



April 6, 2020

[Submitted electronically to [www.regulations.gov](http://www.regulations.gov)]

The Honorable Seema Verma  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services (HHS)  
**Attention: CMS-4190-P**  
P.O. Box 8013  
Baltimore, MD 21244-8013

**Re: Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly. Proposed Rule. (Docket ID: CMS-2020-0010)**

Dear Administrator Verma:

The American Pharmacists Association (APhA) is pleased to submit our comments on the Centers for Medicare & Medicaid Services' (CMS) Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, Proposed Rule (hereinafter "Proposed Rule"). Founded in 1852 as the American Pharmaceutical Association, APhA represents nearly 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, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

APhA thanks CMS for the opportunity to offer our comments regarding the CY 2021 and 2022 policy and technical changes for Part D and other programs.

#### *Proposed Telehealth Provisions*

There are many opportunities to leverage pharmacists in telehealth service delivery across various Medicare programs. Pharmacists, in general, are underutilized for the medication and health-related expertise they can provide to other providers, health care teams and patients, and especially in rural and underserved areas, pharmacists may be the only health care provider accessible to beneficiaries. Existing examples where pharmacists are involved in telehealth delivery include Medicare Part B Chronic Care Management (CCM) and Transitional Care Management (TCM) services and the Part D Medication Therapy Management Program (MTM).

However, pharmacists are not currently recognized as practitioners (providers) under the Medicare Telehealth Benefit of the Social Security Act, Section 1834(m) [42 C.F.R. § 410.78]. Therefore, APhA urges CMS to review and include pharmacists as practitioners (providers) for the Medicare Telehealth Benefit.

Our request is consistent with the recent HHS report, “Reforming America’s Healthcare System Through Choice and Competition,” which states that the federal government should consider legislative and administrative proposals to allow non-physician providers (e.g., pharmacists) to practice to the top of their license, utilizing their full skill set and to be paid directly for their services.<sup>1</sup> As well as Executive Order (“EO”) #13890 – “Protecting and Improving Medicare for Our Nation’s Seniors,” regarding the elimination of specific Medicare regulations that require more stringent supervision than existing state scope of practice laws, or that limit health professionals, such as pharmacists, from practicing at the top of their license.<sup>2</sup> The HHS Secretary has the authority to add to the list of allowable telehealth services, which could include telehealth services provided by pharmacists, which are clinically appropriate, to be provided through electronic exchange for additional telehealth benefits.

Accordingly, we strongly urge HHS to use the new authority under the recently passed “Coronavirus Aid, Relief, and Economic Security Act” or the “CARES Act” (Public Law 116-136) under Sec. 3703. Expanding Medicare Telehealth Flexibilities that eliminated requirements in the Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020 (Public Law 116-123) and allows the HHS Secretary to waive telehealth restrictions to enable beneficiaries to access telehealth, including in their home, from a broader range of providers. Given the significant burdens on the health care system posed by the pandemic, **APhA recommends the HHS Secretary use this new authority under Sec. 3703 to specifically include pharmacists in order to fully utilize their expertise during this health crisis, including the use of pharmacist-provided telehealth services.** This could include a variety of pharmacist-provided patient care services to expand access to needed care such as evaluation and management (E/M) services using a telehealth format to assist in the management of chronic conditions under general supervision.

APhA also advocates that HHS review and implement Medicare telehealth policies to promote medication-related services in Part D. With telehealth, pharmacists can provide first-line triage services, counsel patients on potential medication interactions, remotely supervise technicians and oversee medication dispensing, perform final verification of prescriptions, and monitor patient therapies.

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<sup>1</sup> HHS. Reforming America’s Healthcare System Through Choice and Competition. December 3, 2018, available at: <https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf>

<sup>2</sup> White House. Executive Order on Protecting and Improving Medicare for Our Nation’s Seniors. October 3, 2019, available at: <https://www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-nations-seniors/>

*Improvements to Care Management Requirements for Special Needs Plans (SNPs) (§ 422.101)  
Pages 9013-9016*

APhA appreciates the provisions in the Proposed Rule to require Medicare Advantage (MA) special needs plans (SNPs) to “provide each enrollee with an interdisciplinary team in the management of care that includes a team of providers with demonstrated expertise and training, and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan.” SNPs are MA plans that are specifically designed to provide targeted care and limit enrollment to special needs individuals. Accordingly, APhA urges CMS to require MA plans to attribute the impact pharmacists, as members of interdisciplinary teams, have on Medicare beneficiaries receiving benefits through SNP plans. APhA also supports including telehealth as part of Medicare’s face-to-face encounters between each enrollee and a member of the enrollee’s interdisciplinary team, including pharmacists, or the plan’s case management and coordination staff on an annual basis.

*Out-of-Network Telehealth at Plan Option Pages 9041-9043*

APhA believes §422.135(d) should be revised to allow all MA plans, including preferred provider organizations (PPOs), to offer additional telehealth benefits (ATBs) through non-contracted providers and treat them as basic benefits under MA, especially where non-contracted providers, such as pharmacists, satisfy ATB requirements.

*Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128) Pages 9059-9063*

**APhA recommends any RTBT includes the “net price” of medications (which accounts for all price concessions, including direct and indirect remuneration fees (DIR) and/or similar policies/terminology, such as “true up” to accurately estimate patient cost-sharing liability for prescription drugs.** Under the Proposed Rule, CMS states “should the proposal be finalized, for beneficiary RTBTs to include cost-sharing amounts for medications if purchased at a pharmacy selected by the beneficiary, provided the pharmacy is in the plan’s network. Sponsors would also be allowed to provide cost data for alternative pharmacies in the plan’s network. However, due to concerns with enrollees being improperly steered to different pharmacies, we are not proposing to require that beneficiary RTBTs include pharmacy-specific cost sharing information.” However, “[i]n order to support maximum transparency, CMS also encourages plans to show each drug’s negotiated price (as defined in § 423.100) in the beneficiary RTBTs in addition to the requirement to reflect the beneficiary’s out-of-pocket cost information at the beneficiary’s currently chosen pharmacy. Alternatively, if the beneficiary RTBT does not show the negotiated price, we would encourage plans to provide additional cost data comparing the beneficiary and plan cost comparisons for each drug and its alternatives.” However, CMS concludes that “[a]lthough we encourage the inclusion of the negotiated price and other comparative information in the beneficiary RTBT, we are not proposing to require the inclusion of such information at this time.” Ultimately, CMS states “[p]lans are encouraged, but would not be required, to include the negotiated price.”

In another section of the Proposed Rule CMS states “CMS has concerns regarding the use of negotiated prices of drugs, as the term is currently defined in § 423.100, in the determination of

the specialty-tier cost threshold, because the negotiated prices include all pharmacy payment adjustments except those contingent amounts that cannot reasonably be determined at the point-of-sale. For this reason, negotiated prices typically do not reflect any performance-based pharmacy price concessions that lower the price a Part D sponsor ultimately pays for a drug.”<sup>3</sup>

CMS’ concern regarding the term “negotiated price,” is not unique to specialty drugs. As CMS is requesting feedback on this proposal, it is vital that this “negotiated price,” also include the “net price,” as mentioned above to accurately estimate patient cost-sharing liability for prescription drugs. **Thus, APhA recommends CMS consider using “net price” rather than the “negotiated price” in the final rule.** DIR fees under Part D and similar pharmaceutical benefit manager (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 Office of Inspector General (OIG)<sup>4</sup> and CMS proposed rules,<sup>5</sup> 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. As a stark example, CMS pointed out the shocking 45,000 percent increase in pharmacy price concessions (i.e., DIR fees) between 2010-2017,<sup>6</sup> an increase that is unsustainable for pharmacies, patients and Medicare. **Accordingly, pursuant to CMS’ statutory authority, APhA reiterates our strong support for HHS to implement the proposed rules by both OIG and CMS in the final Part D rule to require Part D plan sponsors to eliminate DIR and give these discounts to our nation’s beneficiaries.**

Generally, APhA is supportive of a RTBT benefit tool requirement on Part D sponsors to work in conjunction with the existing National Council for Prescription Drug Programs (NCPDP) SCRIPT and NCPDP Formulary and Benefits (F&B) electronic standards to provide the prescriber a complete view of the beneficiary’s prescription benefit information, as well as providing complete and accurate real-time formulary information, including drug cost transparency and the beneficiary’s out-of-pocket cost information. However, to achieve this, the RTBT needs to be capable of integrating with the prescriber’s electronic prescription (eRx) and electronic medical record (EMR) systems at the point of prescribing. If integrated properly, this could allow providers access to formulary and benefit information. APhA also recommends the RTBTs conform to emerging standards and capabilities to meet this goal and CMS allow ample time to use RTBTs before naming a standard in regulation.

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<sup>3</sup> See, § 423.100, “Negotiated prices means prices for covered Part D drugs that meet all of the following: (1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug. (2) Are inclusive of all price concessions from network pharmacies **except those contingent price concessions that cannot reasonably be determined at the point-of-sale**; and (3) Include any dispensing fees; but (4) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices and cannot reasonably be determined at the point-of-sale. (5) Must not be rebated back to the Part D sponsor (or other intermediary contracting organization) in full or in part.”

<sup>4</sup> 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>

<sup>5</sup> 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>

<sup>6</sup> 83 Fed. Reg. 62,174 (Nov. 30, 2018).

CMS codified information collection requirements for Part D sponsors in regulation at §423.514. In the Proposed Rule, CMS is utilizing this authority to amend the regulatory language at § 423.514(a) to establish a requirement for Part D sponsors to disclose to CMS the “pharmacy performance measures” they use. APhA strongly supports this proposal. We also appreciate CMS encouraging “...industry to continue to work together on developing a set of pharmacy performance measures through a consensus process and Part D sponsors to adopt such measures to ensure standardization, transparency and fairness.” Accordingly, APhA recommends CMS continue to work with the Pharmacy Quality Alliance (PQA) in efforts to create meaningful measures to address these important areas. APhA also agrees with CMS that “[c]ollecting pharmacy performance measures used to determine whether a financial reward or penalty is incurred by a pharmacy after the point-of-sale (POS) will enable CMS at a minimum to better understand the extent to which the measures are applied, whether it be uniformly or specific to pharmacy type.” “Knowledge of the industry’s pharmacy performance measures would also provide transparency to the process and likely confirm or dispel the idea that many of the measures may not provide appropriate metrics across all types of pharmacies.”

We also strongly support publishing the list of pharmacy performance measures to increase public transparency. As CMS states, this information is essential “[g]iven the growing use of pharmacy performance measures in determining the final cost of a drug under Part D and the impact of these recoupment practices on the amount a beneficiary pays for a Part D drug at the POS,” “...if there is to be predictable reimbursement for pharmacies and cost sharing for beneficiaries.” **Thus, it is imperative that CMS urgently fix the growing and runaway misuse of price concessions (i.e., DIR fees) in the final rule.**

APhA also appreciates CMS soliciting “...comment on the principles that Part D pharmacy performance measures should adhere to, **including potential burden or hardship of performance measures on small, independent, and/or rural pharmacies**, and recommendations for potential Part D Star Ratings metrics related to these measures.” APhA supports the development of feasible, valid, and reliable pharmacy performance measures that can be used to evaluate the value and contributions of pharmacists and pharmacies to the Medicare Part D program, as well as for other Medicare programs. APhA also supports PQA as the consensus-based entity to develop the pharmacy performance measures for CMS.

Overall, APhA supports the six principles for pharmacy performance measures outlined by CMS in the draft Call Letter, but has the following recommendations:

- CMS needs to clearly define terms such as “outcomes,” “beneficiaries served,” “right level of attribution,” “pharmacy type,” and “fair,” for pharmacy performance measures.
- Principle 1: APhA agrees that any measure “should improve medication use and outcomes for the beneficiaries served.” To accomplish that, it is important that pharmacy measures are focused on a health care gap that the pharmacy can actually impact. Source(s) of data will also be an important consideration in meaningful measure development, and CMS should consider data sources beyond prescription claims data as measures are developed.

- Principle 2: APhA recommends that CMS specifically consider a minimum denominator size for reliability in addition to the right level of attribution and appropriate level of comparison considering pharmacy type.
- Principle 3: While factoring “pharmacy accountability and drug plan performance goals” is important for alignment within the Part D program, APhA requests that CMS consider pharmacy performance measurement more broadly than just for the Part D program. Pharmacies administer vaccines that are part of the Medicare Part B program, and they are increasingly involved in Medicare value-based payment programs. There is a critical need for pharmacy performance measures that can be used in various Medicare programs.
- Principle 6: APhA agrees that there should be threshold minimums, but requests clarification on what entity would establish those minimums.

APhA agrees with CMS that “Part D sponsors ... use a third party, independent organization that is free of conflict of interest to assess pharmacy performance on such measures (including data aggregation, development of measure thresholds and cut points, and definition of applicable pharmacy types for each measure).” APhA recommends that CMS clarify the requirements for a third-party independent organization, and that this organization not be a health plan, plan, or certain pharmacy.

Regarding CMS’ request for potential metrics for the Star Ratings Program, APhA believes that there is much work to be done to establish meaningful pharmacy performance measures in the Medicare program, and it is premature to consider specific metrics for the Star Ratings program.

Finally, APhA cautions that in developing any such measures, CMS should consider potential unintended consequences, including the narrowing of networks, and the impact that could have on some pharmacies and the options available to beneficiaries. **APhA looks forward to working with CMS and other stakeholders to determine a standard set of pharmacy performance reporting measures.**

*MA and Cost Plan Network Adequacy (§§ 417.416 and 422.116) Page 9092*

APhA asks CMS to take into account the inclusion of telehealth providers, including pharmacists, in contracted networks when determining network adequacy requirements.

*Eligibility for Medication Therapy Management Programs (§ 423.153) Pages 9029-9037*

APhA supports conforming the requirements with the relevant SUPPORT Act (Public Law No: 115-271) provisions for Medicare Part D plans beginning January 1, 2021. Under the Proposed Rule, Part D sponsors would be required to automatically enroll all at-risk beneficiaries (ARBs) in their MTM programs on an opt-out basis as required in §423.153(d)(1)(v) and be required to offer each ARB enrolled in the MTM program the same level of MTM services that sponsors are currently required to offer beneficiaries enrolled in their MTM programs, which includes an annual comprehensive medication review (CMR) under §423.153(d)(1)(1)(vii)(B) that may be performed by a pharmacist. APhA also supports requiring the CMR to include an interactive,

person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider.

APhA also supports CMS modifying the CMS Standardized Format to allow the form to be completed in a “machine-readable” format. Technology continues evolving and advancing, particularly with regard to digital formats. Machine-readable data could aid in developing health care strategies and optimize health care decision-making to improve health outcomes.

As a member of the Pharmacy Health Information Technology Collaborative (PHIT) Collaborative, APhA supports policies in the Proposed Rule that encourage the use of Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR)-based Application Programming Interfaces (APIs) to make health information more widely accessible, including the CMR. The use of clinical decision support (CDS) tools, especially incorporating HL7 FHIR-based CDS Hooks, are efficient for vendors and providers of MTM services and lets them integrate the process into EHRs. This integration allows information to be sent to the patient so that the patient can work with the health care provider. Encouraging the use of HL7 FHIR-based APIs also aligns with the [Pharmacist eCare Plan](#)<sup>7</sup> and the Office of the National Coordinator’s (ONC) demonstration grant to make the eCare Plan interoperable using FHIR.

For pharmacy, the PHIT Collaborative recommends CMS utilize the eCare Plan using HL7 Companion Guide to Consolidated Clinical Document Architecture (CDA) R2 Implementation Guide: C-CDA Templates for Clinical Notes R1, which incorporates USCDI v1 and FHIR Release 4 for interoperable exchange of medication-related clinical data captured by pharmacists, which are also available through the APIs.

An updated CDA and FHIR R4 Pharmacist eCare Plan Implementation Guides version is now available. The goal of updating to a newer version is “to develop an electronic care plan with enhanced medication management content based on the templates in HL7 Implementation Guide for C-CDA Release 2.1: Consolidated Notes and FHIR profiles based on US Core specifications.”<sup>8</sup> APhA urges CMS to utilize the Pharmacist eCare Plan to incorporate medication-related goals and outcomes into a patient’s care profile and planning. The Pharmacist eCare Plan will serve as a “standardized, interoperable document for exchange of consensus-driven prioritized medication-related activities, plans and goals for an individual needing care.”<sup>9</sup> The Pharmacist eCare Plan can also be used for collecting data that could support more robust pharmacy performance measures.

Thank you for the opportunity to provide comments on the Proposed Rule. We support CMS’ ongoing efforts to continue to improve Medicare’s prescription drug programs (Parts C and D) and look forward to continuing to work with CMS to reach that goal. If you have any questions or require additional information, please contact Michael Baxter, Senior Director, Regulatory Policy, at [mbaxter@aphanet.org](mailto:mbaxter@aphanet.org) or by phone at (202) 429-7538.

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<sup>7</sup> <https://www.ecareplaninitiative.com/>

<sup>8</sup> <http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=1232>

<sup>9</sup> Ibid.

Sincerely,

A handwritten signature in black ink that reads "Thomas E. Menighan". The signature is written in a cursive style with a prominent initial 'T'.

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