Pharmacy Health Information Technology Collaborative

April 6, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4190-P
P.O. Box 8013
Baltimore, MD 21244-803

> **Re: CMS-4190-P: 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 Play Program, and Programs of All-Inclusive Care for the elderly**

Dear Administrator Verma:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative (Collaborative), we are pleased to submit comments regarding *CMS-4190-P: Medicare and Medicaid Programs, et al.*

The Collaborative has been involved with the federal agencies, including the Office of the National Coordinator (ONC) and the Centers for Medicare & Medicaid Services (CMS), developing the national health information technology (HIT) framework since 2010.

Pharmacists provide essential services to Medicare patients through the Part D prescription drug benefit program. Additionally, pharmacists are users of telehealth and health IT, and in particular, e-prescription(eRx) and EMR (EHR) systems. The Collaborative supports the use of these systems, which are important to pharmacists in working with other health care providers to provide needed medications and transmit patient information related to overall patient care, transitions of care, immunization (historical and administered), immunization registry reporting, medication lists, medication allergies, allergy reactions, patient problem lists, smoking status, reporting to public health agencies, clinical decision support services/knowledge artifacts, drug formulary checking, and electronic prescribing.

The following are our comments regarding the *CMS-4190-P: Medicare and Medicaid Programs, et al,* which concern specific areas of the proposal. Generally, the Collaborative is supportive of the overall direction of the proposal under consideration.

Proposed Telehealth (pages 43, 140-42, 161, 318-35)

The Collaborative supports the use of telehealth for delivering clinical health and person-centered care, particularly in rural health areas, and especially during times of national, state, and local emergencies (e.g., covid-19 pandemic outbreak).

Pharmacists are a part of health care management teams providing Medicare services and are telehealth providers. Telehealth enables pharmacists to connect with established health care management teams and patients, particularly when questions arise concerning medications prescribed or changes to medications, independent of geography. In many instances, especially in rural and underserved areas where telehealth would be invaluable, pharmacists are the first point of contact by patients and their caregivers.

Although Medicare routinely pays physicians and other health care providers and practitioners (e.g., social workers, dieticians; see 42 C.F.R. §410.73 and §410.134 respectively) for several kinds of services provided via interactive communication technology, the Collaborative and its members are concerned that Medicare does not reimburse pharmacists for telehealth services provided. The reason for this is because pharmacists are not recognized as practitioners (providers) under the Medicare Telehealth Benefit of the Social Security Act, Section 1834(m) [42 C.F.R. § 410.78. Pharmacists should be included as practitioners.

The role of pharmacists in telehealth is expanding. Many types of medication management services (MMS)[1] provided by pharmacists are clinically appropriate for telehealth, including: medication therapy management, chronic care management (e.g., diabetes, hypertension), medication reconciliation, transitions of care, pharmacogenomics, interpretation of diagnostic tests and providing test results, and consultations with patients and health care providers.

Telehealth is a cost-saving option that can expand pharmacist-provided health care services to patients outside traditional community pharmacy practice settings, while complementing existing pharmacy services and expanding access to the expertise of pharmacists across all settings in which pharmacists practice. Telehealth and telepharmacy could also provide cost-savings for hospitals, particularly rural hospitals.[2]

[1] "Medication Management Services (MMS) Definition and Key Points," Joint Commission of Pharmacy Practitioners, https://jcpp.net/wp-content/uploads/2018/05/Medication-Management-Services-Definition-and-Key-Points-Version-1.pdf

[2] Health IT News, January 2018, https://www.healthcareitnews.com/news/telepharmacy-rural-hospitals-provides-big-savings-quality-improvements

The Bipartisan Budget Act of 2018 modified and removed limitations relating to geography and patient setting for certain telehealth services. Although there may be some statutory restrictions for Medicare telehealth services, <u>we ask the secretary and CMS to review and include pharmacists as practitioners (providers) for the Medicare Telehealth Benefit,</u> as well as adding payment codes for those telehealth services that pharmacists provide to Medicare patients and their health care management teams. We believe this request is consistent with the Department of Health and Human Services (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 be paid directly for their services. Section 1834(m) grants the secretary the authority to add to the list of allowable telehealth services. This would appear to include telehealth services provided by pharmacists, which are clinically appropriate to be provided through electronic exchange for additional telehealth benefits.

Although new authority has been given the secretary under the recently enacted Coronvirus Aid, Relief, and Economic Securities (CARES) Act (Public Law 116-136, Sec. 3703) to temporarily waive telehealth restrictions during an emergency and allow beneficiaries access to telehealth and a broader range of health care providers, we believe this authority to expand telehealth should be extended beyond an emergency situation and become part of this final rule. As mentioned previously, pharmacists provide telehealth services and should be recognized as health care providers for the Medicare Telehealth Benefit.

2. Face-to-face Annual Encounters (page 43)

The Collaborative supports including telehealth as part of Medicare's face-to-face encounters between each enrollee and a member of the enrollee's interdisciplinary team or the plan's case management and coordination staff on an annual basis.

B. Out-of-Network Telehealth at Plan Option (pages 140-42)

The Collaborative believes §422.135(d) should be revised to allow all Medicare Advantage (MA) plan types, 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 satisfy ATB requirements.

1. General Non-Discriminatory Cost Sharing Limits (§422.100(f)(6)) (pages 161)

The Collaborative supports codifying §422.100(f)(6) which includes additional telehealth benefits under Parts A and B.

E. Medicare Advantage (MA) and Cost Plan Network Adequacy (§§417.416 and 422.116)(pages 318-35)

The Collaborative supports modifying the current network adequacy policy to further account for access needs in all counties, including rural counties, and to take into account the impact of telehealth providers in contacted networks, including giving an MA plan a 10-percentage point credit toward the percentage of beneficiaries residing within the applicable time and distance standards of certain provider specialty types when the plan contracts with telehealth providers for those specified specialty types.

With regard to applying the telehealth credit only to the specific provider specialty types, the Collaborative asks CMS to consider adding pharmacists to the listing.

E. Eligibility for Medication Therapy Management Programs (MTMPs)(§423.153) (pages 94-105 and 541)

The Collaborative supports conforming the requirements with the relevant SUPPORT Act provisions for Medicare Part D plans beginning January 1, 2021. As we understand this proposal, 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.

Additionally, the Collaborative supports requiring the CMR to include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider.

With regard to the standardized format developed by CMS, the Collaborative encourages CMS to revisit its rationale for the format not being available as "machine-readable" and to consider moving in that direction. CMS' current rationale is that the format is designed as non-machine readable for sharing with the beneficiary and to allow an MTM provider to elect to share the information with the beneficiary's provider. 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.

The Collaborative supports policies in this proposed rule that encourage the use of Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR)-based 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 electronic

health records (EHR). 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](#)[3] 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 the eCare Plan using HL7 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. These should be available through the API, as well.

These recommendations will help support the progress being made by the pharmacy profession to establish a consensus set of pharmacy measures. In concert with appropriate measurement science methodologies, these recommendations would encourage interoperability and support standardized pharmacy measurement to improve medication use and outcomes for beneficiaries being service.

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."[4] The Pharmacist eCare Plan is key to the incorporation of medication-related goals and outcomes into a patient's care profile and planning. It will serve as a "standardized, interoperable document for exchange of consensus-driven prioritized medication-related activities, plans and goals for an individual needing care."[5]

The Collaborative encourages CMS to examine the Pharmacist eCare Plan.

G. Beneficiary Real Time Benefit Tool (RTBT)(§423.128)(pages 204-19)

As we stated in our January 25, 2019 comments to proposed CMS-4180-P on this same topic, the Collaborative is supportive of a real-time benefit tool (RTBT) requirement on Part D sponsors to work in conjunction with the existing 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. To achieve this, though, the RTBT needs to be capable of integrating with the prescriber's eRx and EMR systems at the point of prescribing. If integrated properly, this could allow enrollees access to formulary and benefit information. We also suggest that such RTBTs conform to emerging standards and capabilities to meet this goal and that CMS allow ample time to use RTBTs before naming a standard in regulation.

[3] https://www.ecareplaninitiative.com/
[4] http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=1232
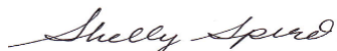[5] Ibid.

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The Pharmacy HIT Collaborative comprises the major national pharmacy associations, representing 250,000 members, including those in pharmacy education and accreditation. The Collaborative's membership is composed of the key national pharmacy associations involved in health information technology (HIT), the National Council of Prescription Drug Programs, and 14 associate members encompassing e-prescribing, health information networks, transaction processing networks, pharmacy companies, system vendors, pharmaceutical manufacturers, and other organizations that support pharmacists' services.

As the leading authority in pharmacy health information technology, the Pharmacy HIT Collaborative's vision and mission are to ensure the U.S. health IT infrastructure better enables pharmacists to optimize person-center care. Supporting and advancing the use, usability, and interoperability of health IT by pharmacists for person-centered care, the Collaborative identifies and voices the health IT needs of pharmacists; promotes awareness of functionality and pharmacists' use of health IT; provides resources, guidance, and support for the adoption and implementation of standards driven health IT; and guides health IT standards development to address pharmacists' needs. For additional information, visit www.pharmacyhit.org.

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On behalf of the Pharmacy HIT Collaborative, thank you again for the opportunity to comment on the *CMS-4190-P: Medicare and Medicaid Programs, et al.*

For more information, contact Shelly Spiro, executive director, Pharmacy HIT Collaborative, at shelly@pharmacyhit.org.

Respectfully submitted,

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