too limited.

In light of these considerations, we are considering several alternative approaches to phasing in the CAP with respect to drug categories. One alternative would be to phase in the CAP by initially including all drugs typically administered by oncologists within the program. We would begin with drugs typically administered by oncologists primarily because these drugs constitute such a major portion of the physician-administered drugs under Part B. Another option is to begin with some set of the drugs that are typically administered in physician offices by other specialties (for example, drugs typically administered by urologists). This option would mean that implementation of the CAP would have

a more limited impact initially on the provision and payment for Part B drugs than beginning with drugs typically administered by oncologists or with all Part B drugs furnished incident to a physician's service. A final option is to implement the CAP for all Part B drugs that are furnished incident to a physician's service. We are not considering categories smaller than drugs typically administered by a physician specialty. For the oncology option, for example, we are not considering to include only the top three oncology drugs. All drugs typically administered by oncologists would be included under this option.

We are actively considering all these options, but we are not proposing any particular option at this time. Rather, we encourage comments on all the options that we have discussed. We also welcome recommendations of other options for consideration, and will also consider other options presented by commenters for adoption in the final rule. We especially encourage 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. For example, physicians may prefer relatively broad drug categories that encompass all the drugs that they commonly furnish, which presumably would allow those physicians to largely avoid purchasing drugs for their Medicare patients. Under this proposed approach one category of drugs might be all the drugs commonly furnished incident to an oncologist's (or other specialist's) service. Other narrower ways of structuring the categories are also possible. After further analysis and consideration of the comments, we may adopt one of the options described above, or an option brought to our attention through the comment process, in the final rule.

It is important to note 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.

It is also important to note that the categories that are established for

physicians to select will be the same categories that would be open for bids by potential vendors. For example, if a category embracing all drugs typically administered by oncologists is established, vendors would bid on all

the HCPCS codes contained in the category and an oncologist who elects to participate in the CAP would be electing to acquire that category from the vendor. 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 vendor. Table 1 below illustrates a potential category.

TABLE 1.—MOST COMMONLY USED HCPCS BY ONCOLOGISTS DEFINED BY SPECIALTY CODE 90

[Using 2003 Medicare Claims Data, Allowed Services Greater Than 100 and Allowed Charges (Adjusted for 2005) Greater Than \$10,000]

HCPC	Description	HCPC	Description
J0207	Amifostine.	J9040	Bleomycin sulfate injection.
J0637	Caspofungin acetate.	J9045	Carboplatin injection.
J0640	Leucovorin calcium injection.	J9050	Carmus bischl nitro inj.
J0696	Ceftriaxone sodium injection.	J9060	Cisplatin 10 mg injection.
J0800	Corticotropin injection.	J9062	Cisplatin 50 mg injection.
J0880	Darbepoetin alfa injection.	J9065	Inj cladribine per 1 mg.
J0895	Deferoxamine mesylate inj.	J9090	Cyclophosphamide 500 mg inj.
J1190	Dexrazoxane HCl injection.	J9096	Cyclophosphamide lyophilized.
J1260	Dolasetron mesylate.	J9160	Denileukin diftitox, 300 mcg.
J1440	Filgrastim 300 mcg injection.	J9170	Docetaxel.
J1441	Filgrastim 480 mcg injection.	J9178	Inj, epirubicin hcl, 2 mg.
J1450	Fluconazole.	J9181	Etoposide 10 mg inj.
J1626	Granisetron HCl injection.	J9182	Etoposide 100 mg inj.
J1642	Inj heparin sodium per 10 u.	J9185	Fludarabine phosphate inj.
J1645	Dalteparin sodium.	J9190	Fluorouracil injection.
J1650	Inj enoxaparin sodium.	J9201	Gemcitabine HCl.
J1655	Tinzaparin sodium injection.	J9202	Goserelin acetate implant.
J1745	Infliximab injection.	J9206	Irinotecan injection.
J1750	Iron dextran.	J9208	Ifosfomide injection.
J1756	Iron sucrose injection.	J9209	Mesna injection.
J2353	Octreotide injection, depot.	J9213	Interferon alfa-2a inj.
J2355	Oprelvekin injection.	J9214	Interferon alfa-2b inj.
J2405	Ondansetron hcl injection.	J3305	Inj trimetrexate glucuronate.
J2430	Pamidronate disodium/30 mg.	J9217	Leuprolide acetate suspension.
J2505	Injection, pegfilgrastim 6 mg.	J9265	Paclitaxel injection.
J2820	Sargramostim injection.	J9280	Mitomycin 5 mg inj.
J2997	Alteplase recombinant.	J9293	Mitoxantrone hydrochl/5 mg.
J3370	Vancomycin hcl injection.	J9310	Rituximab cancer treatment.
J3487	Zoledronic acid.	J9340	Thiotepa injection.
J9000	Doxorubic hcl 10 mg vl chemo.	J9350	Topotecan.
J9001	Doxorubicin hcl liposome inj.	J9355	Trastuzumab.
J9010	Alemtuzumab injection.	J9390	Vinorelbine tartrate/10 mg.
J9015	Aldesleukin/single use vial.	Q0136	Non esrd epoetin alpha inj.
J9017	Arsenic trioxide.	Q3025	IM inj interferon beta 1-a.
J9031	Bcg live intravesical vac.		

In addition, it is important to keep in mind that HCPCS codes 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.

As discussed in proposed § 414.908(d), we are proposing 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 are also proposing that

vendors will 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. In addition, we are proposing that this information will 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. We anticipate that the first physician election process will occur in the fall of 2005.

Finally, we would like to emphasize that, in framing these options, we are relying 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. We do 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. At this time, we have made no findings that including certain drugs in the CAP would not result in significant savings or would have an adverse impact on access to those drugs. We propose to set forth the circumstances for which we may exclude competitively biddable drugs and biologicals (including categories of

drugs) from the CAP at proposed § 414.906(b) of our regulations.

3. Competitive Acquisition Areas

Definition of Competitive Acquisition Areas

(If you choose to comment on issues in this section, please include the caption "Competitive Acquisitions Areas" at the beginning of your comments.)

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 and biological 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. The definition of these areas will therefore 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. At the same time, the statute grants the Secretary broad discretion in defining competitive acquisition areas under the CAP. We believe that several factors must be considered in defining competitive acquisition areas for competitively biddable drugs and biologicals. In particular, the designation of competitive acquisition areas are to take into account how promptly physicians need drugs provided to their practices if distribution capacity varies geographically. In addition, 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. Below we discuss several options for defining "competitive acquisition areas" for purposes of the CAP. Each of these definitions could be adopted initially in a manner that allows for the program to be phased in geographically. For example, defining "competitive acquisition areas" in terms of regions or in terms of States is compatible with phasing in the program by implementing it initially in one or more, but not all, regions or States. Under this phase-in plan, the program would eventually be expanded to all regions or States. Conversely, 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 this 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.

We have identified several basic options for defining the competitive acquisition areas required under the CAP. The basic options for defining these areas include—establishing a national competitive acquisition area; establishing regional competitive acquisition areas; and establishing statewide competitive acquisition areas.

We invite comment on these possible approaches.

National Competitive Acquisition Area

Under this option, the competitive acquisition program would require participating vendors to offer competitively biddable drugs and biologicals to physicians in any State within the United States, as well as the District of Columbia, Puerto Rico, and the U.S. territories. In other words, there would be only a single national competitive acquisition area. Bidders that seek to compete in a national competitive acquisition area would need a national network of distribution points that could serve physicians in a timely manner with products that are properly stored and shipped. In addition, drug vendors would need to be appropriately licensed in all 50 States, the District of Columbia, Puerto Rico, and the U.S. territories in order to comply with FDA rules.

Establishing a single national competitive acquisition area may have several advantages. First, in a single national area, the number of Medicare beneficiaries and physicians is sufficiently large to encourage vendors to participate to gain market share. This option may also impose less administrative burden on potential bidders than other options, because all applicants would be applying for contracts to cover the same region. The administrative burden on CMS might also be less: the fewer the number of acquisition areas, the fewer bids that must be submitted and evaluated. However, smaller regional drug distributors would be less likely to participate in the CAP under this option, because they may not be able to serve the entire country. This would reduce competition in the bidding process.

Regional Competitive Acquisition Areas

Under this general category, there are several possible options. One option is that we could establish multi-State acquisition areas based on existing markets. Under this option, we could define acquisition areas based on existing markets of regional distributors and specialty pharmacies. As an alternative regional approach, we could define four large competitive acquisition areas, which would limit the administrative burden of implementation. With just four acquisition areas, it may be less likely that there would be an insufficient number of vendors in any one area. We could also determine competitive acquisition areas that coincide with the prescription drug plan regions

established under section 1860D-11 of the Act (<http://www.cms.hhs.gov/medicarereform/mmaregions/>) for more information.

Establishing sub-national regions could be a natural first step in a geographic phase-in of the program. As discussed above, for example, we could implement the CAP in only a few areas at first. Overcoming challenges in the first phase would be important in gaining wide physician and vendor participation and successful implementation on a large scale. If we chose this approach, we would consider factors such as the number of potential bidders, the capacity of existing distribution networks, and the distribution of physician specialties in selecting a limited geographic area for the first competitive acquisition bidding process. This approach would also allow regional distributors to participate more easily in the CAP, thereby potentially increasing competition in the bidding process.

However, this approach may impose additional administrative burden on national vendors since they may need to submit multiple bids to cover the entire country.

Competitive Acquisition Areas Based on Single States

Under this option, we would define CAP areas based on State boundaries, the District of Columbia, Puerto Rico, and the territories. This option has the advantage of using clearly defined geopolitical borders as the basis for acquisition areas. As we have noted, current licensing for specialty pharmacies and vendors operates at the State level. Also, establishing State-based regions could support a geographic phase-in of the program, and we could implement the CAP in only some States at first. (As in the case of a possible phase-in of a region-based approach, we would consider factors such as the number of potential bidders, the capacity of existing distribution networks, and the distribution of physician specialties in selecting one or more States for the first competitive acquisition bidding process.) Overcoming challenges in the first phase would be important in gaining wide physician and vendor participation and successful implementation on a large scale. This approach would also allow State-based regional distributors to more easily participate in CAP, thereby potentially increasing competition in the bidding process.

We encourage comments on all the options that we have discussed. We also welcome recommendations of other

options for consideration. We believe that defining competitive acquisition areas, at least initially, on the basis of a level no smaller than the States is the most feasible approach. To our knowledge, there are few distributors of drugs administered incident to physician services that operate on a scale smaller than a State level. However, we welcome comments on this issue, and all other aspects of this discussion. We are still considering all the options described above, and will also consider other options presented by commenters. After further analysis and consideration of the comments, in the final rule, we may adopt one of the options described above, or an option brought to our attention through the comment process.

B. Operational Aspects of the CAP

1. Statutory Requirements Concerning Claims Processing

[If you choose to comment on issues in this section, please include the caption "Statutory Requirements Concerning Claims Processing" at the beginning of your comments.]

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 Part B Drug Competitive Acquisition Program bill the Medicare program for the drug or biological supplied, and collect any applicable deductibles and coinsurance from the Medicare beneficiary. (For purposes of this 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 this 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.

In addition, the Secretary is required to provide for a process for adjustments to payments in those cases 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 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 only supply drugs directly 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 this proposed rule, we have 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 propose to interpret the term to include a written order submitted to the vendor. We note 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." It is not our intention to restrict the physician's flexibility when ordering drugs from a CAP vendor, or to require that a physician participating in CAP would order drugs differently from a CAP vendor than he or she would a non-CAP vendor. (For purposes of this preamble the term "order" and "prescription" are used interchangeably.)

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. This process will apply only if the physician can demonstrate all of the following to the Secretary: 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.

2. Proposed Claims Processing Overview

[If you choose to comment on issues in this section, please include the caption "Claims Processing Overview" at the beginning of your comments.]

To comply with the statutory requirements described above, we propose to implement a claims processing system that will enable selected vendors to bill the Medicare program directly, and to bill the Medicare beneficiary and/or his or her third party insurance after verification that the drug has been administered. We propose to set forth the requirements for

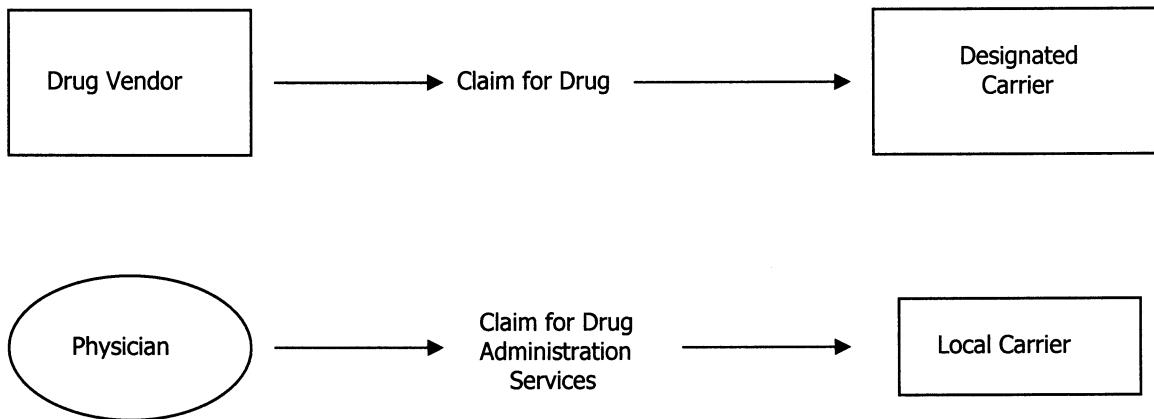
payment under the CAP at proposed § 414.906 of our regulations. For the initial implementation of the CAP, we plan to designate one Medicare fee-for-service claims processing carrier to process all drug vendor's Medicare claims. (In this preamble this entity will be referred to as the designated carrier.) Physicians who elect to participate in the program will continue to bill their local Medicare fee-for-service claims processing carrier for physicians' services.

This proposed rule uses the term "carrier" to describe an entity that processes Medicare benefit claims and performs related functions under Part B.

These entities may service a particular type of provider, or they may service all Part B suppliers within a specified geographic area.

The designated carrier and the physician's local carrier would each 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 following diagram describes the procedures for claims processing under the CAP.

**Proposed Part B Drug Competitive Acquisition Program (CAP)
Claims Processing**



At this time we are proposing to incorporate only drugs incident to a physician's service into the CAP. As noted earlier in section II.B.2. of this preamble, we are seeking comment on a broader definition of "competitively biddable drugs". As described below, consistent with the statute, we propose 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.

As we specify at proposed § 414.906(a)(4) of our regulations, we are proposing that CAP vendors would deliver drugs directly to physicians in their offices. Although the statute allows CMS to provide for the shipment of drugs to other settings under certain conditions, we are not proposing to implement the CAP in alternative settings at this time.

The vendor would use order form information to bill the beneficiary and/or his or her third party insurance for applicable deductible and coinsurance after drug administration has been verified by the Medicare carrier.

The claims processing methodology we propose to implement would verify drug administration to the beneficiary by means of a prescription number that would be placed on the physician claim for drug administration and the drug vendor claim for the drug. Our claims processing system would use the prescription number to match the two claims and authorize payment to the vendor.

We propose that the physician could place an order for a beneficiary's entire course of treatment at one time however; the vendor may split the order into appropriately spaced shipments. The vendor would create a separate prescription number for each shipment and the physician would track each prescription number separately and

place the appropriate prescription number(s) on each drug administration claim. The physician would also have the ability to modify the course of treatment and submit a separate order as necessary.

The drug vendor would generate the prescription number when it prepares the drug for shipping. The drug and prescription number would be shipped to the physician and would be maintained until the date of drug administration. At the time the drug was administered to the beneficiary, the physician or his or her staff would place the prescription number for each drug administered on the claim form. Similarly, when the vendor billed Medicare for the drug it shipped to the physician, it would place the relevant prescription number on the claim form. The electronic version of the Medicare carrier claim form has space for a series

of prescription numbers, which CMS has not utilized previously for Part B drugs.

As part of implementing the CAP program, we would require that vendors and physicians who elect to participate in CAP have the capability of submitting these prescription numbers to us in their claims processing systems. If physicians and potential vendors are not already billing other payors using prescription numbers, they would 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.

Our claims processing methodology would use the prescription number to match the two claims and authorize payment to the vendor. Under our proposed approach, payment to the vendor would be dependent upon the filing of the drug administration claims by the physician, and the physician's claim being approved for payment by the CMS claims processing system. We are seeking public comment on whether there are demonstrable, compelling reasons why CMS should consider making a partial payment to the vendor in cases where the drug administration claim is not received by the CMS claims processing system within 28 calendar days of the anticipated date of administration. We are also seeking public comment on what the appropriate percentage of the partial payment should be.

Although we are not proposing to make a partial payment at this time, the following section describes how we would propose that the partial payment methodology would work, if we decide to implement this option. After the designated carrier makes the partial payment, the CMS 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.

As required by the statute, the vendor would not be allowed to bill the beneficiary and/or his or her third party insurance for any applicable deductible and coinsurance until the Medicare carrier had verified that the physician has administered the drug to the

beneficiary, and final payment is 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 are matched the claims processing system would notify the designated carrier to issue final payment to the vendor. The obligation to pay interest on a clean claim would not arise until drug administration had been verified by the Medicare claims processing system. We propose 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.

We propose that in accordance with section 1847B(b)(5) of the Act, in emergency situations drugs acquired under the CAP could be used to resupply inventories of drugs administered by physicians. We propose that this process would apply if the physician could demonstrate all of the following to the local carrier: (1) The drugs were required immediately. (2) The physician could not have anticipated the need for the drugs. (3) The vendor could not have delivered the drugs in a timely manner. (4) The drugs were administered in an emergency situation.

As discussed in section C.2.a. of the preamble, we are seeking public comment on how to define timeframes for timely delivery, and for emergency delivery.

We propose 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. When the drug was received from the vendor the physician would return the drug to his stock. Both the physician and the vendor would bill normally for the drug or its administration as applicable. We seek comment on the additional criteria we will use to define the replacement process.

We also propose to allow the physician to obtain a drug under the ASP methodology in "furnish as written" cases when medical necessity requires that a specific formulation of a drug be furnished to the patient. This situation closely parallels dispense as written (DAW) prescription orders. In cases when the vendor has not been

contracted to furnish a specific formulation of a drug or a product defined by the product's NDC number, and the specified product is medically necessary, the physician could purchase the product for the beneficiary from a source other than the CAP vendor and bill Medicare for it using the ASP methodology. We would establish this method of alternative payment for a competitively biddable drug under proposed § 414.906(c)(2) of our regulations.

We propose that physicians who elect to participate in the CAP would continue to bill their local carrier for drug administration. In addition, we are proposing that for those drugs that are not included in the CAP, and for drug categories that the physician does not select, the physician would continue to bill and be paid under the ASP methodology. We are seeking public comment on whether physicians must obtain all categories of drugs that a particular CAP vendor provides from the vendor, or whether the physician should be allowed to choose the categories drugs he wishes to obtain from the vendor.

Some physicians have expressed concern that participation in the CAP would be administratively burdensome, for example, involve clerical and inventory resources. We do 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 are not proposing to make a separate payment to physicians for the clerical and inventory resources associated with participation in the CAP program.

In addition, we propose to require prompt claim filing 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. Statistics obtained from Medicare claims filing data indicate that more than 75 percent of physician's claims are currently filed within 14 days of the date of service. We propose that in their CAP election agreements, physicians who choose to participate in 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. We seek public comment on how we should define the extenuating circumstances.

All drug vendors would submit their claims to the designated carrier who would be designated to receive them.

After a physician saw a Medicare beneficiary and ordered a CAP drug, 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. The physician would prepare a drug order and forward it to the drug vendor.

The order transmitted between the physician and the drug vendor may occur in a variety of HIPAA-compliant formats, such as by telephone with a follow-up written order. We propose that the physician would transmit the following 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 info (if
applicable)
 - Medicaid info (if applicable)
 - Shipping address
 - Additional Patient Info: date of
birth, allergies, Ht/Wt/ICD-9, etc.

We are interested in receiving comments on the information we are proposing to require as well as any additional information that might be necessary.

In emergency replacement situations, the physician would also make a notation on the order that the drug was a replacement for a drug already administered to the beneficiary. This notation may involve the use of a modifier to a HCPCS code, or another standardized means of incorporating the information into a claim. The vendor would prepare the drug order, assign the unique transaction identification (or prescription) number and ship the replacement product to the physician. Standard CAP billing and claim processing procedures would follow. We anticipate 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.

We propose that in "furnish as written" situations, when the physician has determined that it is medically necessary to use another brand of product within the HCPCS or a product with an NDC that is not being furnished by the vendor that the physician would be allowed to bill for the drug under ASP, even though he or she had elected to participate in the CAP. We propose that the physician would obtain the specific product through normal distribution channels and bill the product using the ASP methodology. 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 ASP in this case. We anticipate 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.

After the physician submitted an order for the drug, the drug vendor would receive it and check the physician's CAP eligibility from a list provided by the designated carrier and would verify the beneficiary's Medicare eligibility with the designated carrier.

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

We anticipate 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 are proposing that physicians participating in the CAP would be required to maintain a separate electronic or paper inventory for each CAP drug obtained. We seek public comment on additional requirements that we should impose on maintaining CAP inventory.

If for some reason the drug could not be administered to the beneficiary on the expected date of administration, we propose that 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.

We note that billing beneficiaries for applicable deductible and coinsurance would not be allowed at the time the drug is administered at the physician's office as is the current customary practice outside of the CAP. The statute requires that the vendor bill Medicare and the beneficiary, and that the beneficiary may not be billed until after the drug has been administered to the beneficiary. As discussed earlier, we are proposing that the vendor be allowed to bill the beneficiary and/or his or her third party insurance after drug administration has been verified by matching the physician claim with the vendor claim using the prescription number, and final payment is made by the Medicare program.

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

The local carrier would adjudicate the claim 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). If the physician's claim failed LCD edits, the local carrier would deny the claim and

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

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

After shipping the drug to the physician, we propose that the drug vendor would 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 date, the unique provider identification number (UPIN) 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. If the physician claim for administering the drug had not been received in the central claims processing system but the vendor claim had received initial approval for payment, the claims processing system may pay the vendor a percentage of the claim payment amount. **(Note:** At this time, we are not proposing to implement a partial claims payment. However, as described earlier in this section, we are seeking comments on compelling reasons for making such a payment. The following section describes the process that we would follow if a partial payment methodology were implemented.)

If CMS decides to make an initial payment to the vendor, the vendor

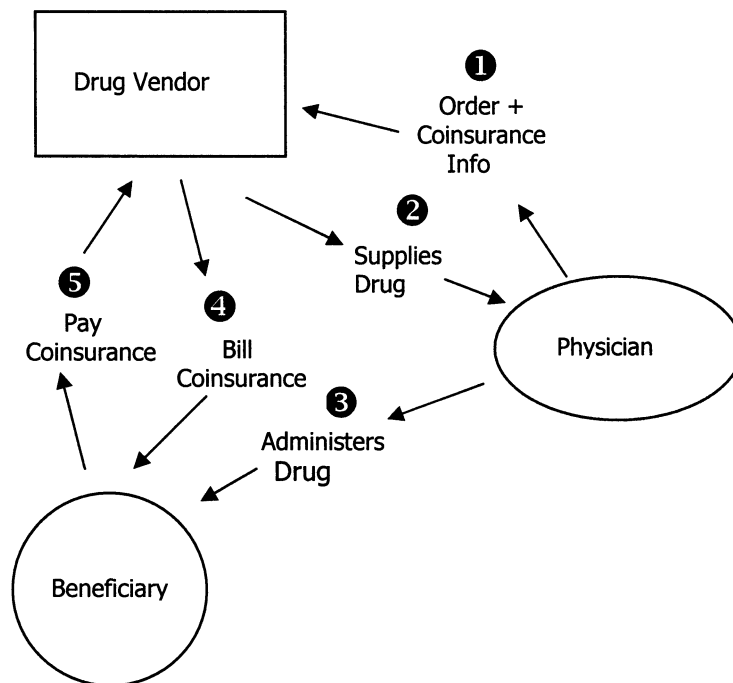
would be paid for the remaining amount of the claim when the physician's claim was matched with the vendor claim in the claims processing system. We note that CMS would not pay interest on partial payments.

If the physician's claim was not received within 90 days, or the claim was not approved for payment, the initial partial payment made to the vendor would be recouped using CMS overpayment recovery processes.

As noted previously, after the Medicare program makes the final payment, the vendor would be allowed to bill the beneficiary or the beneficiary's third party insurance, or both.

The following diagram demonstrates the proposed delivery system:

Proposed Part B Drug Competitive Acquisition Program (CAP) Drug Delivery



3. Dispute Resolution

[If you choose to comment on issues in this section, please include the caption "Dispute Resolution" at the beginning of your comments.]

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.

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.

We have given substantial consideration to the applicability of the Medicare Part B administrative appeals process found at 42 CFR 405.801 *et seq.*

We believe the traditional Part B appeals process continues to be the appropriate dispute resolution process for beneficiaries and 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) 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 see several reasons why disputes raised by the 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 physician drug administration claim properly filed and adjudicated is a more effective remedy. Finally, we believe application of the progressive alternative dispute resolution process described below represents a better use of program administration resources.

We encourage physicians, beneficiaries and vendors to use informal communication to resolve service-related administration issues that occur in a delivery and payment system of this complexity. However, we recognize a certain percentage of these disputes will require the intervention of a neutral third party. Our proposed dispute resolution process is set forth in regulations at proposed § 414.916.

a. Resolution of Vendor's Claim Denial. The physician has exclusive control of the claim filed with the local carrier for drug administration services. The vendor will not be a party to the appeal a physician may file if his or her drug administration claim is denied. The vendor's drug claim may be denied by the designated carrier if there is no unique prescription number match in the central claims processing system. The vendor cannot bill Medicare for the cost of a drug and cannot bill the beneficiary for the appropriate deductible or coinsurance.

The vendor may track its business with the individual physicians who order drugs. When a vendor is not paid and the total dollar amount of the vendor's loss exceeds an acceptable threshold, then the vendor may ask the designated carrier to counsel the 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 participation agreement. The particulars of the

participating CAP physician's CAP election agreement are outlined in § 414.908(a)(3) of our regulations. We seek comment on the appropriate amount for the vendor's loss threshold. If problems persist, we propose the vendor may ask the designated carrier to review the situation and potentially recommend a suspension of the physician's CAP participation agreement. The designated carrier will gather and review the relevant facts, and make a recommendation to CMS 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 revoke the physician's election to participate in the CAP for a period not to exceed the end of the following CAP election cycle.

The physician may appeal our initial decision through the process articulated in proposed § 414.916.

b. Resolution of Physicians' Drug Quality and Service Complaints. Issues connected with drug quality will be given a top priority. Both the vendor and the designated carrier will be required to have qualified staff available to address drug quality complaints upon their receipt. The physician's first point of contact for quality related issues will be the vendor. If the issue is not resolved to the physician's satisfaction through the vendor's grievance process, the physician may escalate the matter to the designated carrier immediately.

We recognize the physician's need for a process to treat vendor service issues as well. Service issues may include timeliness of delivery and quantity of the drug ordered. We propose that a physician be allowed to request intervention from the designated carrier. We propose the designated carrier will attempt to develop solutions that will satisfy both parties. The designated carrier will create a quarterly compendium of the issues and solutions to share with us.

c. Resolution of Beneficiary Billing Issues. 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 will reflect a message instructing the beneficiary 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 vendor's grievance process to request correction of the vendor's file. If

the beneficiary is dissatisfied with the result of the vendor's grievance process, the beneficiary may request intervention from the designated carrier. The designated carrier will first investigate the facts and then facilitate correction to the appropriate claim record and beneficiary file. If the vendor requires targeted education on the subject of beneficiary billing the designated carrier will initiate that effort.

C. CAP Contracting Process

1. Quality and Product Integrity Aspects

[If you choose to comment on issues in this section, please include the caption "Contracting Process-Quality and Product Integrity Aspects" at the beginning of your comments.]

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 vendor level. We propose to use the 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 potential 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 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 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 propose that CMS be allowed to suspend or terminate a 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 under section 1128 of the Act. We note this requirement is enforced through the routine provider enrollment form monitoring process. Finally, section 1847B(b)(3)(C) of the Act states that the ability to ensure product integrity must be included in the criteria for awarding vendor contracts.

At a minimum, we seek to define a set of overall financial and quality standards that would ensure that reputable, and experienced vendors are chosen to participate in the CAP. These features are important for a number of reasons. Physicians would be reluctant to participate in the CAP if they have little confidence that CAP vendors would be reliable and provide quality CAP products. Also, given the importance of the drugs and biologicals currently covered under Medicare Part B to beneficiaries, 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 propose to include this requirement in the contracts signed between CMS and vendors providing drugs or biologicals under this section. However, we invite comment on what records or other evidence that bidders would be required to furnish and approved vendors would be required to maintain during the contract period.

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 propose 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. This means that at a minimum, all drugs and biologicals utilized 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. Vendors would also be required to comply with sections 501 and 502 of the Federal Food, Drug, and Cosmetic Act concerning adulteration and misbranding.

Additionally, applicants would be required to employ trained personnel, have appropriate physical facilities, and utilize 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 propose 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 biologicals in States where they furnish drugs for the CAP.

Although we are not proposing to require applicants to employ measures beyond those required for licensure and regulatory compliance, we do believe those are a minimum standard, and we will request that applicants discuss any additional measures they have taken to assure product integrity. For a more complete discussion of measures available for wholesale distributors to deter and detect counterfeit drugs, we ask applicants to review the report on counterfeit drugs issued by the Food and Drug Administration (FDA) on February 18, 2004. This report, “Combating Counterfeit Drugs,” is available on the FDA Web site at <http://www.fda.gov/counterfeit>. At this time, we propose that applicants describe measures taken to ensure drug product integrity on the vendor application form.

Examples of additional measures that pose minimal burden, but greatly enhance the ability to detect adulterated, misbranded or counterfeit drugs that wholesale distributors have taken to assure product integrity include the following:

- Complying with the “Recommended Guidelines for Pharmaceutical Distribution System Integrity” developed by the Healthcare Distribution Management Association, available at www.healthcaredistribution.org.
- Among other things, these guidelines contain recommended measures for due diligence to ensure the integrity and legitimacy of supply chain business partners including the performance, by a wholesale distributor, of extensive corporate and personnel background checks as well as a physical facility inspection of another wholesale distributor prior to entering into a business relationship.
- 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.

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 vendors. We propose to fold integrity and internal control aspects of fiscal responsibility into this analysis.

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 may vary across States. We seek to assess bidders’ financial solvency in a consistent manner that will demonstrate appropriate scrutiny without creating unnecessary burden on the bidders. We propose 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. We seek to add standards that would demonstrate the following:

- Overall Capitalization and Financial Capability.* We propose 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 seek comment on the potential validity of specific financial indicators for this process and whether or not specific thresholds would be applicable. We also seek comment on this overall requirement from potential bidders, such as group purchasing organizations (GPOs), who do not routinely take possession of drug products.
- Working Capital.* We propose 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 seek comments regarding the appropriateness of these tests, and thresholds to apply for the ratios.
- Record of Integrity.* We propose 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 would also request bidders to provide a conflict of interest mitigation plan to address financial relationships the bidder may have with manufacturers of drugs or biologicals in the CAP.

—*Internal Control.* We propose to review information relating to the establishment and effectiveness of the bidder's internal control system designed to provide reasonable assurance financial and compliance objectives. Examples of information that we may review as evidence of the design and effectiveness of a bidder's internal control system include previous Statement on Auditing Standards 70 review results, independent third party reviews of the system, or other related information as we deem appropriate.

We propose to set forth these requirements in regulations at proposed § 414.908.

Deemed Compliance

Some vendor applicants may already be subject to financial oversight by one or more State or Federal regulators. The vendor's current financial reporting may satisfy one or more of the above requirements. We propose 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's status and we may deem certain portions of the above requirements "met" at our discretion.

2. Bidding Entity Qualifications

a. Quality and Financial Information—Vendor Application.

[If you choose to comment on issues in this section, please include the caption "Bidding Entity Qualifications" at the beginning of your comments.]

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 this purpose, 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. CMS would treat these admissions from vendors in the same manner as it does for other suppliers. Both the Vendor Application Form and the Provider/Supplier Enrollment Application (Form CMS 855B) would be 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.

However, the forms cannot be completed online. They must be printed, completed and mailed to CMS.

We would require that the vendor be prepared to offer complete information in four major areas and also to complete a certification statement. The vendor's business experience would be required to be within the United States. Also required on the Vendor Application Form would be a complete list of drugs that the vendor would intend to bid by National Drug Code (NDC) number.

Management and Operations

We propose 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, 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

The vendor would be required to maintain the operation of a grievance process so that physician, beneficiary, and beneficiary caregiver complaints can be addressed. We expect vendors to provide a prompt response to any inquiry as outlined in the vendor application form. We would require that vendors 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. Vendors would also be required to provide toll free emergency assistance when the call center is closed. Customer service is a primary consideration, especially the ability to respond on an emergency basis to physicians. In addition, we would require that a working telephone customer service number be submitted and will be verified 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 are seeking public comment on how to define timely delivery for routine and emergency drug shipments. For the purposes of this discussion, we propose 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 physician's office or other intended setting. We propose that routine shipments of drugs furnished under the CAP would occur within a one to two 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 seek comments on the feasibility of requiring a shorter duration for routine delivery of CAP drugs. We also propose that emergency drug orders be furnished on the next day for orders received by the vendor before 3 p.m. (vendor's local time), however, we seek comments on the feasibility of providing same-day deliveries for orders received for emergency situations.

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

In addition to providing an audited financial statement as an attachment, we propose that the vendor be required to present a standardized summary of financial information on the collection form. We would require the vendor to have been in the business of furnishing Part B injectable drugs for at least 3 years. We seek comment on this standard, especially 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. The vendor would be prepared to offer and substantiate the drug volume managed (dollars and units) for the immediate previous calendar year. Also, the vendor would be asked to provide specific personnel statistics such as the number of staff assigned to various activities, and its policy-making organizational structure within the United States, including a discussion of the membership of this body and to whom it reports.

Finally, by virtue of the fact that selected vendors would be enrolled Medicare suppliers, a vendor would be a health care provider and would be a covered entity under the HIPAA

Administrative Simplification Rules, to the extent that it conducts any of the standard HIPAA transactions electronically. As a covered entity, vendors would be required to comply with the Administrative Simplification rules, including the Privacy Rule.

Licensure

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 would also require that the vendor certify that any subcontractor or subsidiary also maintains a license that complies with State regulations in every applicable State.

Business Integrity

The vendor is responsible for identifying and disclosing business relationships and conflicts of interest as well as potential conflicts of interest with other organizations. Also, the vendor is required to answer questions and provide information about fraud investigations, settlement agreements, and Federal government exclusions.

Certification

We propose 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 CMS. 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.

b. Specific Information Relating to Prevention of Fraud and Abuse.

[If you choose to comment on issues in this section, please include the caption "Contracting Process-Quality and Product Integrity Aspects" at the beginning of your comments.]

Section 1847B(b)(4)(D)(ii) of the Act requires that the drug 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 Inspector General of the Department of Health and Human Services (OIG). In accordance with this statutory authority, we propose that each 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.

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, CAP vendors should consult a variety of sources including applicable statutes and regulations and compliance guidance issued by CMS, its contractors, Program Safeguard Contractors (PSCs), and the OIG. Publications that may provide relevant information include the OIG's Program Compliance Guidance for Pharmaceutical Manufacturers, (68 FR 23731) and OIG's voluntary Provider Self-Disclosure Protocol, (63 FR 58399). We propose that CAP vendors also consider industry best practices in developing their compliance plans.

We propose that vendors establish effective training and education programs related to waste, fraud, and abuse that address pertinent laws related to fraud and abuse including the Anti-Kickback law and the False Claims Act. In addition, we propose that CAP vendors and contracted entities be trained on detecting and preventing common fraudulent schemes in the pharmaceutical industry, as identified by CMS, the OIG, and/or the DOJ. Some examples of common fraudulent or abusive problems within the pharmaceutical industry include—

Lack of integrity of data used to establish payment amounts;

Kickbacks and other illegal remuneration; and

Lack of compliance with laws regulating drug samples.

To ensure successful internal monitoring and auditing of waste, fraud, and abuse under Part B, we propose that CAP vendors should regularly monitor and audit their processes and procedures to assure 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. Industry best practices related to fraud, waste, and abuse detection include the use of proactive data analysis and or other analytical processes to detect and address potential fraud. Establishing procedures to ensure prompt responses to potential fraud violations is an important element in an effective fraud and abuse plan. CAP vendors would be responsible for monitoring and identifying potentially fraudulent or abusive activity. For

assistance in identifying what constitutes abusive or fraudulent activity, CAP vendors may consult a variety of sources including media reports, DOJ litigation history, OIG published guidance and CMS policy manuals. After a CAP vendor has determined that any misconduct has violated or may violate criminal, civil or administrative law, the CAP drug 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 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 CAP vendors fully cooperate in any investigation that we or our law enforcement partners pursue related to fraud identified in a particular drug vendor's organization.

We are aware that there are many possible approaches to developing an effective compliance plan to implement a successful waste, fraud, and abuse program. Therefore, we are seeking comments on the scope and implementation of an effective compliance plan.

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

A code of conduct should function much like a constitution, that is, it should be a document that details the fundamental principals, values, and framework for action within an organization. We propose that the code of conduct for CAP vendors articulate the 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 or the appearance of such conflicts is critical to the operations of CAP. In accordance with our statutory authority under the Act, we propose to require that each CAP vendor establish and follow a code of conduct that addresses their policies

and procedures for identifying and resolving any conflict of interest. A conflict of interest may occur where a drug vendor, its representative, or contractor provides a product or service for a Medicare provider or beneficiary and the drug vendor, representative or contractor has a relationship with another person, entity, product or service that impairs or appears to impair the drug vendor's or contractor's objectivity to provide the Medicare covered product or service. Situations that compromise or appear to compromise a drug vendor's ability to avoid self-dealing when providing a Medicare product or service create a conflict of interest and must be resolved. Drug 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 provider or beneficiary.

We propose that the code of conduct communicates the need for all management, board of directors, employees, and agents to comply with the CAP vendor's code of conduct and policies and procedures for addressing and resolving conflicts of interest. We propose that the code of conduct reflects the CAP vendor's commitment to detect and resolve any conflict of interest. We propose further that the code of conduct establish procedures for determining whether or not a conflict exists, and if so, how the conflict will be resolved. We propose that the code of conduct address issues such as whether or not the offer or acceptance of some remuneration to or from a 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 propose that drug 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 drug vendors, we propose that each contract contain a conflict of interest clause specific to the CAP vendor for inclusion in the contract.

We are proposing 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 solicit and welcome 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 propose to set forth our conflict of interest policies and procedures in regulations at proposed § 414.912.

3. CAP Bidding Process—Evaluation and Selection

a. Evaluating Bid Prices by the Composite Bid Price.

[If you choose to comment on issues in this section, please include the caption "Cap Bidding Process-Evaluation and Selection" at the beginning of your comments.]

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. Once we have adopted technical and financial criteria for selecting CAP vendors, and bids have been submitted, the bids must be evaluated to determine which bidders will be awarded contracts to furnish drugs under the CAP. In the final rule, our ultimate choice of an appropriate evaluation process will take into account the final policies concerning the drug categories that will be bid, the geographic areas chosen for the program, and comments on our proposed evaluation process. In this proposed rule, we are proposing a basic approach to the evaluation and bidding selection process. We encourage comments on this proposal, and recommendations for alternative approaches. In the discussion of our proposal for the bidding process as set forth in § 414.910, and the various other options that we have identified, we assume that we are conducting competitive bidding for some number of distinct drug categories. We also assume 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 adopt in the final rule). These bidders will be permitted to submit the same bid price for all areas in which they wish to compete, or to submit completely separate bid prices for each acquisition area. The procedure for evaluating the price component of bids (and setting payment rates) would be the same regardless of the exact method for defining categories of HCPCS drugs that is 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) of 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 proposed § 414.910 of the bidding process.

The purpose of requiring vendors to bid for all drugs in a category would be to determine a set of vendors that can supply the range of drugs in that category at an appropriate overall cost. Because bidders have different expectations of the discounts they can negotiate for drugs, one vendor may be able to bid a lower price for one drug, but may expect a lesser discount on another. We have therefore sought to identify a selection process that, in the aggregate, can provide drugs at reasonable cost to the program while maintaining the required quality standards.

We are therefore proposing 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 would be constructed by weighing 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 since bidding is anticipated to occur in mid-2005. (At this time, we have not developed a method to weight drugs introduced during and after 2004, but invite public comment on methods for consideration.) The calculated composite bid would 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 (assuming 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.

To illustrate how the composite bid would be calculated, we are providing the following example. Suppose that there are four drugs in a particular CAP drug category (Drug A, Drug B, Drug C, and Drug D). The first column of Table 2 below provides the total volume (HCPCS units) of these drugs administered in 2004 for this hypothetical drug category.

TABLE 2.—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 2 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 3. The composite bid for Bidder 1 is computed as the weighted sum of the bids for the four drugs: $(\$520 \times 0.3520) + (\$400 \times 0.2395) + (\$135 \times 0.4050) + (\$4,780 \times 0.0035)$, which is equal to \$350.25. The composite bids for the other three bidders are computed similarly.

TABLE 3.—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 3 illustrates, it is possible for a bidder to be the low bidder on more individual drugs than other bidders (Bidder 3, the low bidder for Drug B and Drug D), but have the highest composite bid. This is due to Bidder 3's relatively high bid for Drug A and Drug C, which have the largest volumes (in HCPCS units). Also note that although Bidder 4 is not the low bidder for any of the four drugs, its composite bid is the second lowest.

As we have noted above, 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 propose a two-step bidder selection:

- First, certain quality and financial thresholds must be met by all bidders.
- Then, winning bidders would be selected from those that meet the quality and financial thresholds on the basis of a method for evaluating the composite bids.

We have considered several basic methods for evaluating the composite bids. From these alternatives, we have decided to propose a method that bases the selection of winning bidders on a predetermined threshold. Specifically, under the method we are proposing, we would select, from all those bidders that meet the quality and financial thresholds, up to the five lowest bidders for a drug category in 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.

As an example of this computation, suppose that the ASPs for four drugs in the composite bid example above (see Table 2) 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 2, 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 4.)

TABLE 4.—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

We are proposing this method for selecting bids for several reasons. This method is straightforward and relatively easy to implement. In addition, accepting no bid prices 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 that this method is preferable to other options. For example, one alternative to the method that we are proposing 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 are proposing. Under the process that we are proposing, 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. In this proposed rule, we are therefore proposing to accept up to five composite bids, for a category of drugs, but we do not propose 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 examples above. We welcome comments on this proposal, and recommendations for alternative approaches. In the final rule, after we have considered the comments, we may adopt some variation of this proposal, or some alternative recommended by the commenters.

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 have considered a number of options for determining this single price on the basis of the accepted bid prices. In this proposed rule at § 414.906(c)(1), (which describes the computation of the payment amount), we are proposing to establish a single price, for each drug in a competitive acquisition area, based on the median bid of the winning bidders. As a simple example of how this method might work, consider the bids for one drug submitted by the winning bidders under our proposed composite bid selection method (see Table 4). For Drug D, Bidder 1 submitted a bid of \$4,780, Bidder 2 submitted a bid of \$4,830, and Bidder 4 submitted a bid of \$4,800. The median of these three bids is \$4,800. Under this version of our proposed method, then, the single price for this drug would be \$4,800.

We are proposing to employ the median bid for several reasons. First, this method is straightforward and relatively easy to implement. In addition, this method could realize some savings to the Medicare program. Unless all accepted bids are at the level of the maximum allowable bid (106 percent of ASP), this method for determining the single price would yield savings to the program. Finally, using the median of the acceptable bids is an obvious statistical method to determine a single price on the basis of using the information provided by these bids, as required by the statute.

In cases where there are four winning bidders for a drug category in an area,

we will employ the average of the two bid prices in the middle of the array for a particular drug in that category in order to set the single prices for that drug. Specifically, if four bidders are selected, we would employ the average of the bids of the second and third highest bidders on each drug to set the price for the drug. If only two bidders are selected, we would use the average of the two bids for the drug to set the price for that drug. 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 invite comments on this proposal and also invite commenters to recommend alternative approaches. After analyzing the comments, we may adopt some variation of this proposal, or some alternative recommended by the commenters, in the final rule.

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 are proposing 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 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 that we are proposing 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 are proposing to employ the mechanism provided under section 1847B(b)(7) of the Act for this purpose. That section provides for drug price adjustments on the basis of cost information provided by vendors to the

Secretary. Specifically, that section provides 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.” We are therefore proposing 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. There are obviously a number of possible disclosure schedules. We are proposing 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 will 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 invite comments regarding an appropriate disclosure schedule under section 1847B(b)(7) of the Act for this purpose.

There are also a number of methods that we could adopt to develop an appropriate adjustment on the basis of the net reasonable cost information disclosed by vendors.

We are proposing the following methodology. 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 may establish a threshold percentage change (for example, 5 percent) 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. To return to the example discussed earlier, Bidder 1 submitted a bid of \$4,780, Bidder 2 submitted a bid of \$4,830, and Bidder 4 submitted a bid of \$4,800 for Drug D. The price for the drug in the first year of the contract is therefore the median of these three bids, or \$4,800. Suppose that Bidder 1 submits information prior to the second year of the contract indicating that the reasonable, net acquisition costs for the drugs in a category have increased by 7 percent. At the same time, Bidder 4 submits information indicating that costs have increased by 10 percent. We would adjust each of the original bid prices for the drug accordingly. The bid price of Bidder 1 would increase from \$4,780 to \$5,115 ($\$4,780 \times 1.07$). Similarly, the bid price of Bidder 4 would increase from \$4,800 to \$5,280 ($\$4,800 \times 1.10$). Next, we would recompute the single price for the drug as the median of these adjusted bid prices. Specifically, the new single price for the drug would be \$5,115, the median of \$5,115, \$4,830, and \$5,280.

It is important to note 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.

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 propose 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 these purchases, including contracts, invoices, and other agreements that reflect the actual

purchase prices. This documentation would include all records reflecting discounts that result in a reduction of actual cost to the vendor. These 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.

We also propose 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 invite comments on this approach.

We also welcome comments on every aspect of this discussion, especially on the frequency with which we would collect the requisite data and the precise manner in which we would calculate the changes in single drug prices.

4. Contract Requirements

[If you choose to comment on issues in this section, please include the caption "Contract Requirements" at the beginning of your comments.]

Sections 1847B(b)(4) of the Act discusses items to be incorporated in the contract entered into with a 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 upon receipt of a prescription and other necessary data.

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

5. Judicial Review

[If you choose to comment on issues in this section, please include the caption "Judicial Review" at the beginning of your comments.]

Provisions of 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.

D. Implementation of the CAP

1. Physician Election Process

[If you choose to comment on issues in this section, please include the caption "Physician Election Process" at the beginning of your comments.]

Section 1847B(a)(1)(A) of the Act specifies that each physician is given the opportunity annually to elect to participate in the CAP. Payment for a charge for any drug or biological may be made only on an assignment-related basis in accordance with section 1842(o)(3)(A) of the Act. 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 methodology.

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 vendor from whom they wish to obtain drugs and 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 vendors available to them under the CAP, we are required to post a directory on the CMS Web site or to make such a directory available to interested physicians on an ongoing basis.

We propose 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. We propose that by completing this CAP election agreement, the physician would select the approved vendor that he or she would use under the CAP and would agree to the CAP participating physician requirements. Under these requirements, the physician would agree to—

- Share information with the vendor to facilitate the collection of applicable deductible and coinsurance.
- Promptly file claims.
- Timely and appropriately pursue claims that are denied because of medical necessity issues.
- Notify the vendor when a drug is not administered.
- Maintain an inventory for each CAP drug he or she obtains.

Participating CAP physicians would also agree to comply with emergency drug replacement rules and requirements for using the "furnish as written" provision. If we find it necessary, we may revoke the physician's election to participate in the CAP if the physician fails to abide by the CAP election agreement.

We propose to initiate an annual CAP physician election process. We have modeled our proposed CAP physician election process after the 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 plan to continue to use that vehicle to communicate information about CAP to physicians in future years. However, we note that the annual Physician Participation election process 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 CAP physicians and their drug category selections, update claims processing files, perform testing, and inform vendors so that we are ready to pay CAP claims on January 1, 2006. In addition, a deadline of December 31 would not allow sufficient time for vendors to meet the operational timeframe of January 1. Therefore, we propose that the CAP physician election process would run from October 1 to November 15 of each calendar year. We propose that physicians who intend to continue into subsequent years may signal that preference by executing an abbreviated CAP election agreement. The abbreviated agreement may be used to indicate a preference to change vendors or drug categories from year to year. We propose that a CAP participating physician may select a vendor outside the annual election process if the previously selected vendor ceases participation in CAP, or if the physician leaves the group practice that had selected the given vendor or relocates to another competitive area. We propose to specify the exceptions to the annual selection process at proposed § 414.908(a)(2) of our regulations.

We seek comment on the potential options available to affected physicians when a vendor leaves the program during the middle of the CAP year. Proposed physician options would include leaving the CAP or switching vendors as is required by the proposed CAP election agreement for the

physician to participate in the CAP. We propose 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. Group practices enroll as a group, and are assigned a group PIN number to bill Medicare. 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 propose 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 propose that if the physician in the group practice also has a solo practice, he or she may make a different determination to participate or not to participate in the CAP when using his or her individual PIN.

We also propose that consistent with the Medicare Participating Physician Process, new physicians would be given 90 days in which to decide to elect to participate in the CAP. They would receive information about CAP when they enroll as a Medicare provider and would be instructed how to find the election information and forms on the CMS Web site. If they elect to participate, they would download the forms and submit them to their Medicare carrier.

We propose to implement the following process:

(1) We would prepare a posting on our Web site by October 1, describing the vendors we have selected to participate in the CAP, the categories of drugs they would be providing, and the geographic areas within which each vendor would operate.

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

(3) Physicians would be asked to access the CAP 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 would be asked to download, complete and sign the CAP election agreement. The CAP election agreement would require that they select the 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.

(5) Physicians would be instructed to return completed CAP election agreement to their local carrier. The CAP election agreement must be postmarked by November 15.

(6) The local carrier would make note of the physician's decision to participate in the CAP, and the vendor(s) and categories of drugs selected.

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

(8) The designated carrier would compile a master list of all Medicare physician's vendor and drug selections. In addition, the designated carrier would notify each CAP vendor of the physician who has elected to enroll with that vendor.

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

As we become more experienced with the CAP program, we plan to evaluate these timeframes to determine if adjustments should be made to the dates for the CAP election process. The requirements concerning a physician's election to participate in the CAP are set forth in regulations at proposed § 414.908(a).

2. Vendor or Physician Education

[If you choose to comment on issues in this section, please include the caption "Vendor or Physician Education" at the beginning of your comments.]

To ensure that vendors and physicians have timely access to accurate Medicare program information regarding the CAP, we would instruct the CAP designated carrier to utilize 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 utilize data analyses in tailoring its outreach and educational efforts for vendors and physicians regarding identified areas of confusion about the CAP. Additionally, the CAP designated carrier would be instructed to utilize 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 the CMS provider outreach and education requirements of the CAP designated carrier would be to ensure that those who provide service(s) 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.

3. Beneficiary Education

[If you choose to comment on issues in this section, please include the caption "Beneficiary Education" at the beginning of your comments.]

The CAP would have an impact on beneficiaries who receive physician administered drugs. If a physician elects to participate in the CAP, beneficiaries receiving services from this physician would receive a separate MSN from the designated carrier that processes invoices for the drug vendor as well as a bill from the drug vendor for the copayment of the drug. This may 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 drug 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 propose 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 www.medicare.gov website. Although we are not proposing to require physicians to provide beneficiaries with the fact sheet, we seek comment on the administrative burden associated with this activity. In addition, while we are not proposing to require any additional options for specific outreach, we are also interested in obtaining comments on other mechanisms that might be utilized to inform the beneficiary of services provided as part of the CAP (such as a notice constructed to allow the physician to specifically identify the drugs administered and the CAP vendor which could be handed out to beneficiaries at the end of a physician encounter) and the burden that would be associated with this mechanism.

We also propose to provide information about 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. Information would also be provided 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 CAP.

III. 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:

Section 414.906 Competitive Acquisition Program as the Basis for Payment

A physician who elects to participate in the program and has selected an approved vendor, must provide information to the approved vendor to facilitate collection of applicable deductible and coinsurance as described in § 414.906(a)(3).

The burden associated with this requirement is the time and effort necessary for the physician to provide the information to the vendor to facilitate collection of applicable deductible and coinsurance. CMS is requesting public comment on the extent of burden associated with this requirement. In the final rule CMS will quantify the amount of burden

associated with this requirement based upon public input.

Section 414.908 Competitive Acquisition Program

A physician is provided an application process for the selection of an approved 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.

The burden associated with this requirement is the time and effort necessary for the physician to enroll and designate an approved CAP vendor. We estimate that it will require 70,000 physicians 15 minutes each to fulfill the application requirements.

In addition, physicians participating in the CAP must elect to use an approved vendor for the drug category area as discussed in § 414.904(a)(1); submit a written order or prescription to the approved vendor; not receive payment for the competitively biddable drug except as described in § 414.906(c)(2)(ii); provide information to the approved vendor to facilitate collection of applicable deductible and coinsurance as described in § 414.906(a)(3); notify the approved 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 burden associated with this requirement is the time and effort necessary for the physician to provide and/or maintain the information required as discussed above. CMS is requesting public comment on the extent of burden associated with this requirement. In the final rule CMS will quantify the amount of burden associated with this requirement based upon public input.

Section 414.910 Bidding Process

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 estimate that it will require 25 bid applicants 40 hours each to meet the bidding and contract requirements.

Section 414.914 Terms of Contract

The terms of the contract between CMS and the approved vendor will be for a term of 3 years. During the contract period the vendor must disclose to CMS or its agent, the approved 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 vendor to submit to CMS or its agent, the 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 10 vendors 8 hours on an annual basis to submit the necessary information, for total annual burden of 8 hours per vendor.

Section 414.916 Dispute Resolution

Cases of an approved vendor's dissatisfaction with denied drug claims are resolved through a voluntary alternative dispute resolution process.

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: John Burke, CMS-1325-P, 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.

IV. Response to Public 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. 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.]

We have examined the impact 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 reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, when 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 must be prepared for final 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).

Since this rule is considered to be a major rule because it is economically significant, we have prepared a regulatory impact analysis. The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a Regulatory Flexibility Analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason 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.

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 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 proposed rule on an individual physician is dependent on

the drugs they provide to Medicare beneficiaries and whether these drugs are included in the categories of drugs considered for competitive acquisition and whether the physician chooses to obtain drugs administered to Medicare beneficiaries through the CAP.

In addition, this proposed rule would have an impact on entities, either existing or formed specifically for this purpose, that are involved in the dispensing of drugs. This impact would be dependent on the categories of drugs and geographic areas that are determined to fall under the CAP and on their ability to successfully compete and receive approval as a vendor under the competitive acquisition program.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any proposed rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 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 a Metropolitan Statistical Area and has fewer than 100 beds. We have determined that this proposed 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 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million.

We have examined this proposed rule in accordance with Executive Order 13132 and have determined that this regulation would have no consequential effect on the rights, roles, or responsibilities of State, local, or tribal governments.

A. 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, we are making changes to method of payment for drugs in response to the requirements of section 1847B of the Act. We provide information on the options being considered in the development of the CAP in the relevant sections in this rule. The provisions of this rule discuss changes to our payment for drugs through the establishment of a competitive

acquisition process as an alternative payment system for Part B drugs and biologicals. This rule does not impose reporting, record keeping, and other compliance requirements except as described in sections II.C.3 and II.D.1 of the preamble. We are unaware of any relevant Federal rules that duplicate, overlap, or conflict with this rule.

The effect of this proposed rule on an individual physician would be dependent on the drugs they provide to Medicare beneficiaries and whether these drugs are included in the categories of drugs considered for competitive acquisition. 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 plus six percent methodology, and (3) determine if there is a cost savings associated with either program. Different outcomes may result from these calculations depending on the drug mix, overhead cost, and patient mix.

A physician who elects to participate in the program would obtain all of their Medicare related drugs in categories for which CAP is implemented in their area through a competitive acquisition program vendor. The vendor would then collect applicable deductibles and coinsurance from the beneficiary. Under this option, the physician would never take legal ownership of the drug and would eliminate the cost associated with collecting deductibles and coinsurance. Because the drug remains the property of the vendor until the time of administration, the physician can also reduce the cost associated with storage and individual drug supplier negotiations. The CAP may also save physicians money since they would not be in the drug purchasing and procurement business and would not have to collect coinsurance from beneficiaries.

This rule also proposes establishing rules whereby drugs and biologicals administered by the physician in emergency situations that were not originally acquired through a Medicare vendor may be resupplied through the Medicare competitive acquisition program vendor.

B. Impact of Establishment of a Competitive Acquisition Program

We have simulated the impact of the costs of furnishing or administering drugs through the competitive acquisition program and found it to be negligible. At this time we anticipate no additional cost savings or increases

associated with the competitive acquisition program, particularly relative to the ASP + 6 percentages since the specific parameters under which the CAP will be operating (for example, specific drugs, physicians electing to participate in CAP) will be directed by this rulemaking and are not yet determined. Moreover, some of the key purposes of the CAP program are to provide alternatives to physicians who do not wish to be in the drug purchasing and coinsurance collection business.

C. Alternatives Considered

This proposed rule contains alternative approaches to implementing a competitive acquisition program for Part B drugs that we considered, each of which has been discussed in detail. We will select one of these approaches after reviewing all public comments received on the proposed rule and making any necessary modifications.

D. Impact on Beneficiaries

We have simulated the effect of changes in beneficiary coinsurance for drugs and related changes in beneficiary Part B premium payments resulting from the implementation of competitive acquisition program for Part B drugs. We have concluded that there will be no appreciable difference to the beneficiaries if their drugs were to be administered by a physician participating in the CAP or purchasing them at ASP plus 6 percent, thus there would be no cost or savings to the beneficiary whose physician participates in the CAP.

We do not believe that any beneficiaries would experience drug access issues as a result of implementation of CAP. We intend to monitor beneficiary access closely and may propose additional changes to our payment system in the future if necessary.

We propose to develop educational material to distribute to beneficiaries, such as pamphlets and a discussion in The Medicare Handbook, to help explain the CAP and the changes they will see on their Medicare summary notices. Specifically, under the CAP beneficiaries would now pay their coinsurance and deductibles to their CAP vendor instead of the administering physician.

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget has reviewed this regulation.

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 proposes to amend 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 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 the 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. Republish the introductory text to § 414.902 and add the definitions of “Approved vendor,” “Bid,” “CAP election agreement,” “Competitive acquisition program,” “Competitive area,” “Competitively biddable drugs,” “Designated carrier,” “Local carrier,” and “Participating CAP physician” to read as follows:

§ 414.902 Definitions.

As used in this subpart, unless the context indicates otherwise—

Approved vendor means an entity that has been awarded a contract by CMS to participate in the competitive acquisition program.

Bid means an offer to furnish a competitively biddable drug within a category of competitively biddable drugs in a competitive area for a particular price and time period.

Competitive acquisition program (CAP) means a program as defined under section 1847B of the Act.

CAP election agreement means the form that the physician must complete to notify CMS that he or she elects to participate in the CAP.

Competitive area means the geographic area established by the Secretary for purposes of implementing the CAP required by section 1847B of the Act.

Competitively biddable drugs means a physician-administered drug or biological furnished on or after January 1, 2006 described in section 1842(o)(1)(C) of the Act.

Designated carrier means an entity assigned by CMS to process and pay claims for drugs and biologicals under the Part B drug competitive acquisition program.

* * * * *

Local carrier means an entity assigned by CMS to process and pay claims for administration of drugs and biologicals under the Part B drug competitive acquisition program.

* * * * *

Participating CAP physician means a Medicare physician electing to participate in the CAP described in this subpart. The participating CAP physician must complete and sign the CAP election agreement.

* * * * *

5. Amend § 414.904 by revising the section heading to read as follows

§ 414.904 Average sales price as the basis of 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 drug may be made through competitive acquisition if the following occurs:

(1) The competitively biddable drug is supplied under the program by an approved vendor as specified in § 414.908(b).

(2) The claim for the prescribed drug is submitted by the approved vendor that supplied the drug and payment is only made to that vendor.

(3) The approved vendor collects applicable deductible and coinsurance with respect to the drug furnished under the CAP only after the drug is administered to the individual.

(4) The approved vendor delivers the drugs directly to the participating CAP physician.

(b) *Exceptions to competitive acquisition.* Specific competitively biddable 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 such drugs.

(c) *Computation of payment amount.*

(1) Except as specified in paragraph (c)(2) of this section, payment for competitively biddable drugs is based on bids submitted and accepted as described in § 414.910. Based on these bids, a single payment amount for each competitively biddable drug in the competitive area is determined. This payment is updated on an annual basis based on the approved 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.
(iii) Material shortage that results in a significant price increase for the drug.

(2) The alternative payment amount established under section 1847A of the Act may be used to establish payment for a competitively biddable drug—

(i) For which a payment and BILLING CODE has not been established; or
(ii) When medical necessity requires a certain brand of drug that the approved vendor has not been contracted to furnish under the CAP.

(d) *Adjustments.* There is an established process for adjustments to payments to account for drugs that were billed at the time of dispensing 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 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 vendor could not have delivered the drugs in a timely manner.

(4) The participating CAP physician administered the drugs in an emergency situation.

7. Add § 414.908 to read as follows:

§ 414.908 Competitive acquisition program.

(a) *Physician selection of an approved vendor.* (1) CMS provides the physician with a process for the selection of an approved vendor on an annual basis, with exceptions as specified in § 414.908(a)(2), and will also receive

information about the CAP in the enrollment process for Medicare participation discussed in section 1842(h) of the Act.

(2) A physician may select an approved vendor outside the annual selection process when—

(i) The approved vendor ceases participation in the CAP; or

(ii) Other exigent circumstances defined by the Secretary, for example the participating CAP physician relocates to another competitive area or the physician leaves a group practice participating in the CAP.

(3) The physician participating in the CAP—

(i) Elects to use an approved vendor for the drug category area as set forth in § 414.904(a)(1);

(ii) Completes and signs the CAP election agreement;

(iii) Submits a written order or prescription to the approved vendor;

(iv) Does not receive payment for the competitively biddable drug except as described in § 414.906(c)(2)(ii);

(v) Provides information to the approved vendor to facilitate collection of applicable deductible and coinsurance as described in § 414.906(a)(3);

(vi) Notifies the approved vendor when a drug is not administered;

(vii) Maintains a separate electronic or paper inventory for each CAP drug obtained;

(viii) Agrees to file the Medicare claim within 14 days of the date of drug administration; and

(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 is denied.

(4) *Physician group practices.* If a physician group practice using a group billing number elects to participate in the CAP, all physicians in the group are considered to be participating CAP physicians when using the group number.

(b) *Program requirements.* (1) CMS selects approved vendors through a competition among entities based on the following:

(i) Submitting the bid prices for competitively biddable drugs within the category and competitive area that—

(A) Place the vendor among the lowest five qualified bidders; and

(B) Do 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.

(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 drugs and biological products directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer.

(ix) Other factors as determined by the Secretary.

(2) Approved vendors must also meet the contract requirements under § 414.914.

(c) *Additional considerations.* CMS may refuse to award a contract or terminate an approved 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.

(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 competitively biddable drug with each billing and payment code within each category for each competitive area.

(e) *Multiple contracts for a category.* 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 competitively biddable drugs in all competitive areas of the United States, or a specific competitive area.

(b) There will be uniformity among the bids for any specific competitive 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 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 48 CFR 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 vendors must have a code of conduct that establishes policies and procedures for recognizing and resolving conflicts of interest between the approved vendor and any entity, including the Federal Government, with whom it does business. The code of conduct must—

(1) State the need for management, employees, and agents to comply with the approved vendor's code of conduct, and policies and procedures for conflicts of interest; and

(2) State the approved vendor's expectations of commitment to compliance by management, employees, and agents.

10. Add § 414.914 to read as follows:

§ 414.914 Terms of contract.

(a) The terms of the contract between CMS and the approved vendor will be for a term of 3 years. The contract may be terminated—

(1) By CMS for default if the approved vendor violates any term of the contract; or

(2) In the absence of a contract violation, by either CMS or the approved 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 vendor that includes standards relating to conflicts of interest standards at § 414.912.

(c) The vendor will have 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 standards.

(2) The designation of a compliance officer and compliance committee accountable to senior management.

(3) Effective training and education between 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 a drug vendor.

(i) If the drug 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 drug 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 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 vendor must also—

(1) Have sufficient arrangements to acquire and deliver competitively biddable drugs within the category in the competitive area specified by the contract;

(2) Have arrangements in effect for shipment at least 5 days each week of competitively biddable drugs under the contract, including emergency situations, and for timely delivery of such drugs in the competitive area;

(3) Have procedures in place to address and resolve complaints of participating CAP physicians and individuals and inquiries regarding shipment of competitively biddable drugs;

(4) Have a grievance and appeals process for dispute resolution;

(5) Meet applicable licensure requirements in each State in which it distributes drugs under the CAP;

(6) Enroll in Medicare as a participating provider; and

(7) Comply with all necessary provisions related to the prevention of fraud and abuse.

11. Add § 414.916 to read as follows:

§ 414.916 Dispute resolution.

(a) *General rule.* Cases of an approved 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 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 vendor may ask the designated carrier to—

(i) Review the participating CAP physician's performance; and

(ii) Potentially recommend a suspension of the participating CAP physician's CAP election agreement.

(2) *Responsibility of the designated carrier.* The designated carrier—

(i) Investigates and makes a recommendation to CMS on whether the participating CAP physician has been meeting the claims and appeals obligations in his or her CAP election agreement;

(ii) Gathers information from the local carrier and the approved vendor; and

(iii) 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).

(3) CMS reviews the recommendation of the designated carrier and, if necessary, gathers additional information before deciding whether to suspend the participating CAP physician's CAP election agreement for a period not to exceed the end of the following CAP election cycle. This suspension is limited to the participating CAP physician's ability to order drugs from the specific vendor.

(4) The participating CAP physician may appeal that exclusion by requesting a reconsideration. A determination must be made as to 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. 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.

(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 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 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 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 presents the findings and recommendations to the participating CAP physician who requested the reconsideration. If the hearing officer conducts a hearing in person or by phone, the findings and recommendations are due to the participating CAP physician within 30 days from 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 Centers for Medicare Management or his or her designee chooses to review that decision within 30 days.

(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.

(v) CMS publishes a final reconsideration determination against a participating CAP physician in the **Federal Register**.

(d) The approved vendor treats quality and service issues through its grievance process. If the approved 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 vendor.

(e) The approved vendor may not charge the beneficiary for the full drug coinsurance amount if the designated contractor did not pay the approved vendor in full. When a beneficiary receives a coinsurance bill under these circumstances, the beneficiary may participate in the approved vendor's grievance process to request correction of the approved vendor's file. If the beneficiary is dissatisfied with the result of the approved 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.

12. Add § 414.918 to read as follows:

§ 414.918 Assignment.

Payment for a charge for a competitively biddable drug for which payment is made may be made only on an assignment-related basis.

13. 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 competitively biddable 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: February 10, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: February 24, 2005.

Michael O. Leavitt,

Secretary.

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