October 4, 2004

BY HAND DELIVERY

Mark McClellan, M.D., 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-4068-P (Medicare Program; Medicare Prescription Drug Benefit)

Dear Dr. McClellan:

The Biotechnology Industry Organization ("BIO") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") proposed rule regarding the Medicare Part D prescription drug benefit, published in the Federal Register on August 3, 2004,[1] pursuant to the Medicare Prescription Drug Improvement and Modernization Act of 2003 (the "MMA"). 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 1,000 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] 69 Fed. Reg. 46632 (Aug. 3, 2004).

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 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 strongly supports and appreciates Congress' efforts in creating the Medicare Part D prescription drug benefit as well as CMS' efforts to implement this benefit. We anticipate that the Part D benefit will increase patient access to critical therapies and increase the likelihood that patients will be able to receive and afford the treatment options that best meet their needs. We urge CMS to focus on patient access as it implements the Part D benefit.

Accordingly, BIO's comments on the Proposed Rule center on ensuring that Medicare beneficiaries will have access to required therapies. Specifically, BIO is concerned that the formulary provisions are not sufficient to ensure enrollee access to life-saving and life-preserving therapies. We believe CMS' review of plan formularies is imperative to ensure that beneficiaries are not discriminated against and urge the agency to do what is necessary to ensure that appropriate access to advanced therapies is preserved, particularly for beneficiaries who suffer from rare, intractable and chronic diseases. BIO also requests that CMS clarify that two drugs or biologicals in a category or class is a minimum standard and in many cases may not be sufficient to ensure that a Prescription Drug Plan or Medicare Advantage plan offering prescription drug benefits (collectively referred to in these comments as a "Part D plan" or a "plan") does not discourage enrollment of certain beneficiary groups. BIO requests that CMS strengthen its formulary provisions by establishing a definition of "formulary" that incorporates the categories and classes, the drugs and biologicals that populate those categories and classes, and any cost-sharing mechanisms imposed by a plan. BIO also urges CMS to establish separate formulary standards to reflect the needs of special populations.

Also with respect to formularies, BIO asks CMS to implement the provisions that would allow categories and classes to be changed mid-year to reflect new therapies or new uses of existing therapies. BIO supports CMS' clarification that plans may assign a drug or biological to a category or class based

on an off-label use for that drug or biological, but we are extremely concerned at the suggestion that CMS will interject itself into the clinical decisions regarding off-label use by urging physicians to carefully document such use.

BIO supports CMS' efforts to design a strong and transparent pharmaceutical and therapeutics ("P&T") committee process and urges CMS to further formalize the role of these committees by requiring that any plan cost containment mechanisms be approved by the P&T committee. In addition, BIO requests that CMS require plans to use the P&T committee process to conduct periodic evaluations of treatment protocols and procedures.

BIO is encouraged by CMS' efforts to recognize the challenges that pharmacy access poses for certain Medicare beneficiaries and supports CMS' proposals to require plans to include home infusion pharmacies in their networks. We urge CMS to extend this requirement to specialty pharmacies. BIO requests that CMS adopt Option 3 in defining dispensing fees. With respect to the special needs of Part D enrollees that also receive assistance from AIDS Patient Assistance Programs ("ADAPs"), BIO urges CMS to exercise caution in making 340B prices available through Part D plans and requests that CMS reconsider whether ADAPs may be appropriately defined as a "person" for purposes of cost-sharing contributions, rather than "insurance or otherwise."

The Proposed Rule creates ambiguity with regard to certain self-administered drugs and biologicals that may be covered under Part B. We respectfully request that, as required by the MMA, CMS further clarify the relationship between Part B and Part D. We also urge CMS to finalize its proposal that drugs and biologicals may be covered under Part D when an enrollee receives the therapy from a pharmacy without a Medicare supplier number and in other instances where Part B coverage criteria are not met, such as where Part B does not cover the drug or biological as dispensed or administered. This important provision of the MMA is essential to ensure that enrollees receive the therapies they need in the setting determined most appropriate by the patient in consultation with his or her treating physician.

Moreover, BIO is particularly concerned about dual eligibles as they are transitioned from the Medicaid program to Part D. We urge CMS to fully consider the special needs of this population in facilitating this transition. BIO also believes that the proposed exceptions and appeals process is extremely

burdensome for certain enrollees, and we have highlighted some particular areas that we believe should be simplified. Finally, BIO is concerned that the information manufacturers provide to plans may not adequately be protected when plans submit certain required information to CMS, and we strongly recommend that the agency to extend the Medicaid rebate statute confidentiality protections to a broader range of information.

We have discussed these issues in greater detail below.

I. UNIQUE CONCERNS OF THE BIOTECHNOLOGY INDUSTRY

Implementation of the Part D prescription drug benefit is particularly important for the biotechnology industry because our therapies often have unique handling, administration, and pharmacy service costs. For example, virtually all biologicals must be shipped and stored at certain temperatures and many require other special handling and administration procedures. Accordingly, biologicals often are distributed through specialty pharmacies and administered under special conditions. Therefore, without adequate coverage of all of these costs, patients will be unable to access their required therapies.

Many biologicals are administered incident to physician services and, as such, tend to be covered under Medicare Part B. Some biologicals, however, may be self-administered. Part D coverage should be available for these products, as coverage for them is not generally available under Part B. At the same time, however, CMS must avoid any attempt to mandate a shift in drugs and biologicals that are properly covered under Part B to the new Part D.

Coverage of certain physician-administered drugs under the Part B benefit is a fundamental and vital aspect of patient care that must be preserved. The Part D benefit should be implemented carefully so as not to impede appropriate beneficiary access to physician-administered biologicals under Part B or to self-administered biologicals under Part D.

Moreover, biological therapies tend to have high development and manufacturing costs due to the challenges in producing delicate, complex proteins or other types of large molecules. They often are treatments of last resort and are targeted to patients with chronic conditions or advanced stages of a disease. Biologicals also frequently are cutting-edge treatment breakthroughs. Sometimes

they represent the only treatment option for patients. This is particularly true for drugs and biologicals designed to treat rare diseases and disorders, such as orphan drugs and biologicals.

The unique nature of biological therapies gives BIO a special perspective on the Proposed Rule. On the one hand, our therapies tend to be costly and treat populations that present certain challenges to private plans. On the other hand, our treatments make dramatic improvements in patients' lives and save Medicare costly expenditures by avoiding surgeries and inpatient admissions. The decisions that CMS makes in the final rule regarding issues such as the inclusion of specialty pharmacies in plan networks, the coverage of services and supplies necessary for home infusions, and the rigor of the review process to ensure plans are not discriminating against beneficiaries, will be critical to ensuring that Medicare beneficiaries have access to a real and robust drug benefit. It is with this focus and goal that we offer our comments below.

II. APPROVAL OF PLAN DESIGN, INCLUDING FORMULARIES – Comments on Subpart F: Submission of Bids and Premiums; Plan Approval

BIO strongly supports CMS' intent to closely examine formulary structures to ensure that plans do not discriminate against Medicare beneficiaries. We believe, however, that the Proposed Rule needs to be clarified and strengthened in order to make this examination effective.

The MMA expressly requires the Secretary to disapprove a Part D plan if the design of the plan and its benefits, "including any formulary and tiered formulary structure," are "likely to substantially discourage enrollment by certain Part D eligible individuals."[2] Although the MMA prohibits CMS from disapproving the categories and classes of a formulary that complies with the model set forth by the United States Pharmacopoeia ("USP),[3] both the MMA and the Proposed Rule recognize that conformity with the USP Model Guidelines will not be sufficient to ensure that a plan is not discouraging enrollment of certain groups of Medicare beneficiaries. In fact, CMS is required by the MMA and the Proposed Rule to disapprove a plan's proposed bid if CMS finds that the plan design is likely to substantially discourage enrollment of certain Part D eligible

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[2] Social Security Act ("SSA") § 1860D-11(e)(2)(D).
[3] SSA § 1860D-11(e)(2)(D)(ii).

individuals.[4] Consistent with the statutory language, CMS has proposed to deny approval to plans that discriminate.

BIO strongly supports CMS' efforts to conduct a rigorous review of plan formularies to identify discrimination. Under the MMA and the Proposed Rule, two levels of review are contemplated. The first is a determination of whether the categories and classes are adequate. For plans that adopt the USP categories and classes, this level of review would not occur. Both for plans that utilize the USP Model Guidelines and plans that design their own categories and classes, the second step is for CMS to evaluate the ways in which those categories and classes are populated.

As a threshold issue, BIO is extremely concerned that these categories and classes may not be adequate to meet the needs of the most critically ill Medicare beneficiaries. In particular, BIO is concerned that the draft USP Model Guidelines fail to provide appropriate access to drugs and biologicals used to treat rare diseases and disorders, such as orphan drugs and biologicals. A significant percentage of biological therapies on the market are designed to treat rare diseases and disorders, such as Idiopathic Pulmonary Fibrosis, for example. In our comments to the USP Model Guidelines, we have raised our concerns that these guidelines place many of these therapies into categories with a large number of other therapies, creating the very real possibility that drugs and biologicals designed to treat rare diseases and disorders will not be covered.

Indeed, many of these therapies do not necessarily fall into obvious categories. For example, there is no apparent category for therapies that treat either neurological or neuromuscular diseases, leaving doubt as to whether enrollees will be able to access these therapies through Part D. Enrollees should not lose access to a particular covered Part D therapy simply because there is no specific category or class available. Those therapies for rare diseases and disorders that do fall into a category or class run the risk that they will not be covered, particularly if there are more than two other therapies that could fall into the same category. For example, "Enzyme Replacements/Modifiers" is a category under the draft USP guidelines. Yet this therapeutic category does not have any classes or subdivisions, despite the fact that each disease in this category is a rare disease caused by a unique deficiency or problem, and therefore, therapies are not

[4] SSA § 1860D-11(e)(2)(D); Proposed 42 C.F.R. § 423.272(b)(2).

interchangeable among patients with different diseases. Allowing plans to have just two drugs per category or class will preclude other enrollees with rare diseases from accessing the therapies they need. These therapies warrant special consideration, because, unlike other therapeutic categories, these treatments are not interchangeable. BIO believes that patients with one rare disorder should not be in competition with patients with another rare disorder, and we urge CMS to ensure that enrollees with rare diseases and disorders have appropriate access to the therapies they need.

It is critical that CMS be aware of how access to these therapies may be hindered when examining whether a plan design discriminates against certain groups of beneficiaries. In evaluating a plan's categories and classes – as well as when deciding to adopt the USP model – CMS needs to consider carefully the needs of patients for whom therapies that treat rare diseases or disorders are the only option. A plan's categories and classes must reflect Congress' and CMS' intent that Medicare beneficiaries be provided a comprehensive prescription drug benefit. BIO is extremely concerned that these therapies may be available only through the exceptions process or the potentially lengthy appeals process. We urge CMS to ensure that enrollees needing these treatment options can access drugs and biologicals designed to treat rare diseases and disorders through their Part D plan's formulary.

Similarly, BIO is concerned about the failure of the USP to adequately include vaccines. We understand that certain vaccines are covered under Medicare Part B, and we appreciate the efforts of Congress to ensure that Part D provide coverage of additional vaccines for Medicare beneficiaries. We note, however, that the USP's draft guidelines defeat this purpose by including vaccines as a recommended subdivision. This placement would allow a Part D plan to avoid coverage of vaccines altogether. Should the USP fail to remedy this problem, we urge CMS to carefully scrutinize plan formularies to ensure that enrollees have access to a range of vaccines that target a variety of diseases in the aged and disabled Medicare population. We believe that these vaccines will provide added wellness benefits to enrollees and, in the long term, will prove to have added cost benefits, particularly for the most vulnerable Medicare beneficiaries, such as dual eligibles and immunosuppressed individuals.

III. ACCESS ISSUES – Comments on Subpart C: Benefits and Beneficiary Protections

A. Formularies – Two Drugs or Biologicals Per Category or Class

BIO is concerned that the manner in which CMS has implemented the formulary provisions will not provide enrollees with appropriate access to covered Part D drugs. Under the MMA and the Proposed Rule, formularies must meet certain minimum standards, including covering at least two Part D drugs within each therapeutic category and class of covered Part D drugs, and must make available different strengths and doses for those drugs.[5] Thus, at an absolute minimum, each category and class would need to contain two drugs or biologicals. For many categories and classes, however, this minimum threshold will not be adequate to meet the statutory requirement that a plan design not discourage enrollment. For example, a plan that includes only two drugs in the classes within the antineoplastics category will necessarily be discriminating against individuals with certain types of cancer. Cancer treatment is complex, and the types of agents used continue to evolve. Unlike other therapeutic categories, antineoplastics may be used for more than one organ system, for more than one type of cancer, for different stages of diseases, and often in combination with other agents. More critical, unlike other treatments that may be interchangeable in treating various diseases, cancer therapy does not have the same level of flexibility. The inclusion of only two therapies in these classes would clearly fail to meet CMS' expectation that plans will provide a comprehensive prescription drug benefit.[6]

Another example of where two drugs per class will be inadequate is classes that contain drugs or biologicals used to treat rare diseases. There is a significant risk that these therapies will not be included where they fall into a class that contains more than two other therapies in the same category. The loss of access to these treatments by enrollees would prove disastrous, particularly in the case of orphan drugs and biologicals, as these therapies often are the only viable therapy for Medicare beneficiaries. These therapies warrant special consideration, because, unlike other therapeutic categories, these treatments are not interchangeable. Thus, it is particularly important that a plan not be permitted to include only two drugs or biologicals per class where adhering only to this minimum standard precludes the coverage of these special therapies.

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[5] SSA § 1860D-3(b)(3); Proposed 42 C.F.R. § 423.120(b)(2).

[6] 69 Fed.Reg. at 46660.

We also urge CMS to clarify that this minimum two drug or biological per category and class requirement must be met through drugs or biologicals available on an unrestricted basis (e.g., not subject to prior authorization, step therapy, higher co-pays, or other mechanisms that restrict enrollee's uninhibited access to necessary therapies). Enrollees do not genuinely have access to drugs and biologicals that are subject to such restrictions. Congress intended this minimum two drug or biological requirement as a means of ensuring enrollee access to an absolute minimum number of drugs and biologicals, and this intent clearly cannot be met by limiting access to the minimum number of required drugs and biologicals. CMS should clarify that two drugs and biologicals in each class must be available on an unrestricted basis in order to meet this formulary requirement.

Throughout the rule, CMS makes clear that it intends Part D plans to use cost containment strategies, such as prior authorization, formulary tiers, and step therapy. Yet because the Proposed Rule does not include these aspects of a formulary in the proposed definition of "formulary,"[7] it is not clear that these types of cost containment strategies will be properly reviewed in considering whether a plan's design substantially discourages enrollment of certain groups of beneficiaries. Although CMS explicitly adopts the statutory requirement that a plan design may include a plan's tiered formulary structure, BIO believes that cost containment strategies, including any tiered cost-sharing, must be established as part of a definition of "formulary." Without a clear definition of formulary that includes these types of cost containment strategies, a plan may receive approval from CMS while requiring prior authorization of all biological therapies on the formulary or imposing other severe restrictions. We urge CMS to define a formulary as including: (1) the categories and classes of drugs and biologicals, (2) the drugs and biologicals that populate those categories and classes, and (3) any cost-sharing, prior authorization, step therapy, or other requirements that limit enrollee access to formulary drugs and biologicals. This will allow CMS to properly evaluate whether a plan's formulary structure in fact provides all enrollees with proper access to formulary drugs.

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[7] Proposed 42 C.F.R. § 423.4.

B. Formulary Inclusion of New Drugs and Biologicals

BIO urges CMS to adopt the Proposed Rule provisions that would allow plans to change categories and classes during a calendar year to take into account new therapies or new uses of existing therapies.[8] We believe that it is critical that plans be able to continue to evaluate categories and classes to ensure that new therapies become available as soon as possible. BIO represents an industry that is devoted to discovering new cures and ensuring patient access to them. Our members continually are developing promising new medicines. It is imperative that these new therapies be available to Medicare beneficiaries in a timely manner so that they may have the advantage of life-saving and life prolonging innovations. We appreciate CMS' efforts to ensure that these newly approved therapies are properly incorporated into plan formularies so that enrollees have meaningful access to Part D benefits for the innovative therapies that may offer them new hope for better lives, fewer side effects, or even survival. Although CMS has acknowledged the importance of introducing new therapies by allowing plans to change categories and classes during a calendar year to incorporate new therapies, CMS has not required Part D plans to consider new therapies during the course of a plan year. We urge CMS to mandate that plans evaluate and analyze their formularies – through the P&T committee process – at least quarterly in order to ensure that enrollees are receiving the newest therapies. We also urge CMS to clarify that new uses of existing therapies includes medically accepted off-label uses as well as FDA-approved indications.

C. Off-Label Use

BIO appreciates CMS' recognition of the importance of off-label uses of drugs and biologicals, but we are extremely concerned that CMS suggests that it may monitor the clinical appropriateness of such off-label uses. In the Proposed Rule, CMS clarifies that the USP Model Guidelines would not preclude prescription drug plan ("PDP") sponsors or Medicare Advantage prescription drug plan ("MA-PD") organizations from assigning an FDA-approved drug or biological to a category or class based on an off-label use for that drug or biological, as long as FDA has not made a determination that the drug or biological is unsafe for that use.[9] BIO strongly encourages CMS to adopt this view of off-label uses, appropriately reflecting the manner in which new uses of therapies are

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[8] Proposed 42 C.F.R. § 423.120(b)(3).

[9] 69 Fed.Reg. at 46660.

discovered and used in the clinical setting. Yet BIO is troubled by CMS' statement that it "strongly encourage[s] prescribers to clearly document and justify off-label use in their Part D enrollees' clinical records."[10] BIO is concerned that CMS may inappropriately interject itself into how physicians keep medical records. It is critical that Medicare beneficiaries have adequate access to life-enhancing, life-prolonging, and life-savings therapies. Oncologists and other specialists rely on clinically accepted off-label uses of therapies, especially for Medicare beneficiaries for whom other therapies have not proven sufficiently effective or whom have advanced stages of a disease that is not responding to first-line treatments. We strongly urge CMS to appropriately recognize the critical role that clinically accepted off-label use of therapies plays in the health care needs of Medicare beneficiaries and request that CMS allow these uses without restriction.

D. Pharmaceutical and Therapeutic Committees

Under the MMA and the Proposed Rule, PDPs and MA-PD plans would be permitted to institute formularies, provided that the formulary is developed and reviewed by a P&T committee.[11] CMS expects that a plan's P&T committee will be involved in designing any tiers within a formulary[12] and proposes that P&T committee decisions will be binding on a plan.[13] Consistent with the MMA, CMS also requires that a P&T committee base clinical decisions on the strength of scientific evidence and standards of practice and consider the safety and efficacy of a particular covered Part D drug or biological to determine formulary placement.[14] In general, BIO supports CMS' efforts to strengthen the role of the P&T committee and to make this process more transparent and accountable. We agree that P&T committee decisions should be binding on a plan, and we strongly support the requirements that a P&T committee's decisions be based on clinical evidence and efficacy.

BIO urges CMS to clarify that a P&T committee must review any aspect of a formulary that could place restrictions on a patient's access to covered Part D drugs. Consistent with our request that CMS adopt a definition of formulary that includes any cost-sharing, prior authorization, or other requirements that limit enrollee access to drugs and biologicals, we urge CMS to require that a

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10 *Id.*
11 Proposed 42 C.F.R. § 423.120(b)(1).
12 Proposed 42 C.F.R. § 423.120(b)(1)(iv); 69 Fed.Reg. at 46659.
13 69 Fed.Reg. at 46659.
14 Proposed 42 C.F.R. § 423.120(b)(1)(iii).

plan's P&T committee approve any such restrictions on access as part of the P&T committee's overall approval of the plan's formulary. A plan should be required to use the P&T committee process any time it changes its cost-sharing or tiered structure. This will help to ensure that these decisions appropriately reflect clinical considerations. Similarly, a plan should be required to utilize the P&T committee in designing and implementing any medication therapy management programs to ensure that these programs appropriately promote the health needs of targeted enrollees.

The P&T committee process also should be used to conduct the periodic evaluation of protocols required under Proposed 42 C.F.R. § 423.120(b)(4). This provision requires a PDP sponsor or MA organization that offers an MA-PD plan to periodically evaluate and analyze treatment protocols and procedures related to its plan's formulary. It is not clear how this requirement can be met adequately without the expertise and independence of the P&T committee, and BIO urges CMS to require that a plan's P&T committee oversee this evaluation. We believe that the P&T committee process, when properly implemented, can be critical to ensuring that a drug or biological's therapeutic value is properly considered and that a plan's enrollees have adequate access to the therapies they need. BIO supports CMS' efforts to structure the P&T committee process and urges CMS to take the above steps to further strengthen it.

E. Formulary Changes – 30 Day Notice

We are concerned that PDP sponsors and MA organizations offering a prescription drug plan would be allowed to make changes to a formulary at any point during a year, except for the open enrollment period and the beginning of each enrollment year. The statute requires that PDP sponsors and MA organizations provide "appropriate notice" to CMS, as well as to affected enrollees, authorized prescribers, pharmacists, and pharmacies regarding any decision to either remove a drug from its formulary or make any change in the preferred or tiered cost-sharing status of a drug.[15] CMS has interpreted "appropriate notice" as at least 30 days prior to such a change.[16] BIO believes that 30 days is completely inadequate for providing beneficiaries with "appropriate notice" that their plan has decided to remove a critical therapy from its formulary or has changed the cost-sharing requirements for that therapy. We strongly urge CMS to reconsider its

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[15] SSA § 1860D-4(b)(3)(E).

[16] Proposed 42 C.F.R. § 423.120(b)(5).

definition of "appropriate notice" to be consistent with both the private market and the overall structure of the Part D benefit, and to define "appropriate notice" differently for expansion of a formulary than for removal of a therapy from a formulary. We also ask that CMS ensure that enrollees using a therapy at the time of a mid-year plan change be allowed to continue receiving the therapy at the same cost-sharing level for the remainder of the plan year.

CMS has interpreted "appropriate notice" as 30 days; however, the private health insurance market operates under a very different standard. Typically, in the private market, plans infrequently change their formularies. Allowing Part D plans to modify their formulary every 30 days is tremendously burdensome to enrollees, as well as to physicians and pharmacists. Under this interpretation, enrollees who choose to enroll in a particular plan based on their individual drug needs will have no assurances that the plan will maintain coverage for those particular drugs they need during the course of the enrollment year. For an enrollee who chooses a plan based on the favorable negotiated price and formulary status of a necessary therapy, such a change could be extremely financially burdensome. If the enrollee cannot afford the drug or biological once it goes off formulary or changes tiered status, the enrollee may not be able to access the critical therapies he or she needs.

CMS has prohibited a plan from making changes to its formulary during the annual coordinated election period and for the first 30 days of the contract year, noting that "both current and prospective enrollees of a prescription drug plan or an MA-PD plan will need to have the most current formulary information by the time of the annual coordinated election period … in order to enroll in the Part D plan that best suits their particular covered Part D drug needs."[17] We agree that enrollees will need to have this information in order to choose the plan that best meets their individual needs. We fail to understand, however, how CMS intends for enrollees to make these choices when the formulary needs only to remain the same for 30 days after the onset of the new coverage year. CMS expressly has noted that beneficiaries are likely to pick a particular plan due to coverage of specific drugs: "Because beneficiaries will choose a drug plan based on drug prices and formulary coverage, the plans have strong incentives to negotiate lower prices on drugs that beneficiaries use."[18]

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[17] 69 Fed.Reg. at 46661.
[18] 69 Fed.Reg. at 46681.

An enrollee who relies on a specific therapy for a chronic condition likely will seek a plan that provides favorable coverage of that therapy. This is particularly true for patients with rheumatoid arthritis, multiple sclerosis, or rare diseases and conditions. Typically, that beneficiary will enroll in his or her chosen plan effective January 1 and will be prohibited from enrolling in a different plan for the duration of the calendar year.[19] Yet on January 31 that plan may provide 30 days notice that it is removing that particular therapy from its formulary. From March until the end of the calendar year – at which point the beneficiary may begin enrollment in a different plan – the beneficiary will not be able to access that therapy through Part D. The beneficiary would be required to pay for a necessary therapy out-of-pocket, while simultaneously paying premiums to a plan that fails to offer the very benefits that induced the beneficiary to enroll in the first place. In essence, CMS has forced the beneficiary to commit to a plan without requiring a plan to commit to the beneficiary. This lack of predictability for enrollees renders meaningless the notion that a Medicare beneficiary has a choice of prescription drug plans, as the plan an enrollee chooses in December may bear no relation to the plan the enrollee receives benefits from in February. Congress designed the Part D prescription drug benefit on an annual cycle. Plan requirements – especially ones so central to enrollee access – should mirror this annual cycle in order to ensure that enrollees have reasonable access to the therapies and the co-pays that induced them to enroll in the first place. We urge CMS to prohibit plans from removing drugs or biologicals from the formulary or imposing greater cost-sharing requirements on a particular drug or biological during the course of the calendar year, absent specific circumstances for drugs or biologicals removed from the market for safety or other reasons.

Although CMS has made the exceptions process available to enrollees who find their drugs or biologicals no longer covered due to a mid-year formulary change,[20] this process will be burdensome for enrollees and, at a minimum, leave these enrollees without adequate access to necessary therapies while seeking an exception from a PDP sponsor. This unfairly places the burden on enrollees and allows plans to eliminate drugs from their formularies without meaningful notice to the enrollees who rely on these vital therapies. Many biologicals are designed to treat serious and chronic conditions. Enrollees relying on these therapies will be particularly likely to choose a Part D plan based on specific coverage and will be most vulnerable to a Part D plan's "bait-and-switch" tactics. Should CMS decline

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[19] Proposed 42 C.F.R. § 423.36.

[20] Proposed 42 C.F.R. § 423.578(a)(1)(i).

to limit mid-year formulary changes that result in removal of a drug or biological or increased cost-sharing, we urge CMS to require plans to permit enrollees already on a therapy to have continued access to the therapy at the existing cost-sharing level for the rest of the plan year.

In addition to the burden on the enrollee, CMS' proposal will be difficult for physicians and pharmacists to implement. It will be very costly for physicians and pharmacists to track constantly changing formularies.

F. Formulary Issues Facing Special Populations

BIO urges CMS to establish different formulary standards for special populations. Low-income beneficiaries and those with special medical needs are likely to face special challenges in making the transition to the Part D prescription drug benefit. Specifically, we are concerned that the transition for those individuals dually eligible for Medicare and Medicaid will experience a significant loss of coverage for the therapies they need. On December 31, 2005, these dual eligibles will receive prescription drugs and biologicals through the Medicaid program. On January 1, 2006 – assuming CMS resolves the auto-enrollment issues, discussed below – these same individuals will receive drugs and biologicals through Part D plans that are expected to establish restrictive formularies and probably will not cover the broad range of Medicaid-covered therapies on which these enrollees currently rely.

At a minimum, CMS needs to establish a transition formulary plan for these enrollees; otherwise, we anticipate considerable chaos as providers scramble for prior authorization or other mechanisms to cover drugs and biologicals that were previously covered for these enrollees. This problem will be aggravated by the likelihood that many of these enrollees will not choose a Part D plan based upon their therapeutic needs but instead will be automatically enrolled in a Part D plan. Also, these enrollees may not have the range of plan choices available to other Medicare beneficiaries, as their premiums only will be subsidized for Part D plans with premiums at or below certain levels. This may result in the enrollment of these beneficiaries in plans with particularly restrictive formularies. These enrollees are among Medicare's most vulnerable and fragile beneficiaries, including many individuals in long term care facilities and those with multiple medical conditions that may require several medications. From a clinical

perspective, requiring these enrollees to suddenly switch therapies will be complicated and potentially dangerous.

As CMS has acknowledged, enrollees with chronic diseases such as AIDS also will be "negatively impacted financially if they do not have access to a wide range of drugs in certain therapeutic classes and categories."[21] Enrollees with serious and chronic illnesses have special needs that cannot adequately be met through a restrictive formulary. The transition to Part D may be particularly difficult for enrollees that rely on constant access to specific therapies. BIO is concerned that the formulary standards and the exceptions process may not be adequate to protect these enrollees. For example, enrollees with End Stage Renal Disease ("ESRD") are a particularly vulnerable Medicare population. ESRD patients are at high risk for co-morbidities, often are indigent, have high drug and biological utilization, and tend to have difficulty obtaining supplemental insurance to cover their prescription needs. These enrollees also are vulnerable to step therapy and other restrictions that plans may impose as a means of reducing access to drugs and biologicals. It will be particularly important to ensure full access to necessary therapies for this medically fragile population. Additionally, sufferers from chronic pain have special pharmaceutical needs will not be treated with a restrictive formulary. We urge CMS to ensure that enrollees with AIDS, ESRD and other serious and chronic diseases have true access to an alternative or open formulary that accounts for their unique medical needs. Alternatively, CMS could require Part D plans to establish special rules with respect to access to therapies, including dosage forms, that may be required by these populations but not by other Part D enrollees.

G. Pharmacy Access Issues

1. Special Rules for Access to Covered Part D Drugs at Out-of-Network Pharmacies

BIO appreciates CMS' efforts to ensure that enrollees have "adequate access" to covered Part D drugs, including out-of-network access when an enrollee cannot reasonably be expected to access a therapy through a network pharmacy.[22] This proposed provision will be critical to enrollees who need to access a therapy only available through specialty pharmacies or a pharmacy that provides home

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[21] 69 Fed.Reg. at 46661.

[22] Proposed 42 C.F.R. § 423.124(a).

infusion services. In the Proposed Rule, CMS explicitly recognizes that this access will be critical for enrollees that must fill a prescription for a drug or biological that is "not regularly stocked at accessible network retail or mail-order pharmacies."[23] As CMS notes, this likely will occur when an enrollee is seeking to fill a prescription for an orphan drug or other specialty drug or biological that must be obtained directly from a manufacturer or a specialty pharmacy. Under these circumstances, CMS states that it believes that "enrollees under the aforementioned circumstances could not reasonably be expected to access a network pharmacy and must therefore be assured access to an out-of-network pharmacy."[24] BIO strongly supports CMS' recognition of the special needs certain groups of enrollees are likely to have with respect to pharmacy access and urges CMS to adopt Proposed 42 C.F.R. § 423.124(a) in the final rule.

We are concerned, however, that CMS proposes to allow plans to "establish reasonable rules to assure that enrollees use out-of-network pharmacies appropriately."[25] These restrictions could include limits on "the amount of covered Part D drugs dispensed at an out-of-network pharmacy" or prior notification requirements.[26] If plans are permitted to limit the amount of Part D drugs and biologicals that an enrollee may receive at an out-of-network pharmacy, enrollees who must rely on out-of-network pharmacies to obtain the therapies they need – such as orphan drugs or biologicals carried only at specialty pharmacies – may not be able to access the full Part D benefit to which they are entitled. In order to ensure that these medically vulnerable enrollees will be able to access critical therapies, we urge CMS to clarify that such restrictions will not be permitted to the extent that they impede enrollee access to drugs and biologicals not generally available at an enrollee's network pharmacies, specifically those therapies that tend to be available only through specialty pharmacies. As discussed in greater detail below, BIO also urges CMS to require Part D plans to include at least some specialty pharmacies in their pharmacy networks to minimize the burdens on enrollees needing these therapies.

2. Access to Home Infusion and Specialty Pharmacies

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[23] 69 Fed.Reg. at 46662.
[24] *Id.*
[25] *Id.*
[26] *Id.*.

As we have discussed below, BIO greatly appreciates CMS' efforts to recognize the costs associated with administering infused covered Part D drugs to enrollees when considering the most appropriate way to define dispensing fees. In the Proposed Rule, CMS also has recognized that PDPs that will offer a stand-alone prescription drug benefit likely will not have an incentive to include home infusion pharmacies in their pharmacy networks.[27] CMS states in the Proposed Rule that it is considering using its authority under section 1860D-4(b)(1)(C) to require both PDPs and MA-PD plans to contract with a sufficient number of home infusion pharmacies in their service areas to provide reasonable access for Part D enrollees.[28] BIO agrees that, absent an incentive from CMS, PDPs are not likely to include home infusion pharmacies in their networks. We urge CMS to use its authority to require MA-PD plans and PDPs to contract with a sufficient number of home infusion pharmacies in their networks in order to ensure that enrollees have appropriate access to these services.

BIO urges CMS to extend this requirement to all specialty pharmacies, not simply to home infusion therapy pharmacies. Access to specialty pharmacies is critical for enrollees needing access to specialty products, including home infusion therapies and many therapies for rare conditions. BIO is concerned that enrollees will experience difficulty in accessing special therapies, such as orphan drugs, even when those drugs are on the plan's formularies. Access to specialty pharmacies also will be important for facilitating coordination with Part B, as discussed below. Moreover, because an enrollee will be responsible for the difference between the usual and customary charge of the out-of-network pharmacy and his or her plan allowance for the drug in question,[29] an enrollee who requires a therapy available only through an out-of-network pharmacy – for example, because the plan fails to include any specialty pharmacy in the network and the therapy is available only through specialty pharmacies – will incur greater out-of-pocket costs. Although we appreciate CMS' proposal to count these costs as "incurred costs,"[30] for enrollees who do not reach the catastrophic limit, the failure to include specialty pharmacies still will result in the individual receiving 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 increased costs. CMS can help to ensure that these enrollees

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27 *Id.* at 46658.
28 *Id.*
29 Proposed 42 C.F.R. § 423.124(b)(2).
30 69 Fed.Reg. at 46663.

have adequate access to necessary therapies available only through specialty pharmacies by requiring plans to include these pharmacies in their networks.

H. Vaccines as Covered Part D Drugs

The MMA defines "covered Part D drugs" as including vaccines,[31] and CMS incorporates this definition in the Proposed Rule.[32] Yet the MMA also allows a Part D plan to exclude a covered Part D drug if payment for that drug "would not be made if section 1862(a) applied to this part."[33] Medicare Part B payment is excluded under section 1862(a) of the Social Security Act ("SSA") for items and services that are not "reasonable and necessary" for the "diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Although the reference to § 1862(a) in the definition of covered Part D drugs could thus be read as permitting Part D plans to exclude vaccines from their formularies, Congress clearly anticipated that Part D plans would provide coverage for vaccines. We believe that the appropriate reading of the application of § 1862(a) is to allow plans to exclude coverage where a drug is not "reasonable and necessary." We do not believe that Congress intended to allow plans to exclude therapies not used for the "diagnosis or treatment of illness or injury," such as vaccines, from the Part D benefit. We are concerned that plans may interpret this reference in the definition of covered Part D drugs as permitting the exclusion of vaccines, and we ask CMS to clarify that Part D plans are expected to include vaccines in their formularies.

Immunization is an important public health goal, and we urge CMS to emphasize this in the final rule. It is important that Medicare, as a whole, not impede access to vaccines. Medicare Part B payment policy reflects the importance of this goal by fully covering both the cost of the vaccines and the cost of the administration for influenza and pneumococcal vaccines. This payment approach reflects the important role appropriate vaccination plays in promoting health among the elderly. We respectfully request that CMS strongly encourage Part D plans to include on their formularies all vaccines not covered under Part B. We also ask CMS to require plans to make available to enrollees information regarding which vaccines will be available through the plan's formulary.

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31 SSA §1860D-2(e)(1).
32 Proposed 42 C.F.R. § 423.100.
33 SSA § 1860D-2(e)(3).

I. Dispensing Fees

BIO strongly supports CMS' proposed Option 3 for defining "dispensing fees." We appreciate CMS' recognition of the role Part D can play in filling the gaps in existing Medicare coverage of drugs and biologicals[34] and of the special costs associated with the administration of certain Part D drugs. CMS' implementation of this aspect of the Medicare drug benefit has the potential to greatly improve access to the drugs, supplies, and services necessary to patients with certain life-threatening or chronic debilitating diseases and conditions in the setting determined most appropriate by the patient and treating physician. Currently, home infusion therapy 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. "Homebound" beneficiaries eligible for home health services may receive assistance with nursing services, infusion equipment and supplies; however, drugs and biologicals are excluded from this coverage. Nonetheless, many patients depend on injected or infused therapies yet cannot easily access treatment due to the coverage constraints in the Part B benefit.

The implementation of Medicare Part D provides an opportunity to remedy these gaping holes in coverage – both for the drugs and biologicals that are not covered when administered in the home and for the services and supplies that are necessary for safe and effective home infusion. Home infusion therapy is a cost effective alternative to outpatient clinic or physician's office visits to receive the necessary therapy. It also allows patients greater comfort and convenience, particularly for patients in rural areas who must travel long distances to be treated by a physician. Private insurers and Medicare Advantage plans have long recognized that home infusion therapy is cost-effective. It is time that Medicare beneficiaries enjoyed the same benefits of home infusion as their private sector counterparts. Implementing Option 3 for defining "dispensing fees" will help make this a reality.

Specifically, in proposing to cover home infusion services considered necessary for effective medication usage, CMS has recognized that some patients will not be able to receive "the benefit of a necessary medication in the absence of the associated supplies, equipment or professional services"[35] necessary to use the

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[34] *See id.* at 46646.
[35] *Id.* at 46648.

therapy. CMS' proposed Option 3 likely will encourage patients who have the ability to home infuse to do so through the Part D benefit rather than seeking care in an outpatient facility or physician's office under Part B. This will result in increased savings to Medicare. BIO applauds CMS' proposed approach in Option 3 to ensuring more meaningful coverage of these therapies and strongly urges CMS to adopt this option.

We also believe that the adoption of Option 3 is critical to appropriate coverage of vaccines under Part D. CMS has suggested extending coverage of services, supplies, and administration under proposed Option 3 only to home infusion. Yet there are other circumstances in which the absence of coverage would preclude enrollee use of a covered Part D drug. Most specifically, we urge CMS to extend Option 3 to include vaccine administration services. In proposing Option 3, CMS states that it would limit coverage of administration services to home infusion because home infusion is "the only circumstance we know of where the additional services associated with administering the drug would not already be covered under Medicare Part A or B and would be necessary to ensure effective delivery of the drug."[36] CMS requests comment, however, on whether similar issues may exist respect to the administration of other drugs and biologicals, such as vaccines.[37]

A limited number of vaccines are covered under Part B. For these vaccines, Part B covers both the cost of the vaccine and the cost of the administration. Congress expressly included vaccines in the statutory definition of covered Part D drugs, clearly intending to extend Part D coverage to those vaccines not already covered under Part B. This is consistent with the intent of Congress and CMS that Part D operate as wrap-around coverage for Part B. This coverage is rendered somewhat meaningless, however, if vaccine administration is not also covered. Typically, vaccines are administered in a physician's office. Thus, the dispensing of a vaccine is actually the same as administering the vaccine.

In the Proposed Rule, CMS suggests a preference for Option 1, suggesting that this option best reflects the statutory language. We would argue, however, that Option 3 in fact best reflects the intent of Congress and CMS that Part D and Part B together provide a seamless benefit and that the beneficiaries with the greatest need for assistance do not receive the least meaningful benefit.

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[36] *Id.*

[37] *Id.*

Moreover, failure to include administration fees, particularly with respect to infusions and vaccines, would not accurately reflect Congress' express inclusion of vaccines in the definition of "covered Part D drugs." If CMS declines to adopt Option 3, we encourage the agency to consider Option 2 rather than Option 1 as the most appropriate choice. Under Option 2, the dispensing fee would include costs associated with the mixing and delivery of drugs and biologicals, pharmacy overhead, and supplies and equipment necessary to administer the drug or biological.[38] This option would at least increase the likelihood that an enrollee for whom home infusion is appropriate may choose to do so and, if appropriately extended to vaccines, would allow enrollees to access these important preventative therapies.

J. AIDS Drug Assistance Programs

CMS specifically has asked for comments on the coordination of AIDS Drug Assistance Programs ("ADAPs") and Part D plans, including whether there is a way to offer drugs and biologicals at 340B prices to ADAP participants who are also Part D enrollees. We strongly agree with CMS that it is of critical importance that enrollees with HIV/AIDS comply with their drug regimens and that their prescription drug benefits and other assistance enable such compliance. We do not believe, however, that 340B prices may be made available through Part D plans. Section 340B limits the cost of drugs to certain covered entities. The law is very specific regarding the types of programs that may participate. First, the organization must be a grantee of an eligible grant program, a federally qualified health center look-alike or a disproportionate share hospital that meets certain requirements. Qualifying programs, including ADAPs, may obtain outpatient drugs and biologicals from manufacturers and wholesalers at significantly reduced prices for purposes of providing these therapies to individuals who receive care through these charitable organizations. 340B prices are mandated by statute. Merging the 340B prices for these drugs and biologicals into the Part D prescription drug benefit would violate the non-interference provisions of the MMA[39] because the government would be directly negotiating the drug prices.

The purpose of the 340B program is to provide charity care for individuals who do not have access to other insurance. ADAPs typically provide free medications for the treatment of HIV/AIDS and opportunistic infections. The

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[38] *Id.*

[39] 1860D-11(i).

drugs and biologicals provided through an ADAP can help people with HIV/AIDS to live longer and treat the symptoms of HIV infection. Access to Part D coverage will greatly assist many ADAP participants. Because ADAPs typically have very limited formularies, many individuals who receive ADAP services truly will benefit from enrollment in the Part D benefit. ADAPs also have limited resources and can serve only a percentage of the individuals who need their care; to the extent that some ADAP participants may receive some coverage of prescription drugs and biologicals through the new Part D benefit, ADAPs may be able to better serve more patients. As ADAP participants who are dually eligible for Medicare and Medicaid begin to receive their prescription drugs and biologicals from Part D rather than Medicare, however, ADAPs may need to devote their resources to further assisting this population with the transition.

CMS has defined ADAP programs as "insurance" for purposes of the Part D cost-sharing and benefit coordination provisions.[40] Certainly, Part D is designed to be coordinated with other insurance coverage.[41] Effective coordination between ADAPs and Part D will be critical for patient compliance. We urge CMS, however, to consider whether ADAPs may be categorized as a "person" – interpreted by CMS to include foundations, not-for-profit corporations, and government or governmental subdivision or agency.[42] We believe that organizations that qualify as ADAPs will meet this definition of "person" – as well as qualify as "insurance or otherwise."[43] Allowing ADAPs to be treated as a "person" would allow ADAP subsidies of a Part D enrollee's cost-sharing to count as incurred costs for purposes of reaching the out-of-pocket limit. This would help to sustain and encourage an existing source of coverage for these patients, as well as help to ensure continuity of care for these patients.

Even if CMS declines to extend the definition of "person" to ADAPs, we urge CMS to support the efforts of ADAPs to provide better care to this vulnerable population by ensuring HIV/AIDS populations access to formularies that fully reflect their medical need, as discussed above, and by ensuring a smooth transition to Part D for dual eligibles.

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40 *See* Proposed 42 C.F.R. § 423.100; 69 Fed. Reg. at 46650.
41 *See* SSA § 1860D-24.
42 Proposed 42 C.F.R. § 423.100.
43 *Id.*

IV. MEDICATION THERAPY MANAGEMENT PROGRAMS – Comments on Subpart D

Under the MMA, a Part D plan must establish a Medication Therapy Management Program ("MTMP").[44] Consistent with the MMA, CMS has proposed that plans be required to establish such a program to ensure that Part D drugs and biologicals are used appropriately to "optimize therapeutic outcomes through improved medication use."[45] MTMPs will be directed at "targeted beneficiaries," including those enrollees (1) with multiple chronic diseases, (2) taking multiple covered Part D drugs, and (3) that are likely to exceed an undetermined threshold in annual Part D costs.[46] CMS observes that neither the agency nor many private insurers have extensive experience operating or reimbursing for MTMPs.[47] Thus, CMS has requested comments on what requirements and/or guidelines should be established for MTMPs in the final rule.

Given this lack of experience with MTMPs, we urge CMS to be particularly careful in defining the targeted populations and in establishing standards and guidelines. Targeted beneficiaries should include those Part D enrollees that meet the criteria noted above and for whom inappropriate use (including both underutilization and overutilization) is likely to be a problem or for whom the likelihood of adverse drug interactions is significant. This would include chronically ill enrollees for whom the lack of medication adherence is likely to have a significant adverse effect on health outcomes. We urge CMS to require that MTMP services, including education and training of a patient about his or her medications, would be provided through one-on-one interactions between the patient and professional providing the service. MTMPs are tools to enhance medical care, not a cost-containment tool; a population targeted for MTMP should not face additional hurdles or constrictions in their drug benefit.

We particularly are concerned about how reimbursement for this program will be established. CMS should prohibit Part D plans from structuring the compensation for MTMP services in a manner that inappropriately guides patients to or away from specific medications or away from particular Part D plans. CMS should consider a plan's proposed MTMP as part of the plan's design,

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44 SSA § 1860D-4(c).
45 Proposed 42 C.F.R. § 423.153(d).
46 *Id.*
47 69 Fed.Reg. at 46668 (Aug. 3, 2004).

subject to CMS' examination of whether a plan is substantially discouraging the enrollment of certain groups of Medicare beneficiaries. We are concerned that plans may market MTMPs in a manner that is perceived as prohibitive to Medicare beneficiaries with multiple chronic diseases. We request that CMS review the marketing materials for MTMPs to protect against this result. We also urge CMS to clarify that fees for MTMPs must be completely independent from dispensing fees.

V. COVERED PART D DRUGS AND COORDINATION OF PART B AND PART D BENEFITS – Comments on Subpart C.1.a. and Subpart J.6.c.

BIO greatly appreciates CMS' efforts to coordinate the benefits available through Part B and Part D. In the Proposed Rule, CMS acknowledges that Part D is designed to "fill any gaps in existing coverage of drugs,"[48] and that the agency intends to "ensure that the Part D benefit 'wraps around' existing Part B drug benefits to the greatest extent possible."[49] Part B coverage for drugs and biologicals is available only in limited circumstances, typically incident to a physician's service. As discussed above, Medicare traditionally has not covered home or self-administration, often forcing patients to travel to physician offices, outpatient facilities or hospitals in order for their therapies to be covered. Medicare reimbursement policies regarding what drugs and biologicals are covered by Part B have been confusing and vary by region; as a result, beneficiaries too frequently cannot obtain the therapies they need.

The Part D benefit will offer critical relief to seniors who rely on therapies not covered by Medicare and beneficiaries who would prefer to receive in-home injection or infusion. BIO generally supports CMS' proposals regarding when each benefit will be available to Medicare beneficiaries and supports CMS' efforts to coordinate the Part B and Part D benefits to ensure that enrollees will receive coverage. BIO is concerned, however, that some confusion may remain regarding how these benefits will be made available, and we urge CMS to provide additional clarification.

The MMA and the Proposed Rule exclude from Part D any drug or biological for which payment is available under Part B for that individual.[50] As

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48 *Id.* at 46646.
49 *Id.* at 46647.
50 SSA § 1860D-2(e)(2)(B); Proposed 42 C.F.R. § 423.100.

acknowledged by the statute and by CMS, some covered Part D drugs could qualify for payment under Part B in some circumstances and for Part D coverage in other circumstances, depending on the way in which those drugs or biologicals are administered or dispensed. It is clear from the statute that these determinations are to be made on an individual basis and not with respect to coverage of a drug or biological as a whole.[51] CMS has reiterated this requirement, stating that "[d]ispensation or administration should be interpreted to include the setting, personnel, and method involved, and not simply the route of administration."[52] This includes situations in which a particular individual happens to be able, or has assistance, to self-administer a drug or biological that normally must be administered in a physician's office or hospital outpatient department. This is consistent with Congressional intent and makes sense from a policy perspective, because it is less expensive for Medicare to pay for a drug or biological administered in the home than to require it to be administered in another setting.

In Subpart C.1.a. of the Proposed Rule, CMS has implemented this interaction between Part B and Part D benefits in a manner that BIO believes is consistent with the statutory language. Beneficiaries will receive Part B coverage, where available, unless the Part B coverage criteria are not met. Part B coverage criteria generally require that the drug or biological be purchased and administered by the physician and that the therapy is not usually self-administered by the patient. If any of these criteria are not met for any reason – including that a Part D enrollee chooses to self-administer a therapy that typically is administered by a physician – the drug or biological clearly should be covered under Part D, assuming that it is included on the plan's formulary or an exception is made.

We are concerned, however, that CMS has created some confusion regarding the availability of Part D coverage. In the preamble to Subpart J.6.c., CMS states that "any drug covered under A or B could not be covered under D, whether it was covered for that individual or not."[53] We believe that CMS intends this to mean that, *for Medicare beneficiaries who are eligible for Part B but decline to enroll in Part B*, Part D coverage would not be available for drugs and biologicals for which Part B coverage would have been available for that

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51 SSA § 1860D-2(e)(2)(B).
52 69 Fed. Reg. at 46646.
53 69 Fed. Reg. at 46703.

individual had that individual enrolled in Part B.[54] We urge CMS to clarify this language in the final rule to ensure that the preamble language is consistent with the statutory requirement that Part D coverage be available where Part B coverage is not available *for that individual* under the specific circumstances involved.

In particular, we respectfully request that CMS finalize its proposal to allow drugs and biologicals to be covered under Part D where the Part B coverage is denied because an enrollee filled the prescription at a pharmacy that did not have a Medicare supplier number. We urge CMS to require Part D plans to include in their networks pharmacies that have Medicare supplier numbers and to educate enrollees about the importance of filling certain prescriptions at such a pharmacy. This will facilitate greatly the coordination of benefits process CMS proposes.[55] We also encourage CMS and plans to educate enrollees that Part D coverage may be available if Part B coverage is denied. It will remain important to allow drugs or biologicals denied coverage because they were filled at a non-Medicare supplier pharmacy to be considered for coverage under Part D, however. Failure to do so could greatly hinder enrollee access to therapies for which Part D benefits should be available. We urge CMS to proactively monitor patient access and benefit coordination issues as it implements Part D as a wrap-around benefit to Part B.

At the same time, CMS should avoid any attempt to mandate a shift in coverage from Part D to Part B for drugs and biologicals that are covered properly under Part B. This is consistent with the Congressional intent that the new drug benefit expand coverage where there was none, yet would appropriately maintain established coverage.

VI. AUTO-ENROLLMENT OF LOW-INCOME BENEFICIARIES – Comments on Subpart B: Eligibility and Enrollment

The Proposed Rule provides for the automatic enrollment of dual eligible individuals who fail to enroll in a Part D plan during their initial enrollment period.[56] This initial enrollment period runs from November 15, 2005 until May 15, 2006. If dual eligibles who fail to enroll during this period are not auto-enrolled until May of 2006, these enrollees – who will lose their Medicaid

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[54] We note that this is not a statutory requirement. Specifically, the MMA does not require that Part D coverage be unavailable for drugs or biologicals covered under Part B where a Part D enrollee has not enrolled in Part B.

[55] *See* 69 Fed. Reg. 46703.

[56] Proposed 42 C.F.R. § 423.34(d).

prescription drug coverage on January 1, 2006 – will be without prescription drug coverage for at least five months. BIO urges CMS to ensure that these Medicare beneficiaries have a smooth transition to prevent any interruptions in medical treatment. Interruptions in care and barriers to access to prescription drugs and biologicals can be especially problematic for dual eligibles, who often suffer from severe and debilitating conditions, such as ESRD, HIV/AIDS or multiple sclerosis.

VII. THE EXCEPTIONS AND APPEALS PROCESS – Comments on Subpart M: Grievances, Coverage Determinations and Appeals

BIO believes that the appeals and grievance process, including the exceptions process, is completely inadequate to protect Medicare beneficiaries enrolled in Part D plans. It is critical that Medicare beneficiaries be able to navigate the appeal process to obtain access to the therapies they need. The proposed exceptions and appeals process for drugs and biologicals is extremely lengthy and confusing. We urge CMS to redesign the framework it has proposed in order to provide Part D enrollees with a clear and reasonable way to obtain the therapies they need.

Specifically, we urge CMS to ensure that the appeals/grievance process accomplish the following: (1) reduce the timeframe for the appeals process to minimize the likelihood that an enrollee will need to go without necessary therapies; (2) require plans to provide notice of a coverage determination to an enrollee; (3) eliminate the provision that eliminates an appeal right when an enrollee has no further cost-sharing obligations; (4) provide enrollees with access to a drug or biological during an exceptions request to mid-year formulary changes; (5) revise the standards of review for the exceptions process, including the use of the term "therapeutically equivalent," to be consistent with the MMA; and (6) allow the exceptions process to be used for non-covered Part D drugs. We have addressed each of these concerns below.

A. Reduce the Timeframe for the Appeals Process -- § 423.568

BIO is concerned that the appeals process is structured in a manner that could greatly delay enrollees access to therapies they need. Under the process CMS has proposed, an appeal could take as long as several months. The enrollee bears the burden of providing sufficient evidence that a prescription drug or biological should be covered under the Part D plan. While the appeals process

occurs, an enrollee must pay for the drug or biological out-of-pocket. These out-of-pocket expenditures will not count as "incurred costs" for purposes of reaching the catastrophic coverage unless the enrollee prevails in the appeal.[57] If an enrollee cannot afford to pay for a necessary drug or biological out-of-pocket, the enrollee will need to take a formulary drug or biological that is less effective or has greater side effects, or the enrollee will be forced to go without this therapy altogether. Recent studies have shown that patients do not take therapies as prescribed when they have higher cost-sharing burdens,[58] and thus even those patients who do purchase the prescribed drug or biological during the appeals process may reduce dosages in order to make a medication last for the duration of the appeals process. Clearly, this would reduce the effectiveness of the therapy. Thus, BIO urges CMS to reduce the length of the appeals process.

Under the MMA, PDPs must follow an appeals process that is consistent with the existing process for seeking appeals of Part C benefits through Medicare Advantage ("MA") plans.[59] CMS proposes a process that mirrors the MA plan process for Part C appeals. The statute does not require, however, that the process for appeals under the Part D benefit incorporate the same timeframes as are set forth for Part C benefits. CMS may reduce those timeframes and still meet the requirement that Part D plans have an appeals process consistent with the process for the Part C appeals. The appeals process available under the MA program tends to involve coverage determinations for physician and hospital services. Typically, an appeal involves payment for benefits after the beneficiary already has received the care. Under Part D, however, an enrollee may be denied a necessary drug or biological at the pharmacy. As described above, the enrollee then will need either to pay for the therapy out-of-pocket or request a different prescription from his or her physician. In either case, the enrollee will forgo the therapy deemed to be most effective by the patient's physician. In addition to the therapeutic and financial burdens the length of this process may impose on an enrollee, this process also may require the enrollee to make multiple visits to his or

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57 SSA §1860D-2(b)(4)(C)(i).

58 *See., e.g.,* Goldman D.P., Joyce G.F., Escarce J.J. et al, "Pharmacy Benefits and the Use of Drugs by the Chronically Ill,", JAMA, 291:2344-2450 (2004); Tseng C-W, Brook R.H., Keller E, Steers W.N., Mangione C.M., "Cost-lowering Strategies Used by Medicare Beneficiaries Who Exceed Drug Benefit Caps and Have a Gap in Drug Coverage," JAMA, 292: 952-960 (2004).

59 SSA § 1860D-4(g).

her physician(s) and the pharmacy, thus increasing the burden on frail or elderly patients.[60]

B. Denial of a Claim as a Coverage Determination -- § 423.566

Typically, under the Medicare program, a denial of benefits is considered an adverse coverage determination and a notice must be sent to a beneficiary explaining a beneficiary's appeal rights. Under the Proposed Rule, however, after receiving a denial at a pharmacy, a Part D enrollee – or his or her authorized representative – would need to seek a "coverage determination" or "exception" from his or her Part D plan. We believe that this creates an extra and unnecessary step that serves only to delay an enrollee's ability to obtain a timely response to an appeal. This is inconsistent with the way in which claims denials are treated under the MA program. For benefits offered under the MA program, an initial claims denial is considered a claims denial, and the enrollee receives a written notice of his or her appeal rights. We respectfully request that CMS revise the Part D appeals process in the final rule so that the denial of the claim at the pharmacy is treated as a coverage determination. This will allow an enrollee to understand that a claim was denied or that a higher co-pay was imposed and will provide the enrollee with information about the appeals process at the point at which that information is likely to be most needed. This also will eliminate the extra step the Proposed Rule imposes by requiring an enrollee whose claim has been denied to request a coverage determination before seeking an appeal.

We also request that CMS treat as a coverage determination the 30 day notice that a drug or biological is being removed from a formulary or that different cost-sharing is being imposed. In the Proposed Rule, CMS requires that a plan provide an enrollee with 30 days notice prior to removing a drug or biological from the plan's formulary or changing the drug or biological's cost-sharing status.[61] This notice, however, does not appear to constitute a coverage determination. Typically, enrollees will not be aware that they can file an exceptions request upon receiving such a notice and instead will wait to receive a denial upon seeking a refill at the pharmacy before initiating the appeals process. BIO urges CMS to clarify that this notice constitutes a coverage determination and

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[60] The financial burden on enrollees here is heightened by the fact that enrollees may not have access to negotiated prices for drugs and biologicals not on the formulary. Under Proposed 42 C.F.R. § 423.104(h), negotiated prices must be available to enrollees if no benefits are payable due to the application of a deductible or 100% coinsurance requirement.

[61] Proposed 42 C.F.R. § 423.120(b)(5).

to require that plans issue to enrollees information about the exceptions and appeals process with this notice. This will help to minimize delays in the appeals process and make it less likely that enrollees who rely on regular use of a particular drug or biological will be forced to go without necessary therapies.

C. Permitting Appeals When the Enrollee Has No Payment Liability -- § 423.562(c)

CMS proposes that an enrollee would have no appeal right when there is no payment liability. This provision is completely inconsistent with the purpose of the Medicare Part D prescription drug benefit, and we strongly urge CMS to eliminate this provision. The MMA and the Proposed regulations expressly allow an enrollee's authorized representative or the prescribing physician to request a coverage determination[62] or to file a request for an exception.[63] CMS' refusal to allow an enrollee or his or her authorized representative or prescribing physician to initiate an appeal where another party – such as a family member, other health insurance, a State Pharmaceutical Assistance Program ("SPAP") – has assumed payment for the prescription pending an appeal of a Part D denial is directly contrary to the underlying purpose of the Part D benefit.

Congress specifically designed the Part D benefit to coordinate with other insurance programs,[64] contemplating that some Medicare beneficiaries will have secondary coverage that complements their Part D benefit. For example, Congress clearly contemplated that employers may in some circumstances provide supplemental coverage for prescription drugs and biologicals that wraps around the Part D benefit. Congress also explicitly required Part D plans to coordinate with SPAPs. Eliminating the ability of these other payers or programs to appeal a Part D coverage determination provides a disincentive for these third parties to provide such coverage or to structure the coverage in a manner that is most beneficial to enrollees. Prohibiting an appeal where an enrollee has no further payment liability also provides Part D plans with a strong incentive to shift costs to an enrollee's other health coverage, even where the Part D plan has a clear obligation to provide it. Ultimately, the burden is likely to shift to enrollees, as they are forced to seek coverage determinations, redeterminations, and exceptions because their other sources of coverage are unable or unwilling to provide assistance until the Part D

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62 Proposed 42 C.F.R. § 423.566.
63 Proposed 42 C.F.R. § 423.578(a)(3).
64 *See, e.g.,* Proposed 42 C.F.R. § 423.452 – 42 C.F.R. § 423.464.

plan has made a determination. BIO strongly urges CMS to eliminate this provision and clarify that Part D plans are required to pay for drugs and biologicals consistent with their agreement with CMS and their obligations under the MMA and implementing regulations, regardless of whether an enrollee has secondary coverage.

D. Access to Therapies After Mid-Year Formulary Changes -- § 423.578

CMS has proposed requiring a Part D plan to establish an exceptions process for circumstances in which an enrollee is using a drug or biological and the formulary status changes mid-year or at the beginning of a plan year.[65] As discussed above, we urge CMS to prohibit plans from making changes mid-year that result in removal of a drug or biological from a formulary or increases the cost-sharing required of an enrollee. Alternately, we require plans to provide some grace period for enrollees currently using a drug or biological that is removed from their plan's formulary or for which the cost-sharing structure is changed. As discussed in above, we are concerned that plans may be allowed to make changes to their formularies with only 30 days notice to beneficiaries. We urge CMS to amend its proposed exceptions process to allow enrollees more appropriate access to the therapies on which they rely.

Currently, the proposed exceptions process requires a plan to provide an enrollee coverage for up to a one month supply *only* when the PDP sponsor is removing the drug or biological from the formulary, the plan fails to make a timely decision on an exceptions request, and fails to provide notice of a decision within the timeframe required in the regulations. There is no provision for an emergency supply of a drug or biological during the course of the appeals process. This limited access to a drug or biological during the exceptions process could prove extremely detrimental to enrollees who need ongoing access to a particular therapy. For the patients BIO members serve – typically those with chronic and severe illnesses who have continuing therapeutic needs – this limited access will greatly undermine access to critical therapies. In many cases it will not be medically feasible for an enrollee to stop using a biological therapy and then later re-start the therapy. Also, switching medications may require laboratory tests and physician

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[65] Proposed 42 C.F.R. § 423.578(a)(1)(i)-(ii); § 423.578(b)(1)(ii).

visits. If an enrollee must switch to a formulary drug (where medically appropriate) the enrollee will need sufficient time to make this transition.

At a minimum, CMS should consider the needs of special and vulnerable populations in requiring plans to provide continued access to emergency supplies of a drug or biological that a plan has removed from a formulary or for which the plan has changed the cost-sharing structure. We note that CMS has expressly allowed plans to impose cost-sharing of 100 percent on a drug or biological. Thus, a shift in cost-sharing could have the same effect for an enrollee that has not reached the out-of-pocket limit as removal of that drug or biological from a formulary. Accordingly, we urge CMS to require access to an emergency supply of a drug or biological during the appeals process.

The availability of an emergency supply will be particularly critical to the dual eligible population. These enrollees tend to be particularly medically vulnerable and require multiple medications. It will be a complicated and time-consuming process, both from a clinical and administrative standpoint, to appropriately switch these enrollees to drugs or biologicals on their Part D plan's formulary or to pursue an exception in order to obtain a therapy that appropriately meets an enrollee's medical needs. At a minimum, BIO urges CMS to ensure that these enrollees have access to an emergency supply of their existing prescriptions, to limit gaps in coverage as these enrollees transition from Medicaid to Medicare Part D.

E. Standards for Review of Exceptions to Tiered Cost-Sharing Structure – § 423.578(a)

CMS proposes that a PDP exceptions criteria include consideration of whether the requested prescription drug that is the subject of the exceptions request is the therapeutic equivalent of any other drug on the sponsor's formulary. We believe that CMS has imposed criteria on the process for requesting an exception to a Part D plan's cost-sharing structure well beyond that contemplated by the MMA. Under the MMA, a plan must pay for a nonpreferred drug under the same terms applicable to preferred drugs where the prescribing physician determines that the preferred drug would not be as effective for the individual for treatment of the same condition, would have adverse effects for the individual, or both.[66] CMS,

[66] SSA § 1860D-4(g)(2).

however, proposes several additional criteria plans must consider when reviewing an exceptions request for a preferred formulary placement. We urge CMS to remove these additional requirements in the final rule and clarify that a plan is obligated to grant an exceptions request where the prescribing physician makes the certifications required by the MMA. As recognized by the MMA, a Part D plan should defer to the judgment of the prescribing physician in determining what drug or biological is safe, effective, and medically necessary for a patient.

We are extremely concerned that CMS has implemented the MMA-established criterion that allows a Part D plan to require a physician's certification that the preferred drug "*would not* be as effective for the individual or *would have* adverse effects for the individual or both."[67] In the Proposed Rule, CMS states that a plan may require the prescribing physician to certify that the preferred drug "*is* not as effective for the enrollee" as the requested drug.[68] Plans could interpret this proposed provision permitting step therapy or similar barriers to access prior to granting a request for an exception. We urge CMS to finalize this provision consistent with the MMA, which permits a plan to request that a physician certify that a therapy *would not* be as effective for an individual.

BIO also believes that in establishing this criteria CMS has inappropriately defined "therapeutically equivalent" for purposes of this subsection. For purposes of the exceptions process, CMS defines "therapeutically equivalent" as a drug that have "equal effect and no difference when substituted for the requested drug."[69] This definition of therapeutically equivalent is different from the definition provided earlier in the Proposed Rule, and is inconsistent with the manner in which this term is most commonly and appropriately used. Proposed section 423.100 defines "therapeutically equivalent" drugs and biologicals as "drugs that are rated as therapeutic equivalent under the Food and Drug Administration's most recent publication of 'Approved Drug Products with Therapeutic Equivalence Evaluations.'" BIO supports this definition, which appropriately incorporates the Orange Book, as the commonly accepted definition of therapeutically equivalent. We urge CMS to eliminate the attempt to define therapeutic equivalence differently in § 423.578.

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67 SSA § 1860D-4(g)(2) (*emphasis added*).
68 Proposed 42 C.F.R. § 423.578(a)(4).
69 Proposed 42 C.F.R. § 423.578(a)(2)(iii).

F. Making the Exceptions Process Available for Drugs and Biologicals that Are Not Covered Part D Drugs – § 423.578(d)

CMS has proposed to prohibit enrollees from using the exceptions process for drugs and biologicals that do not meet the definition of "covered Part D drugs."[70] As we have discussed above, it may not be clear whether a particular drug or biological is covered under Part D. To the extent that the Part D plan (rather than CMS) makes the determination that a particular drug or biological is not covered under Part D, an enrollee should be able to use the exceptions process to determine whether his or her use of a particular therapy qualifies as a covered Part D drug. Furthermore, Part D plans are permitted to offer enhanced or supplemental coverage. To the extent that plans offer such benefits, an enrollee should be permitted to use the exceptions process where a particular drug or biological offered under such a benefit has been removed from the plan's formulary or the plan has changed the drug or biological's cost-sharing status. BIO requests that CMS remove section 423.578(d) when implementing the final rule.

VIII. DISCLOSURE OF PROPRIETARY INFORMATION – Subparts C, F, G, K, Q, and R

BIO is concerned that the Proposed Rule does not adequately protect the information that plans submit to CMS. The Proposed Rule requires PDP sponsors and MA organizations to report to CMS the following information: (1) data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers and passed through to beneficiaries;[71] (2) information necessary to carry out payments to PDP sponsors and MA organizations for qualified prescription drug coverage;[72] and (3) data regarding drug claims at an individual level and other information as CMS deems necessary.[73] CMS also may obtain other information from Part D plans, through the bid process or otherwise.[74] Under the Proposed Rule, the confidentiality protections provided under the Medicaid rebate law[75] apply to the aggregated pricing information, above, but not to the

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70 Proposed 42 C.F.R. § 423.578(d).
71 Proposed 42 C.F.R. § 423.104(h)(3); *see also* 69 Fed.Reg. at 46654.
72 Proposed 42 C.F.R. § 423.322; *see also* 68 Fed.Reg. at 46686.
73 Proposed 42 C.F.R. § 423.329(b)(3); *see also* 69 Fed.Reg. at 46688.
74 *See, e.g.,* Proposed 42 C.F.R. § 423.265; § 423.505; §423.863; § 423.888.
75 SSA §1927(b)(3)(D).

other information that plans must submit to CMS. BIO urges CMS to extend this confidentiality protection to these other types of information.

Under Proposed § 423.104(h)(3), a PDP sponsor or MA organization offering qualified prescription drug coverage is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers and passed through to beneficiaries, via pharmacies and other dispensers. The information on negotiated prices disclosed to CMS under this provision is protected under the confidentiality provisions of § 1927(b)(3)(D) of the SSA, protecting manufacturer information submitted to CMS under the Medicaid rebate program. Proposed § 423.104(h)(4) allows CMS to conduct audits of a Part D plan's financial statements and records pertained to any qualified prescription drug coverage the plan offers under Part D. The information obtained through these audits, however, is not expressly protected by the Medicaid rebate confidentiality provisions.

Proposed § 423.322 states that payments to a PDP sponsor or MA organization are conditioned upon provision of information to CMS that is necessary to carry out this subpart, or as required by law. CMS states that this information "would encompass the quantity, type, and costs of pharmaceutical prescriptions filled by enrollees."[76] The Proposed Rule imposes a restriction on use of information: officers, employees, and contractors of HHS may use the information disclosed or obtained only for purposes of and to extent necessary to carry out this subpart. This use may include, but is not limited to, determination of payments and payment-related oversight and program integrity activities.[77] BIO appreciates CMS' implementation of this restriction on use of this information, but we remain concerned that this restriction will not be sufficient to prevent the *disclosure* of information to other parties.

Under Proposed § 423.329(b)(3), CMS again requires plans to submit specific data regarding drug claims that can be linked at the individual level. The Proposed Rule does not provide for any specific confidentiality protections for this information. Similarly, CMS does not provide any confidentiality protections for the information plans may be required to submit under § 423.265, § 423.505, §423.863, or § 423.888. This lack of protection could result in the release of commercially sensitive information that manufacturers deem proprietary. We

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[76] 69 Fed.Reg. at 46686.

[77] Proposed 42 C.F.R. § 423.322(b).

respectfully request that CMS extend the confidentiality provisions of the Medicaid rebate statute to this information as well. In sum, BIO requests that CMS extend the confidentiality protections of the Medicaid rebate statute to all negotiated pricing information submitted to or reviewed by CMS under Part D, including information obtained under Subparts F, G, K, Q, and R of the Proposed Rule.

IX. CONCLUSION

BIO appreciates this opportunity to comment on the important issues raised in the Proposed Rule and looks forward to working with you to ensure that Medicare beneficiaries continue to have access to new and important drug and biological therapies. In sum, BIO urges CMS to take the following steps in implementing the final rule:

- Use the proposed formulary review process to ensure that Part D enrollees have access to medically necessary drugs and biologicals;
- Clarify that the two drugs or biologicals per class requirement may not be sufficient to ensure that a plan is not discouraging enrollment of certain populations;
- Require plans to consider revising formularies at least quarterly to reflect new drugs and biologicals and new therapeutic uses;
- Continue to allow a drug or biological to be placed in a class based on its off-label use, but refrain from interjecting the agency in physicians' clinical decisions;
- Strengthen the role of the P&T Committees, most specifically by requiring that the committee be involved in all aspects of formulary development, including the establishment of cost containment mechanisms and the use of MTMPs;
- Reconsider its interpretation that 30 days constitutes "appropriate notice" of formulary changes;
- Establish separate formulary standards for special populations to ensure a smooth transition to Part D;
- Ensure enrollee access to out-of-network pharmacies, limit restrictions on such use for enrollees needing specialty therapies, and require plans to include both home infusion and specialty pharmacies in their networks;
- Adopt Option 3 in establishing a definition of dispensing fees;

- Allow ADAP expenditures to count toward TrOOP and exercise caution in deciding whether 340B prices may be offered under Part D;
- Ensure that MTMPs are designed to encourage appropriate patient utilization of drugs and biologicals and to promote quality care, and not simply to contain costs;
- Ensure seamless coordination of Part B and Part D to improve enrollee access to both benefits;
- Revise the auto-enrollment process for dual eligibles to minimize any possible gap in coverage;
- Revise the appeals and exceptions processes to ensure that enrollees have adequate access to prescription drugs; and
- Extend the Medicaid rebate confidentiality protections to all of the proprietary information manufacturers must submit to Part D plans.

We would welcome the opportunity to discuss these issues in depth. Please contact Jayson Slotnik at (202) 312-9273 if you have any questions regarding our comments. Thank you for your consideration of these very important matters. We applaud Congress and CMS for their enactment and implementation of this important program, providing much needed relief to this country's senior citizens.

Respectfully submitted by,

/s/

Michael Werner,
Chief of Policy