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[Submitted electronically to amy.bassano@cms.hhs.gov and PartDPaymentModel@cms.hhs.gov]

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Centers for Medicare and Medicaid Services (CMS)
U.S. Department of Health and Human Services (HHS)
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RE: Pharmacist Opposition to Weakening Statutory Patient Protections under the Part D Payment Modernization Model (PDM Model) for Calendar Year (CY) 2022

Dear Acting Deputy Administrator and Director Bassano:

The nation's pharmacy community writes to request the removal of provisions in the CY 2022 Request for Applications (RFA) for the PDM Model that would allow insurers and pharmaceutical benefit managers (PBMs) to weaken two vital statutory patient protections in the Medicare Part D program,[1] requiring plans cover:

1) "[A]ll or substantially all" of the six protected drug classes (immunosuppressants (used to prevent organ rejection), anticonvulsants (used to treat epilepsy), antidepressants, antineoplastics (used to treat cancer), antipsychotics, and antiretrovirals (used to treat HIV);[2]

[1] See,1860D–4(b)(3)(G)(i) of the Social Security Act – which states "(ii) Formulary requirements.—Subject to clause (iii), PDP sponsors offering prescription drug plans shall be required to include all covered part D drugs in the categories and classes identified by the Secretary under clause (i)," available at: https://www.ssa.gov/OP_Home/ssact/title18/1860D-04.htm. Also, See, 1860D–11(e)(2)(D)(i) – which states "(i) In general.—The Secretary ***does <u>not</u> find that 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 under the plan***" [emphasis added], available at: https://www.ssa.gov/OP_Home/ssact/title18/1860D-11.htm.

[2] Centers for Medicare & Medicaid Services, "Medicare Prescription Drug Benefit Manual Chapter 6—Part D Drugs and Formulary Requirements" (2016), available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf - which states "CMS 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*** [emphasis added]."

2) At least two drugs in each class.[3]

The PDM RFA states "the Secretary intends to waive certain requirements under Title XVIII of the Social Security Act and its implementing regulations for purposes of testing the PDM Model":

> *"For CY 2022, and the remaining years of the Model, CMS will permit Part D sponsors participating in the Model to treat **five** [emphasis added] of the six protected classes (anticonvulsants, immunosuppressants, antidepressants, antipsychotics, and antineoplastics) as they would other Part D drugs, waiving the requirement that all drugs in these classes be included in formularies (with limited exceptions based on meeting other applicable formulary requirements). In addition, for CY 2022, participating Part D sponsors will be required to include on their formulary at least one drug per class (including the five protected classes), under a waiver of the current requirement of two drugs **per class** [emphasis added]. Participating Part D sponsors must, however, continue to comply with all other Part D formulary requirements."*

Two consecutive Administrations have correctly rejected previous proposals to weaken the six protected drug classes. Furthermore, as the medication experts in our nation's health care system, pharmacists know that given varying patient tolerabilities, patients need more than one drug in a class. Such dangerous changes wrongfully inserts harmful PBM "middlemen," and health plans into the practice of medicine and violates the physician-patient-pharmacist relationship for some of our nation's most vulnerable patients. Without any changes, the PDM Model would allow PBMs and health plans to force stable, often low-income, patients off medicines that have already been proven as effective treatments and jeopardize patient health.

Weakening the six protected drug classes would also disproportionately impact minority and underserved populations. For example, regarding access to cancer medications, African Americans have the highest mortality rate of any racial and ethnic group for all cancers combined and for most major cancers.[4] In addition, access to mental health treatments, where research shows that depression continues to be under-detected and undertreated among African Americans enrolled in Medicare—a situation that will only increase with decreased treatment options.[5] Therefore, allowing PBMs and Part D plans under the PDM model to opt-out of covering prescribed medications in the six protected drug classes is in direct conflict with

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[3] See, CMS MEDICARE MODERNIZATION ACT 2007 FINAL GUIDELINES -- FORMULARIES CMS Strategy for Affordable Access to Comprehensive Drug Coverage, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/CY07formularyguidance.pdf - which states "The minimum statutory requirement is that a formulary must include at least two drugs in each approved category and class (unless only one drug is available for a particular category or class), regardless of the classification system that is utilized. ***We view this requirement as a floor rather than an absolute standard*** [emphasis added]. CMS may require more than two drugs per category or class in cases where additional drugs present unique and important therapeutic advantages in terms of safety and efficacy, and their absence from the plan formulary may substantially discourage enrollment in the plan by beneficiaries with certain disease states."

[4] HHS. Office of Minority Health. Cancer and African Americans. Last Modified: 2/28/2020, available at: https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=16

[5] Connor, Kyaien. Et al. Mental Health Treatment Seeking Among Older Adults with Depression: The Impact of Stigma and Race. Am J Geriatr Psychiatry. 2010 June ; 18(6): 531–543, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2875324/pdf/nihms181113.pdf

President Biden's Executive Order "On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government," to "pursue a comprehensive approach to advancing equity for all."[6]

In addition, health care providers and their patients should also not have an "enhanced transition process," forced upon them. Previous "transition," proposals from PBMs and health plans have included lengthy prior authorization, step-therapy and first-fail policies with confusing appeals processes that would only serve to come between providers and their patients' prescribed medications.

Weakening the statutory requirement that insurers cover the six protected drug classes is also unlikely to reduce prescription drug costs. Recent studies have found 92% of all prescriptions filled in the six protected classes were for generics,[7] which demonstrates Part D plans already have sufficient tools to encourage use of generics when appropriate.

Finally, this RFA was released during the final days of the outgoing Administration, as such, at a minimum, implementation of this model would be inappropriate without undergoing a formal comment and rulemaking process.

Accordingly, our nation's pharmacists strongly urge you to remove these provisions in the PDM Model that would effectively strip some of our most vulnerable patients with chronic and mental health conditions from their prescribed medications.

Thank you for your prompt attention to addressing these very serious concerns in the RFA regarding patients' access to necessary medications under the Part D program. Please contact Michael Baxter, APhA Senior Director, Regulatory Policy, at mbaxter@aphanet.org if you need any additional information or would like to meet with our organizations.

Sincerely,

The American Pharmacists Association (APhA)

The American College of Clinical Pharmacy (ACCP)

The Accreditation Council for Pharmacy Education (ACPE)

The American Society of Consultant Pharmacists (ASCP)

The College of Psychiatric and Neurologic Pharmacists (CPNP)

The Hematology/Oncology Pharmacy Association (HOPA)

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[6] https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/

[7] The Pew Charitable Trusts. Policy Proposal: Revising Medicare's Protected Classes Policy
A series that examines policies to manage drug spending. March 7, 2018, https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicares-protected-classes-policy

The National Alliance of State Pharmacy Associations (NASPA)

The National Community Pharmacists Association (NCPA)

The National Pharmaceutical Association (NPhA)

cc: Norris Cochran, Acting Secretary, HHS