Biotechnology Industry Organization

March 7, 2014

BY ELECTRONIC DELIVERY

Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program; Proposed Rule [CMS-4159-P]

Dear Administrator Tavenner:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs (the "Proposed Rule").[1] BIO is the largest trade association to serve and represent the biotechnology industry in the United States and around the globe. Indeed, BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations. BIO members are involved in the research and development of healthcare, agricultural, industrial, and environmental biotechnology products.

Many of the therapies developed by biotechnology companies target conditions that primarily affect the Medicare population. BIO has long been a strong supporter of the Medicare Part D prescription drug benefit and appreciates CMS's significant efforts to implement this program. We believe that the Part D benefit has helped increase patient access to critical therapies as well as ensure that patients will be able to receive and afford the treatments that best meet their needs. We continue to encourage CMS to focus on patient access in its ongoing implementation and refinement of this important program.

BIO is extremely concerned, however, that the Proposed Rule, specifically CMS's proposal to roll back the critical protection afforded by the current six "protected classes," will severely limit patient access to the drugs most appropriate for them. Not only are the proposed criteria for evaluating categories and classes of "clinical concern" overly restrictive, these criteria were applied to eliminate protected classes before they were finalized and without

[1] 79 Fed. Reg. 1918 (Jan. 10, 2014).

1201 Maryland Avenue SW
Suite 900
Washington DC 20024
202.962.9200 P
202.488.6306 F
bio.org

input from a broad group of external stakeholders. Moreover, the numerous exceptions, both current and proposed, threaten to undermine the very purpose of the protected classes policy: to ensure timely access to medically necessary therapies. We also believe that CMS's proposal to eliminate protected status for mental health drugs is not only bad public policy, but also moves in the opposite direction of other government-wide efforts to expand access to these critical therapies.

We also have serious concerns with respect to other aspects of the Proposed Rule, including CMS's proposed non-interference regulation, as the proposed exceptions thereto appear to give CMS authority to interfere with private contract negotiations, contrary to the intent of Congress. We also believe that CMS's proposal to limit Part D sponsors to two enhanced Part D plans (PDPs) per region, together with CMS's proposal on protected classes and the Agency's existing policy to terminate plans that fall below the three-star rating, threatens to significantly limit beneficiary options with respect to the medical therapies covered by their PDPs. Finally, we are concerned that CMS's proposed transparency requirements for purposes of the Medicare Coverage Gap Discount Program (CGDP) fail to ensure that the benefit of the discounts provided under program inure to beneficiaries enrolled in Employer Group Waiver Plans (EGWPs), as required by the statute. We address each of these concerns, in turn, below.

In light of these very grave concerns, we urge CMS to withdraw the Proposed Rule in its entirety to enable the Agency to address these issues in a future notice of proposed rulemaking. This delay would have the added benefit of mitigating concerns that implementation of the protected class proposal in contract year 2015 could "throw a wrench" into the 2015 call letter process, given that these deliberations are slated to occur before the Proposed Rule could be made final.[2] That said, we believe that future rulemaking should retain certain, limited, aspects of the Proposed Rule, including CMS's expansion of the Part D Medication Therapy Management (MTM) program to additional beneficiaries and disease states, as well as the additional clarity that CMS provides with respect to transition fills and its proposal to provide industry access to Medicare data. We are also supportive of CMS's proposals regarding preferred cost-sharing and MA-PD coordination, but urge CMS to implement certain protections with respect to these proposals.

I. The Part D Protected Classes Continue to Serve a Critical Purpose

Contrary to CMS's statements throughout the preamble to the Proposed Rule that the existing protected classes are no longer necessary,[3] we believe that the legislative history of the Part D program, and section 1860D-4(b)(3)(G) of the Social Security Act (SSA) in particular, indicates that Congress firmly believes in the continued need for protected classes under Medicare Part D.

To begin with, as evidenced by the following colloquy between members of the U.S. Senate prior to the enactment of the law that established the Part D benefit—the Medicare

[2] Inside Health Policy, Protected Class Proposed Rule Could Throw a Wrench in Call Letter Negotiations (Jan. 2014), available at: http://insidehealthpolicy.com/201401272459304/Health-Daily-News/Daily-News/protected-class-proposed-rule-could-throw-wrench-in-call-letter-negotiations/menu-id-212.html?s=mu.

[3] See 79 Fed. Reg. at 1937.

Prescription Drug Improvement and Modernization Act (MMA)[4]—Congress' initial intent was to include substantial patient protections with respect to the current protected classes:

> Mrs. FEINSTEIN.
>
> Mr. President, I am concerned about . . . beneficiaries who are living with HIV/AIDS. . . . Is it your understanding that the Medicare conference report will not prevent low-income Medicare beneficiaries who are living with HIV/AIDS from getting all the drugs they need through Medicare Part D?
>
> Mr. BAUCUS.
>
> That is correct, Senator. One of the things I am particularly proud about in this bill is the strong beneficiary protections . . . . You know, Senator Grassley, that there are certain diseases and conditions – like AIDS, and epilepsy – where having access to just the right medicine is especially important.
>
> Mr. GRASSLEY.
>
> I did know that, and I know that certain mental illnesses also fall in that category. This bill contains a number of protections for people who need exactly the right medicine for them.
>
> Mrs. FEINSTEIN.
>
> . . . . [N]o low-income Medicare beneficiaries who have HIV/AIDS will be denied access to the drugs they need in Medicare Part D?
>
> Mr. BAUCUS.
>
> Exactly. . . . [W]e require drug plans to offer at least two drugs in each therapeutic class. And for drugs that treat AIDS, epilepsy, or mental illness, we would expect that plans would carry all clinically appropriate drugs.
>
> Mr. GRASSLEY.
>
> I agree. And I am pleased with the backup protections in this bill.[5]

As CMS is aware, CMS then established its protected classes policy at the beginning of the Part D program in 2006 "because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain PDPs, as well as to mitigate the risks and complications associated with an interruption of

[4] Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003).
[5] 149 Cong. Reg. at S15887-88 (Nov. 25, 2003) (emphasis added).

therapy for these vulnerable populations."[6] In 2008, Congress codified CMS's protected class policy by enacting section 176 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA),[7] which added new section 1860D-4(b)(3)(G) to the SSA. This section provided that, "[b]eginning with plan year 2010, the Secretary shall identify, as appropriate, categories and classes of drugs for which both of the following criteria are met: . . . (I) Restricted access to drugs in the category or class would have major or life threatening clinical consequences for individuals who have a disease or disorder treated by the drugs in such category or class . . . (II) There is significant clinical need for such individuals to have access to multiple drugs within a category or class due to unique chemical actions and pharmacological effects of the drugs within the category or class, such as drugs used in the treatment of cancer."

Then, in 2010, Congress reaffirmed its support for the Part D protected classes by enacting section 3307 of the Affordable Care Act.[8] This section replaced MIPPA's criteria by granting the Secretary the authority to define criteria for identifying categories and classes of drugs of "clinical concern" and added the requirement that PDP sponsors "include all covered Part D drugs" in these categories and classes.[9] Notably, this section specifically identified the existing six protected classes—anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosupressants for the treatment of transplant rejection—and required the Secretary to retain these classes pending the identification of the new criteria.[10] The ACA did not set a deadline for CMS to implement the new statutory requirements with respect to the protected classes, however, meaning that CMS could withdraw this Proposed Rule without running afoul of any statutory timeframes.

Beyond the intent of Congress, we firmly believe that the protected classes continue to serve CMS's original aim of mitigating the risk of complications associated with an interruption of care for vulnerable Medicare beneficiaries by protecting their access to therapies that are most appropriate for them. This protection is particularly critical for beneficiaries with the complex conditions addressed by the current protected classes.

A plan that includes a limited number of therapies from the antineoplastics category, for example, will necessarily be discriminating against individuals with certain types of cancer. Cancer treatment is complex, and the types of agents used continue to evolve rapidly. 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. Thus, it has been critical for cancer patients that CMS has required that all of these therapies be on a plan formulary, in order to ensure that the full range of these therapies are available to Medicare beneficiaries.

Similarly, with respect to antiretrovirals, as CMS recognizes in the preamble to the Proposed Rule, there are a "number of multiple drug combinations and adjunctive therapies involved," drug protocols are subject to change, and changing drug resistance plays a role "in

6 CMS, Pub. 100-18 – Medicare Prescription Drug Benefit Manual, Ch. 6 § 30.2.5.
7 Pub. L. No 110–275, 122 Stat. 2581 (July 15, 2008).
8 Pub. L. No. 111-148, 124 Stat. 471 (March 23, 2010).
9 Id. at § 3307 (emphasis added).
10 SSA § 1860D-4(b)(3)(G)(iv).

determining the selection of among the different antiretroviral drugs."[11] Moreover, "[t]he need to adjust specific combination antiretroviral therapy in real time is complex and must consider, among other things, viral sensitivity to the drugs, drug interactions, pregnancy status (if applicable), and potentially the patient's pharmacogenomic profile of the cytochrome P450 system."[12]

The same is true for all of the classes that CMS has recognized as protected since the beginning of the Part D benefit, each of which helps ensure that Medicare's most vulnerable patients have access to the range of therapies they need.

While we understand that antineoplastics, antiretrovirals, and anticonvulsants are not currently at risk of losing their protected status, we are deeply concerned that the criteria CMS proposes to apply in identifying protected classes fail to fully take into account the negative impacts of delaying access to these therapies. Based on the available scientific evidence, as well as the current treatment guidelines of relevant specialty societies, it is essential that Medicare beneficiaries have access, without onerous restrictions, to the full range of medications in these categories to best meet their individualized needs. Moreover, we believe that CMS's proposed exceptions will allow plan sponsors substantial discretion to limit access to even those therapies that retain protected status, which continues to raise the risk of discrimination against beneficiaries with these conditions. Each of these concerns is described in greater detail, below.

II. CMS's Protected Classes Proposal Appears to be Motivated by Questionable Considerations

Given that the current protected classes continue to serve a critical need, we are therefore concerned that the driving force behind CMS's proposal is cost cutting without concern for beneficiary access to care. As an initial matter, we believe it is highly questionable that cutting back the protected class policy can generate savings in a market that is largely generic, particularly given that the current exceptions to the protected class policy allow for generic preference through prior authorization and step-therapy for patients initiating a new therapy (aka "new starts"). Indeed, the protections currently offered by the protected classes are generally focused on patients who have been stable on existing drugs, and while removing those protections may impact patient outcomes, it is unlikely to generate savings (and may even increase costs) to the Medicare program.[13]

Furthermore, CMS's claims around savings tied to the proposed policy are based largely on estimates by PDPs (the entities most likely to benefit from the proposed change). Indeed, one of the sources CMS relies on for its cost-savings justification—the Milliman study—relies

[11] 79 Fed. Reg. at 1944.
[12] Id.
[13] See National Bureau of Economic Research, Effects of Prescription Drug Insurance on Hospitalization and Mortality: Evidence from Medicare Part D, NBER Working Paper No. 19948 (Feb. 2014) (finding that obtaining prescription drug insurance through Medicare Part D was associated with an 8 percent decrease in the number of hospital admissions, a 7 percent decrease in Medicare expenditures, and a 12 percent decrease in total resource use.).

on estimates of potential rebates by PDPs.[14] The referenced OIG Study, "Concerns with Rebates in the Medicare Part D Program," similarly relies on anecdotal statements from these same plans.[15] While one cited study, "The Effect of Medicare Part D on Pharmaceutical Prices and Utilization," does rely on independent data, this study only covers the period through 2006 (i.e., before the protected classes policy was implemented), and thus does not reflect the impact of the protected classes on drug costs.[16]

While CMS claims that the proposed policy was motivated in part by patient welfare concerns, we believe that these claims are overstated and that the evidence cited by CMS to support these statements is inadequate. Indeed, under current policy, plans have the authority—and are in fact required—to use clinical edits in accordance with the FDA-approved label to identify inappropriate and unsafe prescriptions, even with respect to the protected classes.[17] And, if overprescribing is the problem that CMS is aiming to address, the Agency has proposed the wrong solution, as the protected classes preserve the variety, not volume, of therapies available to Part D beneficiaries. We therefore urge CMS to work with PDPs to ensure appropriate prescribing in nursing homes and other settings, rather than endangering access for all patients who rely on therapies at risk for overprescribing.

Finally, we note that CMS's stated patient welfare concerns are undermined by the actual threat posed to patient welfare by restricting the current protected classes policy. This can be illustrated in the context of immunosuppressants, for which CMS has proposed to eliminate protected status. As you may be aware, transplant rejection can begin as soon as several hours after transplant,[18] requiring patients to begin highly-individualized treatment with immunosuppressants immediately after transplant.[19] And, because organ rejection can occur at any point after a transplant, strict adherence to immunosuppressive therapy is required even years after a transplant to prevent rejection.[20] Without robust access to these therapies, patients are thus at risk for transplant rejection, or worse.

For decades, the biopharmaceutical industry has worked to create a wide variety of therapies to treat Medicare beneficiaries. This access is particularly critical with respect to the current six protected classes. Part D formularies should thus preserve the ability of beneficiaries and their providers to select an appropriate treatment within these categories based on individual needs and physician-choice.

---

[14] 79 Fed. Reg. at 1938 (citing "Potential cost impacts resulting from CMS guidance on 'Special Protections for Six Protected Drug Classifications' and Section 176 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (PL 110-275)," available at http://amcp.org/WorkArea/Download.Asset.aspx?id=9279).

[15] See id. at 1937-38 (citing HHS Office of Inspector General, "Concerns with Rebates in the Medicare Part D Program", March 2011, OEI-02-08-00050).

[16] See id. at 1938 (citing Duggan M., Morton FS. 2010. "The Effect of Medicare Part D on Pharmaceutical Prices and Utilization," American Economic Review, American Economic Association, vol. 100(1), pages 590-607).

[17] See 74 Fed. Reg. 2881, 2883 (Jan. 16, 2009).

[18] Actor, J. K. 2012. *Elsevier's Integrated Review: Immunology and Microbiology*, Transplantation: Control of Immune-Mediated Rejection. Atlanta, GA: Elsevier, Except Available at: https://www.inkling.com/read/elseviers-integrated-review-immunology-and-microbiology-actor-2nd/chapter-8/transplantation-control-of.

[19] UPMC (University of Pittsburg Medical Center). 2014. *Weaning Transplant Recipients from Immunosuppressive Drugs*. Available at: http://www.upmc.com/services/transplant/abdominal-transplants/starzl-institute/pages/drug-weaning.aspx.

[20] UNC (University of North Carolina). 2014. Kidney Transplant: How long will I have to take anti-rejection medications? Available at: http://www.unckidneycenter.org/kidneyhealthlibrary/kidneytransplant.html#antirejection.

III. Existing Beneficiary Protections are Insufficient

Throughout the preamble to the Proposed Rule, CMS relies heavily on the existence of certain regulatory beneficiary protections as grounds for its proposal to restrict, and in some cases eliminate, the existing protected classes.[21] We believe that this reliance is ill-founded, however. Indeed, experience from the Part D program and elsewhere indicates that the cited beneficiary protections are not always sufficient and do not provide the same level of protection as the protected classes themselves.

Take, for example, the cited "formulary requirements."[22] As an initial matter, since the elimination of the "formulary key drug designation" from the U.S. Pharmacopeia's Medicare Model Guidelines (MMG) (the standard for PDP formulary inclusiveness)—which historically had provided an additional layer of granularity to the MMG, helping to ensure that a wide range of drugs were on the formulary—it has been harder for stakeholders to determine what CMS actually does in reviewing formularies, and whether that review really adequately captures potential formulary deficiencies. While CMS provides an unprecedented level of detail on its formulary review process in this preamble, in general, the process remains opaque, as it is still not clear how robust each of the steps in the review process are (e.g., what sources are used, how sources' methodological rigor and potential bias are assessed, the process for handling potentially conflicting information from multiple guidelines). Unless and until CMS formalizes and/or strengthens its formulary review steps, we do not believe that this can serve as an adequate substitute for the protected classes policy. We also take particular issue with CMS's reliance on three of the specific "formulary requirements" referenced in the rule.

First, because the cited "treatment guidelines review"[23] is based on "widely accepted treatment guidelines," CMS does not and cannot take into account innovative therapies or evolving standards of care as part of this process and is less likely to capture information relevant for those with rare forms of diseases treated by drugs in the current protected classes. We find this especially worrisome, given that evolving standards of care and the need for personalized treatment plans for individual patients are so prevalent in the context of the current six protected classes.

Second, we are extremely concerned about the cited "specialty tier review."[24] As we have articulated elsewhere, the current negotiated drug price-per-month threshold ($600) allows for the inclusion of far too wide a range of therapies on the specialty tiers of PDPs. Patients prescribed drugs or biologicals on these specialty tiers are uniquely at risk for high out-of-pocket costs, and are usually those with some of the most complex diseases or conditions to treat. Thus, high cost-sharing challenges their access and adherence to these treatments. Although provisions for CMS to review plans' specialty tiers do exist—as CMS notes in the preamble to the Proposed Rule—we do not view this review to be a particularly robust protection, as such reviews have not been capable of rectifying the discrimination against

21 See 79 Fed. Reg. at 1938.
22 Id. at 1939.
23 See 42 C.F.R. § 423.120(b)(2)(iii).
24 See 42 C.F.R. § 423.578(a)(7).

Medicare's most vulnerable beneficiaries inherent in the cost-sharing structure of specialty tiers.

Third, notwithstanding the referenced "restricted access review,"[25] Part D beneficiaries still face substantial access issues as the result of prior authorization and step therapy requirements.[26] These utilization-management techniques create real barriers to accessing medically necessary therapies and a not-insubstantial administrative burden for providers. Take, for instance, the case in which a patient learns of a prior authorization requirement at the pharmacy where they go to fill their prescription. To obtain the drug his or her doctor prescribed, this patient must: (1) leave the pharmacy without the drug; (2) make an appointment or otherwise arrange to obtain prior authorization from their physician; (3) have their provider submit a prior authorization request; and (4) return to the pharmacy to obtain the drug, assuming that the prior authorization request has been approved.

While this process imposes a burden on all patients and providers, imagine that this patient has a serious mental illness, such as schizophrenia or severe depression. That these patients are at increased risk for more costly outcomes and active mood or psychotic symptoms does not help with their decision-making process and these patients consequently are at a far greater risk of not returning to obtain their medications. Thus, rather than follow the four steps described above, a symptomatic schizophrenic or depressed individual might resort to self-harm or non-adherence, potentially resulting in subsequent re-hospitalization.

We have further concerns regarding this "restricted access review," including that it is conducted against "best practices" that may not take into account the evolving standard of care or the needs of particular patients. For instance, the "step therapy criteria review,"[27] is conducted against "best practices," but it is not clear how these "best practices" are defined, while the "prior authorization criteria review"[28] is conducted by reference to "best practices" defined by the insurance industry, and therefore may not necessarily be designed to match the clinical needs of individual patients or the judgment of their providers. Similarly, the applicable regulations allow PDPs to retain significant prior authorization edits if they can provide a "reasonable justification," yet "reasonable" according to whom is unclear. Likewise, we are concerned that the prior authorization outlier review, under which CMS reviews utilization management policies to identify prior authorization "outliers," encourages a "race to the bottom" among PDPs.

We find the remaining beneficiary protections similarly lacking. For instance, while we believe that the "coverage determination and appeal process" is an important beneficiary protection, we note that this process inherently involves a delay in treatment for

---

[25] See 42 C.F.R. § 423.153(b).

[26] For instance, with respect to anticonvulsants, a study by Avalere found that: (1) commercial plans had higher levels of coverage of anticonvulsants than PDPs; (2) commercial plans placed more covered anticonvulsants on lower tiers than PDPs; and (3) cost-sharing on tiers one and two were higher for commercial plans than PDPs. Avalere, An Analysis of Access to Anticonvulsants in Medicare Part D and Commercial Health Insurance Plans (June 2013), available at: http://www.avalerehealth.net/research/docs/Anticonvulsants_in_Part_D_and_Commercial_Health_Insurance.pdf.

[27] See id.

[28] See id.

beneficiaries that can have real health implications. This delay is most pronounced at the higher levels of the appeals process. Indeed, Nancy Griswold, the chief judge of the Office of Medicare Hearings and Appeals (OMHA), announced in a December 2013 memorandum that her office has a backlog of nearly 357,000 claims and that it often takes up to sixteen months before a claim is even heard by an Administrative Law Judge (ALJ).[29] The exceptions and appeals process also imposes a substantial burden on providers, who often bring exceptions and appeals claims on behalf of their patients, and who also face substantial delays throughout this process. Shockingly, Medicare providers are presently barred from bringing level three appeals before the OMHA. And it goes without saying that this process is not a guarantee that a beneficiary will ultimately obtain coverage for the particular drug that his or her physician has prescribed.

Finally, the other cited beneficiary protections (e.g., mid-year formulary change restrictions,[30] reassignment formulary change notices,[31] and transition requirements[32]) do not afford protections for beneficiaries starting a new therapy, but rather serve to protect access and inform decisions of beneficiaries on a long-term course of treatment. This does nothing for the many beneficiaries who are diagnosed with a new condition or prescribed a new medication in the middle of a plan year or after they are transitioned to a new plan and thus unable to benefit from these protections. Similarly, CMS states in the preamble to the Proposed Rule that the Agency is "not aware of any Part D drug that is not included on at least one Part D formulary."[33] However, we note this fact, standing alone, does little, if anything to support that the current beneficiary protections are sufficient. Not only does this statistic fail to demonstrate the effects of the Part D program's other beneficiary protections in the absence of the current protected classes policy (which applied during all of the "more than 7 years of experience" the Agency has with the program), it fails to recognize that patients do not have access to all Part D formularies. Instead, they can only select from those plans in their geographic area. Not only is CMS proposing to restrict the number of plan options, as described in greater detail below, but low-income subsidy (LIS) patients have an even more restricted set of choices available for no premium (this has been as low as one or two in some regions). And it goes without saying that beneficiaries can only select one plan. So, to the extent a Part D beneficiary has multiple medical conditions—as many do—the fact that each of the drugs they need is covered by one plan, which may not even be available to them, may be of little benefit.

Meanwhile, there are protections specific to the protected classes that are not available to other categories of drugs. For instance, in addition to the requirement that PDPs cover all drugs in a protected class, new drugs in the protected classes are subject to an expedited P&T committee review.[34]

---

[29] Letter from Nancy Griswold, Chief Judge of the office of Medicare Hearings and Appeals (OMHA) to OMHA Medicare Appellants (Dec. 2013), available at: http://capsules.kaiserhealthnews.org/wp-content/uploads/2014/01/nancy-griswold-Medicare-appeals.pdf.

[30] 42 C.F.R. § 423.120(b)(5); CMS, Pub. 100-18 – Medicare Prescription Drug Benefit Manual, Ch. 6 § 30.3.3.

[31] Supra note 8 at § 3304.

[32] 42 C.F.R. § 423.120(b)(3); CMS, Pub. 100-19 – Medicare Prescription Drug Benefit Manual, Ch. 6 § 30.4.

[33] 79 Fed. Reg. at 1939.

[34] See CMS, Pub. 100-18 – Medicare Prescription Drug Benefit Manual, Ch. 6 § 30.2.5.

IV. CMS's Proposed Criteria for Identifying Categories and Classes of "Clinical Concern" Would Not Sufficiently Protect Beneficiary Access

BIO is very concerned that CMS's proposed criteria for identifying categories and classes of "clinical concern" are overly restrictive and thus insufficiently protect beneficiary access to therapies.[35] Specifically, in order to be considered a protected class, CMS proposes to require that:[36]

> . . . the drug category or class of drugs for a typical individual with a disease or condition treated by the drugs in the category or class meets both of the following criteria (as determined by CMS):
>
> 1. Hospitalization, persistent or significant disability or incapacity, or death likely will result if initial administration (including self-administration) of a drug in the category or class does not occur within 7 days of the date the prescription for the drug was presented to the pharmacy to be filled; and
>
> 2. More specific CMS formulary requirements will not suffice to meet the universe of clinical drug-and-disease-specific application due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations.

As an initial matter, we note that the seven-day period articulated in this first criterion is based on the applicable appeals processes running flawlessly up to the Independent Review Entity (IRE) level. CMS has provided no information that this process works in a timely fashion, and patients with mental illness are likely to have unique problems navigating this system, as described above.

We also believe that the first criterion is overly restrictive because beneficiary need for a drug is defined by reference to only the gravest of outcomes, including death. This criterion thus fails to recognize that even a seven-day delay in access to treatment for beneficiaries can have lesser, but not insubstantial, adverse outcomes. For instance, delayed access to the appropriate mental health drugs can have result in a patient harming to himself, harming others, or relapsing (with the associated risks of decreasing brain function). Moreover, because this standard is defined at a population level (i.e., for a "typical individual"), it necessarily does not take into account the disease severity or complexity of individual patients. Additional limitations to this approach include that it does not expressly take into account whether delayed access to the drug would, in turn, lead to a delayed initiation of other treatments, that some drugs take a longer time to take effect, or that delayed access could result in increased costs to the Medicare program elsewhere. For instance, CMS has not taken into account the impact of Major Depression Disorder (MDD) on hospitalization and the need for multiple later-line therapies to provide adequate

[35] See 79 Fed. Reg. at 1941-42.
[36] Id. at 1942.

treatment for this condition. Moreover, as described in greater detail below, CMS has applied these criteria behind closed doors, without providing a mechanism for patients, providers, manufacturers, and other stakeholders to challenge the ultimate determination.

While the first criterion leaves much to be desired, we find the second criterion to be even more problematic. Specifically, we believe that the proposed language of this criterion lacks clear, objective standards, thereby giving the Agency near-limitless discretion to eliminate any given protected class for reasons other than those envisioned by Congress. This is evidenced by CMS's emphasis on the costs associated with drugs in the currently protected classes and its failure to comprehensively review the myriad of disease states and medical treatments in each such class.

CMS's approach to reviewing the current protected class of anti-psychotics illustrates the subjectivity with which the second criterion may be applied.[37] Specifically, in analyzing anti-psychotics under this criterion, CMS notes that "the panel concluded that antipsychotics did not have unique effects that distinguished one drug from another for the purposes of choosing the appropriate drug to initiate therapy," yet guidance issued by the American Academy of Family Physicians notes that a broad class of antipsychotics is required in order to allow physician choice to manage side-effects of the medication.[38] Moreover, CMS gives only examples from one psychotic condition (schizophrenia) to support its conclusion that the class did not satisfy criterion number two, which suggests that CMS may not have reviewed the universe of psychotic disorders in analyzing this category of drugs under the second proposed criterion. Indeed, CMS states that many antipsychotics are interchangeable, and even cites clozapine, yet the USP classification calls out the differences between clozapine and other atypical antipsychotics. Finally, CMS's review does not appear to recognize that the treatment standards for psychotic disorders continue to evolve rapidly, as clinical science is better able to differentiate between different sub-types of these conditions.

CMS's review of the immunosuppressant drug category is similarly deficient. Indeed, while CMS found that this class met criterion number one, the Agency flatly articulated that "[b]ecause widely-accepted treatment guidelines recommend sub-classes of drugs rather than specific, individual drugs, the panel did not believe that every drug product should be required for inclusion on Part D sponsors' formularies."[39] Not only is this statement conclusory, it evidences that CMS is not even taking into account current beneficiary protections, as would arguably be required under the second criterion, as proposed by the Agency itself. Specifically, in spite of evidence that beneficiaries need access to sub-classes of immunosuppressive drugs, existing beneficiary protections afford access to only two drugs per class—there is no current requirement that PDPs cover all sub-classes of a given category or class.[40] Furthermore, it is not clear that the "widely-accepted treatment guidelines" that CMS proposes to use in establishing "additional, specific formulary requirements" with respect to immunosuppressive therapies would reflect the evolving

---

37 See id. at 1945.

38 American Academy of Family Physicians, Adverse Effects of Antipsychotic Medications (March 1, 2010), available at: http://www.aafp.org/afp/2010/0301/p617.html.

39 79 Fed. Reg. at 1945.

40 See 42 C.F.R. § 423.120(b)(2)(i).

standard of care with respect to these products, making this hardly a substitute for protected class status.

Other limitations of the second criterion include that it does not assess the appropriateness of drugs within the class for individual patients with different clinical presentations of a disease, and that it looks only to whether a theoretical patient would need multiple drugs as first-line therapy but not whether it may be necessary to use a specific drug for subsequent therapy.

V. CMS Should Wait to Evaluate the Protected Classes Against the Proposed Criteria Until Stakeholders Have Had an Opportunity to Comment on the Criteria

In light of the statutory requirement that the Secretary establish criteria and any exceptions "through the promulgation of a regulation which includes a public notice and comment period,"[41] we urge CMS to delay review of the existing protected classes against the proposed criteria until there has been an opportunity for public comment (and CMS's review thereof) with respect to the criteria themselves.

Furthermore, once CMS finalizes the criteria, we urge the Agency to use a data-driven process that involves a diverse group of stakeholders to assess the current—and any potential new—protected classes. By contrast, the process CMS used to evaluate the protected classes for purposes of the Proposed Rule was not as "data driven" as the process the Agency had discussed in earlier rules on this topic.[42,43] We also urge CMS to consider only the need for beneficiary access to medically necessary drugs as part of this review.

As stated previously, BIO is extremely concerned that the proposed criteria were applied without beneficiary protections in mind. Instead, CMS appears to have reverse-engineered the criteria after deciding which currently protected classes to eliminate for the sole purpose of reaping cost savings on behalf of PDPs. For instance, in discussing the anti-psychotics protected class, CMS states "[i]n addition to any cost savings that would result from the proposed change for the anti-psychotic drug class, it is important to emphasize that the change also would provide Part D sponsors with an improved capability to address widespread inappropriate overuse of anti-psychotic drugs through better utilization management."[44] In short, CMS appears to have first identified the cost savings to PDPs from eliminating the protected class, and then articulated the second criterion in order to

---

41 SSA § 1860D-4(b)(3)(G)(iii).

42 See, e.g., 74 Fed. Reg. 54,634, 54,688 (Oct. 22, 2009) ("We continue to believe that the best way to determine which drug classes meet the MIPPA criteria is through a data-driven process, which includes an analysis of prescription drug event data, a review of widely used treatment guidelines, validation of the results by a expert committee of clinicians, and acceptance by the Secretary.").

43 For instance, based on the Protected Classes Review Panel document made available together with the rule, the review appears to have involved only CMS staff (i.e., a panel of CMS pharmacists and the Chief Medical Officer for the Center for Medicare) and does not appear to have considered the universe of medical conditions, or the current and evolving treatment options. See Center for Medicare, Protected Class Review Panel, available at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_FOrmularyGuidance.html (last visited Jan. 27, 2013).

44 79 Fed. Reg. at 1945.

make this possible. This is not what Congress intended in codifying the protected class policy.

If CMS nonetheless insists on considering costs as part of this analysis, we urge the Agency to consider not only the potential immediate cost savings of eliminating a class, but also the long-term expenses associated with its elimination across the entire continuum of care. While costs were clearly considered in promulgating this Proposed Rule, it appears that CMS did not, as part of its analysis, consider the potential increase in costs to other aspects of the Medicare program that could result from eliminating any of the protected classes (e.g., hospitalization, readmissions), and appears to have assumed that the proposed policy would cause absolutely no access problems, which is unreasonable. We believe that this siloed approach to assessing Medicare costs is extremely short-sighted in that it limits CMS's ability to set coherent and medially sound policies with respect to the entire Medicare program.

VI. Elimination of the Mental Health Protected Classes is Contrary to Good Public Policy

We believe that CMS's proposal to eliminate the protected status for mental health drugs—namely antidepressants and eventually antipsychotics—is not responsible public policy. We are not alone in this belief: the nation is increasingly focused on supporting access to better mental health care. For example, the Congress and the current administration have both shown an interest in mental health treatment, as evidenced by Congress' inclusion of mental health protections in the Affordable Care Act,[45] the President's National Conference on Mental Health,[46] the recently released Mental Health Parity Final Rule,[47] and the Vice President's recent announcement that $100 million will soon be available to increase access to mental health services and improve mental health facilities.[48] Similarly, many states have taken steps to ensure access to mental health drugs, including by codifying protected status for mental health drugs under their Medicaid programs and enacting laws mandating robust mental health coverage by private insurers.[49]

---

[45] Specifically, section 1302 of the Affordable Care Act established the requirement that all qualified health plans offered through the Exchanges extend coverage to "mental health and substance abuse disorder services, including behavioral health treatment" as part of the Essential Health Benefits, which is extended to all "health insurance issuers that offer[] health insurance in the individual or group market" by section 1201 of the Act. Meanwhile, section 1311(j) requires qualified health plans to comply with federal mental health parity requirements.

[46] The White House, National Conference on Mental Health, http://www.whitehouse.gov/blog/2013/06/03/national-conference-mental-health (last accessed Jan. 31, 2014).

[47] In late 2013, the Department of Health and Human Services (HHS) finalized regulations that apply federal parity rules to mental health and substance use disorder benefits included in Essential Health Benefits. As a result, Americans accessing coverage through non-grandfathered plans in the individual and small group markets will now be able to count on mental health and substance use disorder coverage that is comparable to their general medical and surgical coverage. See 78 Fed. Reg. 68,240 (Nov. 15, 2013). Meanwhile, the VA and DoD are also working to expand access to these products pursuant to a recent Executive Order. See Executive Order—Improving Access to Mental Health Services for Veterans, Service Members, and Military Families (Aug. 31, 2012).

[48] The White House, Vice President Biden Announces $100 Million to Increase Access to Mental Health Services (Dec. 10, 2013), available at:http://www.whitehouse.gov/the-press-office/2013/12/10/vice-president-biden-announces-100-million-increase-access-mental-health.

[49] See, e.g., National Conference of State Legislatures, Mental Health Benefits State Mandates, http://www.ncsl.org/research/health/mental-health-benefits-state-mandates.aspx (last accessed Jan. 29, 2014); National Conference of State Legislatures, Medicaid Pharmaceutical Laws and Policies,

It is imperative that Medicare follow this example. Mental illness impacts the Medicare population significantly: approximately 18 percent of those over 65 years-old suffer from depression.[50] Restricting access to these products under Part D not only moves in the opposite direction, but may result in increased costs to the Medicare program elsewhere (e.g., as a result of increased hospitalizations), and even lower medication adherence rates.[51] Rather than uniformly restrict beneficiary access to these products, we believe that there are better, more targeted ways for CMS to address its concerns regarding the potential abuse of mental health drugs, including through the use of the safety edits described above as well as the proposal to revoke Medicare enrollment for physicians with abusive prescribing practices.

VII. The Proposed Exceptions Threaten to Limit Beneficiary Access to Drugs

BIO is very concerned that CMS's proposed exceptions would substantially undermine the Agency's protected class policy.[52] Specifically, while some of the proposed exceptions serve merely to re-state current regulations or to codify current policy, we are concerned that two of CMS's proposals expand the scope of the current exceptions and will thus threaten beneficiary access to care. We also believe that, in implementing this new protected classes policy, CMS should reconsider at least two of its existing exceptions.

With respect to CMS's proposed new exceptions, we are first concerned about proposed section 42 C.F.R. § 423.120(b)(2)(vi)(D), which would except "[f]ixed combination dosage form prescription drugs other than antiretrovirals, including co-packaged drug products . . ." from inclusion under a protected class. CMS carves out antiretrovirals from this exception on the basis that "the risk associated with non-adherence when beneficiaries have to take the single-entity products has far more severe consequences [in the case of antiretrovirals] . . . than in most other instances, where occasional non-adherence does not present such dire complications."[53] This justification inappropriately overlooks the significant impact of non-adherence to drugs in the current protected classes, especially given non-adherence trends already driven by the often higher cost-sharing requirements imposed on drugs in the current protected classes (e.g., through placement on a plan's specialty tier).

For instance, there are combinations of antidepressants and antipsychotics in use today that have many benefits for patients, not the least of which is improved adherence. Additionally, as cancer care transitions from acute to chronic, there is an increasing market for innovation in fixed-dose combination therapies, as these have a unique potential to improve

---

http://www.ncsl.org/research/health/medicaid-pharmaceutical-laws-and-policies.aspx (last accessed Jan. 29, 2014).

[50] National Alliance on Mental Illness (NAMI). 2009. *Depression in Older Persons Fact Sheet*. Arlington, VA:, NAMI, Available at: http://www.nami.org/Template.cfm?Section=By_Illness&template=/ContentManagement/ContentDisplay.cfm&ContentID=7515.

[51] See MB Tamburrino, RW Nagel, MK Chahal, DJ Lynch, *Antidepressant Medication Adherence: A Study of Primary Care Patients*. Prim Care Companion J Clin. Psychiatry. 2009; 11(5): 205–211 ("Over recent years, it has been recognized that most patients with depression are treated in primary care settings and that the depression is often undertreated. One of the reasons for undertreatment is nonadherence to antidepressant medication.")

[52] See 79 Fed. Reg. at 1942.

[53] Id. at 1943.

the efficacy of the overall treatment course, decrease negative side-effects, and increase patient adherence (seen as a result of their use in other chronic diseases like HIV/AIDS). However, if finalized, this proposed exception would undermine beneficiary access to these drugs, and thus disincentivize innovation in this space, while driving down adherence in the very beneficiary populations that the Proposed Rule aims to protect.

Second, we are concerned about proposed section 423.120(b)(2)(vi)(B), which would make an exception from the protected classes policy "for drug products that are almost always covered under Medicare Parts A or B."[54] While we understand that these drugs are "generally covered under Part B," we disagree with CMS's conclusion that "their absence from drug formularies would not disrupt access." As CMS inherently recognizes by referring to these drugs as "almost always" covered under Parts A or B, there are instances in which they are not so covered (incidentally, CMS expressly states as much in a subsequent section of the preamble to this same Proposed Rule).[55] Indeed, as illustrated in the Medicare Prescription Drug manual, the same drug may be covered under either Part D or Part B, depending on factors such as the characteristics of the beneficiary, medical use of the drug, or route of administration.[56] Thus, excluding all drugs that are "almost always" covered under Part B from the Part D protected classes ignores those cases in which such drugs are actually covered under Part D, and thus unfairly restricts access for the beneficiaries who rely on these therapies.

As noted above, we also believe that CMS should reconsider two of its existing exceptions to the protected classes policy that permit PDPs to implement prior authorization requirements. We are concerned that these exceptions can delay patient access to drugs with protected status, thereby undermining a critical purpose of the protected class policy: ensuring immediate access to these indispensable therapies. We are particularly concerned about the exception under which PDPs may apply prior authorization requirements to determine whether a drug is prescribed for a medically accepted indication. While we appreciate that the "medically accepted indication" standard is a condition of coverage under Medicare Part D,[57] it can be time-consuming to make this determination, especially with respect to oncology products for which medical compendia and peer-reviewed literature must be taken into account.[58] We therefore urge CMS to ensure that the application of this standard does not delay access to drugs, and is not used as a means of discouraging use of specific therapeutic agents, particularly for those therapies with protected status.

In addition, in the preamble to the Proposed Rule, CMS discusses its existing policy "to allow Part D sponsors to implement prior authorization, including PA used to implement step therapy requirements, to convert beneficiaries to preferred alternatives within these drug

---

[54] Id. (42 C.F.R. 423.120(b)(2)(vi)(B) [proposed]).

[55] See id. at 2009 ("'Part D' drugs do not include drugs for which payment as so prescribed and dispensed or administered to an enrollee is available for that enrollee under Part A or Part B. In other circumstances, these drugs are covered under the Part D benefit, but coverage generally cannot be determined based solely on the drug itself").

[56] CMS, Medicare Prescription Drug Manual, Ch. 6, App. C – Attachment I, available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf.

[57] See SSA § 1860D-2(e)(1).

[58] See SSA § 1860D-2(e)(4)(A) (defining the term "medically accepted indication" for purposes of a covered part D drug used in an anticancer chemotherapeutic regimen).

categories or classes for enrollees who are initiating therapy (new starts)."[59] As with proposed section 42 C.F.R. § 423.120(b)(2)(vi)(D), this existing policy threatens to severely restrict immediate beneficiary access to the categories and classes that CMS has gone through the trouble of deeming "protected." Therefore, BIO urges CMS to extend the policy it has adopted in the in the Medicare manuals with respect to maintenance therapies to new starts, namely that "Part D sponsors may not implement prior authorization or step therapy requirements that are intended to steer beneficiaries to preferred alternatives within these classes . . . .".[60]

VIII. CMS Should Rescind Its Proposal to Limit Plan Sponsors to Two Enhanced PDPs per Region

BIO also has concerns with respect to the Proposed Rule aside from the protected classes proposal, including CMS's proposal to further decrease the number of PDPs available in each service area.[61] This policy would needlessly restrict beneficiary choice.

Robust private competition has kept Medicare Part D working well to generate lower costs for seniors, while providing broader choice for enrollees. The success of this market-oriented program is evidenced by the stability of the average beneficiary premium (which has remained at approximately $31 for the last four years) [62] and overwhelming support—as high as 90 percent—by seniors.[63] Particularly if CMS finalizes the proposed changes to the protected classes, and continues to terminate plans that do not meet the three-star metric under section 423.509(a)(13), we believe CMS should retain all other applicable protections to ensure that beneficiaries are able to choose a prescription drug plan that not only accommodates their medical needs, but is also affordable. Moreover, further limiting the number of plans is unnecessary because plan options in any given service area are already limited by a "meaningful difference" standard that prevents duplicative plan offerings. [64] Additional restrictions may therefore serve only to restrict beneficiary choice and undermine the market-based nature of the Part D program.

IX. CMS Should Ensure That Its Non-Interference Regulation Does Not Permit Agency Intervention in Private Contract Negotiations

BIO appreciates CMS' drive for clarity and specificity in its proposed four-part interpretation of section 1860D-11(i) of the Social Security Act, added by the Medicare Modernization Act (referred to as the "non-interference clause"). We are also supportive of the express limitations CMS proposes on the Agency's ability to interfere with private contract negotiations. For instance, CMS proposes to add new section 423.10(b)(1), which would provide that "CMS is not . . . [a] party to discussions between drug manufacturers and

---

59 Id. at 1943.
60 CMS, Medicare Prescription Drug Manual, Ch. 6 § 30.2.5.
61 79 Fed. Reg. at 2054 (42 C.F.R. § 423.265(b)(3) [proposed]).
62 Department of Health and Human Services (HHS). 2013 (July 30). *Medicare drug premiums remain stable four years in a row*. Washington, DC: HHS, Available at: http://www.hhs.gov/news/press/2013pres/07/20130730c.html.
63 Freeman, M. 2012. Survey: U.S. Seniors Overwhelmingly Satisfied with Medicare Part D Coverage. Medicare Today, Available at: http://www.krcresearch.com/pdfs/PART-D-R.pdf.
64 42 CFR § 423.265(b)(2).

pharmacies or between prescription drug manufacturers and Part D sponsors; nor . . . [a]n arbiter of the meaning of or compliance with the terms and conditions of agreements reached between these parties." Moreover, BIO supports CMS's reading of the first part of section 1860D-11(i)(2)—under which CMS "may not require a particular formulary"—in proposed § 423.10(c), which states: "CMS does not determine the specific drug products to be included on Part D sponsor formularies or any tier placement of such products . . . "

BIO is very concerned, however, about the proposed exceptions to these rules. Indeed, as proposed, it appears that CMS could be a party to discussions between private parties and/or an arbiter of the meaning of compliance with the agreements between these parties "as necessary to enforce CMS requirements."[65] Moreover, as proposed, it appears that CMS could determine the specific drug products to be included on Part D formularies (and their tier placement) to the extent "necessary to comply with § 423.120(b)(1)(v) or § 423.272(b)(2)."

We appreciate that CMS reiterates the language of section 1860D-11(i) in the preamble to the Proposed Rule, which expressly provides that CMS "[m]ay not interfere with the negotiations between drug manufacturers and pharmacies and Part D sponsors" and "may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs."[66] Similarly, CMS acknowledges that, while the Agency must enforce certain beneficiary protections in administering the Part D program, the absolute language that Congress employed in this section evidences a clear intent to keep CMS from interfering with private market competition. That said, we are concerned that these proposed exceptions could nonetheless give CMS undue leeway to interfere with private contract negotiations.

First, we believe that the language "as necessary to enforce CMS requirements" in proposed section 423.10(b)(1) does not appear to have any limitations, particularly given the large number of requirements applicable to the Part D program. We therefore urge CMS to specify the particular CMS requirements under which this authority would be invoked. For example, CMS could reference specific regulatory provisions, as they propose to do in section 423.10(c).

Second, BIO has specific concerns about the proposed exceptions in section 423.10(c). For instance, it is not clear why CMS has chosen section 423.120(b)(1)(v) as grounds to potentially determine formulary/tier placement of a particular drug. This regulatory provision establishes requirements for PDP sponsors that use formularies, namely that "[a] Part D sponsor's formulary must be developed and reviewed by a pharmacy and therapeutics committee that . . . [c]onsiders whether the inclusion of a particular Part D drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy." We do not believe this section can be interpreted to allow CMS to interfere in the determination to include or exclude a specific drug product on a PDP's formulary. Rather, the cited provision would appear to leave the determination up to the plan's P&T committee (not CMS).

---

65 See 42 C.F.R. § 423.10(b)(1) (proposed).

66 79 Fed. Reg. at 2061-62 (emphasis added).

While section 423.272(b)(2) does, on the other hand, address a role for CMS,[67] we are concerned about how and when this exception will be applied. Specifically, BIO reiterates our request articulated earlier in this letter that CMS provide stakeholders with more details around how, and against what benchmarks, CMS judges nondiscrimination of formularies and tiered formularies.

BIO is also very concerned about the apparent potential for future contract and pricing disclosure requirements in the proposed non-interference regulation. Specifically, the Proposed Rule expressly refrains from limiting "CMS's authority to . . . [r]equire inclusion of terms and conditions in such agreements when necessary to implement requirements under the [Social Security] Act" or to "require full disclosure or uniform treatment and reporting of costs, prices, or price concessions consistent with rules established by CMS."[68] It is not clear, however, why CMS has gone to the pains of retaining this authority, given that the Agency has no legitimate need for it. Indeed, as CMS itself acknowledges in the preamble to the Proposed Rule, the Agency is prohibited—both by statute and its own regulatory proposals—from involving itself in the negotiations process to which this authority would pertain. We therefore urge the Agency to strike this language in finalizing the proposed non-interference regulation.

X. CMS Should Ensure that EGWP Beneficiaries Benefit from the Medicare Coverage Gap Discount Program, as Required by Statute

In the Proposed Rule, CMS proposes certain new transparency requirements with respect to the Medicare Coverage Gap Discount Program (CGDP) that pertain specifically to Employer Group Waiver Plans (EGWPs).[69] While we generally support these proposed new requirements, in that they address the fact that CGDP discounts have historically gone into a black hole in the EGWP program, we believe that they do not go far enough to ensure that EGWP beneficiaries benefit from CGDP discounts, as required by law.

The statutory language makes clear that coverage gap discounts must be provided to the beneficiary at the point-of-sale,[70] and requires CMS to establish procedures: (1) " . . . under which discounted prices are provided to applicable beneficiaries at pharmacies or by mail order at the point-of-sale of an applicable drug"[71]; and (2) "to ensure that the discounted price for an applicable drug . . . is applied before any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provide of prescription drug coverage on behalf of applicable beneficiaries . . . "[72] The statute also expressly counts the discounts as part of "incurred costs" for purposes

[67] This provision specifies grounds under which CMS will not approve a sponsor's bid on the grounds that the plan/benefit design—including the formulary and tiering structure—is likely to substantially discourage enrollment by certain Part D-eligible individuals.
[68] 42 C.F.R. § 423.10(b)(2)(ii) & (d)(2) (proposed).
[69] 79 Fed. Reg. at 1968-69 (42 C.F.R. § 423.2325(h)(1) [proposed]).
[70] SSA § 1860D-14A(b)(1)(B) ("[e]xcept as provided in subsection (c)(1)(A)(iii) [allowing for a delay for the year of implementation, as needed], such discounted prices shall be provided to the applicable beneficiary at the pharmacy or by mail order service at the point-of-sale of an applicable drug.")
[71] SSA § 1860-14A(c)(1)(A)(ii).
[72] SSA § 1860-14A(c)(1)(A)(v).

of determining when a beneficiary enters catastrophic coverage.[73] As CMS does not have the authority to allow coverage gap payments in the private market that do not adhere to these Part D requirements,[74] the Agency cannot allow these discounts to be applied to reduce premiums or otherwise reduce costs in a manner that does not reduce beneficiary cost-sharing and does not count toward incurred costs.

Yet, in the Proposed Rule, CMS suggests that EGWPs are not required to use coverage gap discount amounts to reduce beneficiary cost-sharing. Indeed, CMS states in the preamble that Part D sponsors administering EGWPs "will receive discount amounts that may not offset the enrollees' final out-of-pocket cost-sharing, as the discounts do in individual market Part D plans when it is applied after Part D supplemental benefits."[75] This is inconsistent with the statutory requirement that the benefits of coverage gap discounts inure to the beneficiary at the point-of-sale. The Part D statute specifically requires that "discounted prices shall be provided to the applicable beneficiary at the pharmacy or by mail order service at the point-of-sale of an applicable drug".[76]

Moreover, it is not clear that these discount amounts are counting towards beneficiaries' true out-of-pocket (TrOOP) expenditures, or "incurred costs," as required by the statute. Section 1860D-2(b)(4) specifically requires that the negotiated price of an applicable drug (minus the dispensing fee) be treated as incurred costs, regardless of whether part of those costs were paid by a manufacturer under the coverage gap discount program. Thus, coverage gap discount amounts count as incurred costs as if paid by the beneficiary. Failure to treat these discounts as incurred costs is not only inconsistent with the statute, but it leaves EGWP beneficiaries in the coverage gap for a longer period of time, and leaves pharmaceutical manufacturers shouldering the costs of retiree coverage. CMS's transparency proposal is inadequate to address this issue: it is not sufficient to simply require EGWPs to notify employer or union sponsors of the coverage gap discounts. Instead, in order to take advantage of these discounts, an EGWP and employer/union sponsor must utilize the discounts as structured under the law, including that the discounts must count toward TrOOP.

We also strongly urge CMS to address gaps in transparency within the CGDP more broadly. Specifically, research highlights concerns with the accuracy and integrity of the claims invoices submitted by the Third Party Administrator (TPA) on behalf of PDP sponsors to manufacturers. These invoices provide minimal supporting documentation and, in essence, represent charges that manufacturers must pay without verification. As outlined in the

---

[73] The ACA amends SSA § 1860D-2(b)(4) to include the negotiated price of an applicable drug (minus the dispensing fee) furnished to an applicable beneficiary under the coverage gap discount program, "regardless of whether part of such costs were paid by a manufacturer under such program" (and excluding those amounts paid by the government as the coverage gap is closed over time). Thus, coverage gap discount program payments made by manufacturers must count toward incurred costs.

[74] While we understand that CMS does have authority to waive certain requirements of the Part D program with respect to EGWPs, waiver of the coverage gap requirements here exceed the Secretary's authority to waive such requirements, which is restricted to plan requirements unrelated to the CGDP program (e.g., enrollment, service areas, marketing and dissemination, premium requirements, premium withhold). See CMS, Medicare Prescription Drug Manual, Ch. 12, available at: http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R6PDB.pdf.

[75] 79 Fed. Reg. at 1969.

[76] SSA § 1860-14A(b)(1)(B).

Manufacturer Coverage Gap Agreement, the discount program supplies little data transparency and allows minimal capacity to rigorously audit these invoices for accuracy. Consequently, manufacturers may be overcharged for coverage gap discounts and do not possess proper contractual authority to verify the integrity of the invoices. It is also difficult to construct a coverage gap liability forecast for the upcoming year. While manufacturers are permitted to conduct audits under the CGDP program, we believe that this should not be the only way that manufacturers have access to data regarding how the coverage gap discounts are calculated. Accordingly, we urge CMS to take steps to improve transparency with respect to the CGDP, including by working with stakeholders to identify additional details that the TPA must provide on the invoices submitted to manufacturers (e.g., contract number; plan ID; adjustment/deletion code; quantity dispensed; Gross Drug Cost Below Out of-Pocket Threshold (GDCB); patient pay amount; patient liability due to other payer amount; negotiated price for the claim; and information detailing the initial coverage limits, out-of-pocket thresholds, and supplemental coverage information associated with each prescription number).

XI. CMS Should Monitor Impact of Preferred Cost-Sharing Proposal on Beneficiaries

When originally implementing the Part D benefit, CMS permitted PDPs to offer lower cost-sharing at preferred pharmacies relative to other pharmacies in their networks. However, recent data suggest that preferred networks in some plans have resulted in higher negotiated prices, increased costs to the federal government, and distorted price signals in the market. CMS is therefore proposing to delete references in Part D rules to preferred and non-preferred pharmacies, and instead refer to preferred cost-sharing, as well as to allow pharmacies willing to meet preferred pricing terms to be included in a plan's preferred cost-sharing offerings.[77] BIO supports this proposal as a means for ensuring patient access to the pharmacy of their choice and to correct current price distortions. That said, we strongly encourage CMS to continually ensure that patients actually benefit from these preferred cost-sharing networks.

XII. MA-PD Coordination Requirements for Drugs Under Parts A, B, and D

In order to "avoid unnecessary delays and inappropriate denials of critical medications," CMS is considering requiring MA-PD plans to authorize coverage of all Part A, Part B and D medications at the place of service so that the enrollee can receive covered medications without delay.[78] While we are supportive of this proposal generally, we urge CMS to ensure that this coordination is equally seamless in both directions (i.e., for B-to-D determinations as well as D-to-B determinations).

[77] 79 Fed. Reg. at 1976.
[78] Id. at 2009.

XIII. BIO Supports CMS' Proposed Expansion of the Medication Therapy Management (MTM) Program under Part D

BIO is generally supportive of the Part D MTM program, as these programs typically have provided patients with access to better care management, particularly for patients in one of the targeted disease areas. To these ends, we support extending the program to additional beneficiaries and disease states. In particular, BIO supports CMS's proposal to extend the MTM program to individuals with Alzheimer's disease. We believe that this condition represents a looming public health threat to the nation and support CMS's efforts to ensure that the health care for Alzheimer's patients enrolled in Medicare is properly coordinated. That said, to the extent that CMS does ultimately expand the MTM program, we urge CMS to pay particular attention to how the program affects the more vulnerable beneficiary populations slated for inclusion, namely Low-Income Subsidy-Eligible beneficiaries. Moreover, we urge CMS to continue to ensure that beneficiary rights and access to novel innovative treatments are protected under the MTM program.

XIV. BIO Appreciates the Additional Clarity CMS Provides Regarding Transition Fills

BIO supports the additional clarity that CMS provides in the Proposed Rule with respect to transition fills. In addition to outlining the transition fill requirements as part of its discussion of the proposed protected classes policy,[79] CMS also proposes to modify the existing transition fill regulation to address the applicable cost-sharing requirements.[80] As CMS notes in the preamble, current regulations do not currently specify the cost sharing that should apply to transition fills. Moreover, as CMS recognizes, existing guidance on this topic in the Part D Manual has caused a substantial amount of confusion. Accordingly, BIO supports CMS's proposal to address this issue by adding new paragraph 423.120(b)(3)(vi) to the Part D regulations. Specifically, in light of the examples provided in the preamble, we agree that it makes sense to vary the cost-sharing requirements depending on whether the drug in question is on the PDP's formulary to take into account tiered formulary designs.

XV. Conclusion

BIO appreciates the opportunity to comment on the Proposed Rule. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact me at 202-962-9220 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/
Laurel L. Todd
Managing Director
Reimbursement and Health Policy

---

79 Id. at 1940.
80 Id. at 1967, 2063.