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September 2, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-IFC
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1325-IFC
Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B

Dear Madam or Sir:

Pharmion Corporation submits this comment in response to Section II.A.2 of the interim final rule with comment period published on July 6, 2005, regarding the Medicare Part B Competitive Acquisition Program (CAP).[1] Pharmion requests that CMS add the drug Vidaza® (azacitidine for injectable suspension) to the list of orphan drugs excluded from the CAP during the initial stages of implementation.

Vidaza®, which is distributed by Pharmion, is the first approved treatment proven effective for patients with a collection of bone marrow disorders known as Myelodysplastic Syndrome (MDS). FDA approved Vidaza® as an orphan drug on May 19, 2004. As a single-indication orphan drug, Vidaza® (HCPCS code C9218) receives separate payment under the Hospital Outpatient Prospective Payment System (OPPS).[2]

A. Drugs that Meet the Criteria for Single-Indication Orphan Drugs Under the OPPS are Excluded From the CAP

In the July 6 interim final rule, CMS stated that it will exclude from the CAP drugs that meet the orphan drug criteria under the OPPS.[3] The criteria are: (1) the drug is designated as an orphan drug by the FDA and approved by the FDA for treatment of only one or more orphan condition(s); and (2) the current United States Pharmacopoeia Drug Information

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[1] 70 Fed. Reg. 39022, 39028 (July 6, 2005).

[2] 69 Fed. Reg. 65681, 65808 (Nov. 15, 2004).

[3] 70 Fed. Reg. at 39028.

(USPDI) shows that the drug has neither an approved use nor an off-label use for other than the orphan condition(s). CMS has identified twelve drugs that meet the OPPS criteria for single-indication orphan drugs and therefore are excluded from the CAP.[4]

B. Vidaza® Meets the OPPS Criteria for Single-Indication Orphan Drugs

After careful review of information submitted by Pharmion, CMS determined that Vidaza® meets the criteria for single-indication orphan drugs established under the OPPS. Therefore, Vidaza® has been included in the list of single-indication orphan drugs eligible for separate payment under the OPPS.[5] Effective January 1, 2005, administration of Vidaza® has been paid in accordance with the payment policy for single-indication orphan drugs.

C. Vidaza® Should be Excluded From the CAP

Vidaza® should be excluded from the CAP for the same reason that it currently receives separate payment under the OPPS: Vidaza® meets the criteria for classification as a single-indication orphan drug.[6] Single-indication orphan drugs are excluded from the CAP, at least initially, to assure that patients have access to orphan drugs in a timely manner. Pharmion shares CMS's goal of assuring patient access to single-indication orphan drugs.

Accordingly, Pharmion respectfully requests that CMS add Vidaza® to the list of single-indication orphan drugs excluded from the CAP.

If you have any questions about Vidaza® or this request, please contact Kristi Wyatt, Director of Regulatory Affairs, by telephone at 913-266-0306, by fax at 913-266-0394, or by e-mail at kwyatt@pharmion.com.

Sincerely,

John A Walker /LPS

John A. Walker
Director, National Accounts

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[4] *Id.*

[5] 69 Fed. Reg. at 65808.

[6] *Id.*; 70 Fed. Reg. at 39028. Vidaza® is one of only two drugs that are listed as single-indication orphan drugs in the OPPS rule, but not in the CAP rule. In the OPPS rule, Vidaza® and Campath were added to the original list of twelve single-indication orphan drugs. In the CAP rule, Campath is listed as an orphan drug along with eleven of the original twelve single-indication orphan drugs. The other drug that is not listed as a single-indication orphan drug in the CAP rule is basiliximab, 20 mg injection (Q2019).

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VIA HAND DELIVERY

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS-1325-IFC: Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B

Dear Dr. McClellan:

Biogen Idec previously commented on CMS' proposed rule implementing the competitive acquisition program (CAP) for outpatient drugs and biologicals contained in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), and appreciates this opportunity to submit additional comments to the Interim Final Rule (IFR). Biogen Idec is a global biotechnology leader with leading products and capabilities in oncology, neurology and immunology. We are headquarted in Cambridge, Massachusetts and maintain centers of excellence in San Diego, California and Cambridge. Biogen Idec invests approximately 31% of its revenues in research and development programs that enable discovery of novel and breakthrough therapies to achieve new standards of care in oncology, neurology, dermatology and rheumatology. Biogen Idec's comments to this Interim Final Rule are offered to encourage CMS to ensure that Medicare enables access to today's breakthrough therapies while maintaining the market forces that have positioned the United States as a world leader in discovery, development, and commercialization of innovative biological treatments.

Biogen Idec's products are infused or injected in a variety of settings, including the physician's office. Biogen Idec is hopeful that the alternative to physician purchase of injected and infused therapies outlined in the CAP IFR will fulfill Medicare's somewhat competing goals of reducing Medicare expenditures for Part B drugs and biologicals and removing barriers to beneficiary access. As Biogen Idec noted in comment to the Proposed Rule, the drug payment reform provisions of the MMA, including the CAP, appear designed to move CMS closer to its private payor counterparts with respect to acquisition and payment for outpatient drugs and biologicals. We continue to urge CMS to recognize the essential differences between Medicare's elderly and disabled beneficiaries and that of the privately insured population that warrant programmatic protections against a purely market-driven approach to therapeutic choices. We support CMS in its efforts toward developing a workable alternative for physicians treating Medicare beneficiaries that enables patient access to the full range of therapies necessary to treat this comparatively fragile and vulnerable patient population.

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As further detailed below, Biogen Idec:

- Supports CMS in its selection of drugs and biologicals for CAP phase-in, its inclusion of all specialties in the initial CAP, and its flexibility in permitting vendors to add new drugs with payment initially set at ASP +6% for these additional products
  - Biogen Idec suggests that CMS clarify its exclusion of radiopharmaceuticals from CAP. While CAP may appear at first glance to be an attractive option that levels the playing field for therapeutic biologicals with a radioactive component such as Zevalin (from a patient access standpoint), we understand that inclusion of these products would be unworkable from a vendor bidding and selection, handling, and state regulation compliance standpoint;
  - We also suggest that CMS clarify its policy regarding inclusion of new products to permit vendors to add:
    - Products that were excluded from the initial category based upon low volume, particularly if the low volume is due to relative novelty of a product that did not receive sufficient time to be incorporated into physician office practices; and
    - Products that have a specific HCPCS code rather than require that a "permanent" code be assigned prior to CAP inclusion
- Urges CMS to require CAP vendors to submit bids for each single-source drug or biological regardless of the HCPCS coding structure;
- Supports CMS selection of a single national region for initial CAP phase-in, so long as the single national region does not remain in effect and without competing regional vendors for the initial 3-year contract period;
- Continues to urge CMS to devise and phase-in final geographic areas for CAP region purposes that coincide with the geographic regions for Part A and B contractors after contractor reform;
- Supports CMS use of a single Designated Carrier for processing vendor claims in the first year of CAP implementation, while urging CMS to work toward a post-contractor reform CAP regional structure that minimizes physician, vendor, and beneficiary confusion and paperwork by enabling the Part A/B contractor processing the physician administration claim to also processes the vendor drug claim;
- Appreciates CMS' recognition of the lack of program integrity concerns with respect to physician restocking of inventory under CAP. This is evident in the agency's reliance on physician clinical judgment for its definition of "emergency" for inventory restocking purposes;
- Urges CMS to reconsider its reliance on the Advance Beneficiary Notice (ABN) to shift the potential risk of drug payment denials from CAP vendors

to beneficiaries, and to clarify whether the "waiver of liability" protections to Medicare suppliers would apply to CAP vendors in the absence of an ABN.

- The selection of a single national region greatly increases the likelihood that beneficiaries will receive inappropriate ABNs that are based upon denials or contractor policies outside the specific beneficiary's contractor jurisdiction;
- CAP vendors will not have access to beneficiaries necessary to secure an ABN and will seek to rely on physicians to handle this task; and
- The physician CAP election agreement contains provisions requiring physicians to order CAP drugs consistent with local and national coverage policies, and provides a grievance process for vendors to utilize in the event of excessive claim denials. CMS encouragement of vendor ABNs without clear guidance on their limited use will result in constriction of beneficiary access to necessary therapies and transfer clinical decision making from the physician to the CAP vendor;

- Reiterates its concerns regarding medical necessity denials presented in comment to the proposed rule and suggests that for the initial phase-in year of CAP, CMS monitor drug payment denials due to medical necessity and consider offering for public notice and comment CAP structural changes to balance vendor risk such as:
  - Physician use of the selected CAP vendor for drugs and biologicals within the FDA approved indication, for any indications covered under a local or national coverage decision, and for compendia listed uses; with
  - Physician purchase of drugs and biologicals with drug claims submitted to the Part B contractor for reimbursement at ASP+6% for all other uses when the vendor expresses concern that a claim may be denied;
- Applauds CMS in requiring that vendors inform beneficiaries of cost-sharing assistance, but suggests that this information be provided with the vendor invoice to the beneficiary and without the need for a specific beneficiary request for the information;
- Suggests that CMS permit physicians treating beneficiaries who have failed to make coinsurance payments to CAP vendors to either (1) opt out of the CAP program; (2) continue in CAP; or (3) continue CAP participation for most of their patients while purchasing drugs for non-paying beneficiaries through the ASP system;
- Requests that CMS clarify applicability of the longstanding discarded drug policy to CAP vendors so that these suppliers are not placed in the position of assuming a risk they have no means to mitigate; and
- Applauds CMS in its statements permitting contractual arrangements between CAP vendors and providers that permit providers to minimize paperwork burden and vendors to minimize risk. We urge CMS to open a dialogue with vendors, providers, and manufacturers to explore potential beneficial

arrangements and to assist parties in working through fraud and abuse considerations, including any anti-kickback concerns with provider/vendor contracting that:

- Permit vendors to act as third-party billing agents for provider submission of drug administration claims, supplemental insurance verification, and similar functions
- Enable CAP vendors to offer or arrange a full range of services to providers including contractual nursing services for injection and infusion, particularly for specialties such as neurology and dermatology in which smaller practices may not traditionally maintain in-office nursing staff.

1. Categories of Drugs to be Included Under the CAP

A. Categories of Drugs To Be Included Under the CAP

Biogen Idec supports CMS' decision to create a single category of 181 drugs and biologicals for CAP phase-in. This approach ensures that all physicians interested in participating in CAP have the opportunity to do so. Biogen Idec expects that CAP will be an important option for physicians who are discouraged from offering injected and infused therapies by the high cost of acquiring products. We appreciate that CMS extended its list of included drugs beyond the oncology products expected to generate the greatest savings to the Medicare program to include biologicals administered to treat chronic medical conditions such as multiple sclerosis and psoriasis.

B. Inclusion of "New" or Additional Drugs and Biologicals

Biogen Idec remains concerned that many important therapies that may be utilized by physicians prescribing the listed products, as well as by other specialties that would benefit from early CAP inclusion, will not be available under the initial CAP phase-in. We again urge CMS to place patient access paramount in permitting vendor flexibility to include products outside the required category. Inclusion of additional products with a payment to vendors equal to 106% of ASP allowed for physician-purchased therapies would treat these products on par with new products included in the program and will not impact Medicare's cost savings from CAP. CMS would receive an incidental benefit from this flexibility in the form of additional data on acquisition cost of a greater breadth of products that would further guide CAP implementation.

While Biogen Idec understands the administrative burdens inherent in processing vendor claims utilizing miscellaneous HCPCS codes for new drugs and biologicals, we suggest that those concerns are not present for products that have been assigned a product-specific temporary HCPCS code. We ask that CMS clarify that vendors are permitted to include additional therapies with payment at ASP (or WAC) plus 6% when a temporary

products-specific HCPCS code has been assigned. Biogen Idec also urges CMS to recognize that therapeutic options for physicians can change dramatically during a vendor's 3-year contract period. In order to ensure that beneficiaries treated by CAP participating physicians receive the same level of access to therapeutic innovations as beneficiaries whose physicians choose to continue purchasing therapies, Biogen Idec suggests that CMS update its list of required therapies within each category no less frequently than annually. This is especially important for relatively new products that were not on the market for a sufficient period of time to reach the volume threshold for CAP inclusion. Vendor payment at ASP+6% for these products should ensure that vendors can supply the therapies without undue financial strain, and will not adversely impact the financial integrity of the Medicare program.

C. Excluded Products

Biogen Idec notes that the IFR neither includes nor excludes radiopharmaceuticals, and that the Zevalin anti-cancer regimen is not included within the single CAP category. As CMS knows, Zevalin is in many ways quite different from the products included in the definition of radiopharmaceuticals, as it is an anti-cancer therapeutic regimen rather than a component to a diagnostic test. As such, the therapeutic dose of Zevalin is often purchased by physicians for in-office administration, and Zevalin "competes" with products included in the CAP. While CAP inclusion may offer a more level playing field for Zevalin and similar therapies, Biogen Idec understands that due to complexities in distribution, handling, and local regulations, CAP inclusion is not administratively feasible. We hope to continue working with CMS to ensure that Medicare payment reform, including the CAP, does not discourage Zevalin utilization in favor of therapies with a more robust or lower risk Medicare reimbursement profile.

2. Competitive Acquisition Areas (Definition of Competitive Acquisition Areas)

Biogen Idec generally supports CMS in its decision to phase in CAP through a single, national geographic region. As noted in comment to the Proposed Rule, however, the CAP would ideally be designed so that vendors and physicians submit claims for drugs and administration services to the same local contractor. This would simplify matching administration and drug claims, streamline appeals, and facilitate predictability with respect to local coverage decisions and other claims processing edits. While current contractor jurisdictions are not sufficiently geographic in nature to act as a template for competitive bidding, the upcoming A/B contractor jurisdictions were carefully designed to accommodate and acknowledge regional similarities and differences. These regions, therefore, would present the most logical basis for vendor bids and should be designated as such in the Final Rule, with phase-in that coincides with contractor reform timing. Because vendors will have the opportunity to cancel their 3-year contracts on an annual basis, with 6 months notice, the addition of geographic sub-regions should not harm

initial CAP vendors and will provide physicians with additional vendor alternatives that may increase CAP participation.

Similarly, while Biogen Idec supports CMS' decision to designate a single carrier for vendor claims processing during the 2006 phase-in, we urge CMS to move toward Part B carrier processing of both physician administration and vendor claims upon contractor reform completion in each geographic area. This will reduce Medicare costs of processing CAP claims and matching physician claims with supplier submissions. It will also streamline the physician/vendor grievance process by reducing the number of entities that must be coordinated to resolve disputes.

3. Claims Processing Overview

a. Emergency Re-supply Option

Biogen Idec supports CMS in its decision to define an "emergency situation" for purposes of the emergency re-supply option as "an unforeseen occurrence or situation determined by the participating physician, in his or her clinical judgment, to require prompt action or attention for purposes of permitting the participating CAP physician to use a drug from his or her own stock." This provision ensures that the physician/patient relationship is paramount in clinical decision-making. We appreciate that CMS does not appear to require a higher level of scrutiny over emergency restocking claims than ordinary CAP claims, as this would represent a significant medical review expenditure with little potential gain on recovery for erroneously paid claims. Again, we urge CMS to permit providers and vendors to determine the mechanical processes that work best for each product that is supplied through emergency restocking. Similarly, we suggest that contractor review of the existence of an emergency would not be in the best interests of the Medicare program as it would be unfair to require the vendor to absorb the cost of a medically necessary therapy that was actually administered simply because a contractor did not agree than an emergency situation was presented. Biogen Idec expects that CMS placed this decision within the physician's judgment to eliminate the need for contractor review.

b. Claim Denials

Biogen Idec supports CMS in its clarification that CAP vendors are not permitted to make medical necessity determinations or refuse to ship ordered therapies. In its comments to the Proposed Rule, however, Biogen Idec expressed concern that the shift in risk for denied drug claims from the treating physician to the CAP vendor may have an unintended impact on the Medicare program and coverage for drugs and biologicals. In the IFR, CMS acknowledged that CAP vendors are suppliers and appeared to confirm

applicability of waiver of liability provisions to protect the vendor from unanticipated medical necessity denials. Biogen Idec is concerned, however, that CMS encouraged CAP vendors to mitigate the risk of potential denials by securing an ABN. Specifically Biogen Idec contends that:

- CMS did not explicitly place the same constrictions on CAP vendor ABNs that apply to physicians and other suppliers, including the prohibition on "routine" ABNs; and

- The process of vendors securing ABNs from beneficiaries is filled with logical anomalies:

    - The physician must confirm that the drug claim will not likely be denied by referring to local and national coverage decisions prior to ordering the drug;

    - The vendor can contact the physician if it expects the claim to be denied, and express its concern that the claim will not fit within the applicable coverage policies;

    - If the physician still believes that the claim will be paid and that the drug is medically necessary, the physician will confirm the order to the vendor and the vendor must supply the drug, HOWEVER,

    - The vendor can then request that the physician secure an ABN, which means that the physician will present the beneficiary with a written document stating the belief that the claim will NOT be paid, despite the physician's assertions to the vendor that the order is in compliance with all applicable coverage policies.

As noted in its prior comments, Biogen Idec expects that initial CAP implementation will appear relatively smooth and that unexpected medical necessity denials will be minimal. We oppose the use of ABNs to shift financial risk from vendors and the Medicare program onto Medicare beneficiaries, particularly where a single national vendor region is likely to generate inappropriate ABNs due to applicability of varying local coverage policies. Biogen Idec is also concerned that vendors will seek premature and/or unnecessary local coverage decisions to gain code-specific reimbursement certainty, and that vendors will effectively govern medical necessity decisions through the ABN process.

We suggest that the physician/vendor grievance process should be the means through which vendors mitigate their risk of financial loss due to unpaid drug claims. Biogen Idec also urges CMS to monitor the frequency of medical necessity denials of drug

claims to determine whether refinements to the CAP should be proposed through the notice and comment process. For example, CMS could require vendors to fill orders for on-label and compendia-listed uses and permit physicians to utilize the ASP system (upon vendor request) for additional uses that the physician believes are supported by peer-reviewed medical literature or otherwise medically accepted. This process would be consistent with the current system of communication between physicians and contractor medical directors on ensuring that Medicare responds appropriately to evolving standards of care. It would also prevent drug vendor requests for local coverage decisions based upon a desire for ICD-9 level certainty rather than the access and program integrity justifications that more appropriately drive coverage processes and decisions.

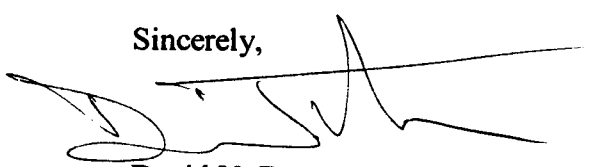
c. Physician/Vendor Contractual Relationships

Biogen Idec appreciates CMS' explicit statement permitting vendors and physicians to engage in contractual arrangements that enhance the benefits of CAP to both parties. We suggest that CMS open a dialogue between potential vendors and physician groups to explore the types of relationships that may be beneficial. CMS may wish to explore the arrangements that exist inn the private sector specialty pharmacies and infusion providers to determine whether any of these models may present cost savings through increased CAP participation. We also suggest that CMS assist vendors and physicians in determining which arrangements may run afoul of fraud and abuse laws, including anti-kickback provisions.

Conclusion

Biogen Idec appreciates the additional opportunity to comment on the CAP offered in CMS' Interim Final Rule. As always, we welcome any questions or additional information that you may have, and look forward to working with you on implementation of this important new program.

Sincerely,



David V. Foster
Vice President, Government Relations

Johnson & Johnson

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KATHLEEN A. BUTO
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September 2, 2005

By Hand Delivery

Mark B. McClellan, MD
Administrator, Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
Attn: CMS-1325-IFC
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200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B (CMS-1325-IFC)

Dear Dr. McClellan:

On behalf of Johnson & Johnson (J&J) operating companies, we are providing the following comments in response to the Interim Final Rule (IFR) issued by the Centers for Medicare and Medicaid Services (CMS) regarding implementation of the Competitive Acquisition Program (CAP) for Part B drugs and biologics published in the Federal Register on July 6, 2005.[1]

J&J is the world's most comprehensive and broadly based manufacturer of health care products, as well as a provider of related services, for the consumer, pharmaceutical and medical devices and diagnostics markets. J&J has more than 200 operating companies in 57 countries around the world employing approximately 109,000 employees and selling products in more than 175 countries. The fundamental objective of Johnson & Johnson is to provide scientifically sound, high quality products and services to help heal, cure disease and improve the quality of life. Of particular relevance to this rulemaking, J&J operating companies manufacture and market some of the most important drugs and biologics covered under Part B of the Medicare program, including PROCRIT® (epoetin alfa), REMICADE® (infliximab), RISPERDAL CONSTA® (risperidone) and NATRECOR® (nesiritide).

J&J has long believed that the CAP can help ensure patient access to important therapies while offering an alternative for physicians to the current "buy and bill" system under

[1] 70 Fed.Reg. 39021.

which physicians purchase the drugs, collect the beneficiary coinsurance and bill the Medicare program for drug reimbursement. We commend CMS for instituting several policies in the IFR that promote Medicare patient access to Part B drug therapies including (1) the creation of a single broad category of drugs that includes mental health products and complex biologics and (2) the nationwide implementation of the program that will allow physicians and their Medicare patients in all parts of the country to have access to the CAP. Given these positive aspects of the CAP IFR, we were disappointed to learn that CMS has planned a 6-month delay in the implementation of the program from January 1 to July 1, 2006.

While it is likely that CMS will work in this interim period to make the program more attractive to the vendor and physician community, we urge CMS to continue to make patient access to medical therapies the paramount goal of the CAP program. **Specifically, we urge CMS not to scale back the number and scope of products included in the CAP and to maintain the national rollout of the program for 2006. We also urge CMS not to delay the initial implementation of the program any later than July 1, 2006 as providers especially in the mental health and rheumatology fields would like to utilize CAP at its earliest possible date.** As CMS stated in the IFR, "it is important to provide an alternative to the 'buy-and-bill' method of drug acquisition for physicians as widely and quickly as possible."[2] We therefore urge CMS not to delay implementation of the program any longer than July 1, 2006.

Our specific comments and recommendations follow. As requested by CMS, we have identified the specific "issue identifier" that precedes the section of the IFR on which we are commenting.

I. Categories of Drugs to Be Included Under the CAP

A. Number of NDCs Provided by the Vendor In a HCPCS Code. CMS stated in the IFR that it would not require vendors to provide every National Drug Code (NDC) associated with a HCPCS code.[3] While we understand that CMS is trying to promote competition and minimize the administrative and financial burden of the CAP vendor, we are concerned that this policy could have negative implications for patient access and overall quality of care if applied in all situations. We think that CMS should institute two general exceptions to this policy described below before final implementation of the CAP.

J&J Recommendation: We recommend that vendors be required to provide all NDCs within a specific HCPCS code in the following two situations:

1. *CAP vendors should be required to bid on all NDCs within a HCPCS code if they are unit doses of the same single-source medication.* For example, if a single-source drug or biologic has three NDCs to describe three different unit strength doses within the same

[2] Id. at 39035.
[3] Id. at 39034.

HCPCS code, a vendor could theoretically bid on and provide only one dosage level to the physician under the current CAP rules. Under such a scenario, the CAP vendor could choose to bid on and provide only the lowest dosage strength of a given product. In this case the physician may be offered only a 25 mg dose of a given product described by a specific NDC, but some of his patients may be in need of larger 75 mg doses. There is the potential that the physician would have to inject the drug three times to appropriately treat the patient. This obviously would have negative implications for quality of care for the patient. While the physician could theoretically obtain other NDC formulations of the product through the "furnish as written" policy, we believe that physicians should not be forced to take on this additional administrative burden just to obtain the correct dosage of a product covered under the CAP program. We strongly recommend that CMS remove this possibility by requiring the vendor to supply all NDCs describing different dosing levels for the same single-source drug within the HCPCS code. This requirement should add no more than minimal administrative and financial burden on the CAP vendor. Accordingly, CMS should take the requested action in the interest of patient welfare as described above.

2. *Vendors should be required to provide the NDCs of branded single-source drugs described by the same HCPCS code.* CMS wisely rejected comments to establish drug formularies under the CAP. As the agency indicated in the IFR, "[w]e are not accepting the recommendation that vendors be permitted to establish drug formularies by offering drugs from only some of the codes included in a category. The statute expressly requires that for multiple source drugs, a competition be conducted for the acquisition of at least one drug per billing code within the category."[4] We agree that the statute expressly requires competition for multiple source drugs, but does not create such a structure for single-source products. We believe that all single-source products should be offered the same status under the CAP regardless of whether they have their own unique HCPCS code or share them with other branded products.

Requiring each CAP vendor to bid on at least one NDC for each single-source drug and biological in a category would ensure that Medicare beneficiaries have access to the brand that works best for them. Single source drugs are unique products that should be carried by each CAP vendor in order to ensure patient access to them. We believe that it is essential that each patient receive the specific brand that is best suited for his or her condition so that patient treatment options are not dependent upon a physician's CAP decision. This recommendation would not add significant administrative or financial burden on CAP vendors given that there are very few examples of similar single source drugs covered under CAP that are described by the same HCPCS code.

B. Inclusion of New Drugs and Biologicals in the CAP. We commend CMS for requiring CAP vendors to bid on and provide the 12 new drugs and biologicals listed in Addendum B,[5] including "Risperidone, long-acting" (J2794) otherwise known as RISPERDAL CONSTA®. Psychiatrists operating at Community Mental Health Centers

[4] Id. at 39034.
[5] Id. at 39102.

(CMHCs) support the CAP and hope to use the program as a way to offer patient access to this important new therapy.

However, we were disappointed that the IFR did not have an explicit provision to require vendors to bid on and provide other new Part B drug therapies likely to be introduced over the initial three-year CAP contracting period. While CMS encourages vendors to add new drugs to the program beyond the initial list in the single category, it does not require them to do so.[6] As a result, physicians electing the CAP program may not be able to access the newest therapies through the CAP unless the vendor agrees to offer such products. Physicians may be forced to devote financial resources to obtaining such products through the "buy-and-bill" acquisition model. In addition, CAP-enrolled physicians who must purchase these newer non-CAP products directly from wholesalers and distributors will likely be extremely low volume purchasers. As a result, such physicians may be forced to pay higher prices for the same product(s) as larger volume practices that continue to buy-and-bill for all their drug purchases.

J&J Recommendation: CMS should require vendors to bid on and provide new Part B therapies by no later than the next calendar quarter following FDA approval. These therapies should be reimbursed to the CAP vendors under the methodology created in section 1847A of the Social Security Act until the next vendor bidding cycle. Newer products should be treated comparably to the 181 drugs in the single drug category so that physicians electing CAP can have full access to the newest technology without having to revert back to the "buy-and-bill" system.

C. Future Drug Categories. For the initial roll-out of CAP, CMS has established a single drug category consisting of 181 drugs and biologicals representing approximately 85 percent of physicians' Part B drugs by billed charges. The agency indicates in the IFR that it plans to phase-in multiple drug categories in future years "probably defined around the drugs commonly used by physicians' specialties (for example, urology, rheumatology)"[7] as CMS refines the program.

J&J Recommendation: We look forward to working with the agency on developing new categories under the CAP. We strongly recommend that CMS maintain a broad category structure to ensure adequate vendor interest for all therapeutic areas in future years. For example, if CMS structured the product categories too narrowly so that very few Part B products would fall into a single specialty category (e.g. psychiatry), vendors may have little interest in bidding on the products if they proved to be insufficiently profitable. As CMS states in the IFR, the broad single drug category will increase the interest of potential vendors by making it more likely that "the fixed costs of being a vendor can be covered across the broad array of Part B physician-administered drugs that are included..."[8] While multiple categories may be necessary in future years, we strongly recommend that CMS structure them broadly enough to maintain sufficient vendor interest in all therapeutic specialty categories.

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[6] Id. at 39075
[7] Id. at 39030.
[8] Id. at 39030.

II. Competitive Acquisition Areas

Subcontractor Responsibilities. CMS has established a single, national distribution area for the initial stage of CAP. Given that there will be a maximum of only five vendors selected to participate in the program, it is highly likely that vendors will need to employ subcontractors to adequately fulfill drug distribution responsibilities in all 50 States, the District of Columbia, Puerto Rico and the U.S. territories. While we support the national implementation of the CAP in 2006, we are concerned about the possibility of product counterfeiting or other product integrity issues with the use of vendor subcontractors in such a broad geographic region. For this reason, we welcome CMS's decision to require subcontractors to comply with all the requirements binding on the CAP vendor themselves, including those relating to product integrity.[9] We also appreciate that CMS holds CAP vendors accountable even for the acts of its subcontractors.[10] We request, however, certain additional safeguards described below.

J&J Recommendation: We believe that CAP vendors should have an obligation to expressly include in their agreements with their subcontractors a covenant binding on the subcontractor to comply with all rules applicable to CAP vendors, including those rules regarding product integrity and drug pedigree set forth in 42 C.F.R. §§ 414.906(a)(4) and 414.914(c)(1). The subcontractor agreement should also include that the Department of Health and Human Services (DHHS) is a third party beneficiary to these agreements with the right to enforce any of the provisions relating to CAP program compliance. The agreement would also need to specify that DHHS should have access to all books and records relating to CAP program compliance.

III. Claims Processing Overview

A. Payment of Coinsurance by Medicaid. The IFR establishes a number of procedures and requirements that the vendors must first address before refusing to make further shipments of drugs to physicians for individual beneficiaries due to non-payment of coinsurance.[11] For most dual eligible beneficiaries, state Medicaid plans will be responsible for the coinsurance for patients receiving their Part B drugs from physicians enrolled in CAP. As CMS is aware, individual state Medicaid plans can have differing policies on the appropriate level of Medicare Part B coinsurance for dual eligible beneficiaries. This inconsistency among the States may be confusing to some vendors in determining when a dual eligible patient in CAP has met his or her coinsurance obligations.

J&J Recommendation: We request that CMS confirm that CAP vendors cannot refuse to make shipments of CAP drugs on behalf of dual eligible beneficiaries when a State Medicaid program has upheld its statutory obligations relating to coinsurance payments. For certain dual eligible beneficiaries, State Medicaid programs can limit coinsurance

[9] 42 C.F.R. § 414.914(f)(9); 70 Fed. Reg. 39022, 39060.
[10] 42 C.F.R. § 414.914(f)(9).
[11] 42 C.F.R. § 414.914(h).

payments to the extent that any such payment, when combined with Medicare payments, equals the amount of reimbursement payable under the State Medicaid program.[12] Accordingly, a State Medicaid program may deem a CAP vendor to be paid in full even if it has received either no coinsurance payment or a reduced payment from the State. Beneficiaries have no liability beyond the State's payment.[13] Thus, CMS should clarify that the State's adjudication of a claim for payment of an outstanding coinsurance amount is final. CAP vendors have no continuing right after the State's adjudication to seek payment from the beneficiary of any purported remaining balance pursuant to 42 C.F.R. § 414.914(h)(2). The State's claim adjudication should preclude the CAP vendor from pursuing any action that would ultimately lead to the CAP vendor's refusal to make future shipments of CAP drugs on behalf of the beneficiary. In order to account for any shortfall in financing to the CAP vendor, CMS may need to take these variable co-payments into account in making payment adjustments to the CAP vendors' administrative costs.

To facilitate the processing of these claims for coinsurance for dual-eligible beneficiaries, J&J recommends that CMS direct Noridian, the designated CAP carrier, to update their claims process systems so that claims can be automatically crossed over from Noridian to the relevant state Medicaid program. This will permit the speedy processing of claims by Medicaid programs for dual-eligibles and allow CAP vendors to submit a single claim for such patients, when automatic cross-over is permitted by the Medicaid program in question.

B. Waiting Period Before a Vendor Can Withhold Delivery of Drug for Non-Payment on Coinsurance. Under the provisions of the IFR, vendors must provide information, when requested by patients, on sources of cost-sharing assistance available to beneficiaries. This assistance can include a referral to a bona fide and independent charitable organization. If the beneficiary requests cost-sharing assistance and the vendor refers the patient to a bona fide independent charitable organization for assistance or offers a payment plan, the vendor must wait an additional 15 days from the postmark of the approved CAP vendor's response to the beneficiary's request for cost-sharing assistance. If at the end of the 15-day period the vendor has not received a cost-sharing payment from the charitable organization or the patient, the vendor may refuse to ship additional drugs to the physician on behalf of that patient. [14]

J&J Recommendation: CMS should extend the time the CAP vendor must wait before discontinuing provision of drug after which the patient has requested assistance and the vendor has provided patients with a referral to third-party. If a patient requests assistance, and if they are referred to a third-party for assistance, they should be provided greater than 15 days to assemble required materials, submit the materials and have the application for assistance reviewed and approved and finalized. We propose that time requirement should be a longer period of time (e.g. 30 to 45 days) to permit patients to

[12] Social Security Act, § 1902(n)(2).
[13] Social Security Act, § 1902(n)(3)(A).
[14] 42 C.F.R. § 414.914(g).

appropriately respond and gather information and submit materials required by various assistance organizations. It is not unreasonable to expect that Medicare beneficiaries in need of financial assistance will need additional time beyond 15 days to navigate the administrative requirements necessary to receive third-party assistance under the new CAP program in 2006 and receive approval and funding from these organizations.

C. Option for Physicians to Opt Out of CAP for Non-Delivery of Drug. The IFR permits CAP physicians to opt out of the single category in the CAP program altogether in 2006 "in instances where a beneficiary has failed to meet his or her obligation to pay coinsurance or deductible for a drug and the vendor has refused to continue providing the drug..."[15]

J&J Recommendation: CMS should clarify that in the situation highlighted above where a vendor has refused to continue providing the drug for a specific beneficiary who has failed to meet his or her cost-sharing obligations, that the physician should instead be afforded the opportunity to seek reimbursement for that specific beneficiary under the Average Sales Price (ASP) plus six percent methodology. However, the physician should still be able to remain in the CAP program for his or her other patients that do not have difficulties meeting their cost-sharing obligations through their own financial means or through secondary insurance. It seems extreme to force physicians to withdraw completely from the new CAP program as a result of cost-sharing difficulties related to one specific patient. Physicians in this situation would face the Hobson's Choice of either abandoning the one financially needy patient or incurring the financial exposure entailed in returning to the purchase of drugs under Section 1847A of the Act. CMS should not put physicians in this position.

D. Payment for Discarded Drugs. The IFR appears to create a new and inconsistent policy that conflicts with long-standing CMS policy on discarded drugs set forth in the Claims Processing Manual. CMS states that "[s]ince the CAP statute authorizes us to pay the approved CAP vendor only upon administration of the drug, any discarded drug (or drug that is considered waste) will not be eligible for payment."[16] However, we are encouraged to see that CMS has since clarified its position and legal interpretation of the CAP statute given the recent "Question & Answer" (Q&A) statement posted on the CMS website. "Generally speaking, under the Average Sales Price system, a physician is able to bill the program for unused drugs if the physician acted in good faith with respect to the ordering and use of the drugs. We expect that vendors will be able to bill the program for unused drugs under the CAP program in a similar fashion if physicians and vendors act in good faith with respect to the ordering and use of the drugs."[17]

J&J Recommendation: We commend CMS for clarifying its position in the recent Q&A. We recommend that CMS modify the regulations governing the CAP program to

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[15] 70 Fed. Reg. at 39053.
[16] Id. at 39063.
[17] See "Response to CAP Vendor Questions," posted at http://www.cms.hhs.gov/providers/drugs/compbid/capquestions081005.pdf

reflect the position in the Q&A posting above to avoid any further confusion for vendors and physicians.

E. Administrative Burden – Need for A Physician Management Fee Under CAP. CMS declined requests it received in the prior comment period to establish a management fee reimbursement for physicians electing the CAP to offset some of the additional costs providers will face under the new program. In stating its rationale for declining such requests CMS stated that "[a]lthough we agree that a physician may have to make some adjustments in his or her practice in order to comply with the requirements under the CAP, we believe that the relief of the financial burden of purchasing the drugs and billing Medicare for these drugs will be a substantial improvement and benefit for many physicians."[18]

This statement assumes that certain efficiencies will accrue to physician practices due to anticipated elimination of certain functions or activities under CAP. However, CAP does not materially reduce the administrative resources associated with the following activities:

- Actual administration of the therapy;
- Billing for the drug administration; and
- Collection of coinsurance for the drug administration.

In addition, CAP requires additional activities that do not occur under the buy and bill model. These include:

- Individualized order entry vs. bulk order entry today;
- Additional discussions with patients regarding their second bill from the CAP vendor, and communication of related patient-specific information;
- Potentially maintaining a duplicative and parallel procurement systems in addition to established purchasing processes;
- Increased vial tracking tasks to comply with CAP provisions; and
- Increased administrative processes associated with use of a replacement or alternative vial (e.g., as in the event of a patient failing to show up for an appointment).

In addition, the CAP imposes a significant change for some practices by establishing "just-in-time" (JIT) processes as explained below. Under CAP, the vendor is required to deliver the drug for administration to each individual patient in two business days from the date of that patient's administration. This type of order fulfillment is known as "just-in-time" inventory management.

[18] 70 Fed. Reg. at 39049.

JIT purchasing is the purchase of goods or materials (the CAP drugs in this case) such that delivery immediately precedes demand or use.[19] It is an accepted cost accounting fact that JIT inventory management incurs certain incremental costs. Such increased incremental costs include:

- Ordering costs per purchase order under JIT;
- Materials requirements planning (i.e., coordination of separate purchasing processes for materials and supplies associated with drug administration);
- Incoming materials inspection and tracking; and
- Inventory stockouts (i.e., management of inventory shortfalls and delays).

In summary, a CAP JIT inventory system in the physician's office will require additional inventory and clerical resources.

J&J Recommendation: CMS should establish a management fee for physicians who participate in the CAP to offset some of these added JIT and other related costs as a result of participating in the program. We also plan to submit a similar comment as part of our comments on the 2006 Physician Fee Schedule proposed rule.

IV. CAP Bidding Process – Evaluation and Selection

Composite Bid: Products with Multiple HCPCS Codes. The IFR establishes a "composite bid" process to evaluate bid prices submitted by prospective CAP vendors. The composite bid will weight a vendor's bid price for each CAP drug by the relative utilization of its HCPCS code in 2004 compared to all other CAP covered HCPCS codes in the category. Addendum A of the IFR lists the assigned relative weights for each HCPCS code within the single drug category. For example, the HCPCS code for PROCRIT® (Q0136) is assigned the highest relative weight for all CAP drugs of 0.2489891.

We note that several single-source drugs and biologicals in the single category have multiple HCPCS codes with considerably different relative weights depending on 2004 utilization for the code. We are concerned that the composite bidding structure described in the IFR could provide an incentive for gaming of the bids for products with multiple HCPCS codes. Consider an example of a single-source product under CAP that has two HCPCS codes to describe different dosage strengths: HCPCS code *JXXX* has a dosage of 1 mcg and has a relative weight of 0.15 and code *JYYY* has dosage of 10 mcg and a relative weight of 0.05 (See table below). Under this scenario, vendors could potentially bid significantly higher amounts on a per dosage unit for the lower weighted HCPCS code *(JYYY)* compared to the higher weighted HCPCS code *(JXXX)*. In the scenario described in the table below, vendors could bid $10 for code *JXXX* or $10 per mcg unit. Alternatively, the vendor could bid $120 for code *JYYY* or $12 per mcg unit.

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[19] C. Horngren, et. al. *Cost Accounting: A Managerial Emphasis*, 8th ed. Englewood Cliffs, NJ: Prentice Hall (1994) 840.

This practice could help allow the vendor to meet the overall ASP plus six percent weighted-average bid, but result in a significantly higher median bid and reimbursement on a per unit basis for the lower-weighted HCPCS code. Such an action by even one winning CAP vendor could have an impact on the eventual median bid of a given drug, especially if only three vendors are eventually selected to participate in the program. Upon implementation of the CAP program vendors could potentially encourage physicians to utilize the HCPCS code with the lower composite bid relative weight that has the higher per unit reimbursement rate.

Drug	HCPCS	Dosage	Weight	Bid for HCPCS Code	Per Unit (mcg) Bid
A	JXXX	1 mcg	0.15	$10	**$10**
A	JYYY	10 mcg	0.05	$120	**$12**

J&J Recommendation: CMS should require vendors to submit consistent "per unit" bids on single-source drug and biologic products with multiple HCPCS codes. This would remove the potential for vendors to have different per unit bids for HCPCS codes with differing relative weights and prevent the gaming scenario described above.

Conclusion: J&J appreciates the opportunity to submit comments and recommendations to CMS. We look forward to working with you and your staff to ensure that Medicare beneficiaries have meaningful access to Part B drugs and biologics under the CAP. If you have any questions related to these comments, please contact Greg White at 202-589-1040.

Sincerely,

Kathy Buto
Vice President, Health Policy

SEP - 1 2005

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September 1, 2005

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Washington, D.C. 20201

RE: CMS-1325-IFC (Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals under Part B)

Dear Administrator McClellan:

Amgen appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Interim Final Rule regarding the competitive acquisition of outpatient drugs and biologicals under Part B, published in the Federal Register on July 6, 2005 (the Interim Final Rule).[1] As a science-based, patient driven company, Amgen is interested in improving access to innovative drugs and biologicals for Medicare beneficiaries. As we wrote you in commenting on the proposed rule, Amgen supports the goal of this program, to provide patients with broad access to the medications their physicians think they need, while providing physicians who are disadvantaged under the new Average Sales Price (ASP) payment system an alternative method to obtain and provide these drugs and biologicals to patients.

Amgen appreciates the progress CMS has made regarding the design of the Competitive Acquisition Program (CAP), and Amgen is pleased that CMS intends to provide further clarification about the program that will help ensure that Medicare beneficiaries being treated by a physician enrolled in the CAP will receive full access to drug and biological therapy with products covered under Medicare Part B. Amgen reiterates that the CAP must be designed to minimize patients' access risks and maximize physicians' opportunities to provide individualized, medically appropriate treatment to patients.

As CMS reviews comments to the Interim Final Rule and moves to implement the CAP for Part B drugs and biologicals, Amgen continues to urge CMS to weigh the full range of potential consequences to patient care, especially in the oncology setting. Amgen commends the agency on designing an Interim Final Rule that protects beneficiaries access to therapies and defers to a

[1] 70 Fed. Reg. 39021 (July 6, 2005).

physician's clinical judgment. Amgen submits this comment in the interest of encouraging CMS to implement the statute with a priority on the following objectives:

1. The statute should be implemented with safeguards that preserve the physician's prescribing authority. The financial goals of the competitive acquisition vendors should not outweigh the clinical decision-making authority of a physician.

2. Any reform should not disrupt Medicare beneficiaries' access to the most effective and highest quality health care that our system has to offer.

3. The CAP should maintain a primary focus on access to quality of care rather than a focus on cost-containment goals.

4. The CAP should not change the foundation of the Medicare Part B system. Patients whose physicians have enrolled in the CAP should not have access to a different set of sole source drugs than those whose physicians do not participate in CAP.

Amgen recognizes that the goal of Section 1847B of the Social Security Act (Competitive Acquisition of Outpatient Drugs and Biologicals) is to provide physicians who may be disadvantaged by the ASP payment system another option to acquire drugs and biologicals. We understand also that CMS believes the CAP could allow the government to realize savings from operational efficiencies. However, we are concerned that if not implemented cautiously and appropriately, patients may lose access and CMS may not realize the expected operational savings.

Amgen would like to emphasize that our greatest concern is that the insertion of an intermediary into the prescribing/treatment/payment continuum not be done in a way that interferes with physicians' ability to prescribe and to administer the drug or biological deemed the most medically appropriate for each individual patient. Therefore, CMS must ensure CAP vendors have no incentive and no regulatory pathway by which they can restrict, limit or change a physician's or patient's access to specific drug and biological therapy. The current design of the Part B system allows physicians to have unrestricted access to Medicare-covered products when prescribed for medically appropriate reasons. We believe that Congress was clear in its intention to maintain the physicians' ability to prescribe and administer the products they deem most appropriate for individual beneficiaries, and we recommend that the Final Rule contain explicit statement to this effect.

Amgen is committed to working with CMS and the medical community to ensure the statute is implemented in a manner consistent with the above four objectives. We believe CAP, if implemented carefully, can provide an important, new delivery model for Medicare Part B.

Respectfully submitted,

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August 31, 2005

SEP - 6 2005

The Honorable Mark McClellan, MD, PhD
Administrator
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445-G Hubert H. Humphrey Building
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Washington, DC 20201

Attention: CMS-1325-IFC

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

Dear Dr. McClellan:

On behalf of the Oncology Nursing Society (ONS) – the largest professional oncology group in the United States, composed of more than 33,000 nurses and other health professionals dedicated to ensuring and advancing access to quality care for all individuals affected by cancer – we appreciate this opportunity to submit formal comments to the Centers for Medicare and Medicaid Services (CMS) related to the Interim Final Rule for the competitive acquisition for Medicare Part B drugs and biologicals. As part of its mission, the Society stands ready to work with policymakers at the local, state, and federal levels to advance policies and programs that will reduce and prevent suffering from cancer, particularly among the Medicare population which is disproportionately affected by cancer.

While ONS opposes "outsourcing" arrangements – such as the competitive acquisition program (CAP) – for prescription drugs related to chemotherapy and supportive care, ONS appreciates that CMS is required by the MMA to implement a CAP. We commend CMS for recognizing the inherent complexity associated with the CAP implementation and for temporarily suspending bidding to allow the agency to fully review and consider public comments on the CAP, make any necessary modifications, and improve the structure, operation, and oversight of the new program.

As we have commented previously, ONS has serious concerns about the implementation and effects of the CAP – or outsourcing of chemotherapy acquisition and preparation. We thank CMS for its attention to our previous comments; however, as many of our concerns in our comments from earlier this year remain unaddressed in the Interim Final Rule, we are attaching those comments here for your reference. In addition to our attached previous comments, we would like to take this opportunity to highlight a number of particular concerns and issues. We appreciate the agency's consideration of our views and stand ready to work with CMS and other stakeholders to ensure that all Medicare beneficiaries with cancer have access to quality, comprehensive cancer care in their own communities.

Ensuring Patient Access to Timely and Uninterrupted Treatment

One of the Society's principal concerns regarding the CAP is ensuring that Medicare beneficiaries will have access to the therapies they need in a timely fashion and will not be put at-risk of suspension of treatment if they are unable to afford the associated co-payment. ONS strongly opposes CMS granting vendors the right to cut off delivery of drugs for patients who fail to meet their cost-sharing obligations. Under the Interim Final Rule, CAP vendors are permitted to stop shipping drugs for patients who have not paid billed cost-sharing amounts within 45 days after the postmark date on the bill, unless the patient has contacted the vendor about payment difficulties. While the Interim Final Rule does provide for notification, waiver, and limited postponement, many patients likely will be unable to cover the full cost of their coinsurance, leaving them vulnerable to treatment cut-off. The possibility of "stop-and-go" - or episodic treatment when patients can afford their care - could lead to myriad problems for patients and the Medicare program, including adverse health effects, compromised efficacy of treatment regimens, increased costs to the Medicare program if patients start and stop courses of therapies and/or experience adverse health effects due to episodic treatment which require hospitalization or other emergency or urgent care.

ONS members indicate that under the current "buy-and-bill" system, most practices assure patients and their family members that treatment will not be suspended due to an inability to pay; forcing an interruption in care due to financial hardship is a tactic that most consider immoral and unconscionable. Most practices work closely with patients to ensure continuity of care throughout the course of treatment while also addressing financial concerns, but do not allow payment challenges to interfere with the needed course of care. By allowing CAP vendors to suspend delivery of much-needed therapies, CMS possibly is making Medicare beneficiaries vulnerable to interruptions in treatment, undue stress and confusion from vendor collection efforts and pressures, and associated adverse health effects that could be caused by these two significant factors.

Also, as noted in our earlier comments, the Society has serious concerns that the CAP, as structured, will not ensure timely delivery of drugs; and, as a result, patients and their family members likely could be inconvenienced. Moreover, when a change is needed in a patient's course of therapy, there could be a multiple day delay which could compromise a patient's health and well-being, and undermine the efficacy of the overall treatment regimen. ONS urges CMS to expand the CAP delivery schedule beyond the current parameters of only five days a week and the standard business day timetable.

Another concern is that in some cases and in some areas of the country, in order to avoid an interruption of treatment either when treatment protocols change and a patient cannot wait to get a drug from a vendor and/or if there is a financial problem between the patient and vendor and the needed therapy is not being shipped, some patients may seek treatment in hospitals. As you know, hospitals are not always a feasible or appropriate alternative site for cancer treatment for myriad reasons, including: the hospital may be less convenient for the patient; the hospital may maintain a lesser capacity in the provision of oncology care, for example it may

not have chemotherapy certified nurses on staff in outpatient areas (and deny in-patient admission because the treatment does not truly require admission as an inpatient); or, the hospital may not have an outpatient chemotherapy department at all. As such, ONS urges CMS to reconsider its granting to vendors the right to cut off delivery of drugs for patients who fail to meet their cost-sharing obligations as well as strongly encourages the agency to expand the CAP delivery schedule beyond the current parameters of only five days a week and the standard business day timetable.

Integrity of Therapies Provided/Acquired through the CAP

ONS remains concerned about the ability of CMS to ensure the integrity of chemotherapeutic agents acquired through the CAP. ONS urges CMS to establish standards for CAP vendors similar to those for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and provide for routine survey requirements under the Interim Final Rule. ONS encourages CMS to conduct and support frequent, random, unannounced site inspections of CAP vendors and their subcontractors to review purchase contracts, shipping documents, and other records that establish and illustrate the chain of custody of drugs delivered to physician practices participating in the CAP.

Summary

ONS again thanks CMS for this opportunity to provide comments on the competitive bidding of chemotherapy under Medicare Part B. As we have commented previously, ONS has serious concerns that taken together - Medicare payment policies, the current and expected nursing shortage, and the projected increase in the overall number of cancer cases over the next twenty years - pose a significant threat to the ability of our nation to provide quality cancer care to all who may be in need. The Society maintains that people with cancer should be assured access to comprehensive quality care that proves the most effective and appropriate for them.

ONS welcomes the opportunity to work with you, Congress, and other cancer community stakeholders to craft and implement Medicare policy changes that provide adequate and appropriate payment for the full range of cancer-related care, ensure access to quality cancer care for seniors with cancer, and prove fiscally responsible for the nation.

As always, if we can be of any assistance to you, or if you have any questions, please feel free to contact us or our Washington, DC Health Policy Associate, Ilisa Halpern (202/230-5145, ihalpern@gcd.com).

Respectfully submitted,

Karen J. Stanley

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NOVARTIS

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September 6, 2005

BY HAND DELIVERY

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RE: CMS-1325-IFC (Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B)

Dear Dr. McClellan,

On behalf of Novartis Pharmaceuticals Corporation (Novartis), I appreciate this opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS's") interim final rule on the Medicare Competitive Acquisition Program (CAP) for Outpatient Drugs and Biologicals Under Part B, published in the Federal Register on July 6, 2005. Novartis Pharmaceuticals Corporation is part of the Novartis Group of Companies, a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. Of particular relevance to this rulemaking, Novartis manufactures and markets drugs in the oncology, ophthalmics, and transplant areas that are covered under Medicare Part B.

We commend you and your staff for your efforts to develop this interim final rule (IFR). Novartis' goal is to ensure that patients have meaningful access to pharmaceuticals covered under Medicare Part B. We appreciate the improvements that CMS has made to the program to help achieve these goals and are encouraged that CMS intends to make additional changes before implementing the program. Our comments on the interim final rule reflect the goal of patient access to care and make suggestions to improve the operation of the program.

If you have any questions or require clarification on any of our positions on these issues do not hesitate to contact me.

Sincerely,

Bonnie Washington

Categories of Drugs To Be Included Under the CAP

Limiting CAP to Physician-Administered Drugs. In the IFR's discussion of the categories to be included in CAP, CMS states that they will "implement the CAP initially for a broad range of drugs administered incident to a physician's service. However, we will continue to consider whether the statute allows extension of the program to Part B drugs that are administered through DME or dispensed by pharmacies." [1] We support CMS' decision to limit CAP to drugs administered incident to a physician's service. We agree that CMS should solicit public comments through a proposed rule if in the future they determine the statute allows such as extension.

As we stated in our comments on the proposed rule, we continue to believe that, in fact, the best reading of the statute is that only physician administered drugs should be included in the CAP. The CAP cannot apply to drugs and biologicals furnished by Medicare suppliers (e.g., pharmacies), including immunosuppressive drugs for the following reasons:

a) The application of CAP to pharmacy supplied drugs might have an adverse impact on beneficiary access to such products. For example, inclusion in CAP could deny beneficiaries access to a full range of oral immunosuppressive drugs that are in the same billing code, yet are not therapeutically interchangeable. An example, Neoral (cyclosporine, USP) MODIFIED and Sandimmune cyclosporine, USP are both cyclosporine preparations that share a common HCPCS code but are not bioequivalent nor interchangeable. The proposed rules do provide for the physician to specify "furnish as written" to the CAP provider in certain cases, but the fact that the carriers responsible for claims adjudication may utilize post-payment review when physicians exercise the "furnish as written" option may well serve as an impediment to using the appropriate agent for the individual patient.

b) The statute does not appear to permit inclusion of pharmacy-furnished drugs in CAP. The language of the statute plainly provides that CAP applies only to drugs that are furnished by physicians. It is only "physicians" that the statute permits to make the election to choose CAP and "physicians" to whom the statute allows CAP contractors to provide products. Elsewhere in the statutory provisions governing Part B drugs, Congress has incorporated the word "supplier" when it intended to address reimbursement for pharmacy provided drugs and it did not do so in the CAP statute. It is reasonable to exclude oral immunosuppressive drugs since the statute provides clear direction that the election to participate in CAP lies with the physician and the included drugs are those administered as incident to a physician's service or procedure.

c) The intent of the statute was to remove the physician from the drug acquisition and billing process by providing a less burdensome means to obtain drugs. By including oral immunosuppressant medications in CAP, which are currently supplied by pharmacies, CMS would dilute the intent of the statute and only create another layer of distribution and logistic issues. This would defeat the very purpose for the CAP program's existence.

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[1] 70 Fed. Reg. at 39027.

d) Pharmacy furnished drugs do not fit within the CAP construct. CAP is intended for drugs that physicians administer and have historically purchased under the "buy and bill" method. Since pharmacies provide oral drugs (including immunosuppressants) to beneficiaries, physicians have not typically provided or administered such drugs in their offices.

Number of Drugs Provided by a Vendor in a HCPCS Code. CMS stated in the IFR that they would not require vendors to provide every NDC associated with a HCPCS code.[2] We agree with CMS' intent to promote competition and to avoid establishing a formulary, however, we believe that there are some circumstances under which CMS should require vendors to provide all NDCs within a specific HCPCS code. Under the IFR, if a single source drug has two NDCs to describe two different unit doses within the same HCPCS code, a vendor could theoretically bid on and provide only one of the dosages. This would deny patients' access to the other dosage form.

Novartis manufacturers Zometa®, which is zoledronic acid (J3487). Its current label indication is for the treatment of hypercalcemia of malignancy as well as for the treatment of bone metastases secondary to solid tumors and multiple myeloma. We are conducting clinical trials for two new indications for zoledronic acid in benign bone disorders. These new indications will have different dosage and dosing frequency, with a separate package insert, trade name and NDC number from Zometa® (pending FDA approval). In addition, it will likely be administered by primary care doctors, rheumatologists, and endocrinologists -- rather than by oncologists. We are concerned that CAP vendors will not provide the new dosage form of zoledronic acid and primary care physicians, rheumatologists and endocrinologists will have problems gaining access to the products.

We recommend that CMS require CAP vendors to bid on all NDCs within a HCPCS code if there are multiple NDCs for different unit doses of the same single-source medication available.

Claims Processing Overview

Unused CAP drugs. In the IFR, CMS states that "since the CAP statute authorizes us to pay the approved CAP vendor only upon administration of the drug, any discarded drug (or drug that is considered waste) will not be eligible for payment."[3] We are pleased that CMS has since modified their position in a recent "Question and Answer" statement posted on the website. In that response, CMS states that they "expect that vendors will be able to bill the program for unused drugs under the CAP program in a similar fashion if physicians and vendors act in good faith with respect to the ordering and use of the drugs."[4]

There are many examples of unavoidable wastage that occur with infused and injected pharmaceuticals:

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[2] Id. at 39035.

[3] Id. at 39063.

[4] See "Response to CAP Vendor Questions", available at http://www.cms.hhs.gov/providers/drugs/compbid/capquestions081005.pdf.

For example, Visudyne® is supplied in a single use glass vial and contains a lyophilized cake with 15mg of verteporfin. Prior to administration, the vial is reconstituted with 7ml of sterile water to provide 7.5ml containing 2mg/ml of verteprofin. The reconstituted Visudyne® must be protected from light and used within 4 hours. The product is administered based on a body surface area calculation which is intended to provide the patient with a dose of 5 mg/m^2 body surface area. Patients typically receive between 10-12 mg of Visudyne®; however the dosage can range from just a few mgs to two full vials depending on the patient's size. Therefore, the vast majority of Visudyne® cases will involve some small amount of appropriate wastage.

The standard dose of Zometa® is 4mg, but for a patient with impaired renal function, the dose must be titrated downward to as low as 3mg. This would lead to wastage of as much as 1 mg.

In both examples, vendors would have to absorb significant costs if CMS prohibited vendors from billing the program for unused drugs under the CAP program. This penalty could lead to dissatisfaction with the program and patient access problems.

We applaud CMS' recent policy clarification and believe that it is consistent with long-standing CMS policy on discarded drugs found in the Claims Processing Manual. We recommend that CMS include this clarification in the final rule to avoid confusion.

CAP Contracting Process

Product Integrity Aspects. We appreciate CMS' efforts to ensure product integrity, including the requirement for drug distributors and CAP vendors "include language with shipping materials stating that the drug was acquired directly from the manufacturer and has been acquired in a manner that is consistent with statutory requirements."[5] We are concerned that CMS will not be able to enforce these requirements to ensure product integrity. Therefore, we recommend that CMS establish standards and survey procedures for CAP vendors to inspect the chain of custody of the drugs delivered to CAP physicians.

CAP Bidding Process – Evaluation and Selection

Adjustment of Reimbursement Amounts. In the IFR, CMS states that they continue to believe that annual reporting and payment updates provide the most appropriate balance between vendor and CMS administrative burden and paying for CAP drugs based upon the most timely data, at least during this initial stage of implementation of CAP."[6] .

As we stated in our comments on the proposed rule, we continue to recommend that CMS update the CAP reimbursement amounts for vendors on a quarterly basis, parallel with the updates in the ASP system. If CMS does not update reimbursement under both systems on the same timetable, there could be serious discrepancies in payment amounts leading to confusion and access issues.

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[5] 70 Fed. Reg. at 39061.

[6] Id. at 39076.

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Pharmaceutical Care Management Association

PCMA

SEP - 6 2005

September 6, 2005

The Honorable Mark McClellan, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-IFC
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: File Code CMS-1325-IFC

Dear Dr. McClellan:

On behalf of America's pharmacy benefit managers (PBMs), the Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments in response to the Interim Final Rule for the Competitive Acquisition Program (CAP) for outpatient Part B drugs and biologics. PBMs are the leaders in providing access to specialty drugs including injectible, infused, and biologic products.

We appreciate the work by the Centers for Medicare and Medicaid Services (CMS) that went into the development of the proposed and interim final rules to implement CAP. However, we are very concerned that the resulting requirements may discourage both physicians and potential vendors from participating in the program. As potential vendors, PCMA members believe that the CAP rules, as provided for in the interim final rule, expose vendors to undue financial risk.

We have focused our comments on our most serious concerns:

1. The failure to exclude CAP prices from the calculation of the Average Sales Price (ASP);
2. The lack of an enforceable timely claims payment process; and
3. The inability of CAP vendors to recover financial losses resulting from drug wastage through no fault of the vendor.

CAP Bidding Process (Section II.C. Preamble)

CAP Prices Should be Excluded from the Calculation of ASP

The proposed CAP rule was silent on the question of whether CAP prices are excluded from ASP. We raised this issue in our comment letter on the proposed rule and indicated that we thought it imperative to a successful CAP program that this exclusion be adopted in the final rule. In the preamble for the interim final rule (p. 39077), CMS argues that it does not have the statutory authority to exclude prices determined under the CAP from the calculation of ASP. We are very concerned about CMS' decision. Including CAP prices in the ASP will make it very difficult for CAP vendors to negotiate the best prices from pharmaceutical manufacturers. The likely effect is that physicians will not really have a viable option between the ASP payment methodology and the CAP program.

Recommendation:

The Part B ASP payment methodology (§1847A of the Social Security Act) and the Competitive Acquisition Program (§1847B of the Social Security Act) were intended by Congress to be treated separately, with distinct requirements. We believe that the Medicare Modernization Act gives the Secretary the discretion to exclude CAP prices from the calculation of ASP. We urge CMS to apply the law as Congress intended and provide for a market environment in which price is determined through unfettered negotiation.

We believe that CMS has at least two bases under current law for excluding CAP prices from ASP. First, under §1927(c)(1)(C), "best price" means, with respect to a single source drug or innovator multiple sourced drug of a manufacturer, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity with the United States, excluding ...." Vendors under the CAP program do not squarely fit into the definition of any of the above included entities. It thus follows that prices paid by CAP vendors to manufacturers for Part B drugs should be excluded in the "best price" calculation. This exclusion can be made by the Secretary. By excluding the CAP vendors from best price, they are then excluded from the calculation of the ASP as a result of the application of 1847A(c)(1).[1]

Second, under §1927(c)(1)(C)(i)(I-II), federal purchasers are explicitly excluded from the calculation of "best price". Since CAP vendors will be Medicare contractors and payments made by Medicare

[1] Under 1847A (c)(1), the manufacturer's "average sales price" means, of a drug or biological for a National Drug Code for a calendar quarter for a manufacturer for a unit—
(A) the manufacturer's sales to all purchasers (excluding sales exempted in paragraph (2)) in the United States for such drug or biological in the calendar quarter; divided by
(B) the total number of such units of such drug or biological sold by the manufacturer in such quarter.
(2) CERTAIN SALES EXEMPTED FROM COMPUTATION.—In calculating the manufacturer's average sales price under this subsection, the following sales shall be excluded:
(A) SALES EXEMPT FROM BEST PRICE.—Sales exempt from the inclusion in the determination of "best price" under section 1927(c)(1)(C)(i).)

to CAP vendors will be established by Medicare (determined on the basis of the composite bidding methodology), vendors should be considered government entities and thus excluded from best price. Again, once they are excluded from best price, they are also excluded from the calculation of the ASP.

Claims Processing (§414.908)

Claims Need to Be Paid on a More Timely Basis (§414.908)

In the preamble to the interim final rule (p. 39024), CMS indicates that among the reasons for establishing the CAP approach to providing Part B covered drugs is to reduce the financial burden on physicians of the risk of non-payment for drugs, including the burden of collecting patient coinsurance. Under CAP, as structured in the interim final rule, this financial burden is not only transferred to the CAP vendors, but a unique situation is established where payment to the vendor is conditioned upon the action of a third party, the physician. The interim final rule would require that the vendor not be paid by Medicare, and not be allowed to bill the patient for cost-sharing, until the physician claim for administration has been approved and paid by Medicare. CAP participating physicians would have 14 days from the date of drug administration to submit their payments to the CAP vendors.

In addition, vendors will already be at increased financial risk since they must collect the 20 percent coinsurance from beneficiaries for CAP drugs. CAP bids must not exceed ASP plus 6 percent, but actual payments from Medicare to vendors to be no more than ASP minus14 percent. Collecting the coinsurance will require a significant expenditure of time and resources by vendors and we anticipate that vendors will experience much more in lost revenues than CMS has acknowledged. CAP vendors will be in a difficult position regarding collecting patient cost-sharing because their only relationship with the patient will come at the point in the process when they send the patient a bill for the coinsurance.

Part B covered drugs are often expensive, and the vendors should not be required to supply product and then not receive any payment for months due to circumstances outside their control. The system for claims processing will impose additional financial risk on the CAP vendors which may be great enough to discourage vendor participation in CAP.

Recommendation:

To address the concern of ensuring timely reimbursement for Part B drugs, PCMA suggested in our comment letter to the NPRM a modification to the program rules. We have worked since then to modify this recommendation. As part of their CAP participation agreement, physicians should be required to submit a copy of their prescription order to carriers for Part B drugs within 14 calendar days of the prescription order sent to the CAP vendor. Should the physician fail to submit the copy of the order within this time period, the CAP vendor should be permitted to bill the physician for reimbursement. In effect, failure to comply with the 14-day requirement would mean that the drug would not be furnished under CAP and the physician would be deemed to have ordered the drug independently from the vendor.

The 14-day requirement should apply regardless of whether the physician has actually administered the drug. If, for example, the physician ordered the drug for a patient and administration failed to occur because the patient did not show up as scheduled, the vendor should still be permitted to bill the physician for the drug. From the vendor's perspective, once the drug is sent to the physician, the drug becomes the property of the physician. The vendor's adequate cash flow depends upon the vendor receiving prompt payment. If the drug is not administered, and consistent with safe drug practices, the physician may then retain the drug in his or her inventory to be administered to a future patient. In no instance in which the vendor has satisfactorily sent the ordered drug to the physician should the vendor be left holding the risk for non-payment because the drug was not administered or because the physician fails to submit a bill for the drug's administration.

CAP Contracting Process- CAP Bidding Process (Section IIC. of Preamble; §414.910 Bidding Process)

Drug Wastage

We are very concerned that CAP vendors will not be allowed to bill Medicare for the amount of the drug ordered by the physician, but only the amount actually administered to the beneficiary. While CMS explains that it is constrained by the statutory language in this regard, PCMA does not believe this is the case.

Although §1847B(c)(6) provides that the costs "related to the administration of the drug or biological, or wastage, spillage, or spoilage" may not be included, it also provides that "all costs related to the delivery of the drug or biological" and "costs of dispensing (including shipping) of such drug or biological and management fees" may be included. PCMA believes that the only consistent way to read this language is that it allows CAP vendors to bill for the amount ordered by the physician, and excludes only the wastage, spillage and/or spoilage incurred by the CAP vendor in delivering the product to the physician.

Drug product that, as a routine part of the treatment, is not administered to the beneficiary because of issues such as weight or body surface adjustments, or the fact that the product is packaged in quantities that do not exactly match the patient's actual dose, should not be viewed as "wastage, spillage or spoilage", but simply the usual routine and unavoidable use of the product to provide the appropriate treatment and dosage to the patient. For example, in oncology practices, physicians invariably change the amount of the drug regimen on the day of administration, based on the needs of the patient. Since drug dosage will be different for each and every patient, it is almost impossible to have an exact matching of the dose ordered vs, the dose administered, and it is misleading and inappropriate to refer to this differential as "wastage."

It is for this reason that CMS' proposed suggestions for handling this differential, such as trying to match the patient's dosing amount and the HCPCS billing amount, will simply limit the "degree" of mismatch, but will not – and cannot –eliminate it. Given that this mismatch is an inevitable and necessary function of adjusting the treatment regimen to the patient, we believe that there is no justification for CMS to wait to see if "it becomes apparent that there is a problem"(70 FR 39091) or whether certain drugs "are more prone to wastage for particular reasons".

Recommendation:

Since CMS believes that it could address the wastage and spoilage issue if it becomes an issue, we believe it can do so now, and that the CAP vendor should be entitled to bill for the amount ***dispensed***, and not simply the amount administered, unless some portion of the drug was wasted, or spilled or spoiled en route to the physician.

In addition, as stated in the current Medicare Claims Processing Manual, Chapter 17, part 40 there is precedence for CMS to allow for billing the amount dispensed—

"CMS encourages physicians to schedule patients in such a way that they can use drugs most efficiently. ***However, if a physician must discard the remainder of a vial or other package after administering it to a Medicare patient, the program covers the amount of drug discarded along with the amount administered."***

We look forward to working with you throughout the implementation process to ensure a competitive CAP program that attracts strong interest from vendors, is an attractive option for doctors, and ultimately reduces the costs to beneficiaries and the Medicare program.

Sincerely,

Mark Merritt
President and Chief Executive Officer

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Rec'd by TFM

SPECIALTY BIOTECH AND DISTRIBUTORS ASSOCIATION
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September 6, 2005

Dr. Mark McClellan, Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Competitive Acquisition Program Interim Final Rule CMS-1325-IFC

Dear Dr. McClellan:

The Specialty and Biotech Distributors Association ("SBDA"), an organization representing specialty distributors that manage the delivery of complex, breakthrough drugs and biologics to physicians and other providers, submits these comments in response to the interim final rule for the competitive acquisition program ("CAP") of outpatient drugs and biologicals under Part B.[1]

SBDA is an organization composed of a number of companies interested in maintaining the integrity of the specialty distribution system in physician office and other settings. Members of SBDA include AmerisourceBergen Specialty Group, Cardinal Health, Inc., Health Coalition, Inc., Henry Schein, Inc., Oncology Therapeutics Network and Priority Healthcare Corporation. Together, these organizations represent over 75 percent of the physician office specialty distribution volume in the United States.

We applaud the Centers for Medicare and Medicaid Services' ("CMS") efforts to implement the CAP program and seek to work constructively with the Agency to effectuate the policy goals of the Medicare Prescription Drug, Improvement and Modernization Act ("MMA") in a manner that best serves the interests of beneficiaries, providers, and taxpayers.

In summary, SBDA presents the following suggestions for consideration:

- Categories of drugs under CAP should be developed to ensure maximum savings to the Medicare program;
- CMS should reconsider some of its positions on the level of risk that must be borne by CAP vendors and make certain policies more consistent with existing Part B practices;

[1] 70 *Fed. Reg.* 39022 (July 6, 2005).

- Timeframes for routine and emergency shipment should remain consistent with current industry standards;
- Product integrity should not include more onerous paper pedigree requirements;
- CAP negotiated prices should be exempted from ASP calculations;
- Determination of the single price for the category of drugs should recognize the distinction between prompt pay discounts and price concessions.

Specialty distributors provide tremendous value and efficiencies to the Medicare Program. While often not visible to the public, specialty distributors manage the increasingly complex handling and delivery requirements of drugs and costly new biologics for virtually all of the physician offices in the country. We perform important services such as warehousing products, providing specialty handling and shipping services, such as packaging, refrigeration, or customized dosing. In addition, we ensure the timely delivery of drugs and biologics to thousands of physicians and providers. Specialty and biotech therapies are diverse and benefit a wide range of patients including those receiving treatment in the areas of dermatology, gastroenterology, hematology, immunology, infectious disease, pediatrics, neurology, pulmonology, ophthalmology, oncology, and rheumatology.

SBDA appreciates your consideration of the following positions and welcomes the opportunity to meaningfully contribute to the development of the final rule.

I. Categories of Drugs to Be Included Under the CAP

According to the interim final rule, the initial stage of the CAP will include drugs commonly provided "incident to" a physician's service. Of approximately 440 drugs that are billed "incident to" a physician service and paid under Part B, CMS has identified 181 drugs that will be included in the CAP. These drugs represent approximately 85 percent of physicians' Part B drugs by billed charges.

Implicit in CMS' decision to reduce the number of available drugs under CAP from 440 to 181 is that cost-efficiencies will not be realized by the Program for small volume or inexpensive drugs. We appreciate the fact that CMS has taken the first step to limit the number of drugs subject to bidding. However, we recommend that the Agency exclude an even wider class of inexpensive and low-volume drugs from the bidding process. Inexpensive and low-volume drugs represent a fixed cost to the CAP vendor that make it considerably more difficult to comply with the Agency's aggregate bidding cap of ASP+6. The CAP simply cannot save money for the Medicare Program if a vendor is required to undertake shipping costs for a product when it may cost more to send the product to the physician than the vendor will realize from Medicare. A policy that limits the inclusion of inexpensive or low-volume drugs from CAP would minimize some of the risks borne by the CAP vendor. It would provide CAP vendors with more cost-efficiencies and may further facilitate vendor interest in the program.

II. Timeframes for Routine and Emergency Shipment

SBDA supports CMS' efforts to ensure timely delivery of CAP drugs and biological products. We commend CMS for implementing a two-business-day timeframe for routine deliveries and a one-business-day timeframe for emergency deliveries, with some

exceptions for deliveries outside the continental United States. Further, we agree that the emergency delivery option should not be used routinely and should be reserved for those situations when the patient's need for the drug could not have been accommodated under the routine delivery timeframe. We find the proposals regarding the beginning of the timeframe and the triggers that initiate the beginning of the delivery timeframe to be based on sound reasoning and generally in line with industry standards.

Furthermore, we note that any changes to accelerate these timeframes may result in excess costs being borne by the CAP vendor and will further reduce the attractiveness of the program. While CAP vendors will continue to voluntarily shorten the routine timeframes for delivery of product, mandatory standards imposed that exceed existing industry standards will only add extra burdens to this system.

III. Unused Drugs

While we are pleased that CMS recently issued guidance providing more clarity concerning the issue of billing for unused portions of drugs, that guidance will not adequately address the concerns of the CAP vendors with respect to single-dose vials. In its August, 2005 guidance, CMS indicates that "good faith" efforts to avoid wastage and to utilize the appropriate amount of drug for a patient will allow the CAP vendor to recoup the full cost of the drug product. Unfortunately, this guidance document is still not consistent with current Part B policies. Under Part B, even if patient specific dosing is less than the amount actually contained within an entire vial, the entire vial is billed to Medicare. This policy recognizes the patient specific nature of each claim and the state laws governing product disposal.

The new guidance, however, relies on "good faith" interactions between the CAP vendor and the physician to bill for an entire vial of drug when the CAP vendor may never possess the ability to verify whether a good faith effort to minimize the "waste" of an unused drug has even occurred. This would leave the CAP vendor in a highly precarious position from both a reimbursement and a fraud and abuse perspective.

SBDA believes that CMS needs to further clarify this policy in the final rule to reflect existing Part B claims policies. Otherwise, if the ASP and CAP methodologies on this provision remain different, CMS will be unable to realize its policy goal of providing physicians with a meaningful choice between the two systems.

IV. Payment to Vendor: Claims, Coverage and Copayments

While SBDA supports the imposition of a 14-day claim submission requirement on CAP physicians, it believes that claims may be processed even sooner. Where physicians have the capacity to verify administration earlier in the process, SBDA finds that more timely verification would minimize the burden on approved CAP vendors.

In the interim final rule, we were particularly disappointed that CMS declined our invitations to limit vendor risk. This risk is particularly high in light of CMS' unwillingness to allow vendors to reasonably confirm coverage and collect copayments at the time the product is

dispensed. As articulated in our comments to CMS' proposed rule, the Agency does possess the ability to take further action on this issue through a variety of statutory authorities. Moreover, we note that CAP vendors are only requesting the same authority available today to Part B providers to deny the provision of product or services if a copayment is not made or a patient refuses to sign an Advanced Beneficiary Notice (ABN).

We reiterate that, from a risk perspective, several major provisions of the interim final rule are not feasible for CAP vendors. If a physician is seeking to administer a product outside of a clearly defined local coverage determination, a patient has not signed an ABN, or a physician orders a prescription when there are no means available to collect a copayment, a CAP vendor should possess the same ability currently available under Part B to other providers to deny Medicare coverage. If the CAP vendor does not possess these capabilities, the financial risk borne by this requirement alone may make the CAP program untenable.

SBDA believes such a policy will not result in any adverse care for Medicare beneficiaries. Indeed, we believe that physicians could "dispense as written" if they believe that coverage will ultimately be provided by Medicare or another payor.

In the final rule, we strongly recommend that CAP vendors be provided with the same authority that physicians currently possess to secure a credit card or means of payment from a patient to guarantee the collection of a copayment prior to a product being shipped. Should even a small number of patients fail to reimburse CAP vendors for their coinsurance obligations, the CAP vendor will lose all ability to manage costs. The financial risk of inadequate copayment collection to the CAP vendor cannot be underestimated.

V. Product Integrity

SBDA notes that most of the product integrity provisions remained unchanged from the proposed rule to the interim final rule. We commend CMS for that decision. In particular, we applaud CMS for avoiding the imposition of onerous paper pedigree requirements. As articulated in our comments to the proposed rule, more stringent burdens on CAP vendors are unnecessary and would not provide additional product integrity protections.

VI. Exclusion of CAP Negotiated Prices from ASP Calculation

SBDA believes that CMS does possess the regulatory discretion to exempt CAP negotiated prices from the computation of Average Sales Price ("ASP"). As you know, Congress very specifically created two separate payment structures in this setting because it wanted to provide physicians with a meaningful choice of how they were reimbursed for drugs. Inextricably linking the two pricing methodologies runs counter to the notion of two separate structures.

Our perspective regarding CMS' discretion on this issue is derived from several statutory provisions. First, as we have articulated previously, CMS' demonstration authority is broad and would permit the Agency to implement the CAP program without incorporating ASP prices. The Social Security Act permits CMS "to determine whether, and if so which, changes in methods of payment or reimbursement...including a change in negotiated rates, would have the

effect of increasing the efficiency and economy of health services..." Social Security Act, 42 U.S.C. 1395b-1. As exempting CAP negotiated prices from ASP calculations would represent a change in negotiated rates and would arguably increase the efficiency of health services, CMS possesses the ability to effectuate this change.

In addition to this demonstration authority, CMS should also find support for its authority to exempt CAP bids from ASP prices from the plain language of the MMA. According to Section 1847B(a)(1)(B), 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."

The aforementioned language establishes that the Secretary shall possess the authority to define drug categories. Accordingly, given congressional intent to delink the ASP and CAP systems, the Secretary would be within its discretion to define the competitively biddable category or categories of drugs to be a class or classes of drugs whose CAP negotiated prices, among other characteristics, are not included in ASP calculations. The term "category" is typically defined as "a class or division of people or things having shared characteristics." If all drugs subject to the CAP bid are exempt from ASP calculations, this would be a "shared characteristic."

Given the clear discretion provided to the Agency to define these terms, CMS possesses the ability to interpret "categories of competitively biddable drugs and biologicals" in this manner in order to ensure that this program works as intended by Congress. Such a policy would be in the financial and programmatic interests of CMS.

VII. Determining the Single Price for the Category of Drugs: Prompt Pay Discounts

SBDA continues to be troubled by CMS' treatment of prompt pay discounts in the CAP. We find it inconsistent with industry standards and common business practices to include prompt pay discounts in the determination of "reasonable, net acquisition costs." Because the interim final rule directly asks whether prompt pay discounts occur exclusively as a term of financing, we offer additional information for CMS to consider. We hope to help CMS to differentiate prompt pay discounts from traditional price concessions such as rebates.

Under the current proposal, CMS will require CAP vendors to submit their "reasonable, net acquisition costs" for obtaining drugs, representing the net of all discounts and rebates provided by the vendor's own suppliers, to include volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, rebates, refunds, and other price concessions.

The term "prompt pay discounts" is a misnomer principally because they are not typically used as price concessions. Rather, prompt pay discounts are fees earned by the distributor for the value it provides to the manufacturer. Monies realized through prompt pay discounts are frequently utilized to compensate the distributor for a host of services provided throughout the supply chain, which include managing the delivery of products, expenses incurred associated with setting up, monitoring and collecting payments, associated credit risk, processing costs, risk of loss due to damage, spillage or other causes, insurance and security expenses,

restocking and handling costs involved in processing returns and the direct costs of sales. Bona fide prompt pay discounts also represent the time value of money.

We ask CMS to consider the intellectual consistency of including prompt pay discounts in the definition of CAP net acquisition costs or in ASP if the Agency believes that the exact type of services that are being compensated through the prompt pay discount are the type that are specifically excluded from the calculation of ASP – if they are defined as a bona fide service.

As you know, in a December 9, 2004 letter to SBDA, CMS noted that "[b]ona fide service fees that are paid by a manufacturer to an entity, that represent fair market value for a bona-fide service provided by the entity, and that are not passed on in whole or in part to a client or customer of the entity should not be included in the calculation of ASP, because those fees would not ultimately affect the price realized by the manufacturer." Accordingly, if prompt pay discounts represent payments for bona fide services, which may include the managing, delivery and financing of products, and are not being passed through to the physician (which they can't in this case because no financial relationship exists between the CAP vendor and the provider), they should not be considered a price concession. How can CMS justify their inclusion in the definition of net acquisition costs?

Under this rationale, so long as prompt pay discounts truly represent the time value of money and the fair market value of the distribution and financial services that are provided and are not passed on to the providers, they should not be included in the CAP vendor's net acquisition costs or ASP. This should be affirmatively stated by CMS in the final rule and clarified in the ASP payment system as well.

Ultimately, prompt pay discounts do not affect the price "realized by the manufacturer." We urge CMS to recognize the value of prompt pay discounts and how they will be earned by the CAP vendor under this program. After all, the CAP vendor is financing the entire value of the transaction before it is reimbursed by CMS. How would CMS reflect the concept of the "time value of money" in its own program financing? Why does CMS analyze the concept of service fees in a manner different than prompt pay discounts?

VIII. Conclusion

SBDA appreciates your consideration of these positions and welcomes the opportunity to meaningfully contribute to the development of the final rule.

***

Steve Collis /PVL

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SEP - 6 2005

September 6, 2005

Mark B. McClellan, MD
Administrator, Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
200 Independence Avenue, S.W., #445-G
Washington, D.C. 20201

Re: Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B (CMS-1325-IFC)

Dear Dr. McClellan:

On behalf of the National Alliance for the Mentally Ill (NAMI), I am writing to offer the following comments in response to the Interim Final Rule (IFR) issued by the Centers for Medicare and Medicaid Services (CMS) regarding implementation of the Competitive Acquisition Program (CAP) for Part B drugs and biologics published in the Federal Register on July 6, 2005 (70 Fed.Reg. 39021).

NAMI has long believed that the CAP offers enormous potential to promote access to important therapies for people with severe mental illness, particularly individuals who struggle to adhere to treatment. The CAP also offers a promising alternative for physicians to the current "buy and bill" system under which physicians purchase Part B medications, collect beneficiary coinsurance and then bill the Medicare program for reimbursement. We commend CMS for instituting several policies in the IFR that promote Medicare patient access to Part B drug therapies including:

1. the creation of a single broad category of drugs that includes mental health products and complex biologics and
2. the nationwide implementation of the program that will allow physicians and their Medicare patients in all parts of the country to have access to the CAP.

Given these positive aspects of the CAP IFR, NAMI was disappointed to learn that CMS has planned a 6-month delay in the implementation of the program from January 1 to July 1, 2006.

While it is NAMI's hope that CMS will work in this interim period to make the program more attractive to the vendor and physician community, we urge CMS to continue to make beneficiary access to medical therapies the paramount goal of the CAP program.

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Specifically, NAMI urges CMS not to scale back the number and scope of products included in the CAP and to maintain the national rollout of the program for 2006. NAMI also urges CMS not to delay the initial implementation of the program any later than July 1, 2006 as providers -- especially those treating beneficiaries with mental illness -- begin to utilize CAP at its earliest possible date. As CMS stated in the IFR, "it is important to provide an alternative to the 'buy-and-bill' method of drug acquisition for physicians as widely and quickly as possible" (70 Fed. Reg. 39035). NAMI would therefore urge CMS not to delay implementation of the program beyond July 1, 2006.

NAMI's specific comments and recommendations are included below. As requested by CMS, we have identified the specific "issue identifier" that precedes the section of the IFR on which we are commenting.

I. Categories of Drugs to Be Included Under the CAP

A. Number of NDCs Provided by the Vendor In a HCPCS Code. CMS stated in the IFR that it would not require vendors to provide every National Drug Code (NDC) associated with a HCPCS code. While we understand that CMS is trying to promote competition and minimize the administrative and financial burden for the CAP vendor, we are concerned that this policy could have negative implications for patient access and overall quality of care if applied in all situations. Instead, CMS should institute two general exceptions to this policy described below before final implementation of the CAP.

NAMI Recommendation: Vendors should be required to provide all NDCs within a specific HCPCS code in the following situations:

1) CAP vendors should be required to bid on all NDCs within a HCPCS code if they are unit doses of the same single-source medication. NAMI recommends that CMS require vendors to supply all NDCs describing different dosing levels for the same single-source drug within the HCPCS code. This requirement should add no more than minimal administrative and financial burden on the CAP vendor.

2) Vendors should be required to provide the NDCs of branded single-source drugs described by the same HCPCS code. CMS wisely rejected requests to establish drug formularies under the CAP. As the agency indicated in the IFR, "[w]e are not accepting the recommendation that vendors be permitted to establish drug formularies by offering drugs from only some of the codes included in a category. The statute expressly requires that for multiple source drugs, a competition be conducted for the acquisition of at least one drug per billing code within the category" (70 Fed. Reg. 39034). NAMI agrees that the statute expressly requires competition for multiple source drugs, but does not create such a structure for single-source products. Single-source products should be offered the same status under the CAP, regardless of whether they have their own unique HCPCS code or share them with other branded products.

Requiring each CAP vendor to bid on at least one NDC for each single-source drug and biological in a category would ensure that Medicare beneficiaries have access to the brand that works best for them. Single source drugs are unique products that should be carried by each CAP vendor in order to ensure patient access to them. It is important that beneficiaries receive the specific brand that is best suited for his or her condition so that patient treatment options are not dependent upon a physician's CAP decision.

B. Inclusion of New Drugs and Biologics in the CAP. NAMI commends CMS for requiring CAP vendors to bid on and provide the 12 new drugs and biologicals listed in Addendum B, including a long-acting atypical antipsychotic medication approved for treatment of schizophrenia. The inclusion of this new medication in the CAP has the potential to offer improved treatment adherence for beneficiaries with schizophrenia. Psychiatrists operating at public mental health agencies and Community and Mental Health Centers (CMHCs) support the CAP and hope to use the program as a way to offer patient access to this important new therapy.

However, it is concerning that the IFR did not have an explicit provision to require vendors to bid on and provide other new Part B drug therapies likely to be introduced over the initial three-year CAP contracting period. While CMS encourages vendors to add new drugs to the program beyond the initial list in the single category, it does not require them to do so (70 Fed. Reg. 39075). As a result, physicians electing the CAP program may not be able to access the newest therapies through the CAP unless the vendor agrees to offer such products. To obtain the newest therapies, physicians may be forced to devote administrative resources to obtaining such products through the "buy-and-bill" acquisition model.

NAMI Recommendation: CMS should require vendors to bid on and provide new Part B therapies by no later than the next calendar quarter following FDA approval. Further, these therapies should be reimbursed to the CAP vendors under the methodology created in section 1847A of the Social Security Act until the next vendor bidding cycle. Newer products should be treated comparably to the 181 drugs in the single drug category so that physicians electing CAP can have full access to the newest technology without having to revert back to the "buy-and-bill" system.

II. Competitive Acquisition Areas

Subcontractor Responsibilities. The IFR establishes a single, national distribution area for the initial stage of CAP. Given that there will be a maximum of only five vendors selected to participate in the program, it is highly likely that vendors will need to employ subcontractors to adequately fulfill national drug distribution responsibilities. While NAMI support the national implementation of the CAP in 2006, we are concerned about the possibility of product counterfeiting or other product integrity issues with the use of vendor subcontractors in such a broad geographic region. For this reason, we welcome CMS' decision to require subcontractors to comply with all the requirements binding on the CAP vendor themselves, including those relating to product integrity. We also

appreciate that CMS holds CAP vendors accountable even for the acts of its subcontractors. We request, however, certain additional safeguards described below.

NAMI Recommendation: *First*, we believe that CAP vendors should have an obligation to expressly include in their agreements with their subcontractors a covenant binding on the subcontractor to comply with all rules applicable to CAP vendors, including those rules regarding product integrity and drug pedigree set forth in 42 C.F.R. §§ 414.906(a)(4) and 414.914(c)(1). The subcontractor agreement should also direct HHS to serve as a third-party beneficiary to these agreements with the right to enforce any of the provisions relating to CAP program compliance. The agreement would also need to specify that DHHS should have access to all books and records relating to CAP program compliance.

Second, in the interest of the safety of Medicare beneficiaries, NAMI recommends that CMS closely monitor compliance with the product integrity requirements by CAP vendors and their subcontractors. We recognize that the FDA has jurisdiction over certain product integrity matters. Nevertheless, we believe that Congress intended for CMS to have joint jurisdiction over product integrity matters affecting drugs administered to Medicare beneficiaries through the CAP program. Accordingly, CMS should actively monitor product integrity matters and take all necessary enforcement actions.

III. Claims Processing Overview

A. Payment of Coinsurance by Medicaid. The IFR establishes a number of procedures and requirements that the vendors must first address before refusing to make further shipments of drugs to physicians for individual beneficiaries due to non-payment of coinsurance. For most dual eligible beneficiaries, state Medicaid plans will be responsible for the coinsurance for patients receiving their Part B drugs from physicians enrolled in CAP. As CMS is aware, individual state Medicaid plans can have differing policies on the appropriate level of Medicare Part B coinsurance for dual eligible beneficiaries. This inconsistency among states will likely create confusion to some vendors in determining when a dual eligible patient in CAP has met his or her coinsurance obligations.

NAMI Recommendation: CMS needs to ensure that CAP vendors cannot refuse to make shipments of CAP drugs on behalf of dual eligible beneficiaries when a State Medicaid program has upheld its statutory obligations relating to coinsurance payments. For dual eligible beneficiaries with severe mental illness, state Medicaid programs can limit coinsurance payments to the extent that any such payment, when combined with Medicare payments, equals the amount of reimbursement payable under the State Medicaid program (§ 1902(n)(2)). Accordingly, a State Medicaid program may deem a CAP vendor to be paid in full, even if it has received either no coinsurance payment, or a reduced payment from the state. Beneficiaries have no liability beyond the State's payment (§ 1902(n)(3)(A)). Thus, CMS should clarify that the state's adjudication of a claim for payment of an outstanding coinsurance amount is final. CAP vendors have no

continuing right after the State's adjudication to seek payment from the beneficiary of any purported remaining balance pursuant to 42 C.F.R. § 414.914(h)(2). The state's claim adjudication should preclude the CAP vendor from pursuing any action that would ultimately lead to the CAP vendor's refusal to make future shipments of CAP drugs on behalf of the beneficiary.

B. Waiting Period Before a Vendor Can Withhold Delivery of Drug for Non-Payment on Coinsurance. Under the IFR, vendors must provide information, when requested by beneficiaries, on sources of available cost-sharing assistance. This assistance can include a referral to a bona fide and independent charitable organization. If the beneficiary requests cost-sharing assistance and the vendor refers the patient to a bona fide independent charitable organization for assistance or offers a payment plan, the vendor must wait an additional 15 days from the postmark of the approved CAP vendor's response to the beneficiary's request for cost-sharing assistance. If at the end of the 15-day period the vendor has not received a cost-sharing payment from the charitable organization or the patient, the vendor may refuse to ship additional drugs to the physician on behalf of that patient (42 C.F.R. § 414.914(g)).

NAMI Recommendation: CMS should extend the time the CAP vendor must wait before discontinuing provision of drug after which the beneficiary has requested assistance and the vendor has provided the beneficiary with a referral to a third-party. If a beneficiary requests assistance, and if they are referred to a third-party for assistance, they should be provided more than 15 days to assemble required materials, submit the materials and have the application for assistance reviewed and approved and finalized.

At minimum, that time requirement should be extended, to at least 30 to 45 days, in order to allow beneficiaries to appropriately respond and gather information and submit materials required by various assistance organizations. It is not unreasonable to expect that Medicare beneficiaries in need of financial assistance will need additional time beyond 15 days to navigate the administrative requirements necessary to receive third-party assistance under the new CAP program in 2006 and receive approval and funding from these organizations.

Moreover, CMS needs recognize that the process of gathering, organizing and submitting this type of complicated documentation is likely to be overwhelming to Medicare beneficiaries living with an illness such as schizophrenia. Many of these beneficiaries are among the most vulnerable served by the Medicare program and CMS needs to realign its expectations for their ability to navigate this process without significant assistance.

C. Option for Physicians to Opt Out of CAP for Non-Delivery of Drug. The IFR permits CAP physicians to opt out of the CAP program all together in 2006 "in instances where a beneficiary has failed to meet his or her obligation to pay coinsurance or deductible for a drug and the vendor has refused to continue providing the drug..." (70 Fed. Reg. 39053)).

NAMI Recommendation: CMS needs to clarify circumstances where a vendor has refused to continue providing the drug for a specific beneficiary who has failed to meet his or her cost-sharing obligations. Physicians should instead be afforded the opportunity to seek reimbursement for that specific beneficiary under the Average Sales Price (ASP) plus six percent methodology. However, the physician should still be able to remain in the CAP program for his or her other patients that do not have difficulties meeting their cost-sharing obligations through their own financial means or through secondary insurance. It seems extreme to force physicians to completely withdraw from the CAP as a result of cost-sharing difficulties related to a single beneficiary. Physicians in this situation would face the choice of either abandoning the one financially needy beneficiary, or incurring the financial exposure entailed in returning to the purchase of drugs under Section 1847A of the Act. CMS should not put physicians in this position.

D. Payment for Discarded Drugs. The IFR appears to create a new and inconsistent policy that conflicts with long-standing CMS policy on discarded drugs set forth in the Claims Processing Manual. CMS states that "[s]ince the CAP statute authorizes us to pay the approved CAP vendor only upon administration of the drug, any discarded drug (or drug that is considered waste) will not be eligible for payment." (70 Fed. Reg. 39063). However, NAMI is encouraged to see that CMS has since clarified its position and legal interpretation of the CAP statute given the recent "Question & Answer" (Q&A) statement posted on the CMS website. "Generally speaking, under the Average Sales Price system, a physician is able to bill the program for unused drugs if the physician acted in good faith with respect to the ordering and use of the drugs. We expect that vendors will be able to bill the program for unused drugs under the CAP program in a similar fashion if physicians and vendors act in good faith with respect to the ordering and use of the drugs" (http://www.cms.hhs.gov/providers/drugs/compbid/capquestions081005.pdf).

NAMI Recommendation: NAMI commends CMS for clarifying its position in the recent Q&A. We recommend that CMS further clarify this position consistent with the Q&A posting above in 42 C.F.R. § 406(a)(5) to avoid any further confusion for vendors and physicians.

E. Administrative Burden – Need for A Physician Management Fee Under CAP. CMS declined requests it received in the prior comment period to establish a management fee reimbursement for physicians electing the CAP to offset some of the additional costs providers will face under the new program. In stating its rationale for declining such requests CMS stated that "[a]lthough we agree that a physician may have to make some adjustments in his or her practice in order to comply with the requirements under the CAP, we believe that the relief of the financial burden of purchasing the drugs and billing Medicare for these drugs will be a substantial improvement and benefit for many physicians" (70 Fed. Reg. at 39049).

This statement assumes that certain efficiencies will accrue to physician practices due to anticipated elimination of certain functions or activities under CAP. However, CAP does not materially reduce the administrative resources associated with the following activities:

- Actual administration of the therapy;
- Billing for the drug administration; and
- Collection of coinsurance for the drug administration.

In addition, CAP requires additional activities that do not occur under the buy and bill model. These include:

- Individualized purchasing;
- Additional discussions with patients regarding their second bill from the CAP vendor, and communication of related patient-specific information;
- Potentially maintaining a parallel procurement systems in addition to established purchasing processes;
- Increased vial tracking tasks to comply with CAP provisions;
- Changing billing systems to accommodate CAP billing provisions;
- Personnel training about new CAP program changes; and
- Increased administrative processes associated with use of a replacement or alternative vial (e.g., as in the event of a patient failing to show up for an appointment).

In addition, the CAP imposes a significant change for some practices by establishing "just-in-time" processes by requiring administration to each individual beneficiary within 2 business days from the date of that beneficiary's administration.

NAMI Recommendation: CMS should establish a management fee for physicians who participate in the CAP in order to offset some of the added "just-in-time" and other related costs as a result of participating in the program.

Conclusion

NAMI appreciates the opportunity to submit comments and recommendations to CMS. We look forward to working with you and your staff to ensure that Medicare beneficiaries have meaningful access to Part B drugs and biologics under the CAP.

Sincerely,

Michael J. Fitzpatrick, M.S.W.
Executive Director

Paid by TFM

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genzyme
GOVERNMENT RELATIONS

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September 6, 2005

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Washington, D.C. 20201

Re: CMS-1325-IFC (Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B)

Dear Dr. McClellan:

Genzyme Corporation ("Genzyme") is pleased to have the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") interim final rule published in the *Federal Register* on July 6, 2005 regarding the competitive acquisition program ("CAP") – the "Interim Final Rule."[1] Genzyme is a global leader among biotechnology companies and is headquartered in Cambridge, Massachusetts. The company specializes in the research and development of new treatments for rare and debilitating genetic diseases, as well as renal disease, orthopedic injuries and cancer. Because of the importance of our products to the affected patient populations, ensuring patient access is paramount. We write principally because we believe that CAP offers a means of enhancing patient access to certain of these critical treatments, but that CMS is not taking full advantage of this opportunity. As explained in more detail below, we urge CMS to include all of the so-called "single indication orphan drugs" in the CAP category CMS has selected. This would include three of our products within CAP – Thyrogen® (J3240 – injection, thyrotropin alpha, 0.9 mg); Cerezyme® (J1785 – injection, imiglucerase, per unit); and Cerezyme® (J0205 – injection, alglucerase, per 10 units). In addition, we believe that CMS must clarify the definition of emergency situation so that electing physicians know that they can provide a CAP drug determined to be appropriate on the day a beneficiary is seen, rather than forcing the patient to return to the office another day. A failure to do so could keep numerous physicians from electing CAP.

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[1] 70 Fed. Reg. 39022 (Jul. 6, 2005).

Background

Thyrogen (J3240, thyrotropin alfa for injection, .9 mg) is a recombinant form of human thyroid stimulating hormone which is indicated for use as an adjunctive diagnostic tool for testing and follow up care for patients with thyroid cancer. The product allows patients that must undergo important testing related to this condition to continue to receive their thyroid hormones without interruption. That, in turn, can help patients with thyroid cancer to avoid experiencing symptoms of hypothyroidism that are often severely debilitating for a number of weeks each year. Thyrogen is designated by the Food and Drug Administration ("FDA") as an orphan drug.

Cerezyme and Ceredase are expensive enzyme replacement therapies that are infused in physician offices. They are both designated by the FDA as orphan drugs. Nearly all Gaucher patients are treated with Cerezyme, which is an analogue of the human enzyme glucocerebrosidase produced by recombinant DNA technology. Ceredase, the original treatment developed by Genzyme for Gaucher disease, is derived from human placenta tissue collected from selected donors. Fewer than 10 Gaucher patients worldwide remain on Ceredase as most patients have been switched to the recombinant DNA form, Cerezyme. At present, Genzyme estimates that there are approximately 125 Medicare patients treated in physician offices with Cerezyme. Genzyme estimates that there are two Medicare patients being treated with Ceredase.

Discussion

As noted earlier, Genzyme believes that CAP has the potential to increase beneficiary access to Part B drugs. However, we see two specific areas that may cause these potential to be unrealized. In our view, the exclusion of single indication orphan drugs (with one exception) from CAP does not enhance access to these products. Similarly, access to CAP drugs will not be enhanced if physicians do not elect CAP. We understand that many physicians may be reluctant to elect CAP if they would be forced routinely to make patients return to their offices to receive a CAP drug. These issues are addressed in more detail below.

I. CMS Should Promote Access By Including Thyrogen, Cerezyme and Ceredase in CAP

In the Interim Final Rule, CMS decided to exclude certain orphan drugs from the initial stages of CAP – specifically, the drugs that meet the agency's criteria to qualify as "single indication orphan drugs" under the outpatient prospective payment system. The agency did so in response to concerns from commenters about access problems for orphan drugs. As the manufacturer of a number of orphan drugs, including three of the single indication orphan drugs, we fully agree with the commenters "that orphan drugs often pose access challenges." 70 Fed. Reg. at 39028. Unlike the commenters, however, we believe that inclusion of these products in CAP would enhance access to these products. As you know, under CAP, physicians decide

whether to elect CAP, and providing them with another means for accessing orphan drugs should promote access to these products. Indeed, some of the excluded single indication orphan drugs are provided by physicians that do not furnish many Medicare Part B drugs and they might welcome the opportunity to lessen the risks and burdens of the "buy and bill" system. Finally, exclusion of some enzyme replacement therapies from CAP while others are included in CAP may create confusion for physicians using these products. Accordingly, we recommend that CMS use CAP to promote access to single indication orphan drugs by including them in the initial CAP category.

A. Increasing Physician Choice Can Increase Beneficiary Access

Genzyme believes that giving physicians a choice as to whether to elect CAP or not can improve beneficiary access to products such as Thyrogen, Cerezyme, and Ceredase. Currently, physicians have only one option to provide beneficiaries with Part B drugs in their offices – buy drugs and be reimbursed under the average sales price ("ASP") methodology through Medicare and the beneficiary. CAP will present physicians with another option – not having to buy the drug or bill a beneficiary, which presents risks of insufficient payments (particularly on copayments) and administrative burdens to bill and collect for drugs. Genzyme believes that providing another option to physicians that furnish one of the single indication orphan drugs can increase patient access to these drugs.

B. Physicians May Provide Greater Access to Orphan Drugs Included in CAP

Some of the single indication orphan drugs are provided principally by physicians that do not furnish a significant amount of Part B drugs to Medicare beneficiaries. For instance, Thyrogen is administered most frequently in endocrinologists' offices. But, endocrinologists furnish very few other Part B drugs to beneficiaries in their offices. As a result, we understand that these physicians likely would prefer to elect CAP to avoid the burdens and risks associated with the buy and bill method of providing drugs to beneficiaries. Their reduced Part B drug portfolio diminishes their ability to spread these risks and administrative burdens among a significant number of drugs and can place the risks and burdens squarely on costly orphan drugs, such as Thyrogen. Including Thyrogen in CAP would give endocrinologists the choice to eliminate these risks and administrative burdens thereby increasing beneficiary access to the product.

C. Streamlined Treatment of Enzyme Replacement Therapies Will Diminish Confusion and Avoid Creating Access Problems

Under the Interim Final Rule, two of the enzyme replacement therapies that we manufacture Fabrazyme® (J0180 – injection, agalsidase beta, 1 mg) and Aldurazyme® (J1931 – injection, laronidase, 0.1 mg) are included in CAP, while two other enzyme replacement therapies, Cerezyme and Ceredase, are excluded from CAP. In addition to the similarity in function of these products, all four are also provided by the same type of physicians, principally

hematologist/oncologists. For such physicians that see a variety of patients that use enzyme replacement therapies, that two enzyme replacement therapies they furnish to beneficiaries are in CAP, but two others are not could create confusion or consternation and provide a disincentive to elect CAP. Genzyme believes that CMS should make the decisionmaking process simpler by including Cerezyme and Ceredase in CAP.

II. Physicians Must be Given the Ability to Provide CAP Drugs Without Delay

Following issuance of the Interim Final Rule on the CAP program, Genzyme conducted market research with providers in the orthopedic and rheumatology communities to review the program and determine likely participation. Genzyme commissioned research that included one- to two-hour in-depth discussions of CAP with over 30 physicians in multiple cities, as well as a number of office management staff (Genzyme was anonymous in these discussions). While many of these individuals applaud the general concept of CAP for Medicare of those we spoke with, only one physician would likely enroll in the CAP program as described in the Interim Final Rule. Surprisingly, the reason behind the reluctance of most of the physicians we contacted to participate in CAP is because of the perceived inability to use a drug for which the physician could not anticipate furnishing to the patient prior to the office visit.

While the physicians recognized the inclusion of a policy on resupplying inventory in CAP, they pointed to two distinct situations in which they were unsure whether the criteria for the resupply option, specifically the emergency situation criterion, would be satisfied. Physicians use injectable steroids on a daily basis, and those interviewed estimated that these drugs are used in an urgent capacity in more than 80% of cases. Other physicians expressed concern regarding the timely and appropriate use of viscosupplements for the treatment of osteoarthritis of the knee. Often, the need for immediate administration of viscosupplements is not foreseen and is typically apparent upon exam. Viscosupplements tend to require from three to five weekly injections depending on the therapy selected. Requiring a patient to return to the physician's office on a different day for the first administration, rather than offering it immediately from the physician's stock and being resupplied by the vendor, would significantly inconvenience patients and possibly add costs to both the Medicare program and the beneficiary, as a physician may bill for an office visit on the day the beneficiary returns for the first injection. Based on the Interim Final Rule, many physicians we contacted could not conclude that the resupply criteria would be met. Physicians use both steroids and viscosupplements to provide urgent treatment. The CAP resupply provision is meant to be used for exceptions only. Indeed, particularly in the injectable steroid scenario, numerous physicians stated that if they would have to ask beneficiaries to return on a different day in these circumstances, they would decline to elect CAP.

Genzyme believes that both scenarios discussed above need clarification. In both situations described above, the requirements that the drugs be required immediately, that the physician could not have anticipated the need for the drugs and that the vendors could not have delivered them timely would be satisfied. In our view, the source of the confusion is the

requirement that the drugs be administered in an emergency situation. Physicians have a general conception of what an emergency situation is and, in our discussions with them, they believed that both of the above scenarios may not be an emergency situation, likely relying on that conception. However, as you know, the regulations specifically define an emergency situation as one determined by the physician "in his or her clinical judgment, to require prompt action or attention for purposes of permitting the participating CAP physician to use a drug from his or her own stock." 42 C.F.R. § 414.902. Genzyme believes that CMS should adopt a flexible approach to the resupply of products that is broad enough to encompass the array of circumstances where an immediate, unanticipated need for a particular drug may arise. This may be done by simply changing the language from requiring all four of the provisions be met to any one alone being sufficient. Without a change, our research shows that the orthopedic and rheumatology physician segments will decline to participate in CAP rather than to enroll with a guaranteed result of compromising patient care. We recommend that CMS provide more guidance on how this definition will function in practice, and we suggest that the agency use the above two examples to demonstrate what constitutes an emergency situation.

III. Conclusion

Genzyme appreciates CMS' willingness to act upon comments from the public to ensure that Medicare beneficiaries have access to orphan drugs. However, we believe that the suggestion to exclude orphan drugs such as Thyrogen, Cerezyme, and Ceredase from CAP would not promote access to these products. Instead, Genzyme believes that including the products in CAP would give physicians more choice as to how to furnish these drugs and would enhance beneficiary access to these products. Accordingly, we ask that CMS reconsider its decision to exclude these products from the initial list of CAP drugs.

We also ask CMS to provide more clarity on how the definition of "emergency situation" will be applied to the resupplying of inventory provision in CAP. In providing such guidance, CMS should be aware that many physicians view an inability to be able to provide drugs that they did not anticipate furnishing prior to seeing the patient during that office visit (as opposed to a return trip on another day) as a large disincentive to elect CAP.

If you have any questions concerning this matter, please contact Sara Froelich or Mary McGrane at 202-296-3280. Thank you for your attention to this very important matter.

Respectfully submitted,

Sara Froelich

Sara Froelich
Vice President, Government Relations
Genzyme Corporation

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September 6, 2005

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RE: Comments on the Proposed Rule for Competitive Acquisition of Outpatient Drugs & Biologicals Under Medicare Part B; CMS-1325-IFC

Dear Dr. McClellan:

The American Society of Hematology (ASH) appreciates the opportunity to comment on the interim final rule establishing the Competitive Acquisition Program (CAP) of Outpatient Drugs and Biologicals Under Part B, which was published in the *Federal Register* on August 8, 2005. ASH represents approximately 10,000 hematologists in the United States who are committed to the treatment of blood and blood-related diseases. These diseases include malignant disorders such as leukemia, lymphoma, and myeloma as well as non-malignant conditions such as anemia, thrombosis, and bleeding disorders. Drugs covered by Medicare Part B represent a substantial portion of the drugs used by our practicing members, and, therefore, the Society is very interested in the design and implementation of the CAP. We recognize the challenges designing and implementing this new program present to CMS. For the CAP to be a viable program and in order to preserve high quality care to Medicare beneficiaries, we ask CMS to consider the following recommendations.

Patient Safety

We are extremely concerned that the interim rule allows vendors to refuse shipments of drugs based on non-payment of the coinsurance by the beneficiaries, even in cases where the beneficiaries have requested financial assistance. Coinsurance can be particularly challenging for cancer patients given the high cost of many chemotherapy agents and the duration of the treatment. We believe undue pressure may be placed on beneficiaries who are unable to pay the coinsurance. In addition, some vendors may try to exert pressure on the physician to move the patient to a hospital setting and/or substitute less costly therapy. We strongly urge that CMS establish policies to guard against this practice. This should include establishing collection standards in the contractual agreement and establishing a monitoring program to detect instances of such behavior. ASH believes the rule should state explicitly that the vendor may not refuse to fill a properly completed physician's order.

The interim final rule implements vendor-initiated contact with the physician for various purposes, such as to request the physician deliver an Advance Beneficiary Notice (ABN) and to explain why they physician believes a drug will be covered by a carrier under a Local Coverage Determination (LCD). ASH believes that to protect patient care, any contact initiated by the vendor that involves clinical decision-making should be held on a peer-to-peer level. Additionally, a vendor should not request that a physician deliver an ABN, as the physician is not collecting the coinsurance.

ASH does not consider referral to a charitable organization a viable strategy for beneficiaries to rely on for medications that are essential for their health and quality of life. We believe that if this strategy is implemented, the vendor must ensure that all such referrals are made only to organizations that have been screened and can provide sufficient financial assistance to the beneficiary referred for the drug involved. The organization will obtain any required information or documentation from the vendor. Additionally, CMS will have responsibility for monitoring and oversight of this process.

Administrative Costs
We submitted comments on the CAP proposed rule that we absolutely disagree with the CMS assumption that the CAP will not create additional burdens on physicians. We have reexamined the proposal and remain convinced, with much of the physician community, that the program will add significantly to the administrative costs of operating an oncology practice. ASH recognizes that CMS does not agree with the hematology/oncology community that the CAP will increase administrative costs of operating a practice; however, we urge CMS to reconsider its assumptions and establish a dispensing fee to be paid to physicians, such as it pays to pharmacists who dispense Part B drugs.

Liability
We are concerned that prescribing physicians might be held liable for errors on the part of a CAP vendor due to mistakes in the drug delivered, contamination of the product, etc. We think that the contractual agreement should make it clear that (1) the vendor is solely responsible for such errors, and (2) the vendor needs to maintain adequate liability insurance to indemnify a physician for any damages from suits which might result from the provision of the drug.

Option to Terminate Agreement
A decision to participate in the CAP is generally irrevocable for one year with no ability to "opt out". We recommend as a reasonable balance that for the first year physicians be allowed to withdraw their election CAP for any reason after the first 3 months of the program. This will give vendors a chance to work through some of the inevitable start up problems inherent in any new program and for physicians to have had some meaningful experience with the vendor. Additionally, a provider should be permitted to "opt out" if changes are made to the drug category during the year.

Additional Comments
In addition to the comments above, the Society feels very strongly that CMS needs to address the impact of the CAP on the calculation of the Average Sales Price (ASP). We urge CMS to explore alternatives for having manufacturers exclude sales to the vendors from the calculation of ASP.

ASH is also concerned with the lack of assistance and education available to the CAP physician implemented in the rule. CMS has not elaborated on continuing education for physicians and how they can seek assistance throughout the year regarding problems with the CAP. As a new program, it is likely that physicians will have questions related to processes and/or other technical aspects not clear at the beginning of the program. Additionally, CMS may make changes during the course of the year as problems present once the program is implemented and improvements are instituted. CMS should anticipate the need for on-going, real-time assistance to the physicians utilizing the CAP, particularly in the first year and implement a proactive education strategy.

Additionally, ASH is very concerned that the rule does not outline clear guidance on resolving grievances between the physician and vendor, other than to recommend they try to work it out and possibly escalate to the carrier level. CMS should provide clear guidance on resolving grievances to avoid escalating the administrative burden of the program on all parties, including CMS. It is not realistic to expect such a complex program not to have a variety of grievances as it is implemented and having guidance available on steps to resolve grievances may assist in identifying and implementing best practices.

Given the six month delay in implementing the CAP, ASH urges CMS to carefully consider the recommendations of ASH and other subspecialty organizations. In addition, the input of practicing physicians and the recommendations of the Practicing Physicians Advisory Council (PPAC) should be considered.

In Summary
To summarize, ASH appreciates the CMS' efforts to design and implement this new program. To maximize participation and promote long-term viability of the CAP, ASH recommends that CMS:

- Protect patient safety by:
  - Disallowing vendors to refuse to ship drug for a properly completed order;
  - Disallowing referral to a charitable organization that cannot or will not provide sufficient financial assistance to the beneficiary referred or for the drug involved; and
  - Supporting clinical decision-making on a peer-to-peer level.

- Encourage physician participation by:
  - Providing physicians with a dispensing fee, as done for pharmacists;

  - CAP contracts indicate vendor responsibility for drug integrity and that vendors maintain adequate liability insurance to indemnify a physician for any damages; and
  - Allowing physicians to opt out of the CAP after the first three months if they so choose.

- Promote long-term viability by:
  - Considering alternatives to including the CAP in the calculations for ASP;
  - Providing on-going, real-time education and assistance to CAP providers;
  - Providing clear guidance on resolving grievances; and
  - Giving careful consideration to input provided by practicing physicians.

Thank you for the opportunity to submit these comments. If you have any questions or would like additional information, please contact Pamela Ferraro, Practice Advocacy Manager, at 202-776-0544 or pferraro@hematology.org.

Sincerely yours,

James N. George

James N. George, MD
President

42

September 6, 2005

BY HAND DELIVERY

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200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1325-IFC (Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals under Part B)

Dear Administrator McClellan:

Hoffmann-La Roche Inc. ("Roche"), a research-based pharmaceutical company, submits the following comments in response to the interim final rule implementing the competitive acquisition program for certain Medicare Part B drugs not paid on a cost or prospective payment system basis (the interim final rule). [1] We appreciate the work undertaken by the Centers for Medicare and Medicaid Services ("CMS") to implement the competitive acquisition program ("CAP"), and also support the agency's decision to delay implementation of CAP to allow the agency more time to fully review public comments on the interim final rule. We welcome this second opportunity to present our suggestions on how to improve CAP so that it best serves the interests of beneficiaries, providers, and other stakeholders of the Medicare Program.

Our comments will focus on:

- The categories of drugs to be included in the competitive acquisition program;
- Claims processing, including:
  - Use of CAP to re-supply inventories;
  - Use of the "furnish as written" option;
  - Application of least costly alternative policies;
  - Payment of vendor drug claims; and
  - Options for physicians if a vendor ceases drug shipments for a particular beneficiary due to failure to meet copayment obligations;
- The bidding process, including how new drugs will be included in the program and confidentiality of bid prices; and

[1] 70 Fed. Reg. 39022 (July 6, 2005).

- Exclusion of competitive acquisition program prices from manufacturers' calculations of average sales price.

All of our comments are submitted in the spirit of assisting CMS's efforts to preserve beneficiaries' access to appropriate health care items and services. Pursuant to the instructions included in the interim final rule, each comment is set forth under a caption referencing the section of the proposed rule to which that comment relates.

Categories of Drugs to be Included in CAP

Limiting CAP to "Incident To" Part B Drugs and Biologicals

Roche continues to support CMS' decision to limit the application of CAP to Part B drugs and biologicals provided "incident to" a physician office visit. Consequently, CAP should be limited only to drugs that are commonly provided directly to patients by physicians and thus are covered under Part B by virtue of the "incident to" provisions of the statute. So, certain oral anti-cancer drugs, oral immunosuppressives, and oral anti-emetics products which are very infrequently dispensed by physicians should be excluded from CAP as previously outlined by CMS. Limiting CAP to "incident to" drugs is also consistent with the overall structure of CAP, which is voluntary for physicians.

Requirement to Bid All HCPCS Codes

We also want to reiterate our support for the requirement that CAP vendors must bid all HCPCS codes associated with a drug category that is included in CAP. Further, we agree with CMS that the CAP statute does not contemplate a formulary for single source drugs, and we appreciate CMS clarifying in the interim final rule that vendors will not be permitted to establish formularies by offering drugs from only some of the codes included in a drug category.[2] We believe CMS's assessment of whether formularies are permitted for single source drugs included in CAP is consistent with both the provisions of the Social Security Act governing Part B benefits and the intent behind CAP. Congress expressly authorized vendors to conduct a competition for multiple source drugs but declined to extend the same authority to single source products. CAP was never envisioned as a mechanism for limiting beneficiary access to otherwise covered Part B drugs. Because we continue to hear that prospective vendors are putting pressure on CMS to allow the use of formularies for single source drugs, we respectfully request that CMS affirm in the final rule that vendors must bid all HCPCS codes associated with a drug category covered by CAP.

Claims Processing Overview

Use of CAP to Re-Supply Inventories

In our comments to the proposed CAP rule, we urged CMS to allow physicians more liberal use of drugs covered by CAP from existing inventories in order to acknowledge the broad range of circumstances where physicians would need to use existing inventory to treat a patient. In the interim final rule, CMS clarified that the re-supply provisions apply when the drugs are administered

[2] 70 Fed. Reg. at 39034.

in an emergency, which CMS defines to mean "a situation determined by the physician's clinical judgment to be an unforeseen situation [requiring] prompt action or attention."[3] Roche agrees that the decision about whether or not an "emergency situation" exists should be left to the physician's clinical judgment and knowledge of the patient's circumstances, and we appreciate CMS clarifying this in the interim final rule.

Use of "Furnish as Written" Option

In clarifying the circumstances under which it is appropriate for physicians to use the "furnish as written" option and obtain particular NDCs not supplied by a CAP vendor outside of CAP through the normal "buy and bill" process, CMS states in the interim final rule that this option is intended to be used only in limited circumstances where a patient's medical condition requires a particular formulation of a drug at the NDC level.[4] The emphasis in this provision is on physicians exercising their clinical judgment and determining which particular treatment is best for the patient. But we are concerned that the examples provided in the interim final rule of appropriate circumstances for use of the "furnish as written" option are too narrow, and imply that a beneficiary must have a documented allergy or first suffer an adverse event or fail on the treatment actually offered by the CAP vendor before the "furnish as written" option can be used. Specifically, CMS states that "documentation of treatment failure or adverse events" *may* provide justification to use another product,"[5] which strongly suggests that a physician would need to document actual treatment failure or adverse event before he or she could prescribe the treatment that is right for the beneficiary. The only other example offered is the instance where a beneficiary has a "documented allergy to certain excipients or preservatives" and therefore requires a specific formulation of a product not provided by the vendor. None of these examples leaves much room for the physician's exercise of clinical judgment and using "furnish as written" to proactively prescribe the treatment that he or she believes will work best for the patient. CMS should offer additional examples in the final rule of circumstances where use of the "furnish as written" option would be appropriate.

Defaulting to Least Costly Alternative Policies

In the interim final rule, CMS states that in cases where a local coverage decision (LCD) exists that contains a least costly alternative provision, and the drug is included in CAP, "the drug claim will be paid subject to the LCA policy, rather than the CAP-established price."[6] Roche believes that this interpretation directly conflicts with the statutory requirement that CMS must determine a "single" payment amount 'for each competitively biddable drug or biological" in a competitive acquisition area, based on the bids submitted by vendors.[7] Although Medicare carriers are generally authorized to issue local coverage determinations in order to implement Section 1862(a)(1)(A) of the Social Security Act, which prohibits CMS from making payment for items and

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[3] 70 Fed. Reg. at 39047.

[4] 70 Fed. Reg. at 39043.

[5] *Id.* (emphasis added).

[6] 70 Fed. Reg. at 39039.

[7] Section 1847B(d)(1) of the Social Security Act (2005).

services that are not "reasonable and necessary," a local carrier application of a least costly alternative policy, which arguably is not permissible under law, should not be permitted to trump a clear statutory provision requiring all CAP prices to be uniform within a CAP acquisition area. In addition, allowing least costly alternative policies to trump the single prices set in CAP puts vendors at risk for costs that may not have been captured in their bids – and this is particularly problematic where the least costly alternative policy is instituted after the vendor has signed a CAP contract. Roche urges CMS to clarify in the final rule that CAP vendors will be reimbursed for CAP drugs at the single drug prices set by CMS based on the bids, and updated yearly based on vendor submission of reasonable net acquisition costs, regardless of whether or not an LCA is in place.

Partial Payment of Vendor Claims

We further note that in the interim final rule, CMS has decided that it will make payment on a vendor drug claim only when that claim can be matched with the physician claim for administering the drug.[8] Although CMS is requiring physicians to submit claims for drug administration within 14 calendar days of the date of administration, there are still likely to be considerable delays for vendors in being paid for drug claims under CAP. Ensuring that vendors are promptly paid the full payment amount due for drugs shipped pursuant to CAP is further compounded by prohibitions on billing beneficiaries for co-insurance liabilities until the drug claim has been paid.[9] To ease the burden on vendors, CMS should reconsider its position on this issue and establish a policy that allows for prompt partial payment of vendor drug claims pending processing of the drug administration claim. For instance, CAP vendors could be permitted to bill CMS no sooner than 14 days after the shipping date of the product to the physician.

Reimbursement for the Full Amount of Drug Shipped

CMS states in the interim final rule that it will reimburse vendors only for the exact amount of drug that is administered to the patient and will not pay for any discarded drug (or drug that is considered waste).[10] Failing to reimburse vendors for the entire amount of drugs shipped to a physician per the physician's order is contrary to how Part B drugs are currently reimbursed when they are shipped directly to physicians and puts vendors at risk for physician decisions that are not in their control. The CAP statute expressly requires vendor bid prices to exclude costs related to drug administration or wastage, spillage, or spoilage[11] – but this provision does not govern CMS actual payment for those drugs once they are shipped to the physician and administered to a patient. CMS should continue its existing policy of paying for the amount of Part B drug actually ordered by the physician and clarify in the final rule that CAP vendors will be paid in full for drugs shipped per physician order.

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[8] 70 Fed. Reg. at 39052.

[9] *Id.*

[10] 70 Fed. Reg. at 39063.

[11] Section 1847B(c)(6)(B) of the Social Security Act (2005).

Physician Opt-Out if Vendor Ceases Shipment Due to Beneficiary Non-Payment

In the interim final rule, CMS notes that it will allow vendors to stop shipping drugs on behalf of beneficiaries who fail to meet their coinsurance or deductible obligations.[12] CMS further provides that a CAP physician may opt-out of the drug category if a vendor exercises this option for a beneficiary in the physician's care – but this opt-out would apply to all physician purchases under CAP.[13] In other words, if one beneficiary fails to meet his or her coinsurance or deductible obligations and the vendor stops shipping drugs for that beneficiary, the physician participating in CAP has only one choice if he or she wants to continue treating that beneficiary: to opt-out of CAP altogether for all of his or her patients. This option seems particularly harsh for physicians, as it could disrupt existing beneficiary-physician relationships, and potentially jeopardizes the success of CAP. Roche recommends that CMS include provisions in the final rule that allow physicians to obtain drugs outside of CAP for those beneficiaries who have been "cut off" by the vendor for failure to meet coinsurance liabilities while participating in CAP for all the other eligible beneficiaries.

Cap Bidding Process – Evaluation and Selection

Inclusion of New Drugs and Biologicals in CAP

With respect to new drugs and biologicals that were introduced too late to be included in CAP bidding, or which will be introduced further in the second and third years of a CAP vendor contract, CMS states in the interim final rule that it will not require vendors to include these drugs in CAP but will instead consider vendor requests to add new drugs if the drug is "appropriate" for inclusion in CAP. Roche strongly urges CMS to reconsider this provision and instead require that vendors include new drugs and biologicals in CAP, particularly where those newer agents offer advances in treatment options over older drugs that are already included in CAP. Beneficiary access to the new product is likely to be hindered if physicians participating in CAP cannot have equal access to all competitive products in the therapeutic area in CAP and therefore limit prescribing to older therapies which may not be suitable for all patients. By participating in CAP, physicians will demonstrate their preference for avoiding the buy and bill process. Requiring them to pursue that process to obtain what could be medically necessary drugs may equate to less efficacious treatments being provided to beneficiaries.

CMS should establish a process in the final rule for promptly notifying vendors about new drugs and biologicals that are to be included in CAP. Furthermore, in cases where excluding certain drugs and biologicals would diminish the competitiveness that CAP is intended to promote, those items should not be subject to volume threshold requirements as a condition of inclusion in CAP. CMS should further clarify in the final rule that vendors will be required to offer the new drugs to participating physicians no later than the second quarter after introduction, and that such drugs will be reimbursed at ASP+6%, as set forth in the statute,[14] until the next annual pricing update.

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[12] 70 Fed. Reg. at 39053.

[13] *Id.*

[14] Section 1847B(d)(2)(A) of the Social Security Act.

Payment for New Drugs and Biologicals

CMS further states in the interim final rule that if a vendor adds a new drug or biological to its CAP offerings, CMS will not provide payment for this drug until the next quarterly pricing update. If these new drugs are to be reimbursed based on the ASP methodology set forth in Section 1847A of the Social Security Act, we do not understand why CMS cannot begin reimbursing for these drugs under CAP as soon as the drug has been formally added to CAP. The ASP methodology in Section 1847A is set up to ensure a payment mechanism is in place for reimbursing new drugs and biologicals covered under Part B as soon as the new drug is released onto the market and beneficiaries begin using the treatment. Because CAP defaults to ASP for new drugs and biologicals, there is no reason for CMS to delay making payment to vendors for new drugs under CAP until the next quarterly update.

Confidentiality of Bid Prices

In response to questions about whether CAP bid prices would remain confidential, CMS's response in the interim final rule suggests that there might be circumstances under which this information could be publicly disclosed. In one section of the preamble, CMS clearly provides that bid prices will be kept confidential and not made available for public display.[15] CMS also states in another section of the preamble that the confidentiality provisions of the Federal Acquisition Regulation (FAR) also apply to data submitted by bidders and vendors under CAP.[16] But CMS states in that same section that "what is confidential for FAR purposes may not necessarily be protected under the provisions of the Freedom of Information Act (FOIA)" – and that if CMS receives a FOIA request for pricing information, the request will be processed by the CMS FOIA officer to determine if any exemptions apply to protect the information.[17]

Drug pricing information submitted by vendors is extremely sensitive, and we are greatly concerned that CMS has suggested that this information might be subject to disclosure under FOIA. We believe this information is clearly protected from disclosure under FOIA exemption (b)(4) protecting business or financial information. Furthermore, we believe that drug pricing information provided under CAP should be treated the same as the price information provided in the outpatient prospective payment setting. Section 1927 of the Social Security Act clearly establishes that pricing data supplied by manufacturers for HOPPS purposes is confidential, "notwithstanding any other provision of law."[18] These protections also apply to pricing data submitted pursuant to the Part D prescription drug benefit.[19] We see no policy justification for treating drug pricing information differently in CAP than it is in the HOPPS and Part D settings. CMS should investigate this further with the agency's FOIA officer and make clear in the final rule that sensitive pricing information provided by manufacturers will remain confidential.

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[15] 70 Fed. Reg. 39022, at 39065.

[16] 70 Fed. Reg. at 39077.

[17] *Id.*

[18] Section 1927(b)(3)(D) of the Social Security Act (2005).

[19] *Id. See also* Section 1860D-2(d)(2) of the Social Security Act.

Exclusion of CAP from ASP Calculations

CMS clarifies in the interim final rule that it does not believe it has the statutory authority to exclude prices determined under CAP from calculation of ASP for a drug included in CAP. We respectfully disagree.

The statutory language could be interpreted to allow CMS to exclude CAP sales from calculation of ASP. The statutory provisions establishing the ASP payment methodology state very clearly that the section governing calculation of ASP "shall not apply in the case of a physician who elects" for the provisions governing CAP to apply instead of the ASP provisions for the payment of drugs and biologicals.[20] Although the MMA states that a manufacturer's average sales price for a drug means "the manufacturer's sales to all purchasers ... in the United States for such drug or biological in the calendar quarter,"[21] the statute also clearly provides that the provisions governing ASP do not apply where a physician has elected to participate in CAP.[22] The statutory language therefore indicates that CAP and ASP payment methodologies are severable, and suggests that drug sales under the CAP program should not be included in the calculation of ASP. Given Congressional intent to de-link the CAP pricing from ASP, we believe the Secretary possesses the discretion to define competitively biddable categories of drugs and biologicals to be a class of drugs whose CAP negotiated prices are not included in ASP.

Given the overall purposes of the CAP program, and that the drug prices negotiated between CAP vendors and manufacturers must include all of a CAP vendor's costs for participating in the program *and* be below the weighted ASP+6% for the entire category, CMS should affirm or clarify that CAP sales do not apply ASP in order to avoid frustrating the purposes of the program.

Conclusion

We appreciate this opportunity to submit comments to CMS regarding its proposed rule implementing the competitive acquisition program for certain Medicare Part B drugs. In summary, our recommendations are:

- Continue to limit CAP to Part B drugs provided "incident to" a physician's office visit and require CAP vendors to bid all HCPCS codes in a drug category covered by CAP;
- Provide additional examples in the final rule of appropriate use of the "furnish as written" option so that it is more clear that physician's clinical judgment about appropriate treatment for a beneficiary will be honored;
- Clarify in the final rule that CAP prices apply to all drugs and biologicals included in CAP, regardless of the existence of a least costly alternative policy;

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[20] Section 1847A(a)(2) of the Social Security Act.

[21] *Id.* at Section 1847A(c)(1).

[22] *Id.* at Section 1847A(a)(2).

- Allow for partial payment of vendor drug claims pending approval and processing of the drug administration claim;

- Clarify in the final rule that vendors will be reimbursed for the full amount of drug shipped to the physician per the physician's order, as is currently the practice for Part B drugs ordered directly by physicians, rather than billing only for the amount of drug administered to the patient;

- Permit physicians to purchase drugs outside of CAP for beneficiaries for whom vendors refuse to ship drugs due to beneficiary failure to meet co-payment obligations;

- Require vendors to include new drugs and biologicals in CAP, particularly in circumstances where omission from CAP would potentially undermine the program's intent to encourage competition;

- Clarify in the final rule that new drugs added to CAP will be reimbursed to vendors in a timely manner based on the ASP methodology;

- Clarify in the final rule that Freedom of Information Act Exemption (b)4, which exempts financial or business information from disclosure, protects CAP bid prices from being disclosed; and

- Clarify in the final rule that drug sales under CAP are excluded from a manufacturer's calculation of ASP.

We hope that CMS will incorporate our suggestions into its final rulemaking and look forward to working with CMS on the issues identified in our comments.

Respectfully submitted,

Michael J. Eging
Executive Director
Public Policy and Federal Government Affairs

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Hugh M. O'NEILL
Vice President

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September 6, 2005

BY HAND DELIVERY

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1325-IFC (Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals under Part B)

Dear Administrator McClellan:

Sanofi-aventis[1] appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) interim final rule implementing provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) that require implementation of a competitive acquisition program (CAP) for certain Medicare Part B drugs[2] not paid on a cost or prospective payment system basis (the Interim Final Rule).[3]

As a company dedicated to bringing advanced therapies to patients, sanofi-aventis supports the overall goal of the CAP – to ease the administrative burden on physicians of ordering, storing and collecting reimbursement for certain Part B drugs. We have a number of comments and recommendations about the CAP as described in the Interim Final Rule, however. Specifically:

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1 These comments are submitted on behalf of Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals, both members of the sanofi-aventis Group.

2 We use the term "drug" throughout these comments to refer collectively to both drugs and biologicals.

3 70 Fed. Reg. 39022 (July 6, 2005).

- CAP vendors should not be allowed to implement formulary controls that limit access to certain drugs.
    - CAP vendors should not be allowed to limit access to certain drugs by limiting access to certain NDC codes for that drug.
    - CMS should closely regulate CAP vendors to ensure that their policies do not constrain access to certain drugs that technically should be available or unduly influence market prices under the program.
- Consider using a measure other than volume of billing units as the weight for bidding purposes.
- Any significant changes to the CAP in the initial implementation phase should be accompanied by another formal comment period as required by the Administrative Procedure Act.

A more detailed explanation of these concerns, and our specific recommendations for the final CAP rule, are set forth below.

I. Vendor Implications

A. Access to and Choice of Drugs under the CAP

It should be a priority for CMS to ensure that physicians and patients have access to a broad array of drugs that will meet patients' medical needs. The CAP's goal of ensuring access while easing physicians' administrative burdens associated with acquiring and billing for drugs administered to their patients can be met only if physicians can obtain the therapies their patients need through the program. Sanofi-aventis applauds CMS for requiring CAP vendors to bid and make available to participating physicians all of the Healthcare Common Procedural Coding System (HCPCS) codes included in a particular drug category covered by the CAP.

The Medicare statute and its legislative history require CAP vendors to offer at least one drug for each billing and payment code within a CAP category.[4] Because this requirement applies equally to multiple source and single source drugs,[5] CAP vendors do not have the option of excluding certain codes from the CAP. Sanofi-aventis therefore requests that CMS clearly prohibit CAP vendors from creating formularies, even through indirect means. It is not the intent of the law that CAP vendors limit NDCs in a manner that, in effect, limits beneficiary access to certain drugs. CMS' decision to prohibit formularies in the CAP is critical in preserving choices for patients of participating physicians.

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4 Social Security Act (SSA) § 1847B(b)(1).

5 See H. Rep. No. 108-391, at 594 (2003) (explaining that the Secretary must conduct a competition "among entities for the acquisition of at least one competitively biddable drug or biological that is a multiple source or a single source drug or biological within each billing and payment code within each category for each area").

We believe that CMS would further protect beneficiary access to critical therapies under the CAP by adopting our proposal to require vendors to provide at least one NDC for each single source and each brand name[6] product contained in a shared HCPCS code. A HCPCS code can be used to describe many unique therapies, and sharing a HCPCS code in no way indicates that two or more products are interchangeable. In fact, several brand name therapies can be included in a single HCPCS code, even though the therapies are not rated as therapeutically equivalent by the Food and Drug Administration (FDA). Each of these therapies may have different formulations, indications, uses, and effects that make them appropriate for some patients but not for others with the same condition. The Interim Final Rule would allow a vendor to provide just one of these therapies, denying participating physicians access to the appropriate therapy for their patients through the CAP. Rather than requiring physicians to use the "furnish as written" option, discussed below, to obtain these therapies, sanofi-aventis recommends that CMS require CAP vendors to provide at least one NDC for each single source and each brand name therapy within each HCPCS code in the CAP category. This requirement would greatly simplify physicians' administrative burdens under the CAP and would help ensure beneficiaries access to the most appropriate therapies.

In addition, the Interim Final Rule does not allow vendors to offer drugs from only some of the codes included in a category. Nevertheless, even for codes with a single drug, vendors are only required to bid one NDC per code. Although CMS believes it will be difficult for a vendor to attract business from physicians if its list of CAP NDCs is too restrictive, we believe that CMS must implement special protections to prevent CAP policies from limiting treatment options. Therefore, we believe CMS should encourage vendors to provide multiple NDCs for each drug to allow physicians to choose the best formulation, strength and package size for the patient's dosage. Otherwise, physicians and pharmacists will often be forced to choose an NDC that does not meet the patient's needs, which results in waste of the excess drug product, and exacerbates the use of "furnish as written" prescribing practices.

It is also not clear from the Interim Final Rule what the process will be for vendors to add NDCs after the program starts. We are very concerned about the entry of new products and believe that there should be a clear process for CAP vendors to add new NDCs as they become available. The Interim Final Rule describes the circumstances in which a vendor may substitute a different NDC for an NDC currently offered,[7] but it does not address whether a vendor can supplement its offerings with new or additional NDCs. Instead of restricting vendors to a single list of NDCs for the whole year, we believe that vendors should be allowed to expand their list of NDCs offered to CAP participants to include additional NDCs or package sizes that better reflect patient needs. We urge CMS to clarify that vendors may expand beneficiaries and physicians' choices under the CAP by adding new NDCs throughout the year. We recommend that payment for additional NDCs

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6 By "brand name," we mean a product that does not have a therapeutic equivalent according to the Food and Drug Administration.

7 42 C.F.R. § 414.906(f).

be based on the established price for the HCPCS code, just as payment is set when a vendor offers multiple NDCs from the beginning of the CAP.

B. Use of the "Furnish as Written" Option

As we explained above, it is essential that CAP vendors provide physicians access to a broad range of drugs to meet their patients' unique needs. Although we urge CMS to require CAP vendors to provide a wide choice of NDC codes, we recognize that there will be instances when a physician prescribes a specific formulation or brand of a drug that is not being furnished by a vendor through the CAP. We are concerned that the final CAP rule will impose new requirements on physicians that will impede patient access to the most appropriate therapy. For example, CMS proposes to require physicians to use a "furnish as written" modifier to identify claims made under this option to their local carrier. CMS further adds that physicians' local carriers will at times conduct post payment reviews of the use of the "furnish as written" modifier, and if the carrier determines 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.[8] If the physician chose not to participate in the CAP and bought and billed for the same drug directly, the physician would not be subject to this review. We continue to have concerns that CMS is imposing requirements on physician prescribing of covered Part B drugs under the CAP that are more onerous than the processes already in place at the local contractor level for determining coverage of these therapies. At a minimum, we believe that CMS should routinely audit "furnish as written" orders to determine if vendors have constrained access by severely limiting choice of NDC codes.

II. CAP Bidding Process – Evaluation and Selection

The Interim Final Rule explains how a vendor's composite bid will be constructed from the bid prices for the individual drugs in the CAP category by weighting each HCPCS bid by the HCPCS code's share of volume (measured in HCPCS units) of drugs in the single drug category during the prior year.[9] This methodology may overemphasize the importance of drugs coded in small unit sizes, however. The use of expenditures rather than just the volume of billing units may be a more appropriate measure of a drug's significance to the Medicare program. CMS may want to consider making this change in the final rule.

III. Administrative Procedure Act

The Administrative Procedure Act (APA) requires that a federal agency publish rules of general applicability in the Federal Register. Federal courts have consistently refused to recognize or enforce unpublished agency "interpretations." As stated by the Supreme Court in the seminal case Morton v. Ruiz,[10] "the Administrative Procedure Act was adopted

8 70 Fed. Reg. 39022, at 39043.

9 70 Fed. Reg. 39022, at 39072.

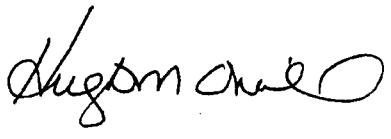
10 415 US 199, 94 S. Ct. 1055, 1073 (1974).

to provide, *inter alia*, that administrative policies effecting individual rights and obligations be promulgated pursuant to certain stated procedures so as to avoid the inherently arbitrary nature of unpublished ad hoc determinations." As such, we believe that any significant changes to CAP in the initial implementation phase should be accompanied by another formal comment period before becoming final.

IV. Conclusion

Sanofi-aventis appreciates this opportunity to comment on our concerns about the Interim Final Rule, and we look forward to working with CMS to protect Medicare beneficiaries' access to life-improving drug therapies. We hope our suggestions will help CMS address these important issues in the final rule. Please contact me if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,



Hugh O'Neill
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SEP - 6 2005

Mail or Hand-Deliver Comments to CMS Competitive Acquisition Program (CAP) Interim Final Rule

Comments must be received by 5 p.m. on Tuesday, September 6, 2005

MAIL COMMENTS

You may mail written comments (one original and two copies) to the following address ONLY (Please allow sufficient time for mailed comments to be received before the close of the comment period, Tuesday, September 6, 2005).

In commenting, please refer to file code CMS-1325-IFC.

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

HAND-DELIVER OR COURIER COMMENTS

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 the CMS 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 and extra copy of the comments being filed.)

Comment Online	Mail or Hand Deliver Comments	Federal Register, Press Release and Announcements

Product Integrity

MMA requires CAP vendors to buy the drugs they dispense directly from the product's manufacturer or from a wholesaler that buys direct. This provision is designed to address the grave threat posed by counterfeit drugs. US Oncology applauded this requirement in its comments on the proposed rule but noted the lack of oversight procedures needed to ensure CAP vendors comply with this requirement. The Interim Final Rule appears to suffer from the same deficiency.

The IFR relies heavily on a vendor credentialing process that focuses on financial data and vendor experience in the drug distribution business. In addition, it requires CAP vendors to include "language with shipping material stating that the drug was acquired directly from the manufacturer or that the vendor possesses verification that the drug was acquired directly from the manufacturer and has been acquired in a manner that is consistent with the statutory requirements." CMS supplements these attestations with state regulation of the CAP vendor as a licensed wholesaler and, perhaps, as a licensed pharmacy, routine Medicare provider enrollment monitoring, carrier statistics, complaint monitoring, breach of contract sanctions if the vendor fails to honor product integrity requirements, and the threat that CAP vendors could be required to present pedigree documents upon request. None of these oversight tools seems sufficient to guarantee the integrity of drugs shipped under CAP, however, particularly in light of the tight timelines under which CMS will be allotted for reviewing vendor bids.

Wholesaler and pharmacy licensing laws have not historically restricted the supply sources of licensed entities. Florida has begun to enforce a requirement for paper pedigrees under its authority to license prescription drug wholesalers and a few other states are preparing to do the same, but the Florida pedigree requirement is limited to a defined list of drugs with a high risk of counterfeiting. Meanwhile, the majority of states are waiting for the FDA to move forward with a pedigree requirement nationally. And although many in the distribution industry, under the leadership of the Healthcare Distribution Management Association (HDMA), are working hard to stem the tide, radiofrequency identification devices and electronic pedigrees are not yet an affordable reality and paper pedigrees remain easy to forge.

As a result, CMS should establish standards for CAP vendors akin to the DMEPOS supplier standards and provide for routine survey requirements under the interim final rule. CMS should also ensure that auditors from the designated CAP carrier or other appropriate CMS contractor make frequent, randomly timed, unannounced site inspections of CAP vendors and their subcontractors to review purchase contracts, shipping documents and other records that establish the chain of custody of drugs delivered to CAP physicians. CMS also should establish and broadly disseminate information about the procedure that CAP physicians should follow to report a suspected delivery of counterfeit drugs. That procedure must incorporate rapid timelines for the investigation and resolution of the report. A web-based quality reporting system akin to that operated by CMS for nursing homes and home health agencies should also be implemented to alert the physician and patient communities to the quality, service, solvency and other performance accomplishments and shortfalls of CAP vendors.

Finally, CMS should clarify that one substantiated instance of the purchase or distribution of a counterfeit drug by a CAP vendor constitutes a single serious breach of contract that will automatically result in the termination of the vendor's Part B supplier number and CAP contract.

Pankaj Khandelwal MD
West Texas Cancer Center

Implications for Patient Care

Even though CMS undertook major efforts to address concerned comments about the potential impact of CAP on patient care and quality, elements of CAP still present serious implications.

The timeline for drug delivery is a case in point. In general, CAP vendors will not be required to have product to the ordering physician until 5 pm the next *business* day in an emergency situation and 5 pm on the second *business* day after a routine order is placed, assuming the vendor receives the order before 3 pm vendor's local time. Practically speaking, physicians will have to reschedule patients with emergency needs at least *two* days later, and non-emergency patients may not be scheduled any sooner than *three* days after their original appointment.

Indeed, the five-day-a week, business day delivery schedule does not bode well for patient care. A patient in the continental US with an emergency discovered at a late afternoon appointment on Friday may have to wait for a Wednesday appointment to be treated with a drug supplied through the CAP vendor, since one business day delivery would only require the CAP vendor to get the past-3 pm Friday order to the doctor by 5 pm Tuesday.

In addition, the delivery timelines are particularly troubling for oncologists because cancer patients often require unanticipated shifts in their course of therapy, depending on tumor response and patient condition when he or she presents for therapy. In light of state pharmacy limitations on the ability of CAP practices to redirect unused drugs that have been dispensed for another patient, when a change is needed in a patient's course of therapy there usually will be a multiple day delay in the patient's treatment.

Another major area of concern is drug availability. Under the IFR, the drugs available under CAP are limited to an identified list of 181 products, and even then CAP vendors may supply only one drug per HCPCS code. Although the drug list constitutes 85% of Part B drugs based on spending, it leaves out over 250 products covered under Part B. Moreover, CMS acknowledges that CAP will only cover "most of the drugs with access problems under ASP+6%." With low-volume products excluded, CAP physicians will have to buy and bill those drugs for which they are least likely to be able to obtain discounts, further impacting access to drugs. Further, the exclusion of drugs billed on miscellaneous codes could undermine access to advanced treatment options for patients who have failed to respond to old-line treatment regimens.

Concern has also been raised that CAP could compromise patient safety through the potential commingling of patient-specific drug inventories. The traditional physician prescription and pharmacy dispensing process has long played an essential role from a patient safety perspective. However, any commingling of patient prescriptions under CAP could lead to life-threatening medication errors.

Finally, patient care can be severely impacted by the CAP vendor's right to cut off delivery of drugs for patients who fail to meet their cost-sharing obligations. Under the IFR, CAP vendors may stop shipping drugs for patients who have not paid billed cost-sharing amounts within 45 days after the postmark date on the bill unless the patient has contacted the vendor about the payment problem. Although the IFR provides for notification, waiver, and limited postponement, the impact on patients could be significant. Many patients are unable to cover the full cost of their coinsurance, exposing potentially tens of thousands of patients to treatment cut-off. Likewise, increased collection effort pressures from CAP vendors could drive more cancer patients to choose to forego treatment earlier in their course of therapy when the possibility of a successful treatment outcome may be higher. Finally, the stress of vendor collection effort pressures could adversely affect treatment outcomes for certain financially stressed patients.

Pankaj Khandelwal MD
West Texas Cancer Center

Practice Viability

As detailed in comments submitted regarding the CAP proposed rule, neither CAP nor buy-and-bill will be sustainable for many oncology practices if reimbursement for drug administration services remains inadequate to cover their costs. When factoring in the additional administrative costs physicians face if they elect to participate in CAP, the risks to practice viability become even greater.

Based on detailed analyses utilizing current information on 2006 payment policy, community cancer care faces substantial losses beginning January 1, 2006. Absent legislative or regulatory change, several critical sources of support will end on December 31st: the symptom management demonstration program is scheduled to end at that time, the drug administration transition factor of 3% will fall to zero, and the physician fee schedule will be cut by 4.3 percent.

As a result of these factors and the chronic underpayment of oncology drug administration services, the projected impact for all of community oncology is a loss of more than $420 million – assuming every penny of coinsurance is collected (which never happens). If, by contrast, half of all coinsurance is collected, the sector wide impact is projected to be in excess of $830 million next year. This translates into an estimated loss of $1,425 per Medicare beneficiary or over $530,000 for a typical 5-physician oncology practice.

Simply exiting the buy-and-bill system does not relieve practices of these losses, of course, since a major source of the shortfall is the drug administration services underpayment. Instead, practices opting to participate in CAP will experience a net loss on every Medicare patient due to this underpayment. Adding to the financial strain the practice will experience are the additional and as-yet uncompensated costs of pharmacy services and the administrative functions required of CAP practices.

With respect to pharmacy services, CAP practices will continue to engage in a wide range of important and costly activities including: drug receipt and recording, inventory management, drug preparation, and hazardous waste disposal. In the Hospital Outpatient Prospective Payment System (HOPPS) proposed rule, CMS acknowledged the expense of these activities when it observed that "the handling costs for drugs, biologicals, and radiopharmaceuticals ... are not insignificant as [these] medications ... generally require greater pharmacy preparation time...." As a result, while CMS collects data for two years to further define the HOPPS costs, 2% of ASP will be added to drug payments set at ASP+6% to reimburse hospitals for these handling costs, making effective HOPPS reimbursement for drugs with separate APCs ASP+8%.

No such reimbursement currently exists for physician offices, however, making CAP-related pharmacy costs an unreimbursed loss to the practice.

In addition, the multitude of issues raised in the "Burden on Physician" section of US Oncology's proposed rule comments appears to remain. CAP practices will need to engage in order placement processes that involve the submission of substantial detailed information. Software systems may need to be revised to accommodate this requirement. Claims denials must be appealed by the practice on behalf of the CAP vendor. Follow-up tracking and enhanced safety systems will be needed to prevent medication errors under CAP. And the IFR even adds a new burden in that CAP physicians will be expected to secure Advance Beneficiary Notices (ABNs) when CAP vendors ask them to because of concerns about coverage denials or lowest cost alternative issues.

Each of these activities will impose real costs to CAP practices, costs that are not offset by any form of administrative compensation to anyone participating in the CAP program.

Pankaj Khandelwal MD
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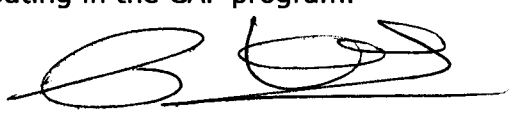

September 1, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-~~1372-~~IFC
PO Box 8013 1325
Baltimore, MD 21244-8013

Dear Centers for Medicare and Medicaid Services:

I am a friend of a thyroid cancer patient and I am writing to request that Thyrogen® (thyrotropin alfa for injection) be included in the list of drugs available through the Medicare competitive acquisition program (CAP) in 2006.

Thyrogen is crucial for the follow-up of her thyroid cancer treatment, in testing used to determine whether or not she is free of disease or whether her thyroid cancer has recurred or spread and requires further treatment.

It would reduce the quality of care for the Center for Medicare and Medicaid Services to deny access to Thyrogen through the Medicare Competitive Acquisition Program.
I am concerned that your proposed guidelines will exclude Thyrogen from the CAP. Medicare beneficiaries who have suffered from thyroid cancer need Thyrogen to be included in the Medicare Competitive Access Program (CAP).

I urge you to reconsider your guidelines. Please include Thyrogen (thyrotropin alfa for injection) in CAP as soon as possible. Allowing physicians to access Thyrogen through CAP will ensure that Medicare beneficiaries have access to the highest standard of thyroid cancer care without the financial and paperwork burdens that otherwise will occur.

Sincerely yours,

June Guay

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special handling and storage. If spoilage or wastage occurs, due to a physician office's error (e.g. ordering , mishandling, etc.), the CAP vendor (under the current Interim Final Rule) is not eligible for any reimbursement. Similarly, if wastage occurs due to an unused portion of the drug administered to the patient (i.e. change in anticipated therapy), the CAP vendor (under the current Interim Final Rule) is not eligible for any reimbursement. This is an unacceptable risk to the CAP vendor.

Instead, WHS would encourage CMS to adopt a policy that protects and reimburses the CAP vendor from any unforeseen spoilage or wastage issues. Specifically anytime the CAP vendor satisfies all the requirements of fulfilling a prescription that a physician ordered, the CAP vendor would be guaranteed the full CAP reimbursement amount for any drug that could not be returned AND reused by the CAP vendor (many states do not permit pharmacies to accept returns except under specific circumstances), whether or not that drug was actually administered to the Medicare beneficiary or not.

This resolution would also protect the CAP vendor from financial risks associated with Local Coverage Determinations that require a Least Costly Alternative (LCA) provision, since under the Interim Final Rule the CAP Vendor drug claim would be paid subject to the LCA policy rather than the CAP-established price.

Claim Adjudication Risk

Under the proposed model, CAP vendors must wait for reimbursement until after the drug is shipped, administered to the beneficiary, billed by the physician, and a match occurs between the Cap Vendor and physician claims. This is a lengthy process that even when it works right (i.e. the current Interim Final Rule only "encourages" physicians to submit their bill within fourteen days of administration date) is problematic from both a time value of money perspective and potential adjudication risk. This problem is further exacerbated since the CAP vendor cannot even try to collect any beneficiary co-payments, coinsurance, or deductibles until after the claim is paid by the CMS vendor.

WHS encourages CMS to adopt policies that allow the CAP vendor to be reimbursed for their services (i.e. once the medication is dispensed) as soon as possible. Specifically, WHS highly recommends CMS to adopt the following changes:

- Institution of a pre-certification process between physicians and CAP vendors to verify medical necessity before a drug order is filled
- Mandatory collection of a advanced beneficiary notice (ABN) from the Medicare beneficiary by the physician's office prior to drug administration
- Notification requirements for physician to notify the CAP vendor upon administration of a drug
- Submission of a physician within one business day upon administration of a drug

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Conclusion

Embedded in the current Final Interim Rule are significant risks for potential CAP vendors that CMS should address in the anticipated Final Rule expected late 2005. It is the belief of WHS, that CMS needs to ensure that CAP vendors be reimbursed in a timely manner for the services they provide (i.e. distribution and fulfillment of a physician's order). Anything less than this would place the CAP vendor in severe financial jeopardy. Therefore as it stands today, absent any changes to the Final Interim Rule, we find that the program lacks in competitive attractiveness and operational efficiencies. WHS appreciates the opportunity to present these comments to CMS. We hope our recommendations will be useful to CMS in developing and implementing the CAP.

Sincerely,

Richard LaVecchia
Director of Strategic Planning