



January 27, 2022

[Submitted electronically via regulations.gov]

Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (HHS)
Attention: CMS-9911-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023, Proposed Rule

The American Pharmacists Association (APhA) is pleased to submit comments on CMS' proposed rule, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023," (hereinafter "proposed rule").

APhA is the only organization advancing the entire pharmacy profession. Our expert staff, and strong volunteer leadership, including many experienced pharmacists, allow us to deliver vital leadership to help pharmacists, pharmaceutical scientists, student pharmacists and pharmacy technicians find success and satisfaction in their work, while advocating for changes that benefit them, their patients and their communities.

Essential Community Providers (§ 156.235) (pgs. 685-686)

Qualified Health Plans (QHPs) in the health insurance exchanges must include a sufficient number and geographic distribution of essential community providers (ECPs) in their networks. ECPs means providers that serve predominantly low-income, medically underserved individuals. Section 156.235(a)(2)(i) provides that a plan has a sufficient number and geographic distribution of ECPs if it demonstrates, among other criteria, that the network includes as participating practitioners at least a minimum percentage, as specified by HHS. For 2023 and beyond, CMS is proposing to increase the ECP threshold from 20 to 35 percent of available ECPs in each plan's service area and believes that raising the ECP threshold will help ensure greater access to health care for vulnerable populations. APhA, like CMS, recognizes the need to increase patients' access to care to promote health equity.

To address access issues across the country and provide care to millions of medically underserved individuals, APhA encourages the adoption of strategies to increase patients' access to pharmacists and their services. CMS' ongoing support for, and recognition of, the value of pharmacists' patient care services, including Medicare Part D medication therapy management (MTM), chronic care management (CCM) and transitional care management (TCM) services, affirms the benefits of using pharmacists to increase access.

In addition, during the COVID-19 pandemic, pharmacists have overwhelmingly stepped up to contribute to some of our most daunting challenges, including shortages of health care staff and burnout of health care professionals—which continues to rise and hinder patient outcomes. HHS has repeatedly recognized the important role that pharmacists play in maintaining and addressing the country's economic, health, and safety efforts during the ongoing pandemic by authorizing pharmacists to order and administer COVID-19 tests¹ and recognizing pharmacies as points of care for COVID-19 testing services.² In addition, HHS also has authorized pharmacists to order and administer COVID-19,³ childhood,⁴ and seasonal influenza vaccines⁵ in states where this authority did not already exist—which has enhanced the position of community pharmacies and pharmacists as primary access points for patients to receive preventive immunizations and pharmacist-provided patient care services. Most recently, as part of the President's "Path Out of the Pandemic Plan," HHS authorized pharmacists to order and administer and pharmacy technicians and pharmacy interns to administer select COVID-19 therapeutics to ensure that more patients can access these lifesaving treatments if they are infected or exposed to COVID-19.⁶

¹ Office of the Assistant Secretary, "Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act," (April 8, 2020), available at: <https://www.hhs.gov/sites/default/files/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf>

² FDA. FAQs on Diagnostic Testing for SARS-CoV-2. Q: When FDA authorizes under an EUA a SARS-CoV-2 test for use at the point of care, does that mean it is CLIA waived? (Updated 5/9). Content current as of: 09/2/2020, available at: <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2>

³ OASH. Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act. September 3, 2020, available at: <https://www.hhs.gov/sites/default/files/authorized-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf>

⁴ HHS. Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19. August 19, 2020, available at: <https://www.hhs.gov/sites/default/files/third-amendment-declaration.pdf>

⁵ HHS. Tenth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19. January 7, 2022, available at: <https://www.federalregister.gov/documents/2022/01/07/2022-00151/tenth-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical>

⁶ HHS. Ninth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19. September 9, 2021, available at: <https://public-inspection.federalregister.gov/2021-19790.pdf> ²

Accordingly, we strongly urge CMS when adopting and enforcing network adequacy standards, to recognize the need for pharmacists' and to support policies that include pharmacists as "participating practitioners." Furthermore, to help meet adequacy standards and allow for patient choice, APhA recommends CMS require QHPs to contract with any pharmacy willing to accept their terms and conditions for network participation, including independents.

With over 90% of Americans living within five miles of a community pharmacy, the inclusion of pharmacists as part of patients' health care teams can have a profound impact on patients' access to health care, particularly those who are underserved. In addition to being medication experts, pharmacists also provide a broad array of services beyond dispensing medications, including disease state and medication management, smoking cessation counseling, health and wellness screenings, preventive services and therapeutics under "test and treat" models.

In addition to increasing access, the inclusion of pharmacists on a patient's care team can positively impact overall quality of care, while increasing patient satisfaction and health outcomes. By better utilizing the medication expertise of pharmacists, QHPs could improve health care delivery by maximizing coordinated and team-based care and better meeting reasonable access and network adequacy standards.

Access to Prescription Drugs for Chronic Health Conditions: Adverse Tiering (pgs. 667-668)

APhA strongly agrees that health plans' essential health benefits (EHBs) design must be clinically based—particularly when it comes to prescription drugs.

In the proposed rule, CMS states "[i]ndividuals with certain chronic health conditions...have reported that the majority of their prescription drugs have been designated as specialty drugs and placed in the highest cost tier. Individuals have also seen most or all prescription drugs in the same therapeutic class, used to treat their chronic health condition, placed on the highest cost tiers." In response, CMS is clarifying for QHPs that "[p]lacing all drugs for a high cost chronic condition on the highest formulary tier is a presumed discriminatory benefit design." APhA appreciates CMS focusing on health plans' and pharmaceutical benefit managers' (PBMs') discriminatory practices where all drugs to treat chronic conditions are placed on the highest-cost tiers.



As CMS understands, ample and growing data analysis clearly shows increasing evidence that consolidation of PBMs with pharmacies and vertical integration in the healthcare space which has led to increases in patients' drug prices through price discrimination, utilization of harmful "clawback" mechanisms on pharmacies, use of "fake" list prices," "spread pricing," and "patient steering" for brand, generic and specialty drugs and to PBM-affiliated pharmacies. Therefore, APhA strongly recommends CMS also prohibit these harmful PBM business practices in all QHPs offered through the federally- facilitated Exchanges and State-based Exchanges on the Federal platform. APhA is happy to meet with CMS to provide additional information and specific examples of these PBM abuses in order to protect enrollees in QHPs.

If you have any questions or require additional information, please contact Michael Baxter, Senior Director of Regulatory Policy, at mbaxter@aphanet.org.

Sincerely,

A handwritten signature in black ink, reading 'Ilisa BG Bernstein'. The signature is fluid and cursive, with the first name 'Ilisa' being the most prominent.

Ilisa BG Bernstein, PharmD, JD, FAPhA
Senior Vice President, Pharmacy Practice and Government Affairs