January 29, 2020

[Submitted electronically via www.regulations.gov]

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9915-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: Transparency in Coverage, Proposed Rule (RIN 0938-AU04)[1]

Dear Administrator Verma:

The American Pharmacists Association ("APhA") is pleased to submit these comments regarding the Internal Revenue Service ("IRS"), Department of the Treasury ("DOT"); Employee Benefits Security Administration ("EBSA"), Department of Labor ("DOL"); Centers for Medicare & Medicaid Service ("CMS"), Department of Health and Human Services ("HHS") proposed rule, "Transparency in Coverage," (hereinafter the "Proposed Rule") to implement Executive Order #13877, "Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First."

APhA, founded in 1852 as the American Pharmaceutical Association, represents 60,000 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, specialty pharmacies, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services. APhA promotes patient access and coverage for pharmacists' quality patient care services.

General Comments

The Proposed Rule states "plans and issuers would be required to disclose to participants, beneficiaries, or enrollees an estimate of cost-sharing liability for items and services, including prescription drugs. This would allow individuals to request cost-sharing information for a specific billing code (as described later in this preamble) associated with a prescription drug or

[1] Per the Proposed Rule "Any comment that is submitted will be shared with the Department of the Treasury (Treasury Department), Internal Revenue Service (IRS) and the Department of Labor (DOL). Please do not submit duplicates."

by descriptive term (such as the name of the prescription drug), which will permit individuals to learn the estimated cost of a prescription drug obtained directly through a provider, *such as a pharmacy or mail order service* [emphasis added]."

Pharmacies are where millions of Americans are first exposed to the impact of complex pharmaceutical pricing policies or confronted with changes in coverage, formularies, prior authorization, deductibles and co-payments, many of which they didn't know or understand. Patient access to affordable medications is an important gap in the health care system and pharmacists are well-qualified to assist in addressing medication-related and cost concerns. However, to find an appropriate treatment that is not only covered but the patient can afford can be time intensive and currently is not incentivized in the health care system.

APhA appreciates the goal of the Proposed Rule "to support a market-driven health care system by giving consumers the information they need to make informed decisions about their health care and health care purchases." As the organization representing pharmacists in all practice settings, APhA is a strong supporter of policies that increase patients' access to affordable and cost-effective medicines. APhA has long had policy supporting the adoption of a "transparent pricing" system for prescription drugs, which would eliminate hidden discounts, free goods, and other subtle economic devices,[2] like rebates and post point-of-sale price fees imposed on pharmacies. These policies generally result in higher prices at point-of-sale and consequently, higher beneficiary co-pays. Accordingly, APhA reiterates our strong support for HHS to implement proposed rules by both the Office of Inspector General ("OIG")[3] and CMS[4] to require issuers to give these discounts to patients at the point-of-sale rather than pharmaceutical benefit managers ("PBMs"), which is the only way to truly meet the goals of EO #13877 under "Sec. 3 Informing Patients About Actual Prices" (b) to accurately estimate patients' "actual" out-of-pocket costs/ cost-sharing liability for prescription drugs.

Information Required to Be Disclosed to Participants, Beneficiaries, or Enrollees (Pgs. 65470 and 65479)

Third Content Element: Negotiated Rate (Pgs. 65472-73)

The Proposed Rule defines "negotiated rate" to mean the amount a plan or issuer, or a third party (such as a third-party administrator (TPA)) on behalf of a plan or issuer, has contractually agreed to pay an in-network provider for a covered item or service pursuant to the terms of an agreement between the provider and the plan, issuer, or third party on behalf of a plan or issuer." However, it is vital that this "negotiated rate" also include the "net price" (which accounts for all price concessions, including direct and indirect remuneration fees ("DIR") and/or similar policies/terminology, such as "true up" practices under employer-sponsored and

[2] APhA. House of Delegates. Current Adopted Policy Statements 1963-2018 (JAPhA NS8:362 July 1968) (JAPhA NS44(5):551 September/October 2004) (Reviewed 2006)(Reviewed 2011)(Reviewed 2016). Pg. 31., available at: https://www.pharmacist.com/sites/default/files/files/16898%20CURRENT%20ADOPTED%20POLICY%20MANUAL%20-%20FINAL.pdf

[3] CMS. Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees. Proposed Rule. February 2, 2019, available at; https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals

[4] CMS. Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses. Proposed Rule. November 30, 2018, available at: https://www.regulations.gov/document?D=CMS-2018-0149-0002

private plans to accurately estimate patient cost-sharing liability for prescription drugs. Accordingly, APhA recommends the federal agencies / departments consider using "net price" rather than the "negotiated rate" for estimating cost-sharing liability for prescription drugs in the final rule. DIR fees under Part D and similar PBM practices in the private marketplace were originally designed to capture rebates and other mechanisms not included at the point-of-sale. However, as HHS has clearly emphasized in the recent OIG and CMS proposed rules, DIR fees and other retractive fees utilized by PBMs are now being used beyond their original purpose to retroactively adjust pharmacies' payment months after the sale, sometimes below the price paid by the pharmacy. Recently, CMS pointed out the shocking 45,000 percent increase in pharmacy price concessions (i.e., DIR fees) between 2010-2017,[5] an increase that is unsustainable for pharmacies, patients and Medicare.

As stated in the Proposed Rule "the Departments acknowledge that outside of a bundled payment arrangement, plans and issuers often base cost-sharing liability for prescription drugs on the undiscounted list price, such as the average wholesale price or wholesale acquisition cost, which frequently differs from the price the plan or issuer has negotiated for the prescription drug." "The Departments also seek comment on whether the relationship between plans or issuers and pharmacy benefit managers allows plans and issuers to disclose rate information for drugs, or if contracts between plans and issuers and pharmacy benefit managers would need to be amended to allow plans and issuers to provide a sufficient level of transparency. If those contracts would need to be amended, the Departments seek comment on the time that would be needed to make those changes."

As mentioned earlier, APhA believes the OIG and CMS proposed rules that would have ensured that all rebates (including DIR fees), discounts, dispensing fees and other pharmacy price concessions are accounted for at the point-of-sale to share these savings directly with patients and not PBMs. Only by finalizing the OIG/ CMS proposed rules to require price concessions between pharmacies and plan sponsors or their PBM contracts (e.g., DIR fees and/or similar policies/terminology, such as "true up" practices under employer-sponsored and private plans) be reflected in the negotiated rate/ price that is made available at the time a medication is dispensed at the point-of-sale can all issuers accurately account for and estimate the "actual" prescription drug cost-sharing liability estimates for enrollees.

As CMS understands, there is simply no connection between price concessions given by manufacturers to PBMs and the prices paid by pharmacies to their wholesalers. Thus, DIR or other retroactive fees "recovered" from pharmacies by PBMs and not reflected at the point-of-sale are totally illogical (i.e., recovering money from pharmacies that pharmacies did not "receive" in the first place). Because current point-of-sale prices or copays paid by beneficiaries can be based on the contracted price before DIR/ retroactive fees are extracted, many beneficiaries actually pay higher out-of-pocket costs. CMS has cited numerous research that further suggest higher cost-sharing can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for beneficiaries and Medicare. Higher costs also have the tendency to cause more harm to racial and ethnic minorities

[5] 83 Fed. Reg. 62,174 (Nov. 30, 2018), available at: https://www.govinfo.gov/content/pkg/FR-2018-11-30/pdf/2018-25945.pdf

than to others.[6] Therefore, APhA strongly urges the federal agencies/ departments to prohibit PBMs' use of such fees as part of their payment methodology for pharmacies in the final rule in order to allow issuers to make accurate cost-sharing liability estimates of the "actual price" of prescription drugs for enrollees.

The Proposed Rule also states, "[i]n addition to allowing individuals to obtain cost-sharing information by using a billing code or descriptive term, the rules would also permit individuals to learn the cost of a set of items or services that include a prescription drug or drugs that is subject to a bundled payment arrangement for a treatment or procedure." As the Administration works to allow pharmacists to practice at the top of their license,[7] APhA recommends all federal agencies/ departments include the provision from OIG's / CMS' proposed rebate rules to clearly exclude additional contingent incentive payments, such as incentive fees or performance-based pharmacy price concessions that cannot "reasonably be determined" at the point-of-sale from the "negotiated rate" or "net price" when calculating cost liability for prescription drugs as these pharmacist-provided patient care services are separate from the dispensing of the product and the product itself (prescription drugs).

Generally, APhA continues to remind federal agencies/departments when developing mechanisms to lower drug costs, they need to separately consider the reimbursement of the product, which is fixed for pharmacists, from the cost of dispensing and any related patient care service or performance incentive payment to provide adequate reimbursement under a sustainable business model that improves and does not disrupt our nation's pharmacy distribution system. Unfortunately, this current system still fails to provide coverage for the true cost of the medication and any payment for pharmacies to provide needed patient care services.

Seventh Content Element: Disclosure Notice (Pgs. 65473-74)

The Proposed Rule also states "plans and issuers would be permitted to include any additional information, including other disclaimers that the plan or issuer determines appropriate, as long as the additional information does not conflict with the information required to be provided. Plans and issuers would be permitted to include additional language so long as the language could not reasonably be read to disclaim the plan's or issuer's responsibility for providing a participant, beneficiary, or enrollee with accurate cost-sharing information." "Furthermore, plans and issuers may also include disclaimer information regarding prescription drug cost estimates and whether rebates, discounts, and dispensing fees may impact the actual cost to the consumer."

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[6] Rice, Thomas. The impact of cost containment efforts on racial and ethnic disparities in health care: a conceptualization. Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care. Institute of Medicine (US) Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care; Smedley BD, Stith AY, Nelson AR, editors. Washington (DC): National Academies Press (US); 2003, available at: https://www.ncbi.nlm.nih.gov/books/NBK220345/

[7] We recommend federal agencies / departments reference the formal joint pharmacy organization response to CMS' recent request for additional input and recommendations, under Executive Order ("EO") #13890 – "Protecting and Improving Medicare for Our Nation's Seniors," regarding elimination of specific Medicare regulations that require more stringent supervision than existing state scope of practice laws, or that limit health professionals from practicing at the top of their license. January 17, 2020, available at: https://www.pharmacist.com/sites/default/files/audience/Joint%20Pharmacy%20Comments%20-%20SOP%20FINAL.pdf

APhA is concerned that issuers attempting to use the disclaimers to clarify the estimated cost-sharing liability for consumers may only end up confusing them more. For example, if patients actually reference these estimates (or disclaimers) and show up at the pharmacy, likely confused, and the "estimated" cost-sharing rate does not match up or the patient is confused between the "negotiated rate" and/or "undiscounted price," they will likely demand answers/ clarity from the pharmacist. Our members, or their pharmacy technicians, will then have to sort out all of the confusion with no compensation for their efforts. Accordingly, pharmacists would be placed in the awkward and uncompensated position to deal with irate and dissatisfied patients with limited or no information or explanation for the patient and undergo the time-consuming task of getting information from the issuer. Therefore, if pharmacists are placed in that position CMS should allow trained pharmacists to bill for each 15-minute insurance consult to all issuers. Under Medicare Part D, PBMs already get paid fees from plans, and plans get paid by CMS to be the agents. If pharmacists do the work of the PBMs and plans, they must be compensated for their time and services.

Request for Information: Provider Quality Measurement and Reporting in the Private Health Insurance Market (Pgs. 65487-89)

To enhance the Administration's efforts in promoting competition in the health care market that is based on value, under the Proposed Rule, the departments are interested in stakeholder input on a number of quality reporting related issues, including "whether health care provider quality reporting and disclosure should be standardized across plans and issuers or if plans and issuers should have the flexibility to include provider quality information that is based on metrics of their choosing, or state-mandated measures." Pharmacists work in a variety of practice settings and, as medication experts, are well suited to impact many quality metrics in existing and emerging in value-based payment models. In fact, pharmacists may in some cases be best positioned to influence certain metrics given their medication expertise, accessibility within communities, and ongoing face-to-face clinical touchpoints with patients. APhA supports CMS' recent efforts to align the Medicare program with private plans and several of the Administration's policies and direction on health care quality, value, transparency, integrity, accountability and care coordination, including the recently announced Part D Payment Modernization Model.[8] APhA has received feedback from members regarding the significant administrative and provider burden on monitoring and reporting disparate measures from various payers and encourages the Administration to standardize measures and measure reporting to the greatest extent possible.

APhA also urges the Administration to implement mechanisms to better monitor, measure and attribute the impact different providers, including pharmacists, have on the health outcomes of Medicare beneficiaries. Currently, pharmacists cannot bill for their Part B services nor can they report their contributions to quality metrics via CMS quality reporting mechanisms for value-based payment models (e.g., Merit-based Incentive Payment System ("MIPS"), alternative payment models ("APMs"). Pharmacists are not fully utilized by CMS under Part B, and while there have been well-intentioned efforts from CMS to allow providers to use pharmacists in team-based care and bundled payment models, CMS has few, if any, mechanisms

[8] CMS. Part D Payment Modernization Model. Last accessed January 23, 2020, available at: https://innovation.cms.gov/initiatives/part-d-payment-modernization-model/

to evaluate pharmacists' contributions under the current system. We suggest that CMS identify mechanisms for pharmacists to report their contributions to meeting quality metrics so their contributions can be better evaluated. CMS could also test such mechanisms in a Center for Medicare and Medicaid Modernization Innovation Center ("CMMI") model or pilot to better understand the contributions of pharmacists to team-based care and better health outcomes in Medicare beneficiaries.

In line with these efforts, APhA also supports CMS working with pharmacists, developers of consensus-based measures for medication safety, adherence and appropriate use, such as the Pharmacy Quality Alliance ("PQA"), and employer-sponsored and private health plans to establish a standard set of metrics that measure pharmacy performance and quality. Such measures should be based on pharmacy-specific, proven and achievable criteria, and would take into account the drugs dispensed, and the disease state being managed. Implementing pharmacy quality incentive programs would realign incentives to advance health outcomes for enrollees through better frontline medication optimization care. Face-to-face interactions with beneficiaries through pharmacy care interventions at the point-of-dispensing medications to counsel and educate on adherence is critical to achieving national-scale improvements in health outcomes and lowered costs.[9,10] This is especially relevant to patients in the current landscape of an aging population, increased chronic disease, and projected physician shortage, reinforcing the need for improved care coordination. Taking action to establish a standard set of metrics that measure pharmacy performance and quality would positively impact the health of patients and ensure a transparent and rigorous quality and cost performance model.

Thank you for your consideration of our comments and continuing to work with us and other pharmacy stakeholders to increase transparency of health care costs and PBM practices for pharmacies and patients. 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

[9] Patients who participated in brief face-to-face counseling sessions with a community pharmacist at the beginning of statin therapy demonstrated greater medication adherence and persistency than a comparison group who did not receive face-to-face counseling. The intervention group had statistically greater Mediation Possession Ratio (MPR) than the control group every month measured. Taitel M, Jiang J, Rudkin K, Ewing S, Duncan I; "The impact of pharmacist face-to-face counseling to improve medication adherence among patients initiating statin therapy;" Patient Prefer Adherence; 2012;6:323-9, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3340117/

[10] A systematic review was conducted using 51 studies determining the optimal modes of delivery for interventions to improve adherence to cardiovascular medications. Among person-dependent interventions (nonautomated phone calls, in-person interventions), phone calls showed low success rates (38%). In-person pharmacist interventions were effective when held in a pharmacy (83% successful) but were less effective in clinics (38%). Cutrona SL, Choudhry NK, et al; "Modes of Delivery for Interventions to Improve Cardiovascular Medication Adherence;" AJMC; December 2010, available at: https://www.ncbi.nlm.nih.gov/pubmed/21348564

cc: The Honorable Alex Azar II, Secretary, HHS
The Honorable Steven Mnuchin, Secretary, DOT
The Honorable Charles P. Rettig, IRS
The Honorable Eugene Scalia, Secretary, DOL
The Honorable Preston Rutledge, Assistant Secretary, EBSA
The Honorable Christi Grimm, Principal Deputy Inspector General, OIG, HHS