



January 16, 2018

[Submitted electronically to www.regulations.gov]

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4159-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-4182-P, RIN 0938-AT08, Medicare Program; Contract Year (CY) 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program; Proposed Rule

Dear Administrator Verma:

APhA is pleased to submit these comments regarding the proposed changes to the Part D program for CY 2019 (the “Proposed Rule”). APhA, founded in 1852 as the American Pharmaceutical Association, represents 64,000 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.

I. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA)

The Proposed Rule implements Section 704 of Comprehensive Addiction and Recovery Act of 2016 (CARA) which allows prescription drug plan sponsors to establish a drug management program (DMP). In the Proposed Rule, CMS outlines a framework under which Part D plan sponsors may establish a DMP for beneficiaries at risk for prescription drug abuse or misuse. Under CMS’s framework, sponsors may limit the access of controlled substances CMS determines are frequently abused to a selected prescriber(s) and/or network pharmacy(ies). In addition, according to the Proposed Rule, CMS plans on integrating DMPs with current Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS). APhA appreciates CMS’s work to help address the opioid epidemic. We offer the following responses and recommendations regarding CMS’s DMP framework in order to better meet CMS’s goals as well as further APhA’s continued efforts to improve patient safety and enhance opioid addiction prevention without unnecessarily restricting patient access to needed medications.

a. Current Part D Opioid DUR Policy and OMS

In the Proposed Rule, CMS indicates its plans to implement CARA Part D DMP provisions by integrating them with the current Part D Opioid Drug Utilization Review (DUR) Policy¹ and the Overutilization Monitoring System (OMS).² Consequently, Part D sponsors implementing a DMP could also limit an at-risk beneficiary's access to opioids beginning 2019 through a point-of-sale claim edit.

APhA is pleased there have been reductions in the overuse of opioids in the Part D program since the implementation of the Overutilization Monitoring System (OMS), as noted in the Proposed Rule. We believe CMS's oversight of DMPs is crucial to help ensure adherence to the program's goals and requirements as defined by Congress and CMS. To further improve DMPs, APhA encourages CMS to consider tracking additional metrics and information to assess these programs' impact on beneficiaries. For example, research on North Carolina Medicaid's lock-in program determined enrollment in a lock-in program was associated with a roughly four-fold increase in the likelihood and frequency of out-of-pocket controlled substance prescription fills.³ APhA encourages CMS to consider gathering additional information, including beneficiary, prescriber and pharmacist feedback and prescription drug monitoring program (PDMP) data, to better determine the overall impact of DMPs on beneficiaries and their outcomes.

b. Buprenorphine exemption

For the 2019 plan year, HHS proposes to designate all opioids as frequently abused drugs except buprenorphine for medication-assisted treatment (MAT) and injectables. APhA supports CMS's intent to provide an exception for buprenorphine in order to unnecessarily limit patient access to treatment. APhA also notes that removing buprenorphine as a frequently abused drug is consistent with the Centers of Disease Control and Prevention's approach to exclude buprenorphine as part of daily opioids MMEs.⁴ Removing access barriers to MAT is an

¹ See Centers for Medicare and Medicaid Services, CMS Final Call Letter 2013-2018 Part D DUR Controls Excerpts, available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/AHIP_Overutilization_Strategies_CMS_-10192015.pdf, last accessed December 13, 2016.

² See Centers for Medicare and Medicaid Services, (April 28, 2017). Analysis of Proposed Opioid Overutilization Criteria Modifications in Medicare Part D, available at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Revised-OMS-Criteria-Modification-Analysis.pdf>, last accessed: December 13, 2017.

³ Roberts, A.W., Farley, J.L., Holmes, G.M., Oramasionwu, C.U., et al., (2016). Controlled Substances Lock-In Programs: Examining and Unintended Consequence of a Prescription Drug Abuse Policy, *Health Affairs*, 35(1), available at: <https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2016.0355>, last accessed: December 13, 2017.

⁴ See Centers for Disease Control and Prevention, response to American Society of Addiction Medicine regarding dosage thresholds in the CDC Guideline for Prescribing Opioids for Chronic Pain – 2016, clarifying that buprenorphine and other drug provided for medication assisted treatment should not be used to benchmark against dosage thresholds meant for opioids prescribed for pain. Also stating, "These buprenorphine products, as partial opioid agonists, are not expected to be associated with overdose risk in the same dose-dependent manner doe doses for full agonist opioids", available at: <https://www.asam.org/docs/default-source/advocacy/letters-and->

important component in addressing the opioid epidemic and helping to ensure individuals get the treatment they need.

c. Selection of frequently abused drugs

APhA appreciates CMS seeking information regarding the potential future inclusion of non-opioid medications in DMPs. In the Proposed Rule, CMS proposes future designations of frequently abused drugs by the Secretary primarily are to be included in the annual Parts C & D Call Letter or in similar guidance, which would be subject to public comment. APhA agrees with the goal of CMS's proposal and recommends the Agency clarify that this same process will also apply when a drug is no longer considered "frequently abused." Additionally, APhA requests CMS outline the methodology it will use for determining whether or which medications should be designated as frequently abused. Specifically, APhA recommends CMS include in a final proposal the criteria, resources (e.g. expert clinicians such as pharmacists), and the evidence basis upon which it will rely.

d. Non-opioid medications

In the Proposed Rule, CMS indicates a plan sponsor may choose to implement a DMP for non-opioid medications. APhA is concerned such a policy could allow plan sponsors to include medications that are not "frequently abused drugs" in DMPs, which goes beyond the purpose of the program to curb opioid abuse and misuse and will also create significant variability between plans. Additionally, while APhA generally encourages patients to use one pharmacy for better coordinated care and medication management, there may be unintended consequences if plan sponsors are allowed to include a wide array of medications in DMPs. For example, a DMP that includes specialty medications may disrupt patient care as the patient's selected pharmacy may not stock specialty medications. Although most pharmacies carry a robust variety of prescriptions, some pharmacies are precluded from carrying certain medications due to REMS or manufacturer-imposed limited distribution requirements. Therefore, APhA strongly urges CMS to only allow plan sponsors' DMPs to include medications that are "frequently abused" to keep with the intent of CARA and not unnecessarily limit patients' choice and care.

e. Exempted beneficiaries

In the Proposed Rule, CMS indicates beneficiaries with a cancer diagnosis are exempted from DMPs because such programs should not administratively interfere with their pain control regimen, such as in the form of additional notices or limitations on their access to coverage for frequently abused drugs. The cancer exemption is in addition to the exempted beneficiaries required by CARA — those in hospice and in long-term care facilities or other facilities in which a single pharmacy dispenses medication to residents. CMS notes an exemption for cancer patients is consistent with a current policy, but acknowledges that an administrative burden is likely also associated with patients suffering from other diseases or in need of other treatments. APhA agrees that different disease states and treatment regimens, such as sickle cell disease and palliative care, may warrant exemption from a DMP and recommends CMS develop a process

[comments/2018-1-4-letter-on-buprenorphine-and-cdcs-guideline-002\).pdf?sfvrsn=7fa840c2_2](https://www.fda.gov/oc/2018/01/12-comment-2018-1-4-letter-on-buprenorphine-and-cdcs-guideline-002.pdf?sfvrsn=7fa840c2_2)), last accessed: January 12, 2018.

for adding and evaluating DMP exemptions that is evidence-based and involves health care practitioners in the determination.

f. Case management

CMS states in the Proposed Rule Part D plan sponsors must address in their written policies the appropriate credentials of the personnel conducting DMP case management. CMS notes “case management is a key feature of the current policy, under which we currently expect Part D plan sponsors’ clinical staff to diligently engage in case management with the relevant opioid prescribers to coordinate care with respect to each beneficiary reported by OMS until the case is resolved[.]” Under the Proposed Rule, CMS requires all beneficiaries reported by OMS to be reviewed by sponsors. Requirements for the review includes the plan sponsor contacting the providers who have prescribed frequently abused drugs for the beneficiary and verifying the beneficiary is an at-risk beneficiary, if the sponsor intends to limit the beneficiary’s access to coverage for frequently abused drugs. Given the important role these reviews and case management will play in regards to patient access, medication safety and care coordination, APhA offers several recommendations to address some concerns.

i. Qualifications of Staff Conducting Case Management

APhA is concerned the Proposed Rule does not provide enough assurance that staff conducting case management will be adequately qualified to perform the various roles assigned. In addition to only a brief mention that appropriate credentials of case management personnel be included in policies, the Proposed Rule simply requires the “sponsor’s clinical staff” to conduct case management when determining if a potentially at-risk beneficiary is at-risk. However, reference to “clinical staff” is not defined with regard to this case management requirement. Consequently, APhA is concerned plan sponsors’ staff managing cases may not possess adequate education and training to effectively meet the needed demands of appropriate case management for DMPs. Additionally, the Proposed Rule gives plan sponsors’ Pharmacy & Therapeutics (P&T) Committees significant flexibility regarding case management requirements, but does not address needed education and training.

Unqualified and variability in case managers could significantly detract from the potential benefits of a DMP. Case managers will be in unique positions to have contact with a patient’s prescribers and a complete view of their medications, creating a significant opportunity to improve care. APhA believes the potential benefits of case management will be lost if case managers do not possess the requisite knowledge and training to make informed clinical decisions and coordinate care. APhA encourages CMS to develop requirements for case managers to better ensure their education and training is sufficient to meet the necessary functions of that position.

ii. At-Risk Determination Process

The Proposed Rule requires the plan sponsor’s clinical staff conduct case management for each potential at-risk beneficiary for the purpose of engaging in clinical contact with the prescribers of frequently abused drugs and verifying whether a potential at-risk beneficiary is at-risk. However, the notice and subsequent sponsor inquiries focus on whether the medications are

appropriately prescribed, without considering other important factors making the potential at-risk beneficiary truly at-risk. Given prescribers' direct contact with patients and their ability to access other resources, such as a prescription drug monitoring program, APhA recommends CMS modify the prescriber notices to directly question whether the prescriber believes the beneficiary is at-risk. In addition, CMS should clarify how a plan sponsor should weigh prescriber responses when making enrollment decisions to ensure prescribers' judgment is meaningfully considered when a sponsor enrolls a patient in a DMP.

g. Notice

The Proposed Rule indicates initial notice of the intent to limit access from Part D sponsors to potentially at-risk and at-risk beneficiaries must use language approved by the Secretary and be in a readable and understandable format. In addition, the plan sponsor is also required to make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs a copy of the notice. APhA believes beneficiary awareness may be improved by plan sponsors also providing language assistance services to identified beneficiaries who may be enrolled in a DMP to enhance understanding for disabled patients and for those in which English is not their first language. APhA also recommends plan sponsors make reasonable efforts to notify the pharmacies dispensing frequently abused drugs to a beneficiary identified to be enrolled in a DMP, similar to the notice provided to prescribers. Moreover, APhA requests CMS monitor how notices are being issued to providers, patients, and pharmacies, and evaluate their effectiveness in order to identify and promote successful communication mechanisms for plan sponsors to utilize. Due to the impact of the limitations contained in these notices, it is critical patients and providers are made aware through effective communication.

h. Pharmacy selection

APhA appreciates CMS's efforts to allow patients enrolled in a DMP some choice when selecting their pharmacy, but believes requiring patients to select an in-network pharmacy unnecessarily limits patient choice. The Proposed Rule states, "it is essential that an at-risk beneficiary must generally select in-network pharmacists and prescribers so that the plan is in the best possible position to coordinate the beneficiary's care..." APhA is concerned CMS's justification to limit patient access to in-network pharmacies is unwarranted because Part D plan sponsors are not primarily responsible for coordinating care. Care coordination is a function of the health care team and must not be conflated with Part D coverage, plan design or plan sponsors' case management. To that end, APhA recommends CMS develop criteria for plans to include out-of-network pharmacies, providing patients with the flexibility to select in- or out-of-network pharmacies, and clarify health care practitioners providing patient care services are primarily responsible for care coordination, not plan sponsors or their case managers.

i. Pharmacy decision-making and choice

The Proposed Rule states, "...plan sponsors can obtain a network provider's confirmation in advance by including a provision in the network agreement specifying that the provider agrees to serve as at-risk beneficiaries' selected prescriber or pharmacy, as applicable." As CMS considers policies and requirements, it is important for the Agency to be aware that pharmacies often do not have the ability to negotiate individual terms in plan sponsors' agreements so

allowing for a plan to include provisions in a network agreement essentially becomes a requirement for a pharmacy or alternatively places a pharmacy's network status at risk. APhA requests that CMS clarify when establishing policies that are not meant to be mandates, plan sponsors must allow for a mechanism for pharmacies to opt out.

j. Sponsor-initiated changes

The Proposed Rule indicates the plan sponsor may change the beneficiary's prescriber and pharmacy selection if there is strong evidence of inappropriate action by the prescriber, pharmacy or beneficiary and if the sponsor provides the beneficiary with 30 days written notice containing the sponsor's rationale for the change. However, the Proposed Rule does not indicate how a pharmacy will be made aware of such changes. APhA requests CMS clarify how notice will be provided to pharmacies regarding sponsor-initiated changes and, as stated earlier, we ask CMS to continue to evaluate the effectiveness of notices to best achieve awareness.

In addition, APhA encourages CMS to provide examples of "strong evidence" that would justify a plan sponsor from changing a beneficiary's pharmacy or prescriber. Without additional context regarding "strong evidence," APhA is concerned variable interpretation of this standard could lead to patients' prescribers and pharmacies being unnecessarily switched.

Lastly, APhA believes a missing component in the many policies and activities implemented to prevent opioid misuse and abuse is identifying what action is needed after an individual is identified as misusing or abusing their medication. APhA encourages CMS, in coordination with other federal agencies, providers and patients, develop and provide guidance for plan sponsors and providers, including pharmacists, regarding steps to take, including treatment options, once a beneficiary is believed to be misusing or diverting frequently abused drugs. Simply changing the patient's prescriber and/or pharmacy is not a treatment solution and may overlook patient needs.

k. Reasonable access

APhA appreciates CMS's effort to maintain "reasonable access" for beneficiaries in DMPs by requiring plan sponsors to take into account a beneficiary's geographic location, preference, predominant usage of prescriber or pharmacy, impact on cost-sharing and reasonable travel time. When considering "reasonable access," CMS proposes to require plan sponsors to also account for individuals with multiple residences, natural disasters and similar situations and emergency services. However, the Proposed Rule does not consider additional factors needed to maintain reasonable access. For example, research regarding pharmacists' perspectives of the DMP in North Carolina indicates pharmacists' need additional flexibility to dispense medications to patients during holidays, closings, and weekends, where it may be difficult for a beneficiary to access their selection prescriber or pharmacy.⁵ Without such an allowance for exceptions, under the Proposed Rule, APhA anticipates beneficiaries may pay out-of-pocket for needed medications or unnecessarily obtain emergency services.

⁵ See Werth, S.R., Sachdeva, N., Roberts, A.W., Garrettson, M., Ringwalt, C., Moss, L.A., Pikoulas, T. & Cockrell Skinner, A. (2014). North Carolina Medicaid Recipient Management Lock-In Program: The Pharmacist's Perspective, *J. Manag Care Spec Pharm*, 20(11), 1122-1128a, available at: <http://www.jmcp.org/doi/pdf/10.18553/jmcp.2014.20.11.1122>.

I. Coordination with the Drug Enforcement Agency

APhA is concerned pharmacies enrolling a larger proportion of DMP beneficiaries may face ordering issues with the Drug Enforcement Agency (DEA). Coordination with DEA is critical to maintaining patient access to needed medications to prevent selected pharmacies from having ordering issues due to DEA policies, including wholesaler imposed limits. For example, pharmacies with many DMP patients may need to increase opioid orders beyond historical averages raising unwarranted suspicion. Accordingly, APhA recommends CMS work with DEA and other stakeholders to identify solutions to prevent the unnecessary stoppage of orders to selected pharmacies. Given DMP patients are already identified as at-risk, access to needed medications must be maintained through the selected pharmacy to prevent patients from seeking alternative, potentially more harmful, solutions.

m. Research

As CMS is likely aware, several states have implemented DMPs for beneficiaries. Research from these DMPs have indicated difficulty in showing effectiveness of such programs and several unintended consequences, including increased out-of-pocket payment for beneficiaries to obtain medications.^{6,7,8} In addition, it is well-documented that many individuals transition from prescription opioids to heroin.^{9,10,11} Factors affecting transition include tolerance, availability and cost.¹² Consequently, it is foreseeable that patients whose access to opioids is limited may turn to illicit drugs, such as heroin. APhA urges CMS to carefully monitor, evaluate and research the varying DMPs and associated data to identify what works and what does not and work with other agencies and stakeholders to on solutions to prevent unintended consequences and problems.

⁶ Keast, S.L., Nesser, N & Farmer, K. (2015). Strategies aimed at controlling misuse and abuse of opioid prescription medications in a state Medicaid program: a policymaker's perspective, *The American Journal of Drug and Alcohol Abuse*, 41:1, 1-6, DOI, available at: 10.3109/00952990.2014.988339

⁷ Roberts, A.W. & Cockrell Skinner, A. (2014). Assessing the Present State and Potential of Medicaid Controlled Substance Lock-In Programs, *J Manag Care Spec Pharm*, 20(5), 439-446, DOI, available at: <https://doi.org/10.18553/jmcp.2014.20.5.439>

⁸ Yang, Z., Wilsey, B., Bohm, M., Weyrich, M., Roy, K., Ritley, D., Jones, C. & Melnikow, J. (2015). Defining Risk of Prescription Opioid Overdose: Pharmacy Shopping and Overlapping Prescriptions Among Long-Term Opioid Users in Medicaid, *The Journal of Pain*, 16(5), 445-453, DOI, available at: <http://dx.doi.org/10.1016/j.jpain.2015.01.475>

⁹ Franklin, G., Sabel, J., Jones, C.M., Mai, J., Baumgartner, C., Banta-Green, C-J., Neve, D. & Tauben, D.J. (2015). A Comprehensive Approach to Address the Prescription Opioid Epidemic in Washington State: Milestones and Lessons Learned, *American Journal of Public Health*, 105(3), 463-469.

¹⁰ Victor, G.A. Walker, R. Cole, J. & Logan, T.K. (2017). Opioid analgesics and heroin: Examining drug misuse trends among a sample of drug treatment client in Kentucky, *International Journal of Drug Policy*, 46, 1-6.

¹¹ Al-Tayyib-Al, A.A., Koester, S. & Riggs, P. (2017). Prescription opioids prior to injection drug use: Comparisons and public health implications, *Addictive Behaviors*, 64, 224-228.

¹² Franklin, G., Sabel, J., Jones, C.M., Mai, J., Baumgartner, C., Banta-Green, C-J., Neve, D. & Tauben, D.J. (2015). A Comprehensive Approach to Address the Prescription Opioid Epidemic in Washington State: Milestones and Lessons Learned, *American Journal of Public Health*, 105(3), 463-469.

II. Any Willing Pharmacy Standards Terms and Conditions and Better Defining Pharmacy Types (§§ 423.100, 423.505)

a. Any willing pharmacy requirement

APhA supports CMS's proposal to address concerns regarding plan sponsors or their pharmacy benefit managers (PBMs) limiting patient access and excluding community pharmacies from participation in Part D standard networks that effectively limit competition and direct patients to PBM-affiliated pharmacies. Section 1860D-4(b)(1)(A) of the Social Security Act already requires Part D plan sponsors to permit the participation of "any pharmacy" that meets the standard terms and conditions. However, as CMS acknowledges, "...the development of "standard" terms and conditions...in some cases has had the effect, in our view, of circumventing the any willing pharmacy requirements and inappropriately excluding pharmacies from network participation."

Specifically, APhA supports CMS's proposal "...to clarify that the any willing pharmacy requirement applies to all pharmacies, regardless of how they have organized one or more lines of pharmacy business." CMS goes on to confirm its "...definitions were never intended to limit the scope of the any willing pharmacy requirement. Nevertheless, we have anecdotal evidence that some Part D plan sponsors have declined to permit willing pharmacies to participate in their networks on the grounds that they do not meet the Part D plan sponsor's definition of a pharmacy type for which it has developed standard terms and conditions." APhA agrees with CMS that "...it is not appropriate for Part D plan sponsors to offer standard terms and conditions for network participation that are specific to only one particular type of pharmacy, and then decline to permit a willing pharmacy to participate on the grounds that it does not squarely fit into that pharmacy type." Accordingly, we support CMS's clarification that "similarly situated" pharmacies "...include any pharmacy that has the capability of complying with standard terms and conditions for a pharmacy type, even if the pharmacy does not operate exclusively as that type of pharmacy."¹³

b. Treatment of accreditation

Like CMS, APhA too has the concern noted in the Proposed Rule "...that Part D plan sponsors might use their standard pharmacy network contracts in a way that inappropriately limits dispensing of specialty drugs to certain pharmacies[.]" CMS notes it has "...received complaints from pharmacies that Part D plan sponsors have begun to require accreditation of pharmacies, including accreditation by multiple accrediting organizations, or additional Part D plan- / PBM specific credentialing criteria, for network participation." APhA appreciates that CMS does "...not support the use of Part D plan sponsor- or PBM-specific credentialing criteria, in lieu of, or in addition to, accreditation by recognized accrediting organizations, apart from

¹³ CMS is defining "mail order pharmacy" "...as a licensed pharmacy that dispenses and delivers extended days' supplies of covered Part D drugs via common carrier at mail-order cost sharing," to avoid plans' exclusion of pharmacies that may offer home delivery services by mail, but, are not mail-order pharmacies, and utilize retail cost sharing. CMS is also defining "retail pharmacy" as "any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy."

drug-specific limited dispensing criteria such as FDA-mandated REMS or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy...” We also appreciate the agency’s concern “... about anecdotal reports that allege such standard terms and conditions for network participation are waived, for example, when a Part D plan sponsor needs a particular pharmacy its network in order to meet convenient access requirements, or even for certain pharmacies that received preferred pharmacy status.” Therefore, APhA strongly supports CMS recognition in the Proposed Rule that “[w]aivers or inconsistent application of such standard terms and conditions is an explicit acknowledgement that such terms and conditions are not necessary for the ability of a pharmacy to perform its core functions, and are thus neither reasonable nor relevant for any willing pharmacy standard terms and conditions.”

c. Limited dispensing requirements

APhA also agrees with CMS that “...because a pharmacy’s ability to dispense certain medications is not dependent on it having the ability to dispense other medications, it is not relevant for sponsors to require pharmacies to dispense a particular roster of certain drugs or drugs for certain disease states in order to receive standard terms and conditions for network participation as a contracted network pharmacy for that Part D plan sponsor.” Accordingly, APhA supports CMS clarifying the Agency “...would not expect Part D plan sponsors to limit dispensing of certain drugs or drugs for certain disease states to a subset of network pharmacies, except when necessary to meet FDA-mandated limited dispensing requirements (for example, Risk Evaluation and Mitigation Strategies (REMS) processes) or except as required by applicable state law(s) if the contracted network pharmacy is capable of and appropriately licensed under applicable state law(s) for doing so.”

d. Timing of contracting requirements

APhA also commends CMS for its proposal to give community pharmacies easier access to Part D plan terms and conditions for network participation. As stated in the Proposed Rule, “CMS has received complaints over the years from pharmacies that have sought to participate in a Part D plan sponsor’s contracted network but have been told by the Part D plan sponsor that its standard terms are not available until the sponsor has completed all other network contracting. In other instances, pharmacies have told us that Part D plan sponsors delay sending them the requested terms and conditions for weeks or months or require pharmacies to complete extensive paperwork demonstrating their eligibility to participate in the sponsor’s network before the sponsor will provide a document containing the standard terms and conditions.” APhA agrees with CMS that “...such actions have the effect of frustrating the intent of the any willing pharmacy requirement, and as a result, we believe it is necessary to codify specific procedural requirements for the delivery of pharmacy network standard terms and conditions.” Accordingly, APhA supports CMS’s proposals to require that “...Part D plan sponsors have standard terms and conditions readily available for requesting pharmacies no later than September 15 of each year for the succeeding benefit year,” and “...Part D plan sponsors must provide the applicable standard terms and conditions document to a requesting pharmacy within two business days of receipt of the request.”

III. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes

Under the Proposed Rule, CMS is proposing to permit Part D plans to immediately remove, or change the preferred or tiered cost-sharing of, brand name drugs and substitute or add therapeutically equivalent generic drugs provided specified requirements are met.¹⁴ APhA is concerned beneficiary care and treatment will be disrupted by CMS shortening the existing 60 days online notification requirement and adding an exception to the lesser 30 day requirement when Part D plans add a therapeutically equivalent generic. In addition, there is no proposed requirement to evaluate the impact of the policy on enrollees' medication access, and to authorized prescribers, pharmacists, and pharmacies. Accordingly, APhA strongly recommends CMS test the implementation of such a major policy change before it applies to all Part D plan sponsors.

IV. Request for Information (RFI) Regarding the Application of Price Concessions to Drug Prices at the Point-of-Sale

a. Including direct and indirect remuneration fees (DIR) at point-of-sale (POS)

As CMS understands, DIR was originally designed to capture rebates and other mechanisms not included at the point-of-sale. However, DIR by PBMs to CMS 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. Because point-of-sale prices or copays paid by beneficiaries can be based on the contracted price before DIR is extracted, DIR fees charged retroactively to pharmacies generally do not positively impact what patients pay and may actually result in the beneficiary paying more.

As stated by CMS in the Proposed Rule, “[b]etween 2010 and 2015, the amount of all forms of price concessions received by Part D sponsors and their PBMs increased nearly 24 percent per year, about twice as fast as total Part D gross drug costs, according to the cost and price concession data Part D sponsors submitted to CMS for payment purposes.” CMS also affirms that when price concessions between pharmacies and Part D plan sponsors or their PBMs (e.g., direct or indirect remuneration (DIR) fees) “...are not reflected in the price of a drug at the point of sale, beneficiaries might see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug.” CMS goes on to acknowledge that “[n]umerous research studies further suggest that the higher cost-sharing that results can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for beneficiaries and Medicare.” Accordingly, APhA supports CMS’s intention to require price

¹⁴ See, Pages. 56413-56416. 1. The Plan Sponsor must give all beneficiaries a prospective general notice that the Plan Sponsor is able to make certain generic substitutions without additional advance notice; 2. The Plan Sponsor could not have as a matter of timing been able to previously request CMS approval of the change because the generic drug had not yet been released to the market; 3. The generic drug must be made available to beneficiaries at the same or lower cost-sharing than the brand drug that is being moved or removed; and 4. Once the formulary change has occurred, the Plan Sponsor must provide a more specific notice to affected beneficiaries, CMS, and other entities (e.g., State Patient Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies, and pharmacists).

concessions between pharmacies and plan sponsors or their PBMs (e.g., DIR fees and/or similar policies/terminology, such as “true up” practices) be reflected in the negotiated price that is made available at the time a medication is dispensed at the point-of-sale. This policy, according to CMS estimates, would significantly reduce net beneficiary costs by \$10.4 billion¹⁵ and give community pharmacies greater predictability regarding reimbursement rates.

b. Separate payments for product fulfillment and delivering quality and patient care

Under this section of the Proposed Rule, CMS would exclude from the point-of-sale or negotiated price any additional contingent amounts that could go to network pharmacies, such as incentive fees under pharmacy-based payment arrangements (i.e., these can be applied after point-of-sale). APhA appreciates CMS’s exclusion of pharmacy-based payment arrangements from the cost for the drug products under the “lowest possible reimbursement.” Furthermore, APhA urges CMS and other payers to collaborate with pharmacists to develop distinct, transparent, fair, and equitable payment strategies for achieving performance measures associated with providing pharmacists’ patient care services that are separate from the reimbursement methods used for product fulfillment.”¹⁶

APhA is confused by the statement in the Proposed Rule which explains CMS’s rationale for revising § 423.100 that would require “...all price concessions from pharmacies be reflected in the negotiated price that is made available at the point of sale and reported to CMS on a PDE record, even when such concessions are contingent upon performance by the pharmacy.” We believe this statement directly conflicts with the policy noted in the previous paragraph which excludes contingent incentive payments for the negotiated price. Accordingly, APhA recommends that CMS address this discrepancy in future rulemaking, clarifying that performance-based incentives should be excluded from the price reported at the point-of-sale. In addition, we ask CMS to better define terms used in this section of the Proposed Rule, including “pharmacy price concessions,” “incentive fees,” and “performance-based payment arrangements.”

V. Policies that Increase Access to Safe, Effective and Affordable Medications

APhA supports policies which increase patient access to safe, effective, and affordable medications as well as patient choice. Accordingly, we support the provision in the Proposed Rule prohibiting Part D plan sponsors from excluding non-preferred generic-drug tiers from tiering exceptions “...when the plan determines that the enrollee cannot take the preferred generic alternative(s), including when the preferred generic alternative(s) are on tier(s) that include only generic drugs or when the lower tier(s) contain a mix of brand and generic alternatives.”

¹⁵ See, TABLE 11: 2019 - 2028 POINT-OF-SALE PHARMACY PRICE CONCESSIONS IMPACTS. Page 338.

¹⁶ APhA. Policy Manual. Pharmacy Performance Networks. 2017. (JAPhA 57(4): 441 July/August 2017). Available at: <http://pharmacist.com/policy-manual?key=Pharmacy%20Performance%20Networks>

Similarly, APhA appreciates CMS's proposal to revise the definition of generic drug at § 423.4 to include follow-on biological products (biosimilars) approved under the section 351(k) pathway in order to expand access for lower cost alternatives.¹⁷ APhA has continuously supported policies that encourage the adoption of a scientifically-based biosimilars regulatory framework that, to the extent possible, resembles the regulatory framework for generic and small-molecule drug products so as not to create barriers to the uptake and utilization of products when evidence demonstrates they are safe and effective.

VI. Medication Therapy Management (MTM) (§§ 422.2430 and 423.2430)

APhA wishes to express our sincere thanks to CMS for clarification in the Proposed Rule that "...all MTM programs that comply with § 423.153(d) and are offered by Part D sponsors (including MA organizations that offer MA-PD plans (described in § 422.2420(a)(2)) are QIA," or Quality Improvement Activities (QIA) under the Affordable Care Act's Medical Loss Ratio (MLR) requirement. In the Proposed Rule, CMS discourages Part D sponsors from restricting eligibility criteria and encourages they implement innovative strategies to strengthen their MTM programs, highlighting MTM's importance in "...providing individualized disease management in conjunction with the ongoing opioid crisis evolving within the Medicare population." APhA urges CMS to also clarify that the Center for Medicare & Medicaid Innovation's (CMMI) Part D Enhanced MTM models¹⁸ are also QIA, thereby incentivizing participation in these models

Thank you for the opportunity to provide comments on the Proposed Rule. 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
Anne Burns, Vice President, Professional Affairs

¹⁷ CMS's proposal would be "...limited to purposes of non-LIS catastrophic and LIS cost sharing only." See, pg. 56417.

¹⁸ See, <https://innovation.cms.gov/initiatives/enhancedmtm/>. Last updated on: 02/13/2017.