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VIA ELECTRONIC FILING TO
PartDPaymentModel@cms.hhs.gov

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Re: CMS Part D Payment Modernization Model Request for Applications for CY 2022

Dear Acting Administrator Richter and Acting Director Bassano,

The Pharmaceutical Research and Manufacturers of America (PhRMA) submits comments to the Centers for Medicare & Medicaid Services (CMS) regarding the Part D Payment Modernization Model (PDM Model) Request for Applications (RFA) for calendar year (CY) 2022, which was released on January 19, 2021.[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. PhRMA member companies are playing an important role in the continued fight against the COVID-19 virus, including through the introduction of new treatments and vaccines. Over the past decade, PhRMA member companies have invested more than half a trillion dollars in biopharmaceutical research and development (R&D), including an estimated $102 billion in 2018 alone. Consistent with that mission, PhRMA companies are committed to the continued success of the Medicare Prescription Drug Benefit Program (Part D).

Almost 18 years have passed since enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The Part D program has been even more successful than expected, delivering affordable prescription drug coverage for more than 45 million seniors and people with disabilities at a far lower cost to taxpayers than was originally projected. The program has been wildly popular among seniors, with the most recent survey results finding that more than 90 percent of seniors who responded to the poll saying that they were satisfied with their Medicare prescription drug coverage and 87 percent saying that their Part D plan provided good value.[2] A significant contributor to that popularity is the ability for patients to get access to the medicines they need and the

[1] Centers for Medicare & Medicaid Services Part D Payment Modernization Model Request for Applications for CY 2022; https://innovation.cms.gov/media/document/partd-payment-modernization-cy22rfa.
[2] Medicare Today 2020 Senior Satisfaction Survey; http://medicaretoday.org/resources/senior-satisfaction-survey/.

strong patient protections related to formularies designed to ensure the most vulnerable beneficiaries can be treated and remain stable on their medicines.

The five-year PDM Model was announced by the Center for Medicare & Medicaid Innovation (CMMI) in January 2019. The Model took effect on January 1, 2020 and provides participating standalone Part D plans and Medicare Advantage Prescription Drug (MA-PD) plans certain flexibilities. To date, participation has been sparse, and only two plans participated in the demonstration in 2020.[3]

On the evening of January 19, 2021 on the last full day of the Trump Administration, CMS released the PDM Model RFA for CY 2022, which provides new "flexibilities" beyond what was offered in the first two years of the Model. Specifically, beginning in CY 2022, plans participating in the PDM Model would be permitted to treat five of Medicare's six protected classes as if they were any other class of drug, no longer requiring coverage of all the drugs in those classes. The sixth class, antiretrovirals, would be subject to the new flexibility beginning in CY 2023. In addition to the changes to the protected classes policy, the demonstration would allow Part D sponsors to offer Part D formularies that include only one drug per therapeutic class (for all classes of drugs including the protected classes), rather than the two drugs that currently are required per class.

PhRMA strenuously opposes any weakening of these protections for beneficiaries. The PDM Model would modify existing policy in ways that could put American patients' health at risk; would allow Part D plans to design formularies that discourage enrollment of beneficiaries with certain health conditions; and could reduce access to vital and necessary therapies for those enrolled, while achieving little—if any—savings for beneficiaries or Medicare. **PhRMA urges CMS to withdraw the changes to the Model that were announced for the 2022 plan year (year three of the Model), as well as the planned changes in 2023 in this Model.**[4]

Since the inception of the Medicare Part D program, PhRMA has supported the Part D policy of identifying categories or classes in which patients require access to a broad range of treatments without unreasonable delay. We continue to believe that the protected class policy offers valuable protections for vulnerable patients. The critical drug classes subject to the policy are anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants.[5] In these drug classes, Part D plans must cover "all" medicines, subject to certain exceptions. CMS has explained that it "instituted [the six protected classes] 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."[6] The six protected class policy has been integral to the Part D program's success, assuring broad formulary access for many of the nation's most vulnerable seniors and people with disabilities.

Congress has affirmed and expanded the six protected classes policy, recognizing its importance to providing adequate coverage for the most vulnerable Medicare beneficiaries. Specifically, in 2008, the Medicare Improvements for Patients and Providers Act (MIPPA) codified the requirement that Medicare Part D plans include in their formularies access to "all or substantially all" drugs in the six protected classes and also specified criteria for adding additional classes of clinical concern. In 2010, the Affordable Care Act (ACA) provided CMS the authority to make

[3] https://innovation.cms.gov/innovation-models/part-d-payment-modernization-model.
[4] Centers for Medicare & Medicaid Services Part D Payment Modernization Model Request for Applications for CY 2022; https://innovation.cms.gov/media/document/partd-payment-modernization-cy22rfa.
[5] Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit Manual Chapter 6—Part D Drugs and Formulary Requirements, Section 30.2.5 (2016).
[6] Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit Manual Chapter 6—Part D Drugs and Formulary Requirements, Section 30.2.5 (2016).

changes to the protected class policy through rulemaking and mandated that all (not just "substantially all") drugs in those classes be covered.

At a time when many Medicare beneficiaries are already facing challenges with access to health care due to the COVID-19 pandemic, there could be no worse time to institute significant new formulary changes like those put forward in the PDM Model. The access protections in the six protected classes policy are even more critical – not less – during this COVID-19 public health emergency. Therefore, PhRMA urges CMS to act to withdraw the changes to the Model that were announced for the 2022 and 2023 plan years.[7]

The six protected classes remain a critical component to ensuring Medicare beneficiaries have adequate access to essential medicines.

For more than 15 years, the six protected classes policy has provided access to crucial medicines for complex and vulnerable Medicare beneficiary needs. The life-saving medicines in the six protected classes treat patients with serious health conditions such as HIV, epilepsy, organ transplant, cancer and mental health conditions. Therapies for the protected class conditions often have complex interactions, contraindications, side effects and other factors that must be addressed for each individual patient in order to determine the most appropriate course of treatment. Drugs in each of these classes are not therapeutically interchangeable due to different receptor binding profiles, their pharmacokinetic, and their pharmacodynamics properties. These differences have important effects on efficacy, safety, and tolerability in patients. Thus, access to the full range of effective medications in the six protected classes is critical to ensuring successful treatment for these conditions. For example, it can take years for patients with epilepsy to find the optimal combination of medicines to manage and prevent seizures, as epileptic patients are known to have reactions to the different fillers used to bind drugs; thus, forcing patients with epilepsy to switch therapies could completely undermine their treatment or even cause them significant harm.

Patients with cancer also need the full range of therapeutic options available; "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] Some drugs are approved by the FDA specifically for treatment of a condition after another drug in the class has been tried and failed. This is not uncommon in the practice of oncology, where cancers can evolve. Specifically, tyrosine kinase inhibitors (TKIs) specifically target a protein produced by some cancer cells causing them to rapidly grow and reproduce. First approved as a treatment for a rare form of blood cancer called chronic myelogenous leukemia (CML), TKIs represented a tremendous, targeted advance over traditional chemotherapy treatments which destroy healthy and cancerous cells indiscriminately. However, despite their effectiveness, patients' cancer often develops resistance to an individual TKI over time.[9] Researchers have discovered that additional TKIs that can be used if the leukemia cells develop specific mutations and are no longer responding to the original treatment.[10,11] If limited in treatment options

[7] Centers for Medicare & Medicaid Services Part D Payment Modernization Model Request for Applications for CY 2022; https://innovation.cms.gov/media/document/partd-payment-modernization-cy22rfa.

[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). https://www.fightcancer.org/sites/default/files/National%20Documents/ACS%20CAN%20Comments%20on%20Rx%20RFI%20-%207-13-18%20-%20FINAL.pdf.

[9] Assouline, S; Lipton, J. "Monitoring response and resistance to treatment in chronic myeloid leukemia." *Current Oncology*. 2001. 18(2):e71-e83. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3070714/

[10] Breccia, M; Alimena, G. "Second-Generation Tyrosine Kinase Inhibitors (Tki) as Salvage Therapy for Resistant or Intolerant Patients to Prior TKIs." *Mediterranean Journal of Hematology and Infectious Disease*. 2014. 6(1): e2014003. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3894843/

[11] Treating chronic myeloid leukemia by phase. http://www.cancer.org/cancer/leukemia-chronicmyeloidcml/detailedguide/leukemia-chronic-myeloid-myelogenous-treating-treating-by-phase. Accessed February 2016.

or forced to go through to step therapy, patients whose cancer had progressed or proven to be resistant to the initial chemotherapy or other treatments may experience reduced or delayed access to appropriate care.

While one patient may respond well to a certain drug, a similar patient may not respond favorably to the same drug. Also, drugs in the same class often have different side-effect profiles and a patient may only tolerate certain drugs in the class. 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 may also find that certain medications enable improved adherence due to the side effects profile. For patients with HIV, medication choices are based in part on viral resistance profiles. Clinically significant drug interactions have been reported in 27 to 40 percent of HIV patients taking antiretroviral therapy requiring regimen changes or dose modifications.[12] The National Institutes of Health states that when it comes to treating HIV "the best regimen for a person depends on their individual needs,"[13] thereby necessitating that patients have access to the full range of therapies. In addition, similarly-situated patients often respond differently to the same medicine.

In these classes, even minor disruptions in access to treatment can have significant and lasting consequences for wellbeing and medical care. For all these reasons, patients with conditions treated by the six protected classes must not have their care disrupted and must maintain access to a wide choice of therapies.

The PDM Model's changes would lead to a violation of Part D's statutory nondiscrimination provision and are inconsistent with congressional intent.

The "new flexibilities" that CMS would add to the PDM Model in 2022 and 2023 would lead to violation of the Part D statute's nondiscrimination requirement, which CMS has not proposed to waive. The protected classes policy stems originally from the Part D statute's nondiscrimination requirement, 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."[14] 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."[15]

PhRMA is concerned that the planned changes to the PDM Model – waiving both the Part D statute's protected classes requirement (for five out of the six protected classes in 2022 and one additional class in 2023) and its two-drug-per-class minimum – would undercut the statutory nondiscrimination requirement. Beyond waiving statutory requirements with no explanation, the proposed waiver of the protected classes policy, especially coupled with a waiver of the two-drug-per-class requirement, would spur violations of the Part D statute's nondiscrimination requirement, opening the door to unlawful plan benefit designs that are "likely to substantially discourage enrollment by certain [Medicare beneficiaries]."[16] In particular, we are concerned that these waivers would inevitably result in benefit designs that substantially discourage enrollment by those high-cost, vulnerable beneficiaries who need treatment for cancer, mental disorders, epilepsy, or to prevent rejection of transplanted organs.

[12] Evans-Jones JG et al. Clin Infect Dis 2010;50:1419–1421; Marzolini C et al. Antivir Ther 2010;15:413–423.
[13] 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
[14] Social Security Act (SSA) § 1860D-11(e)(2)(D)(i).
[15] Prescription Drug Benefit Manual, Ch. 6 § 30.2.5 (emphasis added).
[16] SSA § 1860D-11(e)(2)(D)(i).

The risk of plans adopting benefit designs that discourage enrollment by these vulnerable beneficiaries is exactly what led CMS to adopt the protected classes policy in the first place – and what led Congress to include the nondiscrimination provision in the Part D statute. In the debate leading up to enactment of Part D, on a bipartisan basis, Congress emphasized the critical importance of the bill's Part D patient protections – such as the nondiscrimination provision – in ensuring that Part D plans cover the medicines needed by vulnerable patients who need "exactly the right medicine for them." For example:

> Mr. BAUCUS. ….One of the things I am particularly proud about in this bill is the strong beneficiary protections that will ensure that all Medicare beneficiaries get access to the appropriate medicine they need. ….[T]here are certain diseases and conditions—like AIDS, and epilepsy— where having access to just the right medicine is especially important.
> Mr. GRASSLEY. …. [C]ertain mental illnesses also fall in that category. This bill contains a number of protections for people who need exactly the right medicine for them.
> […]
> Mr. BAUCUS. …. The bill asks the [USP] to develop model formularies with therapeutic classes that can't be gamed. Then we require drug plans to offer at least two drugs in each therapeutic class. And for drugs that treat AIDS, epilepsy, or mental illness, we would expect that plans would carry all clinically appropriate drugs.
> […]
> Mr. BAUCUS. …. If a plan can't adequately ensure all of the proper medication for beneficiaries living with HIV/AIDS, epilepsy, and certain mental illnesses, that plan should not be doing business with Medicare.[17]

Permitting these new flexibilities would weaken the patient protections that Congress saw as central to Part D and increase the risk of nondiscrimination violations. 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.[18] As CMS' Dr. Jeffrey Kelman (the Chief Medical Officer for the then Center for Drug and Health Plan Choice) explicitly warned, denying claims for protected class drugs is "likely to be life-threatening for many of the enrollees impacted."[19] 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 "flexibilities" CMS would add to the PDM Model would generate plan benefit designs that are likely to substantially discourage enrollment by Medicare beneficiaries reliant on these drugs, thus violating Part D's nondiscrimination provision and creating health risks for Medicare's most vulnerable beneficiaries.

The process for changing the six protected classes policy and the two drugs per class requirement is flawed and disregards prior unsuccessful attempts to change these protections.

PhRMA questions the process by which the changes to the six protected classes policy is being effectuated. This policy was announced less than 24 hours before the end of the Trump Administration, outside of the standard rulemaking process. While CMMI may implement some of its models without notice-and-comment rulemaking, we note that it is particularly inappropriate to use a model test to enact policy changes that have repeatedly been rejected after considering public comment through the standard rulemaking process.

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[17] Nov. 2003 Cong. Rec. S31786.

[18] 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 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.[]

[19] Fox Ins. v. CMS, 715 F.3d 1211,1221 (9th Cir. 2013).1221.

In the RFA, CMS states that the six protected classes policy was "a temporary policy for the initial transition to Part D coverage," but as described above, the facts don't support this assertion.[20] In recent years, under both the Obama and Trump Administrations, CMS has twice looked at limiting the six protected classes policy and has been met with fierce opposition both times. First, during the Part D rulemaking process in 2014 under the Obama Administration, CMS proposed new criteria that would refine and limit the Part D program's protected classes.[21] Upon applying its new criteria, CMS proposed to exclude antidepressants and immunosuppressants from inclusion in the protected classes beginning in 2015. CMS was met with an avalanche of opposition by bipartisan members of the House and Senate, patient groups and others concerned with access to medicines for vulnerable Medicare beneficiaries. In the final rule, CMS maintained the existing six protected classes and decided not to finalize any new criteria. CMS stated that its "proposed criteria did not strike the balance among beneficiary access, quality assurance, cost-containment and patient welfare that [the agency] was striving to achieve."[22]

Four years later, under the Trump Administration, CMS once again attempted to weaken the protected classes policy. In a proposed rule related to "modernizing" Medicare Part D, CMS proposed significant changes to the six protected classes which would have allowed prior authorization and step therapy for stable patients, required no coverage for certain new formulations that would not provide a unique route of administration, even if old formulations were no longer on the market, and would have not covered drugs with price increases more than inflation.[23] This proposal was, similarly, met with strong opposition. In response to the opposition, in 2019 CMS decided against implementing the proposed changes and codified the policies in place at the time and did "not place additional limits on beneficiary access to medications."[24] Further, CMS said that it was,

> persuaded by comments that expressed significant concern for the potential disruption of ongoing therapy of protected class Part D drugs used for protected class indications and, after considering all the comments, [it concluded] that the risks associated with inappropriately interrupting therapy for stabilized patients receiving protected class drugs for protected class indications by potentially subjecting them to prior authorization or step therapy requirements [outweighed] the potential clinical benefits that some enrollees could gain from switching therapies that might be more appropriate and the potential cost savings that would accompany the additional formulary management flexibility.[25]

In the context of this regulatory history, there appears to be no rational basis for including these draconian changes to the existing protected classes – which are broader than those explicitly rejected in previous regulatory efforts – and for including them in an RFA released in the last 24 hours of the Trump Administration with no formal opportunity for public comment. CMS presents no clear policy justification and is unlikely to be able to produce any justification, for what circumstances have changed or why this would be an important policy change to test or why access to medications for vulnerable Medicare beneficiaries is no longer a priority.

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[20] Centers for Medicare & Medicaid Services Part D Payment Modernization Model Request for Applications for CY 2022; https://innovation.cms.gov/media/document/partd-payment-modernization-cy22rfa.
[21] 79 Fed. Reg. 1918 (Jan. 10, 2014).
[22] 79 Fed. Reg. 29844, 29865 (May 23, 2014).
[23] 83 Fed. Reg. 62152 (Nov. 30, 2018).
[24] 84 Fed. Reg. 23832 (May 23, 2019). The policies that were codified allowed prior authorization and step therapy only for "new starts" for five of the six protected classes; CMS also stated that prior authorization and step therapy will not be permitted for antiretrovirals. .
[25] 84 Fed. Reg. 23832, 23840 (May 23, 2019).

There is a lack of clarity regarding the intended scope of CMMI's model.
The purpose of CMMI models is to "test *innovative* payment and service delivery models to reduce program expenditures…*while preserving or enhancing the quality of care* furnished to [beneficiaries]."[26]

This CMMI model is neither innovative nor will it preserve or enhance the quality of care provided to Medicare beneficiaries. Instead, the proposed changes in this Model are significant and sweeping coverage changes, which could disrupt access to medicines for the most vulnerable Medicare beneficiaries.

The Model does not follow the statutory requirements for "modification" of a CMMI demonstration.
The new formulary flexibilities that CMS would make available for 2022 – waiving both the Part D protected classes requirements in Social Security Act (SSA) § 1860D-4(b)(3)(C) (for all of the protected classes except HIV/AIDS drugs until 2023), and the requirement in SSA § 1860D-4(b)(3)(G) for plans to include at least two drugs in each formulary class (which would be reduced to one drug per class) – would be a modification of the PDM Model that is not permitted under CMMI's authorizing statute (SSA § 1115A). As CMS has noted previously, SSA § 1115A only permits midstream modifications of CMMI models in circumstances where the modifications are needed because the Model is not meeting the goals of SSA § 1115A.[27] Specifically, the statute provides that the Secretary shall terminate or modify the design and implementation of a model unless the Secretary determines (and the Chief Actuary of [CMS], with respect to program spending, certifies) after testing has begun, that the model is expected to:

(i) improve the quality of care . . . without increasing spending under [Medicare or Medicaid];
(ii) reduce spending under [Medicare or Medicaid] without reducing the quality of care; or
(iii) improve the quality of care and reduce spending.[28]

This is the only reference in SSA § 1115A to modifying models and it does not apply here as there is no indication that the 2022 changes to the PDM Model are needed because otherwise the PDM Model would require termination. The CMS materials on the PDM Model give no indication that the Model is not performing as expected and the "new flexibilities" are mid-course corrections to get the Model back on track.

The statutory provision limiting midstream modifications to models has several important purposes. Specifically, allowing broader midstream modifications could lead to at least three separate problems: (1) creating opportunities for CMS to "expand" a model (as that term is used in SSA § 1115A(c)) under the guise of a "modification" and thereby circumventing the explicit requirements for expansion set forth in § 1115A(c); (2) reducing the incentive to design the model as carefully as possible (with the benefit of robust stakeholder input on how best to meet the goals of SSA § 1115A) at the outset, before the model is launched; and (3) complicating the effort to evaluate a model, as the evaluation results would reflect both the initial (unmodified) model and a later (modified) variant of the initial model. CMMI must evaluate "each model tested" and decide whether "a model that is being tested" meets the criteria for expansion.[29] To that end, upholding the integrity of the evaluation process and associated expansion decisions is critical. CMS has previously acknowledged the risk that modifications to a model can complicate its evaluation, stating that it "aim[s] to preserve the integrity of ongoing model tests without introducing major modifications that could make evaluation of existing models more challenging."[30] Adding the "new flexibilities" to the PDM Model in the

[26] *See* Social Security Act § 1115A(a)(1).(emphasis added).
[27] 81 Fed. Reg. at 50804 ("under Section 1115A(b)(3)(B) of the Act, the Secretary is required to terminate or modify a model unless certain findings can be made with respect to savings and quality after the model has begun. If during the course of testing the model it is determined that termination or modification is necessary, such actions will be undertaken through rulemaking").
[28] SSA § 1115A(b)(3)(B) (emphasis added).
[29] SSA § 1115A(b)(4),(c) (emphasis added).
[30] 81 Fed. Reg. at 50868.

middle of its implementation is the kind of change that the CMMI statute does not allow, because it can make CMMI models difficult to evaluate accurately – thus wasting the Medicare funds used to carry out the model – and reducing the incentives to design CMMI models well before they get started.

The changes to the protected classes will have a negative impact on Medicare beneficiaries.
The PDM Model's changes to the six protected classes policy would jeopardize access to needed medicines for vulnerable Medicare beneficiaries. Beneficiaries who are taking medicines within the six protected classes are among the sickest, with serious and complex health conditions. These often frail or disabled beneficiaries or those with multiple chronic conditions or require a high level of adherence to manage a serious condition. These patients continue to need access to vital medicines protected. Changes to formularies under the PDM Model will be extremely disruptive for vulnerable Medicare beneficiaries, as it could cause a disruption in care and treatment for those who are currently stable on therapy. As discussed above, many medicines are not interchangeable for individuals with conditions treated by the six protected classes and it is critical that Medicare beneficiaries continue to have access to a full range of therapies. Many patients currently taking medications for these illnesses must attempt a variety of therapies before they and their physicians agree on the most appropriate treatment.

Part D plans already have and apply tools to effectively control costs.
PhRMA believes that the current protected classes policy strikes the right balance for both protecting Medicare beneficiaries and controlling costs. The six protected classes protections provide vulnerable Medicare beneficiaries with serious and complex health conditions access to the medicines they need, while also providing plans with tools to manage costs. For example, under CMS's current regulation and guidance, for drugs other than those for HIV treatment, Part D plans may use prior authorization and step therapy to manage therapies for beneficiaries beginning treatment on a medicine that falls within the other protected classes.[31] These tools provide Part D plans with considerable flexibility to limit access to more expensive drugs and with leverage to negotiate rebates with manufacturers. In addition, Part D plans utilize formulary tiering to steer patients toward lower cost drugs. Researchers have found that formulary tiering is associated with greater use of lower cost generics.[32] Part D plans have been very successful in driving generic utilization in the six protected classes. A significant majority of all prescriptions filled for drugs in the protected classes are for generic products – generics represented more than 90 percent of the prescriptions filled within anticonvulsants (90 percent), antidepressants (97 percent), and antipsychotics (91 percent).[33] 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.[34]

Restricting access to medications in the six protected classes could have the unintended consequence of increasing Medicare costs. When patients are unable to receive the medication best suited to their individual needs, their symptoms may worsen, they may experience adverse interactions, and they may experience an impaired quality of life. In the worst-case scenario, patients may require hospitalization. In the case of HIV medicines, ineffective treatment could lead to disease transmission, as well as development of resistant forms of the virus.[35] Delaying optimal treatment for even a short time while trying ineffective treatments may cause irreversible damage to patient

[31] 42 C.F.R. § 423.120(b)(2)(vi)(C), Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit Manual Chapter 6—Part D Drugs and Formulary Requirements, Section 30.2.5 (2016).
[32] 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.
[33] Partnership for Part D Access. "A Balanced Approach to Provide Patients Access to Medications While Allowing Powerful Tools to Control Costs." Nov. 2018.
[34] The PEW Charitable Trusts. Policy Proposal: Revising Medicare's Protected Classes Policy. March 2018.
[35] Jean Nachega, Vincent Marconi et al. HIV Treatment Adherence, Drug Resistance, Virologic Failure: Evolving Concepts. Infectious Disease Drug Targets. 2011 Apr; 11(2): 167–174.

health and increase costs for the broader Medicare program. 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 increase other health care costs.[36]

Restricting formularies to one drug per class will harm Medicare beneficiaries.
In addition to the changes to the protected classes policy, the PDM model would allow Part D sponsors to offer Part D formularies that include just one drug per class, rather than the current two drugs per class. Since the inception of the Medicare Part D program, Part D plans have been required to cover a minimum of two drugs per class. This basic yet fundamental protection has ensured that Medicare beneficiaries, who are more likely to be afflicted with multiple chronic conditions, have access to a broad range of therapies. Seniors and patients with disabilities have complex health needs for which narrow formularies are particularly detrimental. CMS provided no justification whatsoever for this change in long-existing policy in the PDM Model.

Medicare beneficiaries depend on a wide variety of treatment options and choices among therapies. Requiring only one drug per class for this population is antithetical to providing Medicare beneficiaries with quality health care. Access to a broad range of treatment options is fundamental to the promise to provide Medicare beneficiaries with high quality care. In addition, a one-drug-per-class policy ignores that medical advances are moving toward more targeted, personalized medicines that are not interchangeable. These treatments harness the underlying molecular drivers of disease to help identify and direct precise, targeted treatment choices. Limiting the number of covered medicines in a therapeutic class reduces the vast potential of breakthrough science to revolutionize care.[37]

PhRMA notes that under the essential health benefits (EHB) prescription drug requirements of the Affordable Care Act, non-grandfathered individual and small group health insurance coverage must cover *the greater of* one drug in every category/class or the same number of prescription drugs in each category/class at the EHB-benchmark plan.[38] An analysis by Avalere in anticipation of the first EHB-benchmark plans found that most provided drug coverage that well exceeded one drug per class.[39] It is not reasonable policy for CMS to provide Medicare beneficiaries with less protective formulary coverage as compared to what commercial plans provide in coverage for a younger, healthier population.

In fact, evidence demonstrates that moving to one drug per class may lead to negative health outcomes for many Medicare beneficiaries due to the narrower formularies that would likely result from such a change in policy. Specifically, studies have found that switching stable patients to a new medicine for non-clinical reasons can lead to poor side effects and increased nonadherence and can be associated with negative health outcomes.[40] In addition, a requirement to cover just one drug per class is not grounded in an understanding of how medicines are used today. For example, some medicines are typically used after another medicine in the class has been tried and failed.[41] If only one medicine per class were required to be covered, patients who are not responsive to the sole medicine

[36] Feng Zeng , Russell L. Knoth, et al. Impact of Health Plan Restrictions on Antipsychotic Medication Adherence and Persistence. *The American Journal of Pharmacy Benefits*. January/February 2012.
[37] Personalized Medicine Coalition. The Personalized Medicine Report: 2017 Opportunities, Challenges, and the Future. November 2017.
[38] 45 C.F.R. § 156.122(a)(1).
[39] Avalere Health LLC. Drug Coverage in Essential Health Benefits Benchmark Plans: Formulary Analysis. January 2012. Available at: http://avalere.com/pdfs/Avalere_EHB_Formulary_Analysis.pdf.
[40] Nguyen E, Weeda E, Sobieraj D, et al. Impact of Non-Medical Switching on Clinical and Economic Outcomes, Resource Utilization and Medication-Taking Behavior: A Systematic Literature Review. Current Medical Research and Opinion. 2016;32(7):1281-1290.
[41] For example: ASCOPost, "FDA Approves Second-Line Venetoclax for CLL or SLL With or Without 17p Deletion,"June 8, 2018. Available at: http://www.ascopost.com/News/58930.

covered could experience further treatment delays and poor health outcomes when subject to utilization management requirements or lengthy appeals processes.

This one drug per class flexibility coupled with the new protected class flexibilities previously described would produce particularly dire results for oncology patients. For example, the Molecular Target Inhibitors class in the Antineoplastics category of the USP Medicare Model Guidelines is very broad, containing over 60 distinct medications[42] with a diverse array of mechanisms of action (MOAs) and a variety of indications treated. These two new plan flexibilities contemplated under the CY 2022 Model fail to grasp the highly individualized treatment required for cancer patients and risks flat out denying or erecting considerable new barriers to patients' ability to access these life-saving treatment options.

Changes to the two-drugs-per-class policy are not necessary to control costs.
The change in policy to one drug per class is not necessary to contain plan costs. Clear evidence suggests that the requirement to cover two drugs per class has not hindered the ability of plans to control costs in Medicare Part D. Part D premiums have remained stable since the program began, and in 2021, the average monthly beneficiary Part D plan premium is $30.50.[43]

The success of the Medicare Part D program is due to strong competition among Part D plans that help to keep costs low by negotiating with manufacturers for rebates. Plans have been successful in negotiating rebates with manufacturers despite the longstanding requirement to cover two drugs per class. Indeed, the Congressional Budget Office (CBO) found that the "rebates negotiated by Part D plans on preferred brands appear to make the net prices approach the lowest prices obtained in the private sector."[44]

PhRMA is concerned that narrowing of Part D plan formularies and restricting access to medicines could have the opposite effect and instead, increase costs for the Medicare program overall. Unfortunately, stand-alone PDPs, with their sole focus on controlling and limiting drug costs, do not have the incentive to consider or care whether formulary restrictions would result in other increased health costs, that may come from drug-related adverse health events or increased hospitalizations. As discussed earlier, limiting treatment options and forcing Medicare beneficiaries to try ineffective treatments may lead to increased costs for the broader Medicare program. PhRMA asks that as CMS considers these formulary restrictions, they also look at the potential unintended consequences and costs for Medicare as a whole from implementing these policies.

The stated purposes for the CY 2022 Updates to the PDM Model no longer apply.
In addition to PhRMA's many policy and legal concerns with the Part D "formulary flexibilities," which PhRMA has expressed above, the underlying premise and rationale for the modifications to the PDM Model no longer apply. CMS justifies pursuing the CY 2022 Part D Formulary Flexibilities on recent changes to the Federal Anti-Kickback Statute. Specifically, "[f]or CY 2022, in light of the changes to the discount safe harbor to the Federal antikickback statute that removes protection for certain reductions in price in connection with the sale or purchase of prescription pharmaceutical products from pharmaceutical manufacturers to Part D sponsors that will take effect on January 1,

[42] USP Medicare Model Guidelines (MMG) v.8.0 Categories and Classes and Example Part D Drugs.
[43] CMS Press Release. "Trump Administration Continues to Keep Out-of-Pocket Drug Costs Low for Seniors" July 29, 2020
[44] CBO, "Costs under Medicare's Prescription Drug Benefit and a Comparison with the Cost of Drugs under Medicaid Fee-for-Service," as presented by Anna Cook, Health, Retirement, and Long-term Analysis Division, at Academy Health, June 23, 2013.

2022, the PDM Model is being updated with the following changes…"[45] Given the recent court order[46] to delay the scheduled January 1, 2022 implementation of revisions to the discount safe harbor until January 1, 2023, the stated reason for CMS to make changes to the Model for the 2022 plan year no longer applies. This is further rationale for CMS to abandon these harmful changes, and we urge CMS to not implement the revisions to the PDM Model.

Policies that reduce Medicare beneficiary access to medications during the COVID-19 pandemic are particularly ill-timed.

In addition to all the reasons discussed above, we would be remiss not to point out that Medicare beneficiaries are already under tremendous stress and suffering from health care access challenges as a result of the COVID-19 pandemic. The pandemic has caused disruptions in all parts of the health care system, including restricting access to physicians for routine medical care. Thus, there could be no worse time to institute significant new policy changes that will have negative effects on access to medicines for vulnerable Medicare beneficiaries than during the current COVID-19 public health emergency. HHS, under the Trump Administration, recently extended the public health emergency for another 90 days, through at least April 21, 2021. Further COVID-related disruptions in care could extend well past the end of the current public health emergency, including into plan year 2022.

As documented by many studies, the mental health crisis that is emerging out of the COVID-19 pandemic is significant. Increases in mental illness have been documented after other epidemics, financial recessions and periods of civil protest. However, the magnitude of the rates of mental illness symptoms reported so far during the COVID-19 pandemic (April-July 2020) is higher than what was seen in the general population even after other large-scale traumas, such as September 11, 2001 and Hurricane Katrina.[47] A study by the Centers for Disease Control and Prevention (CDC) reports a fourfold increase in the prevalence of symptoms of depressive disorder in June 2020 compared to a similar time of year in 2019, pre-COVID.[48] Furthermore, the pandemic is likely to have both long- and short-term implications for mental health, particularly for groups likely at risk of new or exacerbated mental health struggles. Thus, losing access to vital medications at this incredibly difficult time can have substantial impacts on patients' well-being. Under these circumstances, polices that would further interrupt stable care for patients, such as changing the protected classes policy and the number of drugs in a class that must be covered, should not be pursued.

[45] https://innovation.cms.gov/media/document/partd-payment-modernization-cy22hpms, pp 2-3.
[46] https://www.pcmanet.org/wp-content/uploads/2021/01/2021-01-30-D.E.-19-Order.pdf.
[47] Ettman CK, Abdalla SM, Cohen GH, Sampson L, Vivier PM, Galea S. Prevalence of Depression Symptoms in US Adults Before and During the COVID-19 Pandemic. *JAMA Netw Open.* 2020;3(9):e2019686. doi:10.1001/jamanetworkopen.2020.19686;Galea S, Ahern J, Resnick H, et al. Psychological sequelae of the September 11 terrorist attacks in New York City. N Engl J Med. 2002;346(13):982-987. doi:10.1056/NEJMsa013404; Galea S, Tracy M, Norris F, Coffey SF. Financial and social circumstances and the incidence and course of PTSD in Mississippi during the first two years after Hurricane Katrina.J Trauma Stress. 2008;21(4):357-368. doi:10. 1002/jts.20355.
[48] CDC documented a fourfold increase in the prevalence of symptoms of depressive disorder in June 2020 (24.3%) compared to Q2 of 2019 (6.5%). CDC Czeisler MMWR 2020.

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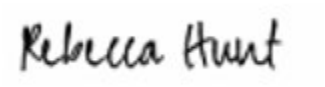
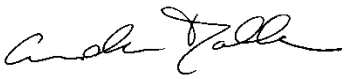
We thank you in advance for your time in reviewing our comments on the CMMI Part D Payment Modernization Model Request for Applications for CY 2022 and look forward to continued engagement with CMS on a thoughtful evolution of the Medicare Part D program that ensures Part D meets the needs of beneficiaries, makes prudent use of federal dollars, and is consistent with the statute.





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