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VIA ELECTRONIC FILING TO:

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

Re: [CMS-4180-P] Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses

Dear Ms. Verma:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on CMS-4180-P: *Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses* (the proposed rule).¹ PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Consistent with that mission, PhRMA companies are committed to the continued success of the Medicare Prescription Drug Benefit Program (Part D).

Nearly 16 years following the enactment of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA), Part D has succeeded beyond expectations, delivering affordable prescription drug coverage for more than 43 million seniors and people with disabilities at a lower cost to taxpayers than was originally anticipated. The six protected class policy has been integral to the program's success, assuring broad formulary access for many of the nation's most vulnerable seniors and people with disabilities. As discussed in detail in our letter, we strenuously oppose any weakening of these protections for vulnerable beneficiaries. The proposed rule would modify existing policy in ways that would put American patients'

¹ Centers for Medicare & Medicaid Services, *Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses*, 83 Fed. Reg. 62152 (Nov. 30, 2018).

health at risk; allow Part D plans to design formularies that discourage enrollment of beneficiaries with certain health conditions and reduce access to vital and necessary therapies for those enrolled, while achieving little—if any—savings for beneficiaries or Medicare.

PhRMA recognizes that CMS is seeking to make changes that will lower drug prices and reduce out-of-pocket costs for beneficiaries. We do not believe that the changes to six protected classes would lower out-of-pocket costs for patients taking brand medicines. In PhRMA’s comments on the *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*,² we supported several policies that would promote competition, reduce current market distortions that can lead to higher list prices, and improve affordability for patients. In this letter we discuss one of these policies, passing through a share of manufacturer rebates to beneficiaries at the point of sale (in addition to pharmacy price concessions, which CMS states it is considering adopting). As CMS works to implement policies informed by responses to that Blueprint, we urge CMS to prioritize policies that address perverse incentives in the current system while ensuring patients’ access to medicines remains strong.

We look forward to continued engagement with CMS on a thoughtful evolution of the Medicare Part D program and the pharmaceutical supply chain that ensures Part D meets the needs of beneficiaries and makes prudent use of federal dollars. An overview of our comments is set out below, followed by detailed comments in each section.

Changes to six protected classes should not be finalized (§ 423.120(b)(2)(vi)). CMS is proposing to allow plans to restrict access to medicines in the protected classes. The changes could have serious health consequences for patients if finalized and are not necessary given that plans already have tools to manage utilization in these classes and significant savings from the proposed changes are unlikely. The proposed changes also are inconsistent with Part D’s non-discrimination protections. CMS’s proposal to allow broader use of step therapy and prior authorization could lead to stable patients being forced to switch medicines for non-medical reasons, putting their health in jeopardy. Another proposed change that would allow plans to refuse to cover medicines that have taken price increases above general inflation is fundamentally flawed and would undo patient safeguards due to economic factors outside of a manufacturer’s control.

The proposed Medicare Advantage Step Therapy policy for Part B medicines would negatively impact patients and providers and is prohibited by statute (§§422.136, 422.568, 422.570, 422.572, 422.584, 422.590, 422.618, and 422.619). CMS is proposing to allow

² Dept. of Health and Human Services, *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, 83 Fed. Reg. 22692 (May 16, 2018).

Medicare Advantage plans to use step therapy for Part B medicines. Step therapy puts vulnerable patients who need access to life-saving medicines at risk by increasing access and adherence issues that can lead to poor health outcomes and increased costs. Step therapy policies also interfere with provider autonomy and increase their administrative burden. Furthermore, the Social Security Act requires that Medicare Advantage plans provide the same benefits as the benefits provided in Original Medicare; accordingly, CMS lacks the authority to permit Medicare Advantage plans to impose step therapy restrictions on Part B drugs that are not required by Original Medicare.

The proposed concept of providing relevant cost sharing information in a real-time benefit tool has the potential to help patients (§ 423.160). CMS is proposing to implement a real-time benefits tool in Medicare Part D that would provide relevant cost-sharing information to patients and providers. Such tools could facilitate more meaningful conversations shared clinical decision making. Technical and operations details will need to be worked out for such tools to reach their full potential.

New requirements for drug price information in Part D explanation of benefits (EOBs) could lead to confusion without providing meaningful information for patients (§ 423.128). CMS is proposing to require that EOBs include information on negotiated drug price changes and lower cost therapeutic alternatives. EOBs should provide information that patients need to be informed health care consumers. Such information should be patient-specific and available in real-time as the patient discusses treatment options with his/her health care professional. The proposed changes to information on EOBs do not meet this test and could create confusion for patients.

Patients should directly benefit from both pharmacy price concessions and manufacturer price concessions (§ 423.100). CMS is considering, though not formally proposing, a change to the definition of “negotiated price” intended to ensure that all pharmacy discounts are reflected in the drug prices beneficiaries pay at the point of sale. This is a missed opportunity to also require that Part D plan sponsors pass through a share of manufacturer rebates and other price concessions to further reduce negotiated price.

Six Protected Classes (§ 423.120(b)(2)(vi))

In the proposed rule, CMS seeks to introduce coverage and access uncertainty by allowing plans to largely bypass current protections for beneficiaries requiring access to medicines in six classes of clinical concern (the six protected classes). CMS developed the six protected class policy in 2005, and it has been a key part of ensuring that plans comply with the Part D statute’s non-

discrimination protections.³ The six protected class policy requires that plans cover “*all or substantially all*” medications within six classes and categories: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, immunosuppressants.⁴ These life-saving medicines treat patients with HIV, epilepsy, organ transplants, cancer, and mental health conditions.

The proposed changes to the six protected class policy would allow plans to add the following new restrictions to their formularies for drugs in the six protected classes:

- (1) Step therapy and prior authorization could be used for patients already stable on a six protected classes medicine. In addition, treatment-naïve HIV patients could be forced to go through step therapy and/or prior authorization.
 - Currently no prior authorization or step therapy is permitted for stable patients in the protected classes. CMS also now does not permit these tools for HIV patients new to therapy based on the recognition that “utilization management tools such as prior authorization and step therapy are generally not employed in widely used, best practice formulary models” for HIV.⁵
- (2) Plans could exclude a new formulation of a protected class drug from a formulary, even if the previous formulation has been taken off the market.
 - Currently new formulations do not have to be covered, if the original formulation is on a plan’s formulary.
- (3) Plans could exclude six protected class medicines from coverage if their list prices have increased by more than general (not medical) inflation during a specified lookback period.⁶
 - Plans are currently not permitted to add any formulary restrictions based on price or price increases.

PhRMA strongly opposes these changes to the six protected classes policy. The protected class policy affords access to vital and life-saving medicines for enrollees with serious and debilitating conditions. Our concerns with the proposed weakening of this policy are multifold. Most significantly, the proposed changes could have serious health consequences for patients. Such changes to the six-protected class policy are not necessary given that plans already have tools to manage utilization in these classes and significant savings from the proposed changes are

³ Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit Manual, Ch. 6, § 30.2.5 (2016); Social Security Act (SSA) § 1860D-11(e)(2)(D)(i).

⁴ Medicare Prescription Drug Benefit Manual, Ch. 6—, § 30.2.5 (2016) (emphasis added).

⁵ Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit Manual, Ch. 6, § 30.2.5. See also 42 C.F.R. § 423.120(b)(2)(vi)(C).

⁶ The proposed rule suggests that list prices would be measured at wholesale acquisition cost (WAC) and price increases would be compared to general inflation as measured by the consumer price index (CPI-U).

unlikely. We also have legal concerns with the proposed changes, which are inconsistent with Part D’s non-discrimination protections. Each of the specific changes to the protected classes that CMS is proposing also raise unique concerns, which are detailed later in this letter.

Robust coverage protections for the protected classes are needed to ensure vulnerable beneficiaries have access to the full range of necessary medicines, as is clinically appropriate.

For beneficiaries relying on one or more medicines in the protected classes, treatments largely are not interchangeable. Instead, patient responses to treatment are unique and disparate, where seemingly “similar” patients may experience clinically meaningful differences when exposed to the same therapy. For example, for patients with epilepsy, it can take years to find the optimal combination of treatments to manage and prevent seizures. Treatment for chronic phase Chronic Myeloid Leukemia (CP-CML) is guided by patient comorbidities, the toxicity profile of treatment, and a risk score that incorporates factors such as a patient’s age, spleen size, and peripheral platelet count, among other clinical markers.⁷ Imposition of step therapy for stable patients with CP-CML could result in use of a treatment that is not compliant with recommended clinical guidelines or to which the patient has already expressed an intolerance. The American Cancer Society Cancer Action Network has also cautioned against weakening access to medicines in the six protected classes because “some [Part D] beneficiaries may have to try different drugs within one class before it is possible to determine the most optimal drug for their condition. Beneficiaries may also have co-morbidities requiring very nuanced treatment regimens.”⁸ For patients with schizophrenia or depression, it may take several tries to find a medicine that controls symptoms and has manageable side effects. Patients with schizophrenia also now often benefit from access to long-acting medicines that improve adherence.⁹ The National Institutes of Health states that when it comes to treating HIV “the best regimen for a person depends on their individual needs,”¹⁰ thereby necessitating that patients have access to the full range of therapies. For transplant patients on anti-rejection drugs, the stakes are obviously very high if they do not have access to the appropriate medicine.

⁷ National Comprehensive Cancer Network Guidelines Version 1.2019. Chronic Myeloid Leukemia. Accessed Jan. 15, 2019.

⁸ American Cancer Society Cancer Action Network, comment letter on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, Request for Information (RIN 0991-ZA49). Available at: <https://www.fightcancer.org/sites/default/files/National%20Documents/ACS%20CAN%20Comments%20on%20Rx%20RFI%20-%207-13-18%20-%20FINAL.pdf>

⁹ M. Greene, et al, “Medication adherence and discontinuation of long-acting injectable versus oral antipsychotics in patients with schizophrenia or bipolar disorder,” *J Med Econ*. 2018 Feb;21(2):127-134

¹⁰ U.S. Department of Health and Human Services, “What to Start: Choosing an HIV Regimen,” available at: <https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/21/53/what-to-start--choosing-an-hiv-regimen>

Contrary to statements in the proposed rule suggesting otherwise, the clinical considerations that made the six protected classes policy necessary in 2005 are as pressing and valid today. As CMS has explained, it “instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in Part D plans and to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations.”¹¹ Maintaining the existing protected classes policy remains clinically necessary for minimizing adverse outcomes that may otherwise result from therapy interruptions or delays. When patients are unable to receive the medication best suited to their individual needs, worsening of symptoms, adverse interaction among therapies, avoidable hospitalization, poor prognosis or impaired quality of life all are likely. Delaying optimal treatment for even a short time while trying ineffective treatments may cause irreversible damage to patient health. In recognition of this fact, the Food and Drug Administration (FDA) has developed several approval pathways to shorten the time to approval, especially for drugs that treat serious diseases such as cancer. For example, VENCLEXTA® (venetoclax), an oral oncolytic, was recently granted accelerated approval by the FDA for a new indication in Acute Myeloid Leukemia (AML) due to existing unmet medical need in AML. Speed to initiation of therapy is very important in AML given how rapidly patients decline: a recent retrospective registry study of AML patients that examined the relationship between time to treatment (TTT) and outcomes in hospitalized patients found that patients who initiated therapy on days 1-5 had better outcomes versus the days 6-10 cohort.¹² This example is just one of the many within the protected classes that demonstrate the clinical importance of ensuring vulnerable beneficiaries have access to the full range of necessary medicines.

Weakening the six protected classes is unlikely to result in significant savings for the Medicare program as Part D Plan sponsors already have tools to manage utilization.

Cost containment is clearly one of the Administration’s primary motivations in pursuing changes to the protected classes; however, allowing plan sponsors to place additional restrictions on access to medicines in the protected classes is unlikely to produce substantial Part D savings. Plan sponsors are already able to manage access to most drugs in the six protected classes, and there is widespread evidence that they have ample flexibility to manage utilization among Part D beneficiaries:

- Formulary tiering: The average Part D beneficiary is enrolled in a plan that places drugs from the protected classes on high cost-sharing tiers (non-preferred or

¹¹ Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit Manual, Ch. 6, § 30.2.5.

¹² Datta, T., Jonas, B. A., et al. (2016). Time to Treatment Initiation Predicts Overall Survival in Hospitalized Acute Myeloid Leukemia (AML) Patients: A California Population-Based Study. *Blood*, 128(22), 3982. Accessed January 14, 2019. Retrieved from <http://www.bloodjournal.org/content/128/22/3982>

specialty) 73 percent of the time.¹³ Plan sponsors use tiers to create large differentials in cost-sharing for generic vs. brand drugs, which researchers have found to be associated with greater use of generics.¹⁴

- Utilization management: A recent analysis found that plans apply prior authorization or step therapy policies for a majority of branded drugs (54 percent) in the protected classes.¹⁵ Such utilization management is currently permitted only for patients starting treatments for conditions in classes other than HIV. New analysis from IQVIA finds that, depending on the class, between 27 percent and 48 percent of patients taking a medicine in one of the five non-HIV protected classes are new to treatment in a given year.¹⁶ This suggests that plans have ample opportunity to use their current utilization management flexibility to influence new patient starts. However, for reasons discussed further below, it is not clinically appropriate to use utilization management for stable patients and would risk patient health.

Although the Administration contends that allowing insurers even more tools to manage utilization or exclude drugs from the six protected classes is necessary to constrain costs, such tools are improper to impose clinically as discussed further below; moreover, clear evidence shows that the current level of formulary flexibility has been successful in both driving utilization of generics and keeping price growth in check:

- Pricing trends reflect strong negotiations: According to the Medicare Payment Advisory Commission (MedPAC), plans' ability to manage utilization and drive the use of generics when appropriate has led cumulative prices for protected class medicines to *decrease* by 13 percent between 2006 and 2014.¹⁷
- Generic utilization: A significant majority of all prescriptions filled for drugs in the protected classes are for generic products – generics represented more than 90 percent

¹³ Partnership for Part D Access. "A Balanced Approach to Provide Patients Access to Medications While Allowing Powerful Tools to Control Costs." Nov. 2018.

¹⁴ Tang Y, Gellad WF, Men A, Donohue JM. Impact of Medicare Part D plan features on use of generic drugs. *Med Care*. 2014;52(6):541-8.

¹⁵ Partnership for Part D Access. "A Balanced Approach to Provide Patients Access to Medications While Allowing Powerful Tools to Control Costs." Nov. 2018.

¹⁶ The Pharmaceutical Research and Manufacturers of America. "New research shows changes to the six protected classes would harm most vulnerable patients and are unnecessary." *The Catalyst(blog)*. January 25, 2019, https://catalyst.phrma.org/new-research-demonstrates-how-proposed-changes-to-the-six-protected-classes-would-removecriticalprotectionsforthemostvulnerablepatientsandareunnecessary?utm_campaign=Subscribe&utm_source=hs_email&utm_medium=email&utm_content=69291951&hsenc=p2ANqtz8UMqTOJIilp5Y1YFKwnflC8yc2zgeo m4PjmRhkRKXq4M8XV7FrUrarCbZ5r7btAWLL4MOxZHs9bvWvEOedRdN1oBdxQ&hsmi=69291951

¹⁷ MedPAC. Report to the Congress: Medicare Payment Policy. March 2017.

of the prescriptions filled within anticonvulsants (90 percent), antidepressants (97 percent), and antipsychotics (91 percent).¹⁸ According to an analysis of CMS data by the Pew Charitable Trusts, *the generic utilization rate in the protected classes is as high as 84 percent.*¹⁹

The current high rate of generic utilization sharply limits the ability of plan sponsors to further drive utilization to lower cost therapies, and CMS’ assumptions about potential savings due to increased generic utilization therefore seem wildly unrealistic. CMS assumes that 5 percent of brand prescriptions in the six protected classes will switch to generics. However, MedPAC has noted that “protected status does not appear to affect plan sponsors’ ability to encourage the use of generics.”²⁰ To the extent that patients are taking brand medicines in the six protected classes, it is primarily for medications without generic alternatives. In these instances, plan sponsors who seek to use more restrictive utilization management to force non-medical (e.g., cost-based) switching run the risk of disrupting established treatment regimens and worsening clinical outcomes for their most vulnerable beneficiaries and leading to higher medical costs for the broader Medicare program. In particular, stand-alone Prescription Drug Plans (PDPs)—which are not responsible for their enrollees’ medical care—may lack the financial incentives to consider the downstream consequences of formulary exclusions and utilization management in the six protected classes, including discontinuation of therapy, poor medication adherence, and increased consumption of inpatient and outpatient services.²¹

Studies show that such downstream consequences are more likely with formulary restrictions. For example, commercially insured patients who faced benefit restrictions on atypical antipsychotic therapy demonstrated a significant reduction in adherence and persistence to their medications, which could have a dire impact on health outcomes as well as health care costs.²² Another example shows that prior authorization requirements for antiretrovirals increase administrative costs for providers and can lead to patients experiencing delays in receiving their medications.²³ HIV patients who face drug benefit design changes are also nearly six times more

¹⁸ Partnership for Part D Access. “A Balanced Approach to Provide Patients Access to Medications While Allowing Powerful Tools to Control Costs.” Nov. 2018.

¹⁹ The PEW Charitable Trusts. Policy Proposal: Revising Medicare’s Protected Classes Policy. March 2018.

²⁰ Medicare Payment Advisory Commission, “Status Report on the Medicare Prescription Drug Program (Part D)” (2017): 412.

²¹ Lavetti K and Simon K. Strategic Formulary Design in Medicare Part D Plans. NBER Working Paper. June 24, 2016.

²² Feng Zeng, Russell L. Knott, et al. Impact of Health Plan Restrictions on Antipsychotic Medication Adherence and Persistence. *The American Journal of Pharmacy Benefits*. January/February 2012.

²³ Casalino LP, Nicholson S, Gans DN, et al. What Does it Cost Physician Practices to Interact with Health Insurance plans? *Health Affairs*. 2009;28(4):w533-w543.; Raper JL, Willig JH, Lin H, et al. Uncompensated Medical Provider Costs Associated with Prior Authorization for Prescription Medications in an HIV Clinic. *Oxford Journal of Clinical Infectious Diseases*. 2010;51(6):718-724.

likely to face treatment interruptions than those with more stable coverage, increasing their risk of virologic rebound, drug resistance, and increased morbidity and mortality.²⁴

CMS also contends that the six protected classes’ “open coverage policy substantially limits Part D sponsors’ ability to negotiate price concessions in exchange for formulary placement of drugs in these categories or classes.”²⁵ However, CMS fails to recognize plan sponsors currently have adequate tools that drive generic utilization when appropriate. Moreover, these tools also allow Part D plans to promote competition among manufacturers of branded medicines in the six protected classes, helping them to extract rebates for favorable formulary placement that also lower their costs.²⁶ And in its own regulatory impact analysis, CMS projects only \$11 million in savings in 2020 as a result of plan sponsors’ increased leverage to negotiate additional rebates from manufacturers under this policy, representing just 6 percent of total savings projected in that year.²⁷ This suggests that even CMS does not expect its policy to result in significant savings from strengthening plans’ ability to negotiate.

CMS’ proposed exceptions to the protected classes policy based on cost considerations – versus any changing scientific evidence, medical standards or clinical practice – represent an unexplained departure from established policy that would violate Part D’s non-discrimination requirement and cause harm to vulnerable Part D beneficiaries.

The protected classes policy stems originally from the non-discrimination requirement in the Part D statute, which prohibits CMS from approving a 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.”²⁸ CMS adopted the protected classes policy as Part D was getting started in 2005, explaining that it instituted this policy “because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations.”²⁹ It is important to note that the protected class policy was developed at a time when CMS had other non-discrimination reviews for formularies in place. At the time, CMS decided that those reviews were not sufficient to protect patients who depend on medicines in the six protected

²⁴ Das-Douglas M, Riley ED, Ragland K, et al. Implementation of the Medicare Part D Prescription Drug Benefit is Associated with Antiretroviral Therapy Interruptions. *AIDS and Behavior*. 2009;13(1): 1-9.

²⁵ 83 Fed. Reg. at 62156.

²⁶ MedPAC. Report to the Congress: Medicare Payment Policy. March 2017.

²⁷ 83 Fed. Reg. at 62184.

²⁸ Social Security Act (SSA) § 1860D-11(e)(2)(D)(i).

²⁹ Prescription Drug Benefit Manual, Ch. 6 § 30.2.5 (emphasis added).

classes. There is no evidence that the non-discrimination reviews today are more rigorous or that the additional six protected class protections are no longer needed.

The six protected class policy’s importance is illustrated by a case where CMS terminated a plan sponsor that imposed unauthorized prior authorization and step therapy policies on protected class drugs, leading to denied claims for drugs for cancer, HIV/AIDS, prevention of transplant rejection, and seizure prevention.³⁰ CMS’ Dr. Jeffrey Kelman (the Chief Medical Officer for what was then the Center for Drug and Health Plan Choice) explained that:

The potential negative effect [of prior authorization and step therapy] to patients with cancer, HIV/AIDS, as well as many other chronic diseases is clearly significant in terms of clinical exacerbations, and is likely to be life threatening for many of the enrollees impacted.³¹

Recognizing the importance of the protected classes policy to Medicare’s most vulnerable patients, Congress codified it, and today the Part D statute establishes special protections for classes “of clinical concern” and requires notice and comment rulemaking to change the existing classes of “clinical concern” or to create exceptions permitting plans to exclude or limit access to protected class drugs.³²

Current Part D regulations permit plans to restrict access to protected class drugs with therapeutic equivalents and to apply utilization management or limit drug quantities for safety reasons.³³ CMS may exclude other drugs “through a process that is based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, is consistent with the [HHS] Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents) and which permits public notice and comment.”³⁴ CMS has not proposed to revise or eliminate this provision,³⁵ which suggests that new exceptions should be based on scientific evidence and medical standards of practice (and HHS’ own Guidelines on the use of HIV/AIDS drugs).

The proposed rule exceptions represent a sharp and unexplained change from CMS’ established position, and which, if finalized and implemented, will negatively impact the health and well-

³⁰ *Fox Ins. Co. v. CMS*, 715 F.3d 1211, 1221 (9th Cir. 2013).

³¹ *Fox Ins. Co. v. CMS*, 715 F.3d at 1221 (emphasis added).

³² SSA § 1860D-4(b)(3)(G).

³³ 42 C.F.R. § 423.120(b)(2)(vi)(A),(B).

³⁴ 42 C.F.R. § 423.120(b)(2)(vi)(C) (emphasis added).

³⁵ 83 Fed. Reg. at 62200 (proposing to redesignate § 423.120(b)(2)(vi)(C) as 423.120(b)(2)(vi)(F) but not to change the text).

being of the protected class patient population. As discussed earlier, the proposed rule would create three new exceptions to the protected class policy by adding to the existing regulation:

(C) Prior authorization and step therapy requirements that are implemented to confirm use is intended for a protected class indication, ensure clinically appropriate use, promote utilization of preferred formulary alternatives, or a combination thereof, subject to CMS review and approval.

(D) In the case of a single-source drug or biological product for which the manufacturer introduces a new formulation with the same active ingredient or moiety that does not provide a unique route of administration.

(E) A single-source drug or biological product . . . for which the wholesale acquisition cost between the baseline date and any point in the applicable period, increased more than the cumulative increase in the consumer price index for all urban consumers over the same period.³⁶

These proposed exceptions sharply diverge from the construct of the protected classes policy that CMS and Congress have long shared—that the policy protects vulnerable beneficiaries with serious diseases from interruptions in their therapy and thus reflects “clinical concern[s]”³⁷—and contradicts the existing regulation providing that new exceptions will be “based upon scientific evidence and medical standards of practice” (and HHS Guidelines on the use of HIV/AIDS drugs).³⁸ CMS has not justified or even acknowledged its change in position.

Instead of creating exceptions based on scientific evidence and medical standards, the proposed rule’s exceptions focus on cost considerations. For example, CMS proposes to rescind protected class safeguards for drugs that have price increases exceeding CPI-U increases and for new formulations based on drug pricing alone.³⁹ If these exceptions were intended to increase Part D plans’ negotiating leverage without compromising patients’ health, CMS would presumably have expressed interest in ensuring patients’ continued access to appropriate treatments and explained why it thought the new exception would not endanger patient care. However, no clinical or scientific justifications are cited in the CMS discussion of its proposed exceptions.⁴⁰

Similarly, CMS’ proposed exception allowing broader use of prior authorization and step therapy is incompatible with its commitment to base any new exceptions on “scientific evidence or medical standards of practice.” This exception could potentially apply even for patients who are

³⁶ 83 Fed. Reg. 62152 at 62200 (proposed 42 C.F.R. § 423.120(b)(2)(vi)(C)-(E)).

³⁷ SSA § 1860D-4(b)(3)(G)(ii)(I).

³⁸ 42 C.F.R. § 423.120(b)(2)(vi)(C).

³⁹ 83 Fed. Reg. at 62159.

⁴⁰ 83 Fed. Reg. at 62159.

already stable on an existing therapy.⁴¹ This would contradict established clinical guidelines (including the HHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents cited in CMS’ regulations, which emphasize the danger of interruptions in therapy⁴²), and the proposed rule itself states that “best practice utilization management practices would not require an enrollee who has been stabilized on an existing therapy of a protected class drug for a protected class indication to change to a different drug in order to progress through step therapy requirements,”⁴³ but still seemingly would permit plans to adopt policies that require such a switch in patients’ therapies.

In failing to acknowledge and explain this radical change in its standards for creating exceptions, CMS falls short of meeting the legal requirements for justifying a change of position. The courts hold that an agency can reverse a policy position so long as it provides a “reasoned explanation for the change,” which must at least: (1) display an awareness that the agency is changing its position, (2) show that there are good reasons for the change, and (3) consider the reliance interests of the regulated parties.⁴⁴ An “unexplained inconsistency” in agency policy is a reason for “holding [the] interpretation to be an arbitrary and capricious change from agency practice,” which is “unlawful and receives no Chevron deference.”⁴⁵ The requirements to justify a change in policy are not onerous, but the proposed rule does not meet them.

Furthermore, the proposed rule contradicts the statutory non-discrimination requirement. Beyond departing from established CMS policy with no explanation, the proposed exceptions to the protected classes policy would spur violations of the Part D statute’s nondiscrimination requirement. This provision prohibits plan designs that are “likely to substantially discourage enrollment by certain part D eligible individuals under the plan.”⁴⁶ But the new exceptions CMS has proposed would inevitably result in benefit designs that substantially discourage enrollment by certain beneficiaries—in particular, those high-cost beneficiaries who need treatment for

⁴¹ 83 Fed. Reg. at 62158 (stating that the new exception permitting broader use of prior authorization and step therapy would “expand the use of prior authorization to be consistent with what is currently permitted for non-protected class drugs given that (1) section 1860D-4(b)(3)(G)(i)(II) if the Act authorizes us to allow Part D sponsors to limit access to protected class drugs through prior authorization and utilization management for both new starts and existing therapy”) (emphasis added). See also *id.* (“while we are proposing to permit prior authorization for both new starts and existing therapy, we would not approve onerous prior authorization criteria that are not clinically supported”).

⁴² Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV. Department of Health and Human Services. Available at <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>, pages H-33 through H-34.

⁴³ 83 Fed. Reg. at 62163.

⁴⁴ Encino Motorcars v. Navarro, 136 S. Ct. 2117, 2125-26 (2016).

⁴⁵ Encino Motorcars v. Navarro, 136 S. Ct. at 2126 (quoting Nat’l Cable & Telecomms. Ass’n v. Brand X Internet Servs., 545 U.S. 967, 981 (2005)) (also citing United States v. Mead Corp., 533 U.S. 218, 227 (2001)). See also, e.g., F.C.C. v. Fox Television Stations, 556 U.S. 502, 516 (2009) (“a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy”).

⁴⁶ SSA § 1860D-11(e)(2)(D)(i).

cancer, HIV/AIDS, mental disorders, epilepsy, or to prevent rejection of transplanted organs. The likelihood that plans would adopt benefit designs discouraging enrollment by these beneficiaries is exactly what led CMS to adopt the protected classes policy in the first place.

The proposed changes threaten to result in market-wide discriminatory Part D plan benefit designs with narrowed access to protected class drugs, substantially discouraging enrollment by, and coverage for, vulnerable Medicare beneficiaries who have no other options.

CMS emphasizes that it is providing plans with the option to increase restrictions on six protected classes medicines and is not mandating any changes. However, plan sponsors will likely be concerned that they will attract sicker, higher cost beneficiaries if they are the only ones that do not reduce access to these medicines. While Part D has market stabilization policies in place to try to prevent plans from engaging in adverse selection to avoid higher cost beneficiaries, these policies are never perfect.⁴⁷ The dramatic scaling back of the six protected classes policy proposed in this rule could create uncertainties that would be difficult for market stabilization policies to fully absorb, thereby likely leading plans to significantly narrow access in protected classes and thereby likely violate the non-discrimination protections in the Part D statute.

From the start of Part D, the protected classes policy has curbed the risk of non-discrimination violations, creating a level playing field in which all plans must generally cover all protected class drugs and observe the same limits on access restrictions. CMS must avoid measures that increase the risk of non-discrimination violations: and this is what the new set of proposed exceptions would do. Research shows that the risks and complications associated with an interruption of therapy for patients with cancer, seizure disorders, mental disorders, HIV/AIDS, or organ transplants are often dangerous.⁴⁸ As noted above, CMS' Dr. Kelman stated in the Fox

⁴⁷ See, e.g., Riley GF *et al.*, Adverse Selection in the Medicare Prescription Drug Program. Health Affairs 28:6:1826-37. Nov. 2009, explaining that:

Adverse selection may occur among Part D plans because beneficiaries with a high demand for prescription drugs have strong incentives to enroll in plans with more comprehensive coverage. The concentration of high-cost beneficiaries in a limited number of plans may be intensified if some insurers structure their benefits so as to attract low-cost beneficiaries or practice aggressive utilization management, which tends to limit choices of drugs or therapies and thereby discourages high-cost individuals from enrolling. If disproportionate numbers of costly beneficiaries enroll in certain plans, this could be detrimental to the Part D program if their participation causes those plans to sustain financial losses or forces them to charge high premiums to remain solvent. Under these circumstances, Part D sponsors would be less likely to offer plans with comprehensive benefits because they might attract high-cost enrollees.

⁴⁸ For example, HIV patients who face drug benefit design changes are nearly six times more likely than those with stable coverage to have treatment interruptions that increase their risk of virologic rebound, drug resistance, and

Insurance case that denied claims for these drugs are “likely to be life-threatening for many of the enrollees impacted.”⁴⁹ Thus, limiting access to protected class drugs can create health risks so serious that it can drive patients who need these drugs away from plans that limit access. The opportunities CMS has proposed to limit access to protected class drugs would generate plan benefit designs that are likely to substantially discourage enrollment by Medicare beneficiaries reliant on these drugs. Those benefit designs are inconsistent with the non-discrimination clause in Part D.

Furthermore, the statute does not support the proposed policy that would base a drug’s protected class status on whether its list price has increased, as the nondiscrimination provision prohibits discriminatory benefit designs that could discourage enrollment by certain beneficiaries.⁵⁰ In interpreting and applying this provision, CMS may not consider factors Congress did not authorize it to consider⁵¹—such as list price movements.

CMS’s specific proposed changes to the six protected classes lack necessary substantial evidence to support their adoption and would harm patients

CMS is proposing three specific changes to the protected classes: additional authority for use of prior authorization and step therapy, increased ability to exclude new formulations from formularies, and a new path for plans to exclude medicines based on a list price increase. Below, PhRMA discusses our concerns with each of these specific policy changes.

First CMS proposed change to six protected classes: The proposed broader use of prior authorization and step therapy would put patients’ health at risk.

CMS proposes to allow the use of prior authorization and step therapy for protected class drugs for both beneficiaries on existing therapies and for those who are seeking a prescription of a drug for the first time (new starts). This is a change from current policy, which only permits the use of prior authorization and step therapy for new starts for six protected classes other than HIV. In making this proposal, CMS also appears to be reversing its policy of strongly discouraging the imposition of prior authorization and step therapy on antiretroviral drugs.

increased morbidity and mortality. Das-Douglas M, Riley ED, Ragland K, et al. Implementation of the Medicare Part D Prescription Drug Benefit is Associated with Antiretroviral Therapy Interruptions. Aids and Behavior. 2009;13(1): 1-9.

⁴⁹ Fox Ins. v. CMS, 715 F.3d at 1221.

⁵⁰ SSA § 1860D-11(e)(2)(D).

⁵¹ See, e.g., Nalco Co. v. EPA, 786 F. Supp. 2d 177, 187 (D.D.C. 2011) (rejecting EPA’s enforcement action as arbitrary and capricious where it acted based on its stated desire “to level the marketplace for competitors,” but the authorizing statute “does not give EPA jurisdiction to control or modify the marketplace”).

CMS’s proposal to eliminate restrictions on the use of prior authorization and step therapy threatens the health of beneficiaries who need medications in the protected classes. As CMS itself acknowledges, “best practice utilization management practices would not require an enrollee who has been stabilized on an existing therapy of a protected class drug for a protected class indication to change to a different drug in order to progress through step therapy requirements.”⁵² In fact, CMS understands the serious risks of imposing step therapy or prior authorization barriers on patients who are already stable on a protected medicine. In its termination letter to Fox Insurance (the plan sponsor in the Fox Insurance case mentioned earlier) CMS explained it was terminating Fox immediately due to practices causing “imminent and serious risks to [enrollees’] health,” including:

Fox failed to allow coverage of protected class drugs and instead required PA or ST in violation of CMS rules. While CMS does not know the total number of beneficiaries who were inappropriately subjected to these requirements, CMS has determined that at least 333 members stabilized (i.e., their medical condition or disease was stabilized) on protected class drugs had PA or ST inappropriately applied in 2010, thus delaying their access to these medications and creating a real risk that their health status might deteriorate, possibly significantly.⁵³

Given its understanding that imposing step therapy or prior authorization on patients who are stable on protected class drugs “creat[es] a real risk that their health status might deteriorate, possibly significantly,” it is hard to understand why CMS now proposes to permit this practice - the same practice that caused it to terminate Fox Insurance immediately due to causing “imminent and serious” risks to patient health. Adopting the proposed policy would be a stark, irresponsible, and unexplained departure from an established policy grounded in preventing serious health risks to vulnerable patients. Nevertheless, CMS proposes to modify its regulations to permit practices it recognizes as dangerous.

CMS also contends that the protected class policy provides a strong incentive to promote overutilization, particularly antipsychotics used for sedation.⁵⁴ However, CMS has previously touted the success of other methods to address this problem as part of its National Partnership to Improve Dementia Care, which has released data showing that the national prevalence of

⁵² 83 Fed. Reg. 62152, 62163 (Nov. 30, 2018).

⁵³ March 9, 2010 letter of Brenda Tranchida, CMS Director of Program Oversight, to Fox CEO Mr. Kary Shankar (emphasis added), at 8. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAAdvPartDENrolData/Downloads/Fox_Termination_Letter.pdf. See also *id.* at 4 (“in numerous cases, Fox improperly denied its enrollees coverage of critical HIV, cancer, and seizure medications. Even short term delays in access to these types of medications not only pose a serious risk to the health and safety of the enrollees in question, they also pose a high risk of permanent damage as well”) (emphasis added).

⁵⁴ 83 Fed. Reg. 62157 (Nov. 30, 2018).

antipsychotic use in nursing home residents decreased from 23.9 percent in the fourth quarter of 2011 to 14.6 percent in the second quarter of 2018.⁵⁵

CMS’s proposal to allow the imposition of prior authorization and step therapy on antiretrovirals also will harm beneficiaries and violate best practices.

CMS had good reason to warn Part D sponsors that they should not require prior authorization for HIV drugs when they stated that “utilization management tools such as prior authorization and step therapy are generally not employed in widely used, best practice formulary models” for HIV.⁵⁶ For some beneficiaries with HIV, many medicines are not clinically interchangeable. This is an important point, which is missed with a focus solely on cost containment. It is critical that beneficiaries and their physicians have access to a full range of therapeutic options including access to innovative medications or therapies. HIV patients often respond differently to the same drug. Additionally, drugs in the same class can have different side-effect profiles, with beneficiaries often best suited to one particular drug. Prior authorization requirements for antiretrovirals increase administrative costs for providers and can lead to patients experiencing delays in receiving their medications.⁵⁷ Studies have shown that applying utilization management and restricting formularies for patients with HIV would have a negative impact on their health outcomes.⁵⁸ This is particularly true for the Medicare population, since aging beneficiaries who are living with HIV often experience non-HIV related comorbidities⁵⁹ that require polypharmacy, which can increase risk for drug-drug interactions. Clinically significant drug interactions have been reported in 27 percent to 40 percent of HIV patients taking antiretroviral therapy requiring regimen changes or dose modifications.⁶⁰ Potential for drug-drug interactions would need to be assessed regularly, especially when starting or switching antiretroviral therapy and concomitant medications.”⁶¹

Restricting access to HIV therapies could also exacerbate racial disparities in treatment. African Americans account for the highest proportion of the HIV population (43 percent) and new

⁵⁵ P. Connoles, “Latest Quarterly Data Records Progress in Reducing Antipsychotics in Nursing Centers,” *Provider*, Dec. 20, 2018. Available at: <http://www.providermagazine.com/news/Pages/2018/DECEMBER%202018/Latest-Quarterly-Data-Records-Progress-in-Reducing-Antipsychotics-in-Nursing-Centers.aspx>

⁵⁶ Medicare Prescription Drug Benefit Manual, ch. 6, § 30.2.5.

⁵⁷ Casalino LP, Nicholson S, Gans DN, et al. What Does it Cost Physician Practices to Interact with Health Insurance plans? *Health Affairs*. 2009;28(4):w533-w543.; Raper JL, Willig JH, Lin H, et al. Uncompensated Medical Provider Costs Associated with Prior Authorization for Prescription Medications in an HIV Clinic. *Oxford Journal of Clinical Infectious Diseases*. 2010;51(6):718-724.

⁵⁸ Baumgardner J, Huber C, et al. “Modeling the Impacts of Restrictive Formularies on Patients with HIV.” *American Journal of Managed Care*. July 2018

⁵⁹ Schouten J, et al. *Clin Infect Dis*. 2014 Dec 15;59(12):1787-97.

⁶⁰ Evans-Jones JG et al. *Clin Infect Dis* 2010;50:1419–1421; Marzolini C et al. *Antivir Ther* 2010;15:413–423.

⁶¹ DHHS guidelines for the use of antiretroviral agents in adults and adolescents living with HIV. May 30, 2018. Accessible at <https://aidsinfo.nih.gov/guidelines> (accessed June 2018)

diagnoses (44 percent).⁶² Data has shown that clinical responses and outcomes in this population can differ from those of other races/ethnicities.⁶³ Successful treatment with an antiretroviral regimen results in virologic suppression and virtually eliminates secondary HIV transmission to others. However, achieving viral load suppression can only occur if people living with HIV have access to appropriate treatments, stay in care and remain adherent to their prescribed therapy.

Legal concerns

Finally, the proposed changes to the protected classes policy would violate the non-discrimination clause of the Part D statute, as discussed above. This provision requires that a plan's design does not “substantially discourage enrollment by certain Part D eligible individuals.”⁶⁴ Yet the proposed changes to the six protected classes would likely lead to plans doing just that—adopting benefit designs that would substantially discourage the enrollment of certain beneficiaries with high costs, such as those seeking treatment for cancer, mental disorders, epilepsy, HIV/AIDS, and to prevent the rejection of transplanted organs.

Second CMS proposed change to six protected classes: Further restrictions on new formulations ignore the value of these advances and could leave patients without access to needed medicines.

CMS proposes to amend its regulations to permit Part D sponsors “to exclude from their formularies a protected-class single-source drug or biological product for which the manufacturer introduces a new formulation with the same active ingredient or moiety that does not provide a unique route of administration.” CMS regulations already permit Part D sponsors to exclude a new formulation of a drug from their formularies when an older formulation with the same route of administration is still available. This proposed policy change could cause significant access issues for patients by excluding the only available formulation from Part D coverage⁶⁵ and also reflects a significant misunderstanding regarding the benefits of new formulations. CMS states that it is proposing this change due to an action from one manufacturer that took the original formulation off the market once an extended-release version was being

⁶² Centers for Disease Control and Prevention, “HIV in the United States, 2017 data,” Available at: <https://www.cdc.gov/hiv/statistics/overview/ata glance.html>.

⁶³ DW Haas et al, *et al.* “Pharmacogenetics of efavirenz and central nervous system side effects: an ADULT AIDS Clinical Trials Group study.” *AIDS*: Dec. 3, 2004, Volume 18, issue 18, p. 2391-2400. Foulkes AS, *et al.*: “Associations among race/ethnicity, *ApoC-III* genotypes, and lipids in HIV-1-infected individuals on antiretroviral therapy.” *PLoS Med.*3(3),E52, 2006

⁶⁴ SSA § 1860D-11(e)(2)(D).

⁶⁵ Part D plans would still have to meet the requirement to cover two drugs per class and so in some cases would still need to cover a new formulation in order to meet that two drug per class minimum. See Social Security Act § 1860D-4(b)(3)(C) and 42 CFR § 423.120(b)(2)(i).

sold.⁶⁶ We have significant policy concerns with the change that CMS is proposing. We also urge particular caution when making a policy change that could limit access to needed medicines based on a single example.

Excluding new formulations when no other formulation is available would significantly impede patient access to life-saving medicines in the protected classes. The purpose of the protected classes is to ensure patients have access to “exactly the right medicine for them.”⁶⁷ Allowing a sponsor to deny access to a drug simply because it is a new formulation is counter to the core principle behind the protected classes.

CMS’s proposal fails to recognize that new formulations often provide significant improvements in adherence and health outcomes over existing older formulations. Novel preparations can have a profound effect on the clinical profile of a medicine and offer many benefits for patients, including more convenient treatment options, reduced side effects and improved quality of life. This may be true even when there is no corresponding change in the route of administration. For example, extended-release products can increase the length of time between doses, reducing the number of doses needed and giving greater flexibility for the patient and physician to determine which dosing schedule best fits the patient’s lifestyle and health needs, with reduced likelihood of missed doses. In the mental health space, less frequent dosing may have positive effects in increasing patient adherence, reducing the likelihood for relapse, and improving clinical care quality.⁶⁸ In the case of HIV, single tablet regimens and longer-acting anti-retroviral medicines improve adherence,⁶⁹ which is critical for a patient’s health and also has a larger public health impact by reducing transmission rates. Moreover, this proposed CMS policy could diminish incentives for the development of future treatments if manufacturers are unsure if patients will have coverage.

CMS’s proposed policy also does not provide protections for cases when the manufacturer producing the new formulation is not the same as the manufacturer of the original formulation. Such a case could occur if a brand manufacturer is producing an extended release version of a

⁶⁶ 83 Fed. Reg. 231 at 62159.

⁶⁷ 149 Cong. Rec. S5882-03 (Nov. 25, 2003).

⁶⁸ Correll, C. U., Citrome, L., Haddad, P. M., Lauriello, J., Olfson, M., Calloway, S. M., & Kane, J. M. (2016). “The Use of Long-Acting Injectable Antipsychotics in Schizophrenia: Evaluating the Evidence.” *The Journal of Clinical Psychiatry*, 77(suppl 3), 1-24; Marcus, S. C., Zummo, J., Pettit, A. R., Stoddard, J., & Doshi, J. A. (2015).

“Antipsychotic adherence and rehospitalization in schizophrenia patients receiving oral versus long-acting injectable antipsychotics following hospital discharge.” *Journal of Managed Care & Specialty Pharmacy*, 21(9), 754-769; Kaplan, G., Casoy, J., & Zummo, J. (2013). “Impact of long-acting injectable antipsychotics on medication adherence and clinical, functional, and economic outcomes of schizophrenia.” *Patient preference and adherence*, 7, 1171-1180.

⁶⁹ J. Parienti, et al., “Better Adherence with Once-Daily Antiretroviral Regimens: A Meta-Analysis” *Clin Infect Dis*. 2009 Feb 15; 48(4): 484–488.

medicine and a generic version of the original formulation is being produced by a separate manufacturer. In this example, the generic manufacturer could decide to stop producing the original formulation. A brand manufacturer would have no control over such a decision. However, under the proposed policy, plans could then decide to not cover the extended release formulation even though the generic original formulation is no longer available.

Third CMS proposed change to six protected classes: The pricing threshold for protected class drug formulary exclusion is flawed and would have dangerous consequences for access to medicines.

We strongly oppose the CMS proposal to allow a Part D sponsor to exclude a protected class drug from its formulary if the list price of the drug increases at a rate faster than inflation, and we question the legality and appropriateness of policy changes that would allow cost considerations to outweigh clinical need and statutory non-discrimination protection—particularly in the case of vulnerable beneficiaries who rely on medicines in the six protected classes. CMS’ proposal is fundamentally flawed in several ways that are outlined below and will have unintended consequences. The proposal is also in conflict with the Part D anti-discrimination provision, and the details of the proposal are not narrowly tailored to the problem it is trying to solve, which makes it punitive to patients and manufacturers alike.

The inflation penalty proposal appears to be based on a flawed understanding of drug pricing data.

CMS’ suggested policy appears to be based on their erroneous belief that prices of protected class drugs are increasing rapidly and that Part D plans need additional leverage to negotiate prices for medicines in the protected classes. However, evidence shows that protected class status does not weaken plan sponsors’ ability to negotiate lower prices for medicines. According to MedPAC, plans’ ability to manage utilization and drive the use of generics when appropriate has helped slow the growth in prices, even when a drug has protected status.⁷⁰

Changes in Wholesale Acquisition Cost (WAC) provide an inaccurate picture of Part D program spending.

The proposal’s focus on list price (wholesale acquisition cost) increases masks competitive dynamics in the biopharmaceutical market today. There is no one price for a medicine, as prices paid by wholesalers, pharmacies, pharmacy benefit managers (PBMs), and Part D plan sponsors all vary and are determined by negotiations between stakeholders, each with varying degrees of negotiating power. WAC is the price manufacturers charge to wholesalers or other direct

⁷⁰ MedPAC, Report to the Congress: Medicare Payment Policy (Mar. 2017).

purchasers before any discounts, rebates, or other price reductions are applied.⁷¹ As CMS acknowledges in the proposed rule, manufacturers of drugs within and outside of the six protected classes offer rebates to Part D plan sponsors as part of the competitive price negotiations that take place in today’s market.⁷²

Analysis that accounts for these manufacturer rebates shows that both net price increases and medicine spending growth have been exceptionally low in recent years:

- For example, according to recently released National Health Expenditures data from CMS, spending on retail medicines grew by just 0.4 percent last year, the slowest growth rate since 2012 and substantially lower than hospital spending growth (4.6 percent) and increases in physician and clinical services spending (4.2 percent) in 2017.⁷³
- According to the 2018 Medicare Trustees Report, over the past 10 years, Part D benefit payments have increased at an annual rate of 3.8 percent on a per enrollee basis.⁷⁴
- IQVIA reports that prices for brand-name medicines increased by just 1.9 percent in 2017 after discounts and rebates, even as many new treatments reached patients.⁷⁵

As a result, changes in WAC provide a misleading and incomplete picture of Part D program spending, and CMS’ proposal to establish a pricing threshold based on WAC will not accurately reflect the competitive negotiations taking place in today’s biopharmaceutical market.

The proposal’s flawed approach could undo protected classes’ safeguards due to macroeconomic factors outside of a manufacturers’ control.

As described above, CMS’ overall approach to creating a pricing threshold is inappropriate and unnecessary. In addition, significant flaws in CMS’ proposed methodology could result in the unraveling of the six protected classes despite a manufacturer’s best efforts to adhere to the proposed policy change.

⁷¹ PhRMA. Follow the Dollar. November 2017. Available at: <http://phrma-docs.phrma.org/files/dmfile/Follow-the-Dollar-Report.pdf>

⁷² 83 Fed. Reg. 62156 (Nov. 30, 2018).

⁷³ CMS. National Health Expenditures 2017 Highlights. Available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf>

⁷⁴ 2018 Medicare Trustees Report.

⁷⁵ IQVIA. “2017 Medicine Use and Spending.” Published April 2018.

In measuring WAC increases against general inflation (the consumer price index for all urban consumers, or CPI-U), CMS proposes to create an unreasonably low benchmark that puts pharmaceutical manufacturers on an unlevel playing field with other health care providers.

Recent history shows that the annual change in CPI-U can be remarkably low, increasing just 0.1 percent in 2015 and even trending negative in some years (for example, the annual change in CPI-U was -0.4 percent in 2009).⁷⁶ CMS frequently provides for increases in reimbursement rates for common Medicare goods and services at rates higher than CPI-U each year. For example, in three out of the past four years, CMS increased Medicare reimbursement for knee replacements at rates that exceeded CPI-U by as much as five percentage points as part of the annual Outpatient Prospective Payment System payment update. And before they were incorporated into the Competitive Bidding Program, reimbursement rates for common types of durable medical equipment, like walkers and respiratory assist devices, were updated at rates that exceeded inflation.⁷⁷ Notably, these increases in reimbursement are likely lower than the increases in the equivalent of these providers' list prices, which most certainly rose by rates greater than CPI-U over this period. Although CMS is correct in acknowledging that CPI-U is occasionally used to update annual parameters used in the Medicare and Medicaid programs,⁷⁸ most Part D program parameters are tied to the "annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals."⁷⁹ By proposing to tie protected class status to CPI-U, CMS is setting an unreasonably low bar that will most certainly unfairly penalize patients and manufacturers.

The proposed methodology for calculating the exclusion threshold increases the likelihood that volatility in the CPI-U will be captured.

CPI-U is calculated monthly on a retrospective basis, and varies seasonally and based on economic conditions, as demonstrated by the chart below from the Bureau of Labor Statistics' press release on the consumer price index update for November 2018.

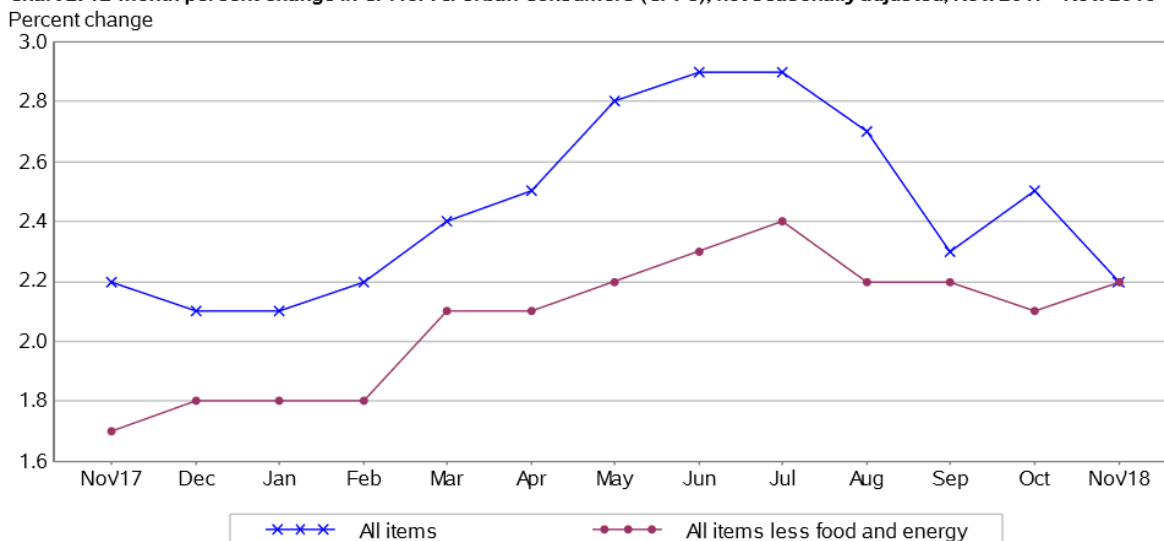
⁷⁶ Federal Reserve Bank of Minneapolis. Consumer Price Index, 1913-. Available at: <https://www.minneapolisfed.org/community/financial-and-economic-education/cpi-calculator-information/consumer-price-index-and-inflation-rates-1913>

⁷⁷ Xcenda analysis for PhRMA of Medicare Durable Medical Equipment, Prosthetics/Orthotics, and Supplies Fee Schedules (ceiling rate), Outpatient Prospective Payment System Addendum B files (payment rates), and Physician Fee Schedules Relative Value Units files (facility rates), December 7, 2018.

⁷⁸ 83 Fed. Reg. 62160 (Nov. 30, 2018).

⁷⁹ SSA § 1860D-2(b)(6).

Chart 2. 12-month percent change in CPI for All Urban Consumers (CPI-U), not seasonally adjusted, Nov. 2017 - Nov. 2018



Source: Bureau of Labor Statistics, U.S. Department of Labor. News Release: Consumer Price Index – November 2018. Available at: <https://www.bls.gov/news.release/pdf/cpi.pdf>. Accessed 15 December 2018.

As described in the proposed rule, loss of protected class status could be triggered if a drug’s “wholesale acquisition cost between the baseline date and *any point in the applicable period*, increased more than the cumulative increase in the consumer price index for all urban consumers over the same period.”⁸⁰ The fluctuation of CPI-U and the retroactive reporting create uncertainty for manufacturer’s best efforts to adhere to the policy and avoid increases above the CPI-U threshold. For example, as shown below, an unexpected decrease in CPI-U for one month could cause a manufacturer’s price increase to inadvertently exceed CPI-U even if the manufacturer’s price increase would have been below the inflation threshold in the months prior to the price increase.

⁸⁰ 83 Fed. Reg. 62200 (Nov. 30, 2018) (emphasis added).

CPI-U Example: Contract Year 2022

Applicable period: 9/1/2019 through 8/31/2020

Baseline WAC (September 2018): \$100

Baseline CPI-U (September 2018): 100

WAC changes:

September 2019 WAC: \$100

October 2019 WAC: \$102.50

November 2019 WAC: \$102.50

Manufacturer takes one time 2.5% increase in October 2019 after monitoring CPI-U increases

CPI-U changes:

September 2019 CPI-U: 103

October 2019 CPI-U: 102

November 2019 CPI-U: 103

Inflation decreases in October 2019 due to seasonal, economic or national event

Insurer can trigger exception for WAC increasing above CPI-U in October 2019 only per NPRM formula

Rate of change for WAC: $(\text{Oct 2019 WAC} - \text{Baseline WAC})/100 = 2.5\%$ growth

Rate of change for CPI-U: $(\text{Oct 2019 CPI-U} - \text{Baseline CPI-U})/100 = 2.0\%$ growth

CMS proposes to put Part D plans in charge of monitoring price increases, requiring them to submit formulary exclusions that meet the proposal's criteria to CMS for approval.⁸¹ There is evidence that CMS is not equipped to monitor whether plans will use the exclusion criteria appropriately, especially given the complex nature of the methodology proposed. For example, CMS frequently issues audit enforcement actions against Part D plan sponsors for inappropriately rejecting formulary medications and administering prior authorization and step therapy edits, among other violations of CMS regulations and guidance.⁸² According to Gorman Health Group, 18 Medicare Advantage and/or Part D plan sponsors were issued almost \$2.6 million in Civil Money Penalties (CMP) between September 2017 and February 2018, with 61 percent of sponsors cited specifically for formulary and benefit administration violations.⁸³ If plans seek to manipulate the complex methodology included in the proposed rule, it is likely beneficiaries would bear the consequences before plans faced any corrective action from CMS.

The proposal could result in unintended consequences.

An inflation penalty is likely to produce unintended consequences that could increase costs to the Medicare program as well as consumers more generally. CMS suggests that plan sponsors will

⁸¹ 83 Fed. Reg. 62162 (Nov. 30, 2018).

⁸² CMS Part C and Part D Enforcement Actions. Available at: <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PartCandPartDEnforcementActions-.html>

⁸³ Regan Pennypacker, Gorman Health Group. Latest Audit Enforcement Actions Issued by CMS. March 22, 2018. Available at: <https://www.gormanhealthgroup.com/blog/latest-audit-enforcement-actions-issued-by-cms/>

not necessarily exclude drugs subject to the inflation penalty from coverage but instead demand the payment of rebates in exchange for formulary placement. CBO, however, has observed in the context of other policy proposals that “drug manufacturers would be expected to set higher ‘launch’ prices for new drugs as a way to limit the effect of [] new rebate[s].”⁸⁴ Thus, the new policy could create incentives for escalating list prices – the exact opposite of the Administration’s stated goal. This could drive up costs for Part D beneficiaries and patients with commercial coverage who may pay cost-sharing based on the list price of a drug.

Alternative policies could achieve the Administration’s goals without putting patients at risk.

If CMS wishes to address patient affordability challenges caused by rising list prices, there are more appropriate policy solutions that would not put patients’ health at risk. The changes to six protected classes being proposed by the Administration are unlikely to lower patients’ out-of-pocket costs for brand medicines and could harm patients by introducing access barriers. In PhRMA’s comments on the *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, we supported several policies that would promote competition and improve patient affordability. Within Part D, we urge the Administration to lower patient costs by requiring plan sponsors to pass through a share of discounts and rebates to Part D beneficiaries at the point of sale. This is consistent with CMS’s discussion in this proposed rule of passing through pharmacy price concessions. Extending this policy to manufacturer rebates could yield lower out-of-pocket costs immediately (upon taking effect) for millions of beneficiaries while also generating multi-billion dollar savings to the federal government over a ten year window.⁸⁵

Requiring that a share of rebates and discounts be shared directly with patients would improve the sustainability of the Part D program by reducing the incentives the Administration has identified as encouraging high list prices.⁸⁶ Rebate pass through would make it harder for Part D plans and pharmacy benefit managers to profit from the spread between list and net prices. This would reduce the current incentives that administration officials have noted can lead plans and PBMs to favor high list price, high rebate medicines over medicines with a lower net price.⁸⁷

⁸⁴ CBO. *Require Manufacturers to Pay a Minimum Rebate on Drugs Covered Under Part D of Medicare for Low-Income Beneficiaries*. December 8, 2016.

⁸⁵ Milliman. *Reducing Part D Beneficiary Costs Through Point-of-Sale Rebates*. January 2018, available at <http://www.phrma.org/report/reducing-part-d-beneficiary-costs-through-point-of-sale-rebates>

⁸⁶ Alex Azar, HHS, *Testimony Before the United States Senate Committee on Finance: Prescription Drug Affordability and Innovation: Addressing Challenges in Today’s Market*, June 26, 2018.; Alex Azar, HHS, *Testimony Before the United States Senate Committee on Health, Education, Labor and Pensions: Full Committee Hearing: The Cost of Prescription Drugs: Examining the President’s Blueprint ‘American Patients First’ to Lower Drug Prices*, June 12, 2018.

⁸⁷ Gottlieb S, “Advancing Patient Care Through Competition,” *Remarks at the Pharmaceutical Care Management Association*, Washington, DC, April 19, 2018.

The proposed inflation threshold policy is fundamentally flawed and should not be expanded.

In the proposed rule CMS contemplates two ways to expand the impact of the proposed CPI-U threshold. Both expansions would exacerbate the negative impact of this flawed policy in ways that are dangerous for patients and should not be finalized. The flaws in these policies are explained below:

- **Extension of inflation policy for future years:** CMS is considering whether “a Part D sponsor could exclude a protected class drug from its formulary for *any* future contract year once its WAC increased more rapidly than the cumulative increase in inflation.”⁸⁸ As discussed above, CPI-U has been low or even negative over many recent periods. Allowing plans to continue to exclude medicines from a formulary for years after the medicines’ price increases exceeded CPI-U would extend the negative impact of a penalty that may have been triggered by a fluke in inflation trends. Such a policy would hurt patients by allowing past pricing decisions to restrict access to needed medicines for years to come. As explained earlier, there are important clinical reasons to provide access to the full set of medicines in the six protected classes, and any restrictions could lead to serious medical complications. We also note that even though plans would not be required to exclude these medicines from their formularies, fear of attracting less healthy, higher-cost beneficiaries would likely lead to narrower formularies persisting over multiple years.
- **Extension of inflation policy to other products in a manufacturer’s portfolio:** CMS is also considering “whether we should apply this price threshold exception to *all* drugs in the protected classes of a given manufacturer if *any one* of those drugs’ WAC, when compared to the baseline WAC, increases beyond the cumulative rate of inflation.”⁸⁹ Such a policy would extend the scope of the dangerous formulary exclusions that CMS is already considering. Each company makes its own pricing decisions based on the unique competitive dynamics facing each product. It would be unreasonable for a WAC increase for one medicine – which may provide an inaccurate picture of changes in that product’s net price to begin with – to have an impact that extended to other products whose WAC prices did not increase. Additionally, like the other expansion of the inflation policy being considered, allowing the exclusion of a manufacturer’s other products would increase the scope of dangerous health impacts of any formulary exclusions.

⁸⁸ FR Vol. 83 No. 231 at 62163.

⁸⁹ FR Vol. 83 No. 231 at 62163.

Legal concerns

As explained above, CMS’s proposal also may run afoul of the Part D law’s non-discrimination clause.⁹⁰ CMS developed the protected classes doctrine at the outset of the Part D program to carry out the Part D law’s non-discrimination clause, which prohibits CMS from approving any Part D plan with a design (including a formulary or formulary structure) that is “likely to substantially discourage enrollment by certain [Medicare beneficiaries].”⁹¹ CMS instituted the protected classes policy “because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs [in the six protected classes] would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations.”⁹² This statement remains true. Excluding a drug otherwise within the six protected classes from protected class status due to a list price increase would therefore violate the non-discrimination clause by permitting Part D plans with benefit designs that discourage enrollment by some of Medicare’s most vulnerable beneficiaries.

The purpose of the protected class policy is that certain medications are essential to the health of vulnerable populations of Medicare beneficiaries, and Part D sponsors therefore should not have the option of denying coverage of such drugs in efforts to trim costs. The law does not permit compromising or subordinating non-discrimination principles in order to promote lower drug prices, and CMS has other tools that will advance the goal of patient affordability and market competition more effectively.

Moreover, tying a drug’s protected class status to whether its list price has increased finds no support in the text of the relevant statutory provisions, which ban discriminatory benefit designs that could discourage enrollment by certain beneficiaries.⁹³ In interpreting and applying these provisions, CMS may not consider factors Congress did not authorize it to consider⁹⁴—such as list price movements.

⁹⁰ SSA § 1860D-11(e)(2)(D).

⁹¹ SSA § 1860D-11(e)(2)(D).

⁹² Medicare Prescription Drug Benefit Manual, Chap. 6, § 30.2.5.

⁹³ SSA § 1860D-11(e)(2)(D).

⁹⁴ See, e.g., *Nalco Co. v. EPA*, 786 F. Supp. 2d 177, 187 (D.D.C. 2011) (rejecting EPA’s enforcement action as arbitrary and capricious where it acted based on its stated desire “to level the marketplace for competitors,” but the authorizing statute “does not give EPA jurisdiction to control or modify the marketplace”); *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (“Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider”).

None of the additional considerations suggested by CMS would ensure that patients have adequate coverage for six protected class medicines.

CMS’s proposal to substantially weaken the protected classes is grounded on the assumption that “other enrollee protections in the Part D program... are mature and have proven workable.” But when it comes to drugs in the protected classes, this assumption is unsound. None of the other protections that CMS highlights—formulary transparency, formulary requirements, and the appeals and exceptions processes—offer the same strong beneficiary protection as the protected class policy.

The formulary transparency requirement is often not useful to beneficiaries, particularly in the context of a change to protected classes.

Many beneficiaries who already have coverage of a particular drug from a Part D sponsor will assume they will continue to be able to access the drug in the new calendar year, and therefore are unlikely to scrupulously review new information on prior authorization criteria or formulary placement that may result in loss of coverage.⁹⁵ Moreover, many of those who receive protected class drugs are low-income subsidy (LIS) beneficiaries who are auto-assigned to a plan, and therefore do not actively make a choice to enroll in a plan. While CMS does provide notice to re-assigned beneficiaries about changes in formulary coverage and gives LIS beneficiaries the ability to select another plan, in reality many LIS beneficiaries, who are a particularly vulnerable population unlikely to carefully read CMS notices,⁹⁶ will not be aware of the coverage changes until their prescription is denied. Additionally, LIS beneficiaries who seek to enroll in a plan with zero dollar premiums, may have limited plan choices and may not be able to find a plan that covers the six protected class medicine they need.

The other formulary requirements that apply across all Part D classes are inadequate for the six protected classes. For example, covering just two drugs per category and class is wholly insufficient for patients who have undergone a transplant or have HIV, cancer, depression, a psychosis, or a seizure disorder. The protected class policy was established out of the recognition that these conditions require beneficiaries to have broad access to multiple drugs in each category and class, since a patient’s reaction to each individual drug varies widely.⁹⁷ This

⁹⁵ Kaiser Family Foundation, “Medicare Advantage Plan Switching: Exception or Norm?” (September 2016). Available at: <http://files.kff.org/attachment/Issue-Brief-Medicare-Advantage-Plan-Switching-Exception-or-Norm>.

⁹⁶ See 79 Fed. Reg. 1936, 1952 (Jan. 10, 2014) (observing that many LIS beneficiaries are of limited English proficiency).

⁹⁷ A Senate exchange that took place just before enactment of the legislation that created Part D emphasized the many layers of patient protections Congress had purposely built into the program to ensure broad coverage of medications for patients—such as those facing HIV/AIDS, epilepsy, or mental illness—“who need exactly the right medicine for them.” 149 Cong. Rec. S5882-03 (Nov. 25, 2003).

is all the more the case because physicians often recommend that individuals with some of these conditions undergo combination therapy, and under the United States Pharmacopeia (USP) guidelines used by many Part D sponsors combination products are not recognized as a separate class (and therefore combination products do not need to be covered under the two-drug per class policy at all).⁹⁸ While CMS reviews plan formularies for discriminatory design, it is inevitable that such review will not stop some Part D sponsors from reducing coverage of critically needed medications once the protected class requirements are weakened. CMS also reviews marketplace plans for discriminatory practices,⁹⁹ yet some marketplace plans have nevertheless been subject to lawsuits claiming that they have limited coverage of HIV drugs in an effort to discourage enrollment of HIV enrollees.¹⁰⁰

The appeals and exceptions processes are clearly difficult for patients to navigate.

A MedPAC analysis found that a “majority of beneficiaries were not aware that they could ask for an exception or appeal a plan decision, nor could they understand how the appeals process works.”¹⁰¹ Even if a beneficiary has the understanding and inclination to file an appeal, the beneficiary typically will need to wait some time before an appeal decision is reached. It can take more than two weeks before a beneficiary can obtain a decision from an independent review entity.¹⁰² While expedited determinations can be made within 24 hours, in practice it can take much longer than a day for a beneficiary to receive a drug following an expedited review. This is because the clock does not begin to run when a beneficiary is denied coverage of a drug at the pharmacy counter, but only when the prescriber submits necessary information to the Part D sponsor, which may be days after the beneficiary attempted to fill the prescription.¹⁰³ And if the Part D sponsor does not side with the beneficiary upon the initial coverage determination, it can

⁹⁸ United State Pharmacopeial Convention, Guiding Principles USP Medicare Model Guidelines v7.0 (March 22, 2016). Available at: https://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/2016_usp_mmg_guiding_principles.pdf.

⁹⁹ 45 C.F.R. § 156.125; *see also* 80 Fed. Reg. 10750, 10822-23 (“we will notify an issuer when we see an indication of a reduction in the generosity of a benefit in some manner for subsets of individuals that is not based on clinically indicated, reasonable medical management practices.”).

¹⁰⁰ Kaiser Health News, 7 Insurers Alleged to use Skimpy Drug Coverage to Discourage HIV Patients (Oct. 18, 2016).

¹⁰¹ Medicare Payment Advisory Commission, “Report to the Congress: Medicare Payment Policy” (March 2014; pgs. 368-369). Available at: http://www.medpac.gov/docs/default-source/reports/mar14_entirereport.pdf.

¹⁰² The standard timeframe for a standard determination is 72 hours, after which the Part D sponsor has 7 days to undertake the first level appeal, and then the independent review entity has another 7 days to undertake its review. 42 C.F.R. §§ 423.568(b), 423.590(a), 423.600(d).

¹⁰³ In the case of an exception request, the timeframe begins when the prescriber submits a statement explaining the medical necessity of the drug; where the beneficiary is seeking to satisfy prior authorization requirements the timeframe begins when the prescriber submits evidence demonstrating the prior authorization criteria has been met. Medicare Prescription Drug Benefit Manual, ch. 18, §§ 30, 30.1, 30.2.2.2. While a beneficiary can obtain a transition fill while waiting for the appeal to resolve itself, doing so represents yet another hurdle for the beneficiary to navigate. Moreover, the transition fill is only available to those continuing a therapy, not new starts.

take another week to obtain a decision from an independent review entity, even when treated on an expedited basis.¹⁰⁴

Provider burden is another area of concern. The appeals and exceptions process places a burden on providers who often must submit paperwork to help justify a patient’s need for a particular medicine. Specialists who see many patients who are taking medicines in the six protected classes may find themselves overwhelmed with additional paperwork.

This difficult and slow-moving appeals process is at odds with best practices in the protected classes, where timely access to medicines is recognized as crucial for improved patient care, better outcomes and reduced costs. CMS itself has concluded that for five of the six protected classes “hospitalization, persistent or significant incapacity or disability, or death likely will result if the 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.”¹⁰⁵ In the case of antiretrovirals, rapid initiation, including starting a medication the same day as diagnosis, is recommended under both U.S. and international guidelines as a means of achieving viral suppression.¹⁰⁶

In fact, CMS recognized the shortcomings of all these other protections when it issued a proposed rule on protected classes in 2014. In analyzing the antiretroviral, antineoplastic and anticonvulsant classes, CMS agreed with a panel’s determination that “different drugs within those categories and classes are used in so many patient-, drug-, or disease-specific clinical applications that an alternative formulary requirement is not feasible.”¹⁰⁷ CMS is in effect seeking to go even further than it did in the 2014 proposed rule—which was withdrawn after vehement opposition from many parties¹⁰⁸—when it suggests that other beneficiary protections can promote access to these drugs.

¹⁰⁴ A Part D sponsor has 72 hours to conduct the first-level appeal of an expedited case. Once the sponsor’s decision has been reached, an independent review entity has another 72 hours to reach a decision. 42 C.F.R. §§ 423.572(a), 423.590(d)(1), 423.600(d).

¹⁰⁵ 79 Fed. Reg. 1936, 1944–45 (Jan. 10, 2014).

¹⁰⁶ U.S. Department of Health and Human Services, Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV (Oct. 17, 2017).

¹⁰⁷ 79 Fed. Reg. 1936, 1944 (Jan. 10, 2014).

¹⁰⁸ Among others, 20 bipartisan members of the Senate Finance Committee wrote to CMS urging the agency to withdraw its proposal.

The Proposed Medicare Advantage Step Therapy Policy for Part B Medicines Would Negatively Impact Patients and Providers and Is Prohibited by Statute (§§422.136, 422.568, 422.570, 422.572, 422.584, 422.590, 422.618, and 422.619)

The proposed rule would codify August 7, 2018 guidance in which CMS reversed long-standing policy prohibiting Medicare Advantage (MA) plans from using step therapy as a form of utilization management for medicines covered under Medicare Part B.¹⁰⁹ This policy is inconsistent with the statutory framework governing the MA program because, as discussed in more detail below, MA coverage policies may not be more restrictive than Original Medicare by imposing additional barriers to Part B drug coverage, such as step therapy. It would also risk substantial harm to elderly or disabled patients with serious illnesses by restricting their access to the most effective or appropriate medicines.

Step therapy policies – often referred to as “fail first” policies – require patients to demonstrate that a medicine preferred by their health plan is not effective or tolerable before receiving the treatment recommended by their provider. Patients who rely on Part B medicines frequently have serious conditions that require intensive management such as cancer, rheumatoid arthritis (RA) and other autoimmune conditions, severe infections, multiple sclerosis, macular degeneration, genetic disorders, and other rare diseases. The dilution of core beneficiary protections in Medicare could greatly limit and impede access for these patients with complex and life-threatening medical conditions, leading to further disease progression and health complications, including potentially permanent harm, loss of function, or even death when their treatment regimens are compromised. Forcing use of inappropriate treatments can also increase use of other health care services such as emergency department visits and hospitalizations, driving up medical costs.

Part B medications are usually administered by physicians (e.g. intravenously, intravitreal injections) who may need to make on-the-spot adjustments to dosing, timing, or treatment due to changes in patient lab results or other health status considerations. Utilization management like step therapy can delay these types of personalized treatment adjustments, risking poor patient outcomes and further increasing the cost of health care. Step therapy policies also often result in time-consuming paperwork and red tape for physicians due to an increase in appeals requests, taking them away from providing patient.

¹⁰⁹ Centers for Medicare and Medicaid Services. “Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage.” August 7, 2018. https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf

For these reasons, PhRMA shares the concerns of many other patient and provider organizations about the challenges the new step therapy policy could create for patients’ access to care.¹¹⁰

PhRMA requests that CMS not move forward with step therapy for Part B medicines in the proposed rule, revoke the August 7, 2018 memo, and continue to prohibit MA plans from using step therapy.

Step therapy can lead to poor health outcomes and increased expenditures, particularly when implemented in a clinically inappropriate manner, simply to control costs.

Restrictive utilization management practices based solely on costs can cause access and adherence issues that ultimately lead to poor health outcomes. In the commercial market, step therapy policies that are clinically inappropriate are increasingly being used for medical benefit medicines used to treat complex conditions like cancer and multiple sclerosis.¹¹¹ Variation in how commercial plans implement these policies raises concerns about their validity. Medicare Part B covers the medicines used to treat vulnerable seniors with these diseases and will likely see increased expenditures if MA plans are allowed to implement clinically inappropriate step therapy policies that prioritize cost over health outcomes.

Recent research published in *Health Affairs* detailed a review of step therapy protocols used by commercial plans and found substantial variation in how commercial plans implement step therapy for specialty medicines.¹¹² The authors stated that while some difference between policies is to be expected, the degree of variation in step therapy protocols “raises questions about whether they are grounded in sound clinical evidence.”¹¹³ MA plans that published their step therapy policies in the fall of 2018 are an example of this type of haphazard variability. While some policies applied to only a handful of medicines and one or two disease groups, Humana published a list of 48 Part B medicines that it will subject to step therapy in the 2019 plan year, including medicines used to treat breast, lung, pancreatic, and ovarian cancer, as well as medicines used to support patients undergoing chemotherapy.¹¹⁴ This variation and focus on cancer treatment calls in to question whether plans are implementing step therapy in a clinically appropriate manner.

¹¹⁰ Part B Access for Seniors and Physicians Coalition. Part B Drug Access, Step Therapy Focus of Capitol Hill Briefing. www.partbaccess.org/wp-content/uploads/2017/06/ASP-Hill-Briefing-Release.pdf. September 20, 2108; 240 patient groups signed a letter to Congressional leaders urging them to ask CMS to reconsidering allowing step therapy in Medicare Part B.

¹¹¹ Park Y, Raza S, George A, Agawal R, Ko J. (2017) The effect of formulary restrictions on patient and payer outcomes: a systematic literature review. *Journal of Managed Care & Specialty Pharmacy*, 23(8), 893-901

¹¹² Chambers JD, Panzer AD, Neumann PJ., Variations In The Use of Step Therapy Protocols Across US Health Plans, *Health Affairs*. <https://www.healthaffairs.org/doi/10.1377/hblog20180912.391231/full/>

¹¹³ Id.

¹¹⁴ Humana. “Medicare Advantage and Dual Medicare-Medicaid Plans: Preauthorization and Notification List.” January 2019. <http://apps.humana.com/marketing/documents.asp?file=3483311>

Humana’s focus on cancer treatments is also concerning as these patients are particularly vulnerable to clinically inappropriate utilization management techniques. A 2016 survey from Cancer Support Community found that 1 in 7 patients were required to try an alternative cancer medication before they could receive the medication originally prescribed by their doctor.¹¹⁵ Half of respondents appealed this requirement and of those who did eventually receive the originally-prescribed treatment, more than half had to wait 7 to 30 days before doing so.¹¹⁶ While in the process of appeal for their physician’s preferred therapy to be approved, sixteen percent of patients chose not to start the treatment their insurance company recommended (potentially out of concerns about negative side effects with long-term consequences) and delayed any treatment until an exception for the originally prescribed medicine was granted.¹¹⁷ As discussed below, delays in accessing optimal cancer treatment can lead to disease progression and declining patient performance status, all of which can result in poor outcomes.

The potential harm can also be seen in research related to delayed access and breast cancer care. A recent study shows that women with breast cancer who experience longer treatment delays had significantly decreased survival time compared to woman who access treatment more quickly.¹¹⁸ In another study, for 1128 patients with colorectal, lung, melanoma skin, breast, or prostate cancer, the authors stated: “we can infer from the increasing trends in mortality that a few weeks can make a difference – that time matters.”¹¹⁹

Another example of poor health outcomes associated with inappropriate, cost-driven utilization management is the increased use of medical services often tied to these policies.¹²⁰ While utilization management can decrease the use of, and therefore spending on, medicines, these savings are often offset by increased medical and associated costs.¹²¹ A recent literature review of the impact of formulary restrictions highlighted this offset, finding that more than half of the studies reviewed showed a negative impact on patient and/or payer outcomes.¹²² A separate study found that formulary restrictions were associated with reduced medication adherence and negative clinical outcomes for patients.¹²³ Other studies on multiple sclerosis found that

¹¹⁵ Cancer Support Community. (2016). Access to Care in Cancer 2016L: Barriers and Challenges.

¹¹⁶ Id.

¹¹⁷ Id.

¹¹⁸ Smith EC, Ziogas A, Anton-Culver H. Delay in surgical treatment and survival after breast cancer diagnosis in young women by race/ethnicity. *JAMA Surg.* 2013 Jun;148(6):516-23

¹¹⁹ Topping ML, Frydenberg M, Hansen RP, Olesen F, Vedsted P. Evidence of increasing mortality with longer diagnostic intervals for five common cancers: a cohort study in primary care. *Eur J Cancer.* 2013 Jun;49(9):2187-98.

¹²⁰ Park Y, Raza S, George A, Agrawal R, Ko J. (2017). The effect of formulary restrictions on patient and payer outcomes: a systemic literature review. *Journal of Managed Care & Specialty Pharmacy*, 23(8), 893-901.

¹²¹ Id.

¹²² Id.

¹²³ Lu CY, Ross-Degnan D, Soumerai SB, Pearson SA. (2008) Interventions designed to improve the quality and efficiency of medication use in managed care: a critical review of the literature- 2001-2007. *BMC Health Services Research*, 8(1), 75

utilization management delays treatment by three months, that this length of treatment delay can increase patients' risk of relapse by 28 percent, and that treatment delays in general lead to faster disease progression.^{124,125} Subjecting seniors to clinically inappropriate, purely cost-based utilization management has the potential to increase costs for Medicare in other areas and to harm beneficiaries' health.

The risks associated with cost-driven utilization management have also been identified by states that have passed legislation to protect patients from inappropriate step therapy. Sixteen states have enacted laws that require payers to grant step therapy override requests from providers who demonstrate that the treatment preferred by the health plan will likely cause an adverse reaction or is not medically appropriate for the patient.¹²⁶ Many of these bills also protect patients who are already stable on a medication from having to undergo step therapy requirements, and establish a presumption of coverage if a health plan fails to respond to an override.¹²⁷ Some bills protect patients who have already tried and failed a drug while covered under a previous plan request from being forced to fail again on the medicine because they changed plans.¹²⁸ In 2017, federal legislation with similar provisions was introduced.¹²⁹ Legislators at both the federal and state level have recognized the inherent dangers clinically inappropriate step therapy can pose to patients.

In implementing this policy, CMS ignores the concerns raised by state and federal policy makers. Specifically, the policy fails to adequately protect patients who were previously stable on their medicine. Many patients receiving treatment for cancer or autoimmune conditions can experience treatment-free intervals that exceed the 108-day lookback period established by CMS. Under this policy, those patients could be forced to step backwards.

Further calling in to question whether step therapy protocols will be based on sound clinical evidence is the provision allowing MA plans to *require* that a patient try and fail an off-label drug before assessing an alternative treatment that has been approved by the FDA for that indication. While CMS covers medicines for medically accepted off-label uses, the decision of

¹²⁴ Charlmer TA, Magyari M, Baggesen LM, Norgaard M, Koch-Henriksen N, Solberg Sorensen P. Early versus later treatment start in multiple sclerosis - a register based cohort study. *Neurology*. 2018 April;90(15):Supplement.

¹²⁵ Kavaliunas A, Manoucherhrinia A, Stawiarz L, et al. Importance of early treatment initiation in the clinical course of multiple sclerosis. *Multiple Sclerosis Journal*. 2016 Oct;23(9):1233-40.

¹²⁶ National Psoriasis Foundation. Step Therapy Legislation by State. <http://www.steptherapy.com/step-therapy-legislation-by-state/>. Accessed January 18, 2019.

¹²⁷ Id.

¹²⁸ State of Iowa. House File 233. An Act relating to the use of step therapy protocols for prescription drugs by health carriers, health benefit plans, and utilization review organizations, and including applicability provisions. 2017. <https://www.legis.iowa.gov/legislation/BillBook?ga=87&ba=HF233>

¹²⁹ H.R. 20711. Restoring the Patient's Voice Act of 2017. <https://www.congress.gov/bill/115th-congress/house-bill/2077/cosponsors>. Accessed January 28, 2019.

whether to prescribe an FDA-approved medicine for an unapproved use is a clinical decision most appropriately made by providers who are able to weigh many important factors about an individual patient’s health. However, as discussed more below, step therapy protocols often interfere with provider autonomy by allowing health plans to make decisions about treatment protocols.

Step therapy policies interfere with provider autonomy and increase administrative burden.

Utilization management tools like step therapy and prior authorization programs interfere with the doctor-patient relationship by preventing prescribers from being able to select the best drug for each patient’s individual circumstances. These procedures are often time-consuming and cumbersome and therefore may discourage doctors from prescribing the most appropriate therapies. Requiring the use of one product over another interferes with a provider’s ability to make complex treatment decisions focused on the best health outcome for their patients. More than 9 out of 10 physicians say prior authorization has a negative impact on patients’ clinical outcomes.¹³⁰ As mentioned above, there is considerable variation in how health plans implement step therapy. Variation can increase provider administrative burden, which has led the American Medical Association to call for standardization of these types of processes.¹³¹

In a recent survey of physicians, 92 percent report prior authorization has caused a delay in care, with 84 percent describing the burden associated with prior authorization as “high or extremely high.”¹³² On average, physicians estimate a total of 14.6 hours (approximately two business days) are spent each week by the physician/staff in their practice to complete the workload related to prior authorization.¹³³ Overall, the amount of time providers spend communicating with payers is estimated to account for \$23 to \$31 billion per year in the U.S.¹³⁴ Provider offices already spend significant time and resources to comply with prior authorization procedures to ensure that the medicines they prescribe are covered by insurance plans which detracts from patient care. Adding step therapy policies, and the administrative burden that comes with overcoming the associated exceptions and appeals processes, will only increase administrative burden on providers. For MA plans, a recent report from the Office of Inspector General (OIG) highlights the difficulties with these processes.

¹³⁰ American Medical Association. (2017). AMA Prior Authorization Physician Survey.

¹³¹ American Medical Association. “Standardization of Prior Authorization Process for Medical Services White Paper.” June 2011. <https://www.stepsforward.org/Static/images/modules/20/downloadable/standardization-prior-auth-whitepaper.pdf>

¹³² American Medical Association. (2017). AMA Prior Authorization Physician Survey.

¹³³ Id.

¹³⁴ Casalino, LP, Nicholson S, Gans DN, Hammons T, Morra D, Karrison T, Levinson W. (2009). What does it cost physician practices to interact with health insurance plans? *Health Affairs*, 28(4), w533-w543.

In September 2018, the OIG found that MA plans overturned 75 percent of their own denials from 2014-2016, and that 45 percent of the denial letters sent from MA plans contained incomplete or incorrect information, further complicating the appeals process for providers and patients.¹³⁵ According to the report, MA plans may be inappropriately denying access to coverage of treatments and services to increase profits.¹³⁶ The OIG also found that some beneficiaries and providers may not be getting services and payment that MA plans are required to provide.¹³⁷

PhRMA urges CMS not to move forward with allowing MA plans to use step therapy in the proposed rule, and to revoke the August 2018 guidance. Step therapy puts vulnerable patients, like those with cancer, rheumatoid arthritis (RA) and other autoimmune conditions, severe infections, multiple sclerosis, macular degeneration, genetic disorders, and other rare diseases who need access to life-saving medicines covered by Part B at risk by increasing access and adherence issues that can lead to poor health outcomes and increased costs. Not subjecting providers to further financial and administrative burden by allowing MA plans to implement step therapy also supports the Administration’s “Patient’s Over Paperwork” initiative, a program implemented in response to an Executive Order from the Administration to remove administrative burdens.¹³⁸ Adding burdensome step therapy protocols is in direct opposition to CMS’s stated objective of increasing the amount of time providers can spend with patients by removing regulatory obstacles.¹³⁹

The Proposed Medicare Advantage Step Therapy Policy for Part B Drugs Exceeds CMS’ Authority

The proposed rule would allow Medicare Advantage (MA) plans to impose step therapy requirements on Part B drugs (and describes requirements for doing so) beginning in 2020. However, the Social Security Act (SSA) requires that MA plans provide the same benefits as the benefits provided in Original Medicare (Parts A and B).¹⁴⁰ Accordingly, CMS lacks the authority to permit MA plans to impose step therapy restrictions on Part B drugs that are not required by Original Medicare.

¹³⁵ Office of Inspector General. “Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials.” Sept. 2018.

¹³⁶ Id.

¹³⁷ Id.

¹³⁸ Center for Medicare and Medicaid Services. Patients Over Paperwork. <https://www.cms.gov/About-CMS/story-page/patients-over-paperwork.html>. Accessed January 22, 2019.

¹³⁹ Center for Medicare and Medicaid Services. Patients Over Paperwork: What is Patients over Paperwork? <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/PatientsOverPaperwork.html>. Accessed January 22, 2019.

¹⁴⁰ SSA § 1852(a)(1).

CMS previously declared that MA plans could impose step therapy restrictions on Part B drugs (beginning in 2019) in an August 7, 2018 memo (August 2018 step therapy memo).¹⁴¹ The 2018 memo rescinded 2012 guidance in which CMS prohibited MA plans from imposing step therapy (or other access restrictions) on Part B drugs and services unless Original Medicare did so.¹⁴² The 2012 guidance explained that the MA statute and regulations prohibit additional access barriers due to the requirement that MA plans cover all benefits covered under Original Medicare. CMS argues in the proposed rule (as it did in the August 2018 step therapy memo) that it can permit MA plans to adopt step therapy policies for a Part B drug because the MA statute “reference[s] an MA plan’s application of utilization management tools, like prior authorization and other ‘procedures used by the [MA plan] to control utilization of services and expenditures.’”¹⁴³ CMS states that “this indicates that MA plans are not prohibited by the statute from implementing utilization tools such as step therapy.”¹⁴⁴ However, as explained below, CMS’ reversal of this policy amounts to a denial of coverage.

Moreover, like the August 2018 step therapy memo, the proposed rule does not explain why CMS abandoned its previous view. The proposed rule merely highlights references in the MA statute to “prior authorization” and “procedures . . . to control utilization,” and it states that CMS now interprets the statute to mean that MA plans are allowed to use step therapy. This is insufficient justification for the agency’s reversal of position, which, under established case law, requires a “reasoned explanation” that at least: (1) displays an awareness that the agency is changing its position; (2) shows that there are good reasons for the change; and (3) considers the reliance interests of the regulated parties.¹⁴⁵

If finalized, the proposed rule’s step therapy provisions would violate the Medicare statute by making a fundamental change in coverage requirements. The statute requires that “benefits provided to an individual by . . . [Medicare] part [B] shall consist of . . . entitlement to have payment made . . . on his behalf . . . for medical and other health services,”¹⁴⁶ and these services

¹⁴¹ Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage (August 2018), https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf.

¹⁴² Medicare Advantage Organization, Section 1876 Cost Contractors, Section 1833 Health Care Prepayment Plans and PACE Organizations (Sept. 17, 2012), https://www.asrs.org/content/documents/cms_step_therapy_memo_091712-2.pdf.

¹⁴³ 83 Fed. Reg. at 62169 (referencing SSA § 1852(c)(1)(G) and (c)(2)(B)). These provisions state that MA plans must disclose to enrollees “[r]ules regarding prior authorization or other review requirements that could result in nonpayment” and upon request must disclose information on “procedures used by the organization to control utilization of services and expenditures.”

¹⁴⁴ 83 Fed. Reg. at 62169.

¹⁴⁵ Encino Motorcars v. Navarro, 136 S.Ct. 2117, 2126 (2016). If a court finds an “unexplained inconsistency” in the agency’s policy, this justifies “holding [the] interpretation to be an arbitrary and capricious change from agency practice.” Encino Motorcars, 136 S. Ct. at 2126 (quoting Nat’l Cable & Telecomms. Ass’n v. Brand X Internet Servs., 545 U.S. 967, 981 (2005)).

¹⁴⁶ SSA § 1832(a)(1).

must include (among other things) “drugs and biologicals which are not usually self-administered by the patient” furnished incident to physicians’ services.¹⁴⁷ Accordingly, if a drug falls within this category (or another Part B benefit category) and meets the “reasonableness and necessity” requirement for Part A and B in SSA § 1862(a)(1), an Original Medicare enrollee is entitled to coverage of the drug. Moreover, the MA statute expressly requires that MA plans “provide to members enrolled under this part [C] . . . benefits under the original Medicare fee-for-service program option,” which means “those items and services (other than hospice care or [kidney acquisitions] . . .) for which benefits are available under parts A and B.”¹⁴⁸

The Medicare statute thus entitles Original Medicare and MA beneficiaries alike to coverage of any drug within a Part B benefit category that is “reasonable and necessary to diagnose or treat illness or injury or improve the functioning of a malformed body member.”¹⁴⁹ The statute also specifically lists those Part A and B benefits that MA plans are not required to cover: hospice care and kidney acquisitions.¹⁵⁰

The MA regulations similarly require that MA plans “provide coverage of . . . all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts)” (except for hospital stays that begin before the individual is enrolled in the MA plan, or hospice care).¹⁵¹ The Medicare Managed Care Manual reiterates that MA plans “must provide Part A and Part B services, if the enrollee is entitled to benefits under both parts.”¹⁵² The Manual adds that “[a]n MA plan’s flexibility to deliver care using cost-effective approaches should not be construed to mean that Medicare coverage policies do not apply to the MA program.”¹⁵³

As noted above, the proposed rule asserts that its MA step therapy proposal is supported by references in SSA §§ 1852(c)(1)(G) and (c)(2)(B) to “prior authorization” and “procedures used by [an MA] organization to control utilization of services.”¹⁵⁴ However, under well-established canons of statutory interpretation, these references must be construed to harmonize with the statute’s clear mandate that MA plans cover Original Medicare benefits.¹⁵⁵ The MA statute

¹⁴⁷ SSA § 1861(s)(2).

¹⁴⁸ SSA § 1852(a)(1).

¹⁴⁹ SSA § 1862(a)(1)(A).

¹⁵⁰ SSA § 1852(a)(1)(B)(i).

¹⁵¹ 42 C.F.R. § 422.101.

¹⁵² Medicare Managed Care Manual Chap. 4 § 10.2.

¹⁵³ Medicare Managed Care Manual Chap. 4 § 90.5 (emphasis added).

¹⁵⁴ 83 Fed. Reg. at 62169.

¹⁵⁵ See, e.g., Epic Systems Corp. v. Lewis, 138 S.Ct. 1612, 1619 (2018) (“It is this Court’s duty to interpret Congress’s statutes as a harmonious whole”); FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000) (“A court must . . . interpret the statute ‘as a symmetrical and coherent regulatory scheme,’ . . . and ‘fit, if possible, all parts into a harmonious whole’”) (citing Gustafson v. Alloyd Co., 513 U.S. 561, 569 (1995) and FTC v. Mandel Brothers, Inc., 359 U.S. 385, 389 (1959)); Wachovia Bank v. United States, 455 F.3d 1261, 1268 (11th Cir. 2006) (“We do not read [statutory] words or strings of them in isolation. We read them in context. We try to make them . . . make sense together, have them singing on the same note, as harmoniously as possible”); Watt v. Alaska,

specifically lists those Part A and B benefits MA plans are not required to cover, and these exceptions do not include any drugs covered by Original Medicare or any items or services on which MA plans impose step therapy barriers: they are limited to hospice care and kidney acquisitions. Therefore, the MA statute must be read in a manner that covers Part A and B benefits (subject to its express exceptions), while also permitting some utilization management. This is a simple task, as these provisions are easily harmonized by recognizing that MA plans may use utilization management procedures that do not curtail Original Medicare benefits.

Furthermore, there is no basis for construing the MA statute’s references to “prior authorization” or similar terms as authorizing MA plans to narrow coverage of Original Medicare benefits in any way. Prior authorization generally does not mean a narrowing of coverage. For example, prior authorization is typically understood as a procedure in which determinations about whether a certain item or service is covered in a particular case must be made before a beneficiary receives the item or service rather than after the fact – but in which the same coverage rules apply to the determination whether made prior to the beneficiary receiving the service or afterward. This is consistent with the Medicare Managed Care Manual definition of prior authorization (“[a] process through which the physician or other health care provider is required to obtain advance approval from the plan that payment will be made for a service or item furnished to an enrollee”).¹⁵⁶ This type of prior authorization process ensures that beneficiaries do not receive items or services Medicare does not cover (or if they do, they do so knowingly); but it does not mean that different coverage rules apply when prior authorization procedures are used.¹⁵⁷

451 U.S. 259, 267 (1981) (a court “must read [two assertedly conflicting] statutes to give effect to each if [it] can do so while preserving their sense and purpose”); Cazun v. Attorney General of United States, 856 F.3d 249, 263 (3d Cir. 2017)(“this appeal requires us ... to attempt to harmonize two statutory provisions that seem, at first blush, to conflict with one another”)(internal quotations omitted); United States v. Gordon, 961 F.2d 426, 431 (3d Cir. 1992)(“Courts should attempt to reconcile two seemingly conflicting statutory provisions whenever possible, instead of allowing one provision effectively to nullify the other provision”); Atwell v. Merit Systems Protection Bd., 670 F.2d 272, 286 (D.C. Cir. 1981)(“we are guided ... by the cardinal canon of statutory construction that dictates that provisions should, whenever possible, be construed to achieve consistency,” and thus “seek to reconcile facially contradictory statutory provisions to effectuate the will of Congress”); A. Scalia & B. Garner, *Reading Law: The Interpretation of Legal Texts* 180 (2012) (“The provisions of a text should be interpreted in a way that renders them compatible, not contradictory.... [T]here can be no justification for needlessly rendering provisions in conflict if they can be interpreted harmoniously”).

¹⁵⁶ Medicare Managed Care Manual, Ch. 4 § 110.1.1. CMS has similarly explained in the context of a prior authorization demo for durable medical equipment items that: “[p]rior authorization helps makes sure that all relevant coverage, coding, and clinical documentation requirements are met before the item is furnished to the beneficiary and before the claim is submitted for payment. Prior authorization requires the same information necessary to support Medicare payment today, just earlier in the process.” December 19, 2016 CMS Fact Sheet, “CMS Announces First Two Items of Durable Medical Equipment Subject to Prior Authorization under the National Program.”

¹⁵⁷ Similarly, MA plans’ use of “gatekeepers” (to ensure enrollees get referrals to in-network providers for medically necessary services) would be another type of utilization management policy that does not contradict the statutory

Interpreting the MA statute to permit plans to impose step therapy restrictions not required by Original Medicare would also contravene another key canon of statutory construction. CMS has called the introduction of MA’s predecessor (Medicare+Choice) “arguably the most significant change in the Medicare program since its inception in 1965.”¹⁵⁸ Given the importance of the MA benefit package, Congress would not have buried authority for MA plans to narrow Original Medicare benefits in a few vague provisions that do not purport to override or limit the clear requirement to cover Original Medicare benefits. As the courts have emphasized, Congress “does not alter fundamental details of a regulatory scheme in vague terms or ancillary provisions -- it does not ... hide elephants in mouseholes.”¹⁵⁹ Accordingly, the MA statute’s few vague references to “prior authorization” and similar terms cannot be read to limit the statute’s clear requirement that MA plans cover Original Medicare benefits. Congress cannot be assumed to have limited the mandate for MA plans to cover Original Medicare benefits in such a cryptic manner. Had Congress done that, in fact, it would have been encouraging Medicare beneficiaries to enroll in MA based on a misunderstanding that they would receive the same benefits covered by Part A and B.

For the reasons described above, we urge CMS not to finalize the MA step therapy provisions in the proposed rule, and to retract the August 7, 2018, step therapy memo. These initiatives contradict clear requirements of the MA statute.

E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards (§ 423.160)

PhRMA supports greater price transparency initiatives that empower patients and providers, improve the quality of health care, and ultimately lower overall health care costs. Patients deserve accurate, timely, and easily understood data that is relevant to their health care needs to better inform decisions about their care. When appropriately structured to support beneficiary decision making, supplementing useful information about the costs and benefits of health care is

requirement to cover all Original Medicare benefits. See Medicare Managed Care Manual, Ch. 4 § 110.7 (listing the types of MA plans that can use gatekeepers and describing the function of gatekeepers).

¹⁵⁸ 63 Fed. Reg. 34968 (June 26, 1998).

¹⁵⁹ Whitman v. American Trucking Ass’n, 531 U.S. 457, 468 (2001)(emphasis added). See also, e.g., King v. Burwell, 135 S.Ct. 2480, 2498 (2015) (“had Congress wished to assign that question [central to the statutory scheme] to an agency, it surely would have done so expressly”) (internal quotations omitted); Util. Air Regulatory Grp v. EPA, 573 U.S. 302, 324 (2014) (“We expect Congress to speak clearly if it wishes to assign to an agency decisions of vast economic and political significance”) (quoting FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 159-60 (2000)) (internal quotations and citation omitted); Gonzales v. Oregon, 546 U.S. 243, 267 (2009)(Congress would not have “[given] the Attorney General such broad and unusual authority though an implicit delegation”); MCI Telecomms. v. AT&T, 512 U.S. 218, 231 (1994) (“It is highly unlikely that Congress would leave the determination of whether an industry will be entirely, or even substantially, rate-regulated to agency discretion—and even more unlikely that it would achieve that through such a subtle device as permission to ‘modify’ rate-filing requirements”).

essential to driving more efficient and higher quality care.

Providing consumers with comprehensive information in an easily accessible and understood format about their anticipated out-of-pocket costs, and utilization management requirements that may impact their care presents patients with the opportunity to make better choices based on their individual needs. There is growing evidence that informed and empowered patients who are engaged in collaborative dialogue and decision-making with their clinicians have the potential to drive better health outcomes, improve care quality and make our health care system more efficient.¹⁶⁰ Encouraging the development of sound, well-structured tools and real-time data to support decision-making will move the health care system beyond treatment silos to a more holistic, value-based paradigm that prioritizes patient needs.

CMS notes that health plans and pharmacy benefit managers (PBMs) are already developing tools that provide prescribers and pharmacists with additional formulary and benefit information. In a request for information earlier this year, CMS had solicited additional ways to inform Medicare beneficiaries in Part B and Part D about cost-sharing and lower-cost alternatives.¹⁶¹ The Agency also unveiled the eMedicare Initiative to provide a more user-friendly, streamlined online health care experience for Medicare beneficiaries that provides greater health care coverage information at their fingertips, including a mobile optimized out-of-pocket cost calculator that provides information on both overall costs and prescription drug costs.¹⁶²

Additionally, Medicare Plan Finder (MPF) provides beneficiaries with an estimate of their cost-sharing for the upcoming plan year based on their medication list. While the information provided to beneficiaries in MPF is a step in the right direction, complex drug formularies and the lack of standardization of such formulary and benefit information in real-time from health plans can make it difficult for patients to understand their expected prescription costs as they progress through the plan year. Thus, we encourage CMS to continue to work with health plans and other stakeholders to ensure that patients receive timely information about their prescription drug benefits, such as the coinsurance or copayment applicable to each tier or each drug and whether any tier or drug is subject to a deductible.

PhRMA commends CMS for its efforts to date to make plan benefit and cost-sharing information more accessible. We support the proposed concept of implementing a real-time benefits tool

¹⁶⁰ The Promise of Shared Decision Making in Improving Value in the US Healthcare System. Avalere Health. December 2017. <http://go.avalere.com/acton/attachment/12909/f-0506/1/-/-/-/-/Avalere%20Shared%20Decision%20Making%20Issue%20Brief.pdf>

¹⁶¹ 83 Fed. Reg. at 22699, 62165.

¹⁶² CMS announces new streamlined user experience for Medicare beneficiaries. October 2018 Press Release: <https://www.cms.gov/newsroom/press-releases/cms-announces-new-streamlined-user-experience-medicare-beneficiaries-0>

(RTBT) in Medicare Part D that would provide relevant cost-sharing information to patients and their prescribers. Such tools could facilitate more meaningful conversations and shared clinical decision making to improve outcomes, reduce provider burden and generate greater efficiencies for Medicare.¹⁶³ Additionally, plans should provide clear information on any utilization management requirements that a patient’s drug is subject to, such as step therapy or prior authorization.¹⁶⁴

In an age of technological advancements that can generate instantaneous information, we can appreciate CMS’ sense of urgency to implement a RTBT as soon as possible. While we are supportive of these patient-centric tools, several technical and operational details must be worked through for such tools to reach their full potential. These include the absence of an industry-adopted transaction standard for RTBTs in their current form, and a fairly aggressive timeline for full implementation by January 1, 2020. We strongly recommend that CMS continue to work with affected stakeholders and standards development and accrediting organizations (SDOs) in expediting a real-time benefit standard that is patient-centric, has undergone rigorous testing to ensure data accuracy, and does not create undue burden for prescribers before requiring implementation in the Part D program. We also note with concern that CMS suggests including negotiated price—along with a patient’s out-of-pocket costs—as part of the information the RTBT provides.¹⁶⁵ This additional information is not directly relevant to the patient and such extraneous information could cause confusion or distract from the information the patient and provider need to make the best decision for the patient’s care.

We encourage CMS to incorporate best practices from Medicare Plan Finder and the Star Ratings program in its plans to implement the RTBT in Part D. While MPF could be improved for easier use, which CMS is working on through its eMedicare initiative, it provides useful information about premiums and information to help patients understand the differences among prescription drug formularies, accompanied by quality measures of plan performance across several domains, including the Drug Safety and Accuracy of Drug Pricing measure. Providing robust information about beneficiary cost-sharing and quality of care allows patients to weigh cost and quality according to their preferences when selecting a plan. A thoughtfully-developed RTBT that has gained industry adoption and standardization, would be a complementary addition to the cost-sharing tools available to beneficiaries today. PhRMA looks forward to continued efforts and collaboration with CMS to implement a RTBT that provides meaningful

¹⁶³ CMS Patients Over Paperwork Initiative: <https://www.cms.gov/About-CMS/story-page/patients-over-paperwork.html>

¹⁶⁴ Dusetzina, SB, Mello, MM. Disclosing Prescription-Drug Prices in Advertisements – Legal and Public Health Issues. *New England Journal of Medicine* [published online ahead of print Nov. 14, 2018]. DOI: 10.1056/NEJMp1814065

¹⁶⁵ 83 Fed. Reg. 231 at 62166.

and timely information to beneficiaries that can improve their care decisions.

Part D Explanation of Benefits (§ 423.128)

CMS is proposing to require plan sponsors to add information about negotiated drug price changes and lower cost therapeutic alternatives to the explanation of benefits (EOB) sent to enrollees, including the cumulative percent change of the negotiated price since the first day of the benefit year for each prescription. CMS also proposes that information on lower-cost therapeutic options would include drugs that are therapeutic alternatives with lower cost-sharing (determined by the plan) from the plan formulary for each prescription claim. This could include drugs that are not within the same category or class, but that have a medically-accepted indication to treat the same condition. Plans also would have the option to include alternatives with the same copayment if the negotiated price is lower, though this is not required. Finally, CMS notes that it will not require information about therapeutic alternatives to be specific to the beneficiary's unique clinical information, though the agency encourages plans to include relevant information when available.

PhRMA supports the goal of providing meaningful drug price information to beneficiaries. However, we strongly believe such information should be patient-specific and available in real-time as the patient discusses treatment options with his/her health care professional. Patients will likely have difficulty interpreting population-based drug data and pricing information included on an EOB because it will be devoid of context and lack real time interpretation from a health care professional. CMS's proposed approach to include data in the EOB on negotiated drug prices will only be misleading. Even though the negotiated price is the price paid to the network pharmacy or other network dispensing provider for the Part D drug reasonably determined at the point of sale,¹⁶⁶ patients will not be aware of other post-point of sale reconciliations that can occur between PBMs, plans and pharmacies. Further, CMS's proposed approach of providing information on therapeutic alternatives with lower cost-sharing determined by the plan in the EOB could have a potential to confuse and mislead patients. Such proposal would undermine the importance of consultation between the physician and the patient in choosing a therapy. Rather it would allow plans to suggest clinically inappropriate alternatives for an individual patient solely based on cost considerations.

As noted in our comments above on Section II.C.3, PhRMA recommends that CMS focus its efforts on supporting and encouraging the implementation of real time benefit tools (RTBT) which will strengthen the shared-decision-making dialogue between the patient and provider. CMS is well aware that numerous Part D plan sponsors are working to adopt tools that provide prescribers with expanded visibility into lower-cost alternatives at the point-of-prescribing,

¹⁶⁶ 42 CFR § 423.100.

through electronic health records.¹⁶⁷ CMS' support of RTBT will provide real-time, member-specific drug benefit information—including information about drug cost, coverage, cost-sharing, and lower cost options—in the doctor's office. Real-time benefit tools will help ensure that the beneficiary is accessing the most clinically effective and affordable medication, which helps lower costs for the entire health care system.

Pharmacy Price Concessions in Negotiated Price (§ 423.100)

CMS is considering, though not formally proposing, a change to the definition of “negotiated price” intended to ensure that all pharmacy discounts are reflected in the drug prices beneficiaries pay at the point of sale. Under consideration is a requirement that the negotiated price include all pharmacy price concessions, even those not determinable at the point of sale. The negotiated price would reflect the lowest possible price payable to the pharmacy, but exclude any contingent amounts payable to pharmacies, such as incentive fees.

The new approach is entirely focused on reflecting pharmacy discounts in the negotiated price. There is no requirement for Part D sponsors to pass through a share of manufacturer rebates to further reduce the negotiated price. This is a missed opportunity.

As stated in our comment letter¹⁶⁸ to CMS in response to the proposed rule on contract year 2019 changes to the Medicare prescription drug benefit program, PhRMA strongly believes that beneficiaries should directly benefit from the significant price negotiations taking place in the Part D market today. In this vein, we encourage CMS to reflect pharmacy discounts in the drug prices beneficiaries pay. We are disappointed, however, that CMS does not propose any requirement for Part D sponsors to pass through a minimum portion of manufacturer rebates to further reduce the Part D negotiated price. PhRMA believes that requiring a minimum portion of manufacturer rebates to be passed through at the point of sale (POS) would improve affordability for patients, better align stakeholder incentives, and make the successful Part D program work even better for millions of beneficiaries. In our previous comments, we noted Part D plan sponsors often negotiate substantial rebates, but the savings aren't always used to lower beneficiary out-of-pocket and government costs.¹⁶⁹ Additionally, estimates show that applying negotiated rebates at the POS could generate up to \$73B in federal government savings over ten years. We also noted that CMS has clear statutory authority to establish a POS rebate policy with a minimum pass-through requirement and has legal

¹⁶⁷ 83 Fed. Reg. 62165 (Nov. 30, 2018).

¹⁶⁸ PhRMA, Comment Letter in response to CMS-4182-P (Jan. 16, 2017).

¹⁶⁹ Id.

authority to incorporate passed-through rebates in negotiated price for calculating manufacturer coverage gap discounts.¹⁷⁰

We encourage CMS to implement pass through pharmacy concessions and to address pass-through of a minimum portion of manufacturer rebates as soon as possible. If these changes are implemented, millions of beneficiaries would begin paying lower cost-sharing at the pharmacy immediately in the year the policy takes effect. For low-income-subsidy beneficiaries, cost-sharing savings resulting from lower point of sale prices would instantly accrue to the government.

Legal considerations

As discussed above, the new regulatory definition of “negotiated price” CMS is considering would be the lowest possible total reimbursement for a drug negotiated by the plan and a network pharmacy, (i) including all pharmacy price concessions (but not contingent amounts that increase prices, such as incentive fees), (ii) including dispensing fees, and (iii) reduced by non-pharmacy price concessions the plan elects to pass through at the point of sale.¹⁷¹

For purposes of determining beneficiary cost-sharing in the coverage gap and manufacturer coverage gap discounts, negotiated price is defined by SSA § 1860D-14A(g)(6),¹⁷² which references the negotiated price definition in the version of 42 C.F.R. § 423.100 that was in effect when the Affordable Care Act was enacted in 2010. Under that definition, the negotiated price is “reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale.”¹⁷³ In the proposed rule, CMS analyzed whether this “election” language is consistent with the new regulatory definition of negotiated price CMS is considering, which would require plans to pass through a subset of price concessions (specifically, all pharmacy price concessions). CMS concluded that these definitions were consistent:

[P]harmacy price concessions account for only a share of all price concessions a sponsor might receive. Thus, even if a plan sponsor is required to include all pharmacy price concessions in the negotiated price at the point of sale, the plan sponsor must still

¹⁷⁰ *Id.*

¹⁷¹ 83 Fed. Reg. at 62179. This definition would be similar to the current negotiated price definition at 42 C.F.R. § 423.100 except that the current definition includes “all pharmacy price concessions from network pharmacies except those contingent price concessions that cannot be reasonably be determined at the point-of-sale” and does not explicitly refer to non-pharmacy price concessions that the plan elects to pass through at the point of sale.

¹⁷² SSA § 1860D-2(b)(2)(D)(i) (coinsurance for brand drugs in the coverage gap is based on negotiated price as defined in SSA § 1860D-14A(g)(6)); SSA § 1860D-14A (using the negotiated price definition at § 1860D-14A(g)(6), not including dispensing fees, in the coverage gap discount formula).

¹⁷³ 42 C.F.R. § 423.100 (2010) (emphasis added). The negotiated price definition used in calculating manufacturer coverage gap discounts also does not take into account dispensing fees.

make an election as to how much of the overall price concessions (including manufacturer rebates and other non-pharmacy price concessions) it receives will be passed through at the point of sale.¹⁷⁴

We agree with this analysis. If plans must pass through all pharmacy price concessions, they can elect either to stop there or to pass through all pharmacy price concessions plus additional price concessions from other parties. Whatever level of price concessions a plan passed through would be the elected amount and would thus be used in determining negotiated price.

Importantly, CMS notes that under the new regulatory definition it is considering, “the same negotiated price could be used to adjudicate claims during all phases of the Part D benefit.”¹⁷⁵ (That is, a requirement to pass through a subset of price concessions is consistent with plans electing whether to pass through additional price concessions, thus allowing a uniform definition of negotiated price across the benefit.¹⁷⁶) Adopting different definitions of negotiated price in the coverage gap and the other phases of the Part D benefit – the “alternative” approach mentioned in the proposed rule – would contradict CMS guidance requiring that a particular drug dispensed at a particular pharmacy must have the same negotiated price across all phases of the Part D benefit. CMS has embraced this principle from 2005 to the present.¹⁷⁷

Under the “alternative” approach, enrollees could face a higher negotiated price for a drug in the coverage gap than in other phases of the benefit¹⁷⁸ – generally imposing higher cost-sharing on

¹⁷⁴ 83 Fed. Reg. at 62179 (emphasis added).

¹⁷⁵ *Id.* (emphasis added).

¹⁷⁶ In fact, CMS is already taking this approach under the current regulatory definition of negotiated price (42 C.F.R. § 423.100), which requires that all non-contingent pharmacy price concessions be passed through. Because plans make an election about whether to pass through additional price concessions, the current regulatory definition of negotiated price is consistent with the coverage gap definition of negotiated price (SSA § 1860D-14A(g)(6)) and accordingly CMS has not permitted or required plans to use non-uniform negotiated prices.

¹⁷⁷ Under § 206 Chapter 5 of the Prescription Drug Benefit Manual, “the negotiated price for a particular covered Part D drug purchased at a particular pharmacy must always be the same regardless of what phase of the Part D benefit an enrollee is in.” CMS established this principle in 2005, in its first Part D final rule, stating at 70 Fed. Reg. 4194, 4245 (Jan. 28, 2005) that: “[w]e interpret the requirement that negotiated prices always be provided to mean that uniform negotiated prices must be available to beneficiaries for a particular drug when purchased from the same pharmacy. In other words, the negotiated price for a particular drug will be the same, at a particular pharmacy, regardless of whether a beneficiary’s drug spending is between \$0 and the deductible, between the deductible and initial coverage limit, between the initial coverage limit and the out-of-pocket threshold, or in excess of the out-of-pocket threshold. We believe that non-uniform negotiated prices would discourage enrollment by certain Part D eligible individuals in violation of section 1860D-11(e)(2)(D)(i) of the [Social Security] Act and, therefore, plans will not be able to apply differential negotiated prices to any drug purchased from a given pharmacy.”

¹⁷⁸ The proposed rule states that if plans are not required to include pharmacy price concessions in the negotiated price in the coverage gap, then CMS “would need to operationalize different definitions of ‘negotiated price’ for the coverage gap versus the non-coverage gap phases of the Part D benefit. Under this alternative approach, during the non-coverage-gap phases, claims would be adjudicated using the negotiated price determined [based on the lowest possible reimbursement approach]. In contrast, during the coverage gap, plans would have the flexibility to

enrollees with higher spending and discouraging their enrollment in plans with such a benefit structure, in violation of Part D’s non-discrimination clause.¹⁷⁹ This approach is not necessary to harmonize SSA § 1860D-14A(g) with the regulatory definition of negotiated price CMS is considering, and not permitted by the Part D statute. CMS has never before even mentioned the possibility of permitting different negotiated prices for the same drug dispensed at the same pharmacy—an idea that would complicate beneficiaries’ cost-sharing at a time when we are trying to make it more understandable—and there is no reason to take up this idea now. Therefore, we recommend that CMS adopt the regulatory definition of negotiated price it is considering, and to do so across the benefit.

* * *

PhRMA appreciates CMS’s consideration of our concerns. We stand ready to assist with any of the issues raised in our letter. Please contact Karyn Schwartz at 202-835-3491 or kschwartz@phrma.org with any questions.

Sincerely,

/S/



Karyn Schwartz
Vice President
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Amanda Pezalla
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determine how much of the pharmacy price concessions to pass through at the point of sale and beneficiary, plan, and manufacturer liability would be calculated using this alternative negotiated price.” 83 Fed. Reg. at 62179. The alternative negotiated price in the coverage gap would be higher than the negotiated price in the other phases of the benefit, since plans would not be obliged to pass through all pharmacy price concessions.

¹⁷⁹ SSA § 1860D-11(e)(2)(D).