BIO

BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

September 6, 2005

BY ELECTRONIC 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:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) interim final rule with comment period regarding the competitive acquisition program (CAP) for outpatient drugs and biologicals under Part B, published in the Federal Register on July 6, 2005 (IFC).1 BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

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

1225 EYE STREET, N.W., SUITE 400
WASHINGTON, D.C. 20005-5958

202-962-9200
FAX 202-962-9201
http://www.bio.org

Representing an industry that is devoted to discovering new cures and ensuring patient access to them, BIO is pleased that the CAP will offer physicians a choice of methods of obtaining drugs and biologicals for their patients. We appreciate the improvements CMS has made to the program to protect patients' access to drug and biological therapies obtained through the CAP and are encouraged that the agency intends to make additional modifications in the final rule before implementing the program. BIO applauds CMS for its hard work to implement the CAP as soon as possible, ensuring that it is a viable program that will provide a true option for all physicians.

BIO supports CMS' decision to phase in the CAP with an initial nationwide region and a single, broad drug category that addresses many specialties' drug needs. We also agree with the exclusion of certain types of drugs and biologicals, such as contrast agents, blood and blood products, plasma-derived and recombinant analog therapies, and intravenous immune globulin (IVIG). We appreciate CMS' clear statement that vendors do not have the authority to create formularies by offering only certain Health Care Common Procedure Coding System (HCPCS) codes in the category.[2] It is imperative that this not be changed as the rule is finalized.

We also commend CMS' efforts to protect beneficiaries' access to appropriate therapies by including provisions that respect physicians' clinical judgment. In particular, we support the IFC's clarification that vendors cannot make determinations of medical necessity and generally must ship the therapy ordered by the physician. CMS' definition of "emergency situations" allows physicians to determine the best course of treatment for their patients and to order replacement inventory of necessary therapies through the CAP.

We also support the provisions of the IFC that address beneficiaries, physicians, and vendors' concerns about the costs of participating in the CAP. The requirement for vendors to provide beneficiaries with information on sources of cost-sharing assistance when requested by the beneficiary will facilitate continued access to drug and biological therapies, regardless of the beneficiary's ability to pay. CMS has eased physicians' burdens somewhat by allowing vendors to appeal denied claims. The clarification that vendors bear the cost of returned drugs and biologicals also lessens physicians' concerns about the cost of participating in the CAP. Finally, we support the decision to update the single prices for CAP drugs and biologicals to the mid-point of

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[2] Id. at 39034.

calendar year 2006 by the Producer Price Index for prescription preparations. Updating prices through this mechanism will encourage more potential vendors to participate in the CAP by helping to ensure that payment for CAP drugs reflects current market conditions.

To further improve the CAP, we ask CMS to make the following changes in the final rule:

- CAP vendors should be permitted to incorporate new or additional National Drug Codes (NDCs) during the year;
- Orphan drugs and biologicals should not be excluded categorically from the CAP. In fact, these tend to be the very therapies that should be included to ensure patient access to them. We ask CMS to individually evaluate each orphan drug or biological for inclusion in the single category in the final rule. However, Alpha 1-proteinase inhibitor should be excluded from the CAP;
- CMS should instruct carriers should not apply their least costly alternative (LCA) policies to the CAP;
- New drugs and biologicals should be added to the CAP as soon as possible after they are available on the market and should be paid at their average sales price (ASP) plus 6 percent or at their wholesale acquisition cost (WAC) plus 6 percent until an ASP-based rate can be implemented;
- Physicians should be permitted to request from the CAP vendor an advance supply of drugs likely to be used in emergency situations;
- CMS should state explicitly in the next CAP final rule that its longstanding discarded drug policy also applies to CAP, in the spirit of a recent response to a CAP vendor question;
- CMS should make partial payment to CAP vendors at the time a drug or biological is dispensed;
- CMS should clarify that the CAP does not impose any forced sale requirements on manufacturers; and
- When a patient is denied drug shipments by a CAP vendor, the physician should have the option of obtaining drugs and biologicals outside of the CAP program for that patient and be allowed reimbursement at ASP plus 6 percent, while continuing to participate in the CAP for other Medicare beneficiaries, in addition to the option of discontinuing CAP altogether.

We are pleased by CMS' progress toward addressing our concerns about the proposed rule and look forward to working with the agency as it moves toward implementing CAP. We hope that our comments will help CMS resolve our remaining concerns about the program.

A. Categories of Drugs to be Included Under the CAP

1. Choice of Drugs and Biologicals in the Single Category

BIO supports CMS' selection of a single category of 169 drugs and biologicals, plus 12 new therapies, for inclusion in the initial CAP category.[3] We believe this category, which represents approximately 85 percent of physicians' Part B drugs by billed charges, will make the CAP a workable option for many physicians. By including a broad range of products, the CAP category is likely to include therapies to serve most patients' needs and attract more physicians to the program. To make the CAP even more useful for beneficiaries and physicians, we urge CMS to expand the CAP to include additional therapies as soon as possible. As discussed in further depth below, we believe most orphan drugs and biologicals and new drugs should be added to the CAP's single category in the final rule.

CMS protected beneficiary access to biologicals and single-source drugs by explicitly stating CAP vendors must provide at least one National Drug Code (NDC) for each HCPCS in the category.[4] This requirement reflects the statute's clear instructions for vendors to provide "at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area."[5] To better address Medicare beneficiaries' drug and biological needs and provide greater choice and flexibility in clinical management under the CAP, we believe that CAP vendors should provide substantially more than one NDC per HCPCS. When a vendor offers more than one NDC per HCPCS, physicians should be permitted to specify which NDC they are ordering.

We also recommend that vendors be allowed to incorporate new NDCs as soon as they are available on the market or additional NDCs during the year for drugs already included in a CAP HCPCS. The IFC allows vendors to

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3 Id. at 39030.
4 Id. at 39034.
5 Social Security Act (SSA) § 1847B(b)(1).

furnish more than one NDC for a HCPCS code, and, in limited circumstances, vendors may substitute a different NDC for the NDC currently offered.[6] The IFC does not clearly state whether vendors can incorporate new or additional NDCs, not merely to substitute for NDCs offered, but also to expand choice and flexibility under the CAP. We firmly believe that CAP vendors should be allowed to add NDCs throughout the year to improve beneficiary and physician choice of treatment options so the treatment regimen ordered can be the most appropriate regimen for the patient and to minimize discard of excess supplies. We suggest that payment for these additional NDCs continue to be based upon the established price for the HCPCS code.

2. Drugs and Biologicals Excluded from the Single Category

Additionally, we appreciate CMS' efforts to exclude drugs and biologicals that are likely to face access problems under the CAP. We agree with the agency's decision to exclude contrast agents and blood and blood products from the CAP.[7] We thank CMS for deciding not to include IVIG in the CAP, but we remain concerned that the agency has not acknowledged Congress' clear intent to exclude this therapy from the program.[8] Likewise, we believe that CMS should acknowledge Congressional intent to exclude radiopharmaceuticals from the CAP as well.[9] Congress recognized that the unique characteristics of radiopharmaceuticals made these products highly unsuitable for the CAP structure, and these therapies are excluded by statute, not solely at CMS' discretion.

In response to several commenters' concerns about access problems, the agency decided to exclude CMS-designated single indication orphan drugs from the CAP.[10] BIO urges CMS to reconsider this decision. In general, we believe that access to orphan drugs would be enhanced, not harmed, by inclusion in the CAP. The CAP is intended to improve access to drugs and biologicals by reducing physicians' costs of acquiring and billing for therapies. Because demand for orphan drugs is extremely low and variable, they are costly to

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6 42 C.F.R. § 414.906(f).
7 70 Fed. Reg. at 39029.
8 SSA § 1842(o)(1)(E) establishes payment for IVIG at 106 percent of ASP; See also H. Rep. No. 108-391, at 593.
9 MMA § 303(h) states that "nothing in the amendments made by this section [including the creation of the CAP in section 303(d)] shall be construed as changing the payment methodology under part B of title XVIII of the Social Security Act for radiopharmaceuticals;" See also H. Rep. No. 108-391, at 593.
10 70 Fed. Reg. at 39028.

manufacture and costly for physicians to keep in inventory. Orphan drugs are precisely the types of therapies for which physicians most want to be relieved of the financial burdens of acquisition and payment collection and for which patients most need to be assured of uninterrupted access. Many patients with rare diseases rely on orphan drugs to keep them alive. Including these therapies in the CAP would allow physicians to provide their patients with critical therapies without assuming the risk of not collecting beneficiary coinsurance or receiving adequate reimbursement.

Moreover, excluding only the designated single indication orphans and not other drugs and biologicals used to treat rare disorders leads to inconsistent results. It also may make electing the CAP less attractive for physicians who cannot get all the therapies they need through the program. For example, one of our members manufactures four orphan enzyme replacement therapies. Although the therapies are similar, two are designated single indication orphan drugs that have been excluded from the CAP – Cerezyme® and Ceredase®, and two – Fabrazyme® and Aldurazyme® – are included in the program. All four therapies are administered by the same physician specialty, typically hematologist/oncologists. Including all four therapies in the CAP would make the program more consistent and would increase its attractiveness to physicians.

For these reasons, we urge CMS not to exclude orphan drugs categorically from the CAP. Each orphan therapy should be eligible for inclusion under the CAP under criteria applicable to other drugs and biologicals unless a concern about patient access from inclusion under CAP is raised to CMS by interested stakeholders with respect to a specific orphan drug. Accordingly, we sincerely hope CMS will add most orphan drugs and biologicals to the CAP's single category in the final rule.

We recommend that one orphan therapy, alpha 1-proteinase inhibitor (J0256), continue to be excluded from the CAP. Alpha 1-proteinase inhibitor is a plasma-derived and recombinant analog therapy. Several brand name versions of this therapy are included in code J0256, but the individual brands are not therapeutically equivalent. Each brand has a unique effect on the patient, and response to each brand can vary from patient to patient, making it critical that each patient receives the specific brand that is best suited for his or her condition. As long as CAP vendors are required to offer only one NDC for this HCPCS code, it is highly unlikely that a CAP vendor would provide each patient's specific brand. We expect that physicians would have to use the

"furnish as written" option frequently for patients who need alpha 1-proteinase inhibitor. It makes more sense, therefore, to exclude alpha 1-proteinase inhibitor from the CAP than to require physicians to routinely use the "furnish as written" option. Each patient's access to alpha 1-proteinase inhibitor would be protected best by excluding these products from the CAP.

CMS also decided to exclude injectable forms of leuprolide from the CAP because carriers have applied LCA policies to this therapy that set its payment at the rate applicable to goserelin.[11] CMS explains that including leuprolide in the CAP "would have the effect of requiring vendors to supply the drug at the cost of goserelin in each instance in which a participating CAP physician orders it, regardless of the price established for leuprolide under the bidding and single price determination processes."[12] We agree that substituting one drug or biological's price for another's is inconsistent in a system where a vendor competitively bids to supply each HCPCS in a given category and the composite bids are capped at 106 percent of ASP. We believe that a better approach to this issue would be to instruct carriers not to apply their LCA policies to the CAP.

3. Inclusion of New Drugs and Biologicals in the CAP

BIO thanks CMS for requiring CAP vendors to bid on and provide the 12 new drugs and biologicals listed in Addendum B.[13] By including these drugs and biologicals, CMS allows physicians participating in the CAP to provide Medicare beneficiaries with the most advanced therapies available. We are concerned, however, that the agency does not require CAP vendors to include other new drugs and biologicals in the program once they are available on the market. We urge CMS to make this change in the final rule and reimburse vendors 106 percent of ASP (or 106 percent of WAC until an ASP-based payment rate can be established) for these therapies as soon as they become available.

The IFC places new drugs at a significant disadvantage among physicians opting for CAP, effectively denying access to the best available therapies to patients whose physicians have chosen to obtain products in this manner. Currently, the IFC excludes drugs from the CAP that have not yet been

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11 70 Fed. Reg. at 39029.
12 Id.
13 Id at 39072, 39102.

assigned a permanent HCPCS code. Unfortunately, it typically takes more than a year to obtain a permanent J-code, meaning new drugs will not be available in the CAP until they have been widely adopted in other Medicare treatment settings. For some drugs, CMS recognizes the need to assign product specific HCPCs codes such as Q-codes prior to the assignment of a permanent J-code for claims processing purposes. Some of these drugs retain Q-codes for years before being assigned a J-code, if ever.

Because vendor contracts are for a three-year period, the availability of new drugs could be delayed for this period of time – three years. Once a permanent code is assigned, the IFC states that CAP vendors have the *option* of offering the product through CAP, and if so, they will be reimbursed ASP plus 6 percent – the same amount physicians declining CAP participation will be reimbursed.

Although the IFC does allow CAP-participating physicians to purchase non-CAP products through the buy-and-bill method, such a requirement is inconsistent with the overall goal of CAP – to provide physicians with a choice of obtaining therapies through either method. Physicians opting to participate in CAP will do so due to the administrative advantages CAP offers and, therefore, should not be forced to go outside of the program to purchase and prescribe newer drugs. This is particularly the case for certain specialties that have little experience with "buy-and-bill." As written, this provision serves as a significant disincentive to prescribe new and innovative drugs, creating barriers for access to these therapies within the Medicare program. In addition, the provision creates perverse incentives for competing products in a therapeutic class. If this issue is not resolved, the CAP program will be the only venue within Part B of Medicare in which new products are not made available to Medicare beneficiaries immediately upon FDA approval.

To ensure access to new products by physicians and Medicare beneficiaries, we urge CMS to modify the final rule to allow for immediate adoption of new drugs within the CAP program. We ask that CMS:

1) Mandate that vendors make available to CAP-participating physicians new drugs upon FDA approval and reimburse vendors at 106 percent of ASP (WAC plus 6 percent until ASP data are gathered and reported). As written, the IFC specifies reimbursement of 106 percent of ASP for CAP vendors voluntarily offering new drugs to physicians. As such, this modification would

ensure vendors are held harmless on the costs of offering new drugs and would ensure consistency between the CAP and physician office settings within Part B.

2) Specify that vendors may bill for new products using product specific Q-codes. Currently the IFR includes three drugs which Q-codes are used to bill Medicare in its list of 169 drugs to be provided by CAP vendors. In the interest of consistency, BIO urges CMS to clarify in the final rule the definition of "permanent HCPCS codes" to mean any product-specific HCPCS code nationally recognized in the physician office setting by Medicare, including both J-codes and Q-codes.

3) Specify that vendors may bill for new products using the same miscellaneous J-codes available to physician offices under buy-and-bill (e.g., J9999 for oncology products). Although miscellaneous J-codes are used to bill multiple products, they can be (and are) annotated with specific NDCs to identify the specific therapy used. A similar mechanism is used to bill for new drugs in the hospital outpatient department prospective payment system.

These changes will ensure consistency between the physician office, hospital outpatient, and CAP settings and will help ensure patients and providers have equal access to new drugs upon FDA approval.

B. Claims Processing Overview

1. Emergency Re-supply Option

BIO commends CMS for the improvements it has made to the claims processing provisions of the CAP. We applaud the agency's efforts to "ensure that the physician's judgment about the appropriate treatment for the beneficiary is primary in the decision-making process."[14] First, we support CMS' definition of an "emergency situation" as "an unforeseen occurrence or situation determined by the participating CAP physician, in his or her clinical judgment, to require prompt action or attention for purposes of permitting the participating CAP physician to use a drug from his or her own stock."[15] This definition will allow physicians to provide critical treatments to their patients without concerns about obtaining replacement drugs through the CAP.

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14 70 Fed. Reg. at 39039.
15 42 C.F.R. § 414.902.

We recommend that now and as the CAP is expanded CMS further improve access to drugs and biologicals used in emergency situations, such as anti-emetics and therapies that dissolve blood clots, by allowing physicians to request an advanced supply of these therapies from the CAP vendor. Instead of having to maintain his or her own stock of these treatments, the physician should be allowed to request them from the CAP vendor and submit claims as they are used. Such a process would not disrupt claims processing or even require additional steps. The physician would order the drug or biological by giving the date of administration and other beneficiary information, the vendor would supply a doses-specific prescription number for the claim, and the vendor would re-supply the physician under provisions specifically agreed upon between the physician and the vendor under the sort of contractual arrangements CMS has endorsed in the IFR.

2. Determinations of Medical Necessity

BIO endorses CMS' clarification that CAP vendors cannot make determinations of medical necessity and must ship the therapy ordered by the physician.[16] Thanks to this clarification, the CAP vendor will not be able to overrule a physician's judgment about the most appropriate therapy for his or her patient. If a physician determines that a drug or biological is appropriate for the patient and prescribes it consistently with any local coverage determinations, the beneficiary will be able to receive it through the CAP. This clarification will help protect beneficiaries' access to drugs prescribed for medically accepted off-label uses. It also simplifies physicians' participation in the CAP by reassuring them that the same coverage policies are in effect regardless of whether the drug is reimbursed under the ASP system or obtained through the CAP.[17]

3. Payment for Discarded Drugs

We also thank CMS for its response to CAP vendor questions regarding whether CAP vendors may file claims for unused portions of drug, and we ask CMS to include this response in the next CAP final rule. In response to this question, CMS explained that it "expect[s] that vendors will be able to bill the program for unused drugs under the CAP program in a similar fashion if

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16 70 Fed. Reg. at 39038-39.
17 Id. at 39039.

physicians and vendors act in good faith with respect to the ordering and use of the drugs."[18] For the reasons discussed below, we believe the position articulated in this response is consistent with the statute, and best maintains uniform policies for Part B drugs furnished by physicians, whether electing CAP or not.

The statute does not prohibit CMS from applying its current discarded drug policy to CAP drugs. Without citing to a statutory provision, the IFC states that discarded drugs will not be eligible for payment because the CAP statute only authorizes CMS to pay upon the administration of a drug. Presumably, the agency is referencing SSA § 1847B(a)(3)(A)(ii), (iii)(II), conditioning payment and collection of deductible and coinsurance amounts on administration of a drug or biological. Paying a CAP vendor for discarded product would be consistent with these provisions, however, because, under CMS's discarded drug policy, there *is* an administration of a drug. That is all the statute requires. It does not address how much drug can be billed for; it only insists that a drug be administered.[19] Accordingly, we believe that the agency's reading of the statute in the IFC was overly narrow and that the statute is susceptible to another reading. BIO submits that an alternate reading of the statute permitting the continued application of the discarded drug policy is a better one because it harmonizes the statute with the agency's preexisting policy and would apply like policies to Part B drugs regardless of whether a physician elects CAP or not.

CMS also could look to other provisions of the statute to authorize the continued application of the discarded drug policy in the CAP context. For instance, the statutory authority to provide a process for making payment adjustments when payment is made for drugs and biologicals which were dispensed but not actually administered[20] could support the application of the policy to CAP. If the agency were to determine that CAP vendors only could bill for the amount of product administered, the process CMS is supposed to

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

19 One also can argue that these statutory provisions mainly govern the order of steps to be followed in submitting CAP claims. They require the vendor first to submit a claim for the drug or biological, but prohibit the vendor from collecting payment from Medicare or the patient until the drug has been administered, but do not address the quantity of the drug to be reimbursed. Because the discarded drug policy is about the quantity of drug Medicare will pay for, these statutory provisions should not be read to prohibit the continued application of the discarded drug policy.

20 SSA § 1847B(a)(3)(B).

provide could include a payment adjustment for a drug that is not administered consistent with its discarded drug policy.

Although not cited by CMS as prohibiting the application of the discard policy to CAP, BIO recognizes that the statute instructs that bid prices "shall not include any costs related to the administration of the drug or biological, or wastage, spillage, or spoilage."[21] This applies only to the bid prices that are used to set the payment rates to CAP vendors, not to the billing policy that directs entities as to how to capture discarded drugs from single use vials. Just as wastage, spillage, or spoilage does not factor into setting ASP-based rates, yet physicians can follow the discarded drug policy, so too should the lack of inclusion in the bid prices not affect the ability of the CAP vendor to follow that policy.[22]

BIO urges CMS to state explicitly in the next CAP final rule that the discarded drug policy applies to CAP vendors just as it applies to physicians, as the agency recently has done in response to CAP vendor questions. For the above reasons, BIO believes that CMS has discretion under the statute to take such action and that doing so appropriately would continue to apply a longstanding Part B drug and biological policy uniformly in the physician office setting, regardless of whether the physician participates in CAP or is administering a CAP drug. Moreover, failing to pay for discarded drugs also could discourage vendors from bidding and ultimately could jeopardize the success of the program.

4. Beneficiary Coinsurance

BIO also supports CMS' efforts to address beneficiaries' concerns about payment of coinsurance for drugs obtained through the CAP. Currently, many physicians allow beneficiaries to continue their treatment, even if they cannot meet their coinsurance obligations. Physicians often work with beneficiaries to find assistance or ultimately do not to collect unpaid coinsurance.[23] Under the proposed rule, it was not clear that beneficiaries would be assured of access to

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21 SSA § 1847B(c)(6)(B).

22 Moreover, it is not clear that "wastage" must include discarded drugs. Because that term is not defined in the statute, CMS could interpret "wastage" to involve therapies that are prepared for administration, but no part of which is given to the patient due to changes in the patient's condition, cancellation of the appointment, or other reasons. That reading would mean that SSA § 1847B(c)(6)(B) has no bearing on the application of the discarded drug policy to CAP.

23 70 Fed. Reg. at 39053.

care or payment assistance if they could not pay their coinsurance debts to the CAP vendor. We support the IFC's requirement for vendors to provide beneficiaries with information on sources of cost-sharing assistance if requested by the beneficiary. This requirement, along with the procedures that must be followed before a CAP vendor may refuse to make further shipments for a beneficiary,[24] will help beneficiaries continue to receive care while they investigate sources of financial support.

5. Partial Payments to Vendors

BIO asks CMS to reconsider its decision to pay only when both the vendor claim and the physician's administration claim have been matched in the claims processing system.[25] BIO remains concerned that delayed cash flow could harm vendors' ability to continue to participate in the CAP and therefore could limit physicians' choice of drug acquisition methods. We recommend that the agency make a partial payment to a vendor when a drug administration claim is delayed by more than 28 days. CMS should consult with the specialty pharmacy industry to set an appropriate percentage for these payments.

C. Dispute Resolution

We support CMS' clarification that CAP vendors may file appeals of denied claims directly to the local carrier. The proposed rule would have assigned the physician full responsibility for appealing a denial of a drug or biological administration claim.[26] This could have placed a significant burden on physicians to pursue all appeals, regardless of the amount at issue for the physician, so the CAP vendor could have its claims reconsidered as well. The clarification somewhat relieves physicians of this considerable burden.

D. CAP Bidding Process – Evaluation and Selection

BIO supports the decision to update the single prices for CAP drugs and biologicals to the mid-point of calendar year 2006 by the Producer Price Index for prescription preparations. Updating prices through this mechanism will encourage more potential vendors to participate in the CAP by helping to ensure that payment for CAP drugs will keep up with inflation.

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24 42 C.F.R. § 414.914(h).
25 70 Fed. Reg. at 39052.
26 70 Fed. Reg. 10747, 10758 (March 4, 2005).

We request an additional clarification to the CAP bidding process. CMS should be clear that the CAP vendor's requirement to provide at least one NDC per biological in a HCPCS code does not impose any forced sale requirements on manufacturers. The statute requires vendors to acquire drugs and biological products "from the manufacturer or from a distributor that has acquired the products directly from the manufacturer."[27] BIO asks CMS to clarify that the statute does not interfere with a manufacturer's exclusive contract with a distributor. CAP vendors can acquire drugs and biologicals as required by the statute while respecting manufacturers' existing distribution agreements by seeking to obtain the drugs or biologicals from the distributor.

Likewise, CMS should confirm that CAP will not interfere or impose additional obligations or requirements with respect to manufacturer distribution models in which manufacturers ship products directly to physicians, which is how some products are delivered under the current buy-and-bill system. BIO believes that vendors should be permitted to allow a manufacturer to ship a CAP product that it makes directly to the ordering physician on the vendor's behalf without imposing additional obligations on manufacturers. In other words, a manufacturer should not have to be treated as a subcontractor that must meet all of CMS' CAP vendor requirements in these limited circumstances.[28] Those requirements are not appropriate for manufacturers that supply their own products directly to physicians. Therefore, BIO asks that CMS confirm that manufacturers are permitted to ship an ordered CAP product directly to a physician on the vendor's behalf without having to be treated as a subcontractor of the vendor.

E. Physician Election

Finally, the IFC allows a physician to opt out of the CAP for the remainder of the year if the CAP vendor refuses to ship drugs for one of his or her patients.[29] This provision allows the physician to continue to treat the patient by buying the necessary drugs and billing under the ASP system. It also requires the physician to forgo the benefits of participating in the CAP for all of his or her patients based on the needs of a *single* patient. We believe this remedy is unnecessarily harsh and might discourage many physicians from

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27 SSA § 1847B(b)(4)(C).
28 *See* 70 Fed. Reg. at 39060 (allowing vendors to subcontract with a drug distributor or pharmacy if the entity meets CAP vendor requirements).
29 42 C.F.R. § 414.908(a)(5).

choosing to participate in the CAP. We recommend instead that the physician be allowed to opt out of the CAP for that specific beneficiary, but continue to obtain drugs and biologicals for other beneficiaries through the CAP. CMS should work with physicians to develop an appropriate monitoring system to verify that physicians exercise this option only for a limited number of patients in their practice.

F. Conclusion

BIO appreciates this opportunity to comment on our concerns about the IFC, 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 Jayson Slotnik at 202-962-9200 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Jim Greenwood
President and CEO