September 18, 2006

BY ELECTRONIC DELIVERY

Cynthia Tudor, Ph.D.
Director, Medicare Drug Benefit Group
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-13-01
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Prescription Drug Benefit Manual – Draft Chapter 5

Dear Dr. Tudor:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) draft of Chapter 5 of the Medicare Prescription Drug Benefit Manual, posted on the CMS web site on September 6, 2006 (Draft Chapter 5). BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the world. BIO represents more than 1,100 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.

Representing an industry that is devoted to discovering new cures and ensuring patient access to them, BIO has long supported extending Medicare coverage to all drug and biological therapies regardless of how they are

administered. Biotechnology companies are at the forefront of discovering, developing, and bringing to market a new generation of life-saving medicines. Many of the therapies in biotech companies' pipelines target conditions that primarily affect seniors. In recent years, drugs and biologicals have become an even more integral part of health care.

BIO has strongly supported and appreciated Congress' efforts in creating the Medicare Part D prescription drug benefit as well as CMS' efforts to implement this benefit. We believe that the Part D benefit has helped increase patient access to critical therapies as well as the likelihood that patients will be able to receive and afford the treatment options that best meet their needs. Nonetheless, we are concerned that certain Part D implementation policies unnecessarily impede patient access to critical therapies. We urge CMS to continue to focus on patient access in its implementation of the Part D benefit, particularly with respect to those aspects of the benefit that continue to result in gaps in coverage for beneficiaries. Specifically, BIO urges CMS to reconsider the coverage policies that continue to impede beneficiary access to home infusion therapies as well as to vaccines that are Part D drugs. BIO supports CMS' efforts to encourage Part D plans to provide access to specialty pharmacies. Finally, BIO also requests that CMS continue to make every effort to ensure that its policies regarding patient assistance programs allow beneficiaries access the full range of access to these programs. These comments are discussed in greater detail below.

I. Home Infusion Pharmacies and Dispensing Fees

Medicare currently fails to cover the home infusion services considered necessary for effective medication usage, forcing many patients to forgo medically necessary therapy because the associated supplies, equipment, or professional services needed to use the therapy are not covered. Part D provides critical coverage, filling one part of this gap in Medicare coverage by providing payment for many drugs and biologicals administered in the home setting. Yet Part D plans are precluded from paying for the special costs associated with the administration of these drugs under the Part D benefit. Draft Chapter 5 expressly states that Part D plans are not permitted to provide coverage of the supplies, equipment, and services associated with the administration of home infusion therapies.[1] In Draft Chapter 5, CMS also states that "Part D sponsors must require that contracted network pharmacies that deliver home infusion drugs ensure that the professional services and ancillary supplies necessary for the provision of home

[1] Draft Chapter 5 at page 16.

infusion therapy are in place before dispensing home infusion drugs."[2] This requires a home infusion pharmacy to provide the Part D plan with assurances that the professional services and supplies necessary to provide the home infusion therapy are provided through Medicare Parts A, B, or C, or through a third party insurance plan or some other arrangement, including self-pay, prior to dispensing the drugs.

In many cases there is no other Medicare coverage available for these supplies and services. Currently, home infusion only infrequently is covered under Part B, typically under the durable medical equipment (DME) benefit when an external infusion pump is used and strictly controlled infusion of the medication is medically necessary. Certain homebound beneficiaries eligible for home health services under Part A may receive assistance with nursing services, as well as with infusion equipment and supplies. Yet for many Medicare beneficiaries, payment for these supplies and services is not available, and the beneficiary must pay for these supplies and services out-of-pocket; many will instead chose to forgo therapy for lack of funding.

Home infusion therapy is a cost effective alternative to patients using outpatient clinics, physician offices, or inpatient stays. As CMS also noted in the Part D proposed rule, most commercial payers and Medicare Advantage plans cover home infusion costs as a cost-effective alternative to inpatient care "for administering drugs that cannot be self-administered for treatment of acute or chronic medical conditions in patients who are sufficiently ill to be unable to visit an outpatient clinic or physician's office to receive the necessary therapy."[3] Forcing patients to seek care in provider settings often results in increased costs to Medicare. For example, a patient in a rural area who must travel a long distance to a provider site may forego recommended treatment only to suffer an acute episode requiring otherwise avoidable Medicare expenditures. Also, treatment in the home may reduce beneficiaries' exposure to hospital-acquired, antibiotic-resistant infections. We urge CMS to reconsider the approach that precludes payment under Part D for the supplies and services necessary to make home infusion a reality for many patients. In doing so, CMS should require that Part D plans provide coverage for a broad range of drug formulations and delivery methods[4] to ensure

---

[2] *Id.* at 27.

[3] 69 Fed.Reg. 46632, 46648 (Aug. 3, 2004).

[4] For example, CMS should instruct plans to cover medications supplied as frozen or pre-mixed formulations and pre-filled syringes. Plans should also provide access to delivery devices that support the safe and accurate administration of specific medication-types, including electro-mechanical pumps and disposable elastomeric pumps.

that patients have safe and appropriate access to all medically necessary home infusion medication regimens as prescribed. Current Part D policy does not bring us to a fully rational and cost-effective Medicare policy that ensures patient access to an important treatment alternative. Furthermore, the current fragmented approach to covering home infusion therapy creates additional administrative burden and confusion for providers and suppliers, who must verify the different source of coverage available to a patient for each individual service component. The potential delay that may result in having to coordinate these different sources of coverage, or the lack of coverage for certain aspects of care, may lead to suboptimal treatment outcomes for beneficiaries. Coverage of home infusion products under Part D was an important step forward in the provision of meaningful and comprehensive coverage for Medicare beneficiaries, but it is only part of the solution – CMS needs to find a way to cover the related (and absolutely necessary) supplies and professional services.

The lack of coverage is not a result of the Medicare statute but of CMS-created regulations and policies. One solution to ensuring more meaningful coverage of these therapies would be for CMS to reconsider its approach to dispensing fees. In the Part D proposed rule, CMS proposed three different options for dispensing fees. In proposing both Options 2 and 3, providing for a more expansive approach to dispensing fees, CMS recognized that these options "would eliminate gaps in coverage relative to home infused drugs,"[5] because the additional administration services necessary to ensure effective delivery of the therapy otherwise would not be covered. Both proposed Options 2 and 3 allow plans to include in the Part D dispensing fee items and services that are essential for the effective utilization of the Part D drug benefit. Under proposed Option 3, dispensing fees would include coverage of the drug or biological, the supplies and equipment necessary for the drugs to be provided in a state in which they can be effectively administered, and the activities associated with ensuring proper ongoing administration of the drugs, such as the professional services of skilled nursing visits and ongoing monitoring of a clinical pharmacist. Reverting to this approach to dispensing fees would provide Medicare beneficiaries with meaningful coverage for home infusion, saving Medicare money on inpatient stays and ensuring better patient compliance with home infusion therapies. BIO also urges CMS to treat beneficiary out-of-pocket costs for home infusion therapies, including costs associated with supplies and administration, as part of a beneficiary's true-out-of-pocket ("TrOOP") costs for purposes of reaching catastrophic coverage.

[5] *Id.*

II. Vaccines

BIO strongly supports CMS' efforts to facilitate cost-effective and real-time billing of vaccines. It is critical that Part D plans provide a payment mechanism that does not require a patient having to pay for a vaccine out-of-pocket and then wait for plan reimbursement. We support CMS' efforts to develop both in-network and facilitated out-of-network access to vaccines that accomplish this goal. We are concerned, however, that CMS' implementation of Part D vaccine policies will have the effect of preventing Medicare beneficiaries enrolled in Medicare Part D from accessing vaccines. These include existing and new vaccines that will protect millions of Medicare beneficiaries against the life-threatening tetanus toxin and shingles, one of the most painful and disabling vaccine-preventable diseases in the elderly. BIO members play a critical role in the research and development of new vaccines and ensuring patient access to them.

BIO recommends that CMS take several steps to improve appropriate access to vaccines under Part D. First, CMS should specify to Part D Plans that a paper claims/beneficiary reimbursement process is not an acceptable approach to vaccine access. Second, CMS should stipulate that it prefers solutions that offer real time provider access to coverage and eligibility information at point of service and that allow for payment for the vaccine at the Part D negotiated price. The two "in-network" solutions CMS offers in Draft Chapter 5 focus on retail and specialty pharmacies, and both of these solutions have significant drawbacks, as described below. A web-based billing approach, however, has the potential to offer beneficiaries and physicians a more meaningful solution, but one that should not come with added out-of-network costs to patients.

BIO is concerned that CMS' in-network proposal in which a pharmacist would administer the vaccination directly is not an adequate solution. For some types of vaccines pharmacist administration may be medically appropriate (as well as permissible under state law); however, in other circumstances the administration of a vaccine in a pharmacy setting may not be medically appropriate or may not be permitted under state law.[6] If the pharmacist is not able to administer the vaccine, then the beneficiary would 'brown bag" the vaccine; in other words, the beneficiary would receive a prescription from his or her provider, obtain the vaccine at the pharmacy, and return to the physician office for injection. Although the degree of potential harm resulting from a patient

[6] While a majority of states permit pharmacists to vaccinate, in a number of states the authority is limited to vaccines for flu and pneumonia.

carrying a vaccine from a pharmacy to a physician's office will vary depending upon a particular vaccine's handling and storage requirements, in most cases it is not likely to be medically appropriate to use this method for products requiring special storage and handling. Indeed, this practice raises significant safety concerns and is opposed by several medical societies.

Draft Chapter 5 also suggests that retail pharmacies should act as modified specialty pharmacies by billing for a vaccine and then shipping the vaccine to local physician offices on a patient-by-patient basis. While this approach would eliminate the clinical concerns related to "brown-bagging", it is not clear how a retail pharmacy would be compensated for the costs of shipping single dose units of products requiring special handling – an expensive proposition beyond compensation typically provided in a dispensing fee. In order for retail pharmacies to be able to cover these administrative costs, BIO urges CMS to include costs related to shipping a vaccine to a physician's office in Table 3 of Draft Chapter 5, which sets forth costs that may and may not be included in dispensing fees. We are concerned that, as currently drafted, Table 3 could be interpreted to preclude Part D sponsors from taking such vaccine delivery costs into account when setting dispensing fees for retail pharmacies.

Even for specialty pharmacies, the billing and shipping of a single dose of a vaccine with special storage and handling requirements is an expensive approach and will be more costly than current vaccine distribution systems. Pharmacies will need to be adequately reimbursed for these expenses in order to be willing to provide vaccines in this manner, and the substantial administrative costs may make Part D sponsors reluctant to facilitate broad access through this mechanism. In some cases, the administrative costs will exceed a product cost. For these reasons, this approach may not make sense from an overarching Medicare payment policy perspective.

BIO appreciates CMS' efforts to develop and facilitate these in-network approaches to vaccine payment under Part D, and we welcome the role that retail and specialty pharmacies will have providing Medicare beneficiaries with appropriate vaccine access. Nonetheless, these two in-network approaches are not likely to be adequate to serve a range of Part D enrollees. BIO urges CMS to stipulate that its preferred approach to vaccine access under Part D involves direct physician billing to Part D plans in a 5.1 pharmacy claims format as well as provides coverage at the Plan's negotiated prices or otherwise protects beneficiaries against non-routine out-of-pocket costs. BIO believes that such a

physician based, internet solution will provide beneficiaries with better access to medically appropriate vaccines.

Additionally, Draft Chapter 5 fails to address coverage of vaccine administration services. This is of particular concern given that on May 8, 2006 CMS issued a memorandum to Part D plans suggesting that payment of administration fees available under Part B applies only to vaccines covered by Part B. On July 11, 2006, CMS again issued a memorandum to Part D plans stating that Part B administration fees cover only those vaccines specifically covered under Part B. Under this set of new policy interpretations, neither Part B nor Part D would be able to provide reimbursement for administration of Part D vaccines. This runs directly counter to established CMS policy. In the final regulations implementing the Part D benefit,[7] CMS clearly recognized the importance of covering vaccine administration in a manner that ensures that Part B and Part D provide a seamless benefit and that accurately reflects Congressional intent that Part D provide beneficiaries with access to vaccines not covered under Part B. In the preamble to this final rule, CMS suggested that costs related to the administration of Part D vaccines could be paid as a component of physician fees under Part B.[8] In its Coordination of Benefits guidance for 2006, CMS reiterated this policy, expressly stating that "costs directly related to vaccine administration may be included in physician fees under Part B, since Part B pays for the medically necessary administration of non-Part B covered drugs and biologicals."[9]

Congress clearly intended that vaccines not covered under Part B be covered under Part D, expressly defining these vaccines as "Part D drugs." That Congress expressly included vaccines in the statutory definition of Part D drugs, strongly suggests that Congress' intended for Part D to provide access to those vaccines not covered under Part B. Congress intended that Part B and Part D together provide a seamless benefit and that these programs be designed so that beneficiaries with the greatest need for assistance do not receive the least meaningful benefit. In the proposed Part D rule, CMS expressly recognized this Congressional intent, stating that "[o]ne goal of Part D is to fill any gaps in existing Part B coverage…"[10] Beneficiaries are not afforded meaningful access to vaccines where the costs of administering those vaccines are not also covered by Medicare.

---

[7] 70 Fed.Reg. 4194 (Jan. 28, 2005).
[8] *Id*. at 4328, 4231.
[9] Part D Coordination of Benefits Guidance for 2006 (July 1, 2005).
[10] 69 Fed.Reg. 46632, 46646 (Aug. 3, 2004).

In order to provide Medicare beneficiaries with access to these preventative therapies, the cost of administering the vaccines must be covered by Medicare. We believe that CMS' new approach to the administration of Part D vaccines will greatly limit access to these highly effective, safe, and cost-saving therapies. In addition to being inconsistent with past CMS guidance, this approach is contrary to the recent pro-active, public health-oriented approaches being taken by CMS to encourage vaccinations and other preventive health interventions in the Medicare population. We support CMS' increase of provider payment rates for administering other life-saving and highly-cost effective influenza and pneumococcal vaccines and for the agency's leadership in aggressively implementing "Welcome to Medicare" health care provider visits. From both a public health and economic policy perspective, it is clearly in the interest of the federal government and CMS to eliminate economic barriers for Medicare beneficiaries in accessing these critical vaccines at and after the "Welcome to Medicare" provider visits.

BIO strongly urges CMS to issue a HCPCS code for Part D vaccine administration, consistent with the codes already available for administering Part B vaccines. Another option for providing meaningful coverage of vaccines would be to expand the definition of dispensing fees, as CMS suggested in the proposed Part D rule,[11] to include the professional services necessary to administer a Part D drug such as a vaccine.

III. Specialty Pharmacies

BIO supports CMS' efforts to enhance pharmacy networks with specialty pharmacies while ensuring that Part D plans not restrict access to certain therapies by limiting the dispensing of those therapies to the specialty pharmacy setting. Access to in-network specialty pharmacies is critical for enrollees needing specialty products, including home infusion therapies and many therapies for rare conditions. Without adequate access to specialty pharmacies, enrollees will experience difficulty in accessing special therapies even when those therapies are on the plan's formularies. At the same time, a Part D plan should not be permitted to require a beneficiary to obtain a particular drug or biological from a specialty pharmacy simply because of that drug or biological's placement on a plan's "specialty tier." Any requirement that a drug or biological be obtained at a specialty pharmacy should be based only on that therapy's specific handling and

[11] 69 Fed.Reg. 46632.

dispensing requirements. A beneficiary should be able to obtain a therapy at any network pharmacies capable of appropriately dispensing the particular drug or biological. BIO supports CMS' clarifications to Part D plans regarding the appropriate role of specialty pharmacies in a pharmacy network and urges CMS to reiterate this approach in the final version of Chapter 5.

We also urge CMS to require that Part D plans include specialty pharmacies in their pharmacy networks. Because an enrollee is responsible for the difference between the usual and customary charge of the out-of-network and the plan allowance for a drug or biological product, an enrollee who requires a therapy available only through an out-of-network pharmacy will incur greater out-of-pocket costs. This will occur when a plan fails to include any specialty pharmacy in its network and a specific therapy – because of its particular storage and handling requirements – is available only through a specialty pharmacy. Where a Part D plan fails to include specialty pharmacies, an individual needing access to these pharmacies will receive a lesser benefit through his or her Part D plan than would be available to a less medically vulnerable individual. For enrollees eligible for low-income assistance, CMS will incur these additional costs. CMS can help to ensure that these enrollees have adequate access to necessary therapies available only through specialty pharmacies by requiring plans to include these pharmacies in their networks.

IV. Patient Assistance Programs

In Draft Chapter 5, CMS lists examples of TrOOP-Eligible and TrOOP-Ineligible Payers.[12] This list includes patient assistance programs operating outside the Part D benefit among the "TrOOP-Excluded Entities." BIO appreciates CMS' efforts to continue to clarify the ways that patient assistance programs may continue to provide assistance to Medicare beneficiaries enrolled in Part D. Nonetheless, we encourage CMS to continue to work with the Office of Inspector General on other models that also may allow patient assistance programs to provide assistance to Part D enrollees and to better facilitate the coordination of the Part D benefit with these patient assistance programs. We also recommend that CMS add patient assistance programs operating within the Part D benefit (and within OIG parameters) to the "TrOOP-Included Entities" column in order to facilitate such options should they become more readily feasible.

[12] Draft Chapter 5 at 21.

V. Conclusion

We would welcome the opportunity to discuss these issues in depth. Please contact me at (202) 312-9273 if you have any questions regarding our comments. Thank you for your consideration of these very important issues.

Respectfully submitted,

/s/

Jayson Slotnik
Director, Medicare Reimbursement
& Economic Policy,
Biotechnology Industry Organization (BIO)