February 15, 2019

[Submitted electronically via www.regulations.gov]

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-9926-P
P.O. Box 8016
Baltimore, MD 21244-8013

Re: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020 [RIN 0938-AT37] [ID: CMS-2019-0006-0016]

Dear Administrator Verma:

The American Pharmacists Association (APhA) is pleased to submit these comments regarding the Centers for Medicare & Medicaid Services' ("CMS") proposed rule on the "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020," (hereinafter the "Proposed Rule"). APhA, founded in 1852 as the American Pharmaceutical Association, represents 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians' offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

Provisions of the Proposed HHS Notice of Benefit and Payment Parameters for 2020

Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

Mid-Year Formulary Changes

Under the Proposed Rule, CMS would allow issuers in the individual, small group, and large group markets, beginning with plan years on or after January 1, 2020, to update their prescription drug formularies by allowing certain mid-year formulary changes, if permitted by applicable state law, when a generic equivalent of a prescription drug becomes available on the market, within a reasonable time after that drug becomes available. At that time, the issuer also would be permitted to remove the equivalent brand drug(s) from the formulary or move the equivalent brand drug(s) to a different cost-sharing tier on the formulary. Before removing a brand drug from the formulary or moving it to a different cost-sharing tier, a health insurance

issuer would be required to notify all plan enrollees of the change in writing a minimum of 60 days prior to initiating the change. Issuers would also be required to provide enrollees the option to request coverage for a brand drug that was removed from the formulary through the applicable coverage appeal process or the drug exception request process.

As APhA has previously stated to CMS, patients often struggle to find medications that work well for them, and once stabilized, changing formularies could create serious patient-safety issues. While allowing mid-year changes to add a generic equivalent within a formulary may make lower-cost alternatives available to patients, removing the equivalent brand drug or moving it to a different cost sharing tier may actually increase patient costs. While some medications are "therapeutically" equivalent, they may have slightly different side effects. Pharmacists along with other members of the patient's health care team work together to select the best medication for a patient based on their condition, individualized needs and characteristics. Formulary changes made during the year are particularly troubling because most individuals do not have the option of changing to a different insurance plan that would cover his/ her prescription medication. If CMS moves forward this proposal, APhA requests CMS monitor the appeals and/ or outcomes resulting from this and similar provisions to measure their impact on patients.

Cost Sharing Requirements and Drug Manufacturers' Coupons

CMS is proposing to allow issuers to exclude drug manufacturer coupons from counting toward the annual limitation on cost sharing when a medically appropriate generic drug is available. APhA's House of Delegates policy states "APhA advocates the elimination of coupons, rebates, discounts, and other incentives provided to patients that promote the transfer of prescriptions between competitors." However, APhA has concerns with policy changes that would shift additional costs to patients for medications determined by members of their health care team to be "medically appropriate."

Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchange

State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020

In the Proposed Rule, CMS encourages states to explore whether modifications to their EHB-benchmark plan would be helpful in fighting the opioid epidemic. In making this suggestion, CMS highlights additional flexibilities provided in the 2019 Payment Notice, including an option for states to select a set of benefits that would become the states EHB benchmark plan, provided certain conditions are met. While CMS provides examples of Illinois efforts[1], APhA believes additional suggestions would be beneficial. For example, APhA encourages CMS to reiterate its support for expanded coverage of pharmacist-provided services, including those provided under collaborative practice agreements, standing orders or other predetermined protocols (e.g., initiation, modification and monitoring of a patient's drug therapy,

[1] The Proposed Rule states, "[f]or example, Illinois made changes to its EHB-benchmark plan for plan year 2020 that aim to reduce opioid addiction and overdose by including in its EHB-benchmark plan alternative therapies for chronic pain, restricting access to prescription opioids, and expanded coverage of mental health and substance use disorder treatment and services."

provision of naloxone) which CMS recognized as mechanisms to help address national public health challenges, including the opioid epidemic.[2]

Prescription Drug Benefits

Under §156.122 of the Proposed Rule, CMS seeks comment on its proposal related to mid-year formulary changes, consistent with those outlined in §147.106(e). Please see APhA's above comments in response to changes proposed in Part 147 for feedback.

Also, under §156.122, CMS seeks comments regarding two additional drug policies that would be intended to consider the potential of therapeutic substitution. APhA has also addressed these policies above.

Prohibition on Discrimination

In the Proposed Rule, CMS recognizes "there is not comprehensive, nationwide coverage of the drugs used in MAT, at least among QHP issuers" and encourages "issuers to take every opportunity to address opioid use disorder, including increasing access to MAT and normalizing its use." APhA appreciates CMS's ongoing attention to the opioid epidemic and efforts to expand coverage of MAT. However, APhA is concerned CMS does not take a comprehensive view of MAT as the Proposed Rule only focuses on the medication and not on the service components (e.g., assessment visits, induction visits, maintenance visits, screening, counseling and coordination of services with MAT behavioral health providers). APhA urges CMS to also consider implementing policies regarding the coverage of services related to MAT, specifically when such services are provided by pharmacists. APhA recommends CMS clarify pharmacists should not be prevented from billing for such services when the plan covers the same services when provided by a different practitioner. APhA believes providing such clarity will significantly improve patient access to MAT, especially where pharmacists operating under collaborative practice agreements or statewide protocols have authority to provide a broader array of MAT services but are inaccessible to patients due to coverage barriers.

Thank you for the opportunity to provide feedback on the Proposed Rule and for your consideration of our comments. If you have any questions or require additional information, please contact, Michael Baxter, Director of Regulatory Affairs, at mbaxter@aphanet.org or by phone at (202) 429-7538.

Sincerely,

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Stacie S. Maass, RPh, JD, Senior Vice President, Pharmacy Practice and Government Affairs

[2] *See,* Centers for Medicare & Medicaid Services - Center for Medicaid & CHIP Services (2017), CMCS Informational Bulletin, "State Flexibility to Facilitate Timely Access to Drug Therapy by Expanding the Scope of Pharmacy Practice using Collaborative Practice Agreements, Standing Orders or Other Predetermined Protocols", available at: https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf, last accessed February 8, 2019.