



Via Electronic Submission to: <https://www.reginfo.gov/public/do/PRAMain>

June 14, 2021

Ms. Shalanda Young
Director
Office of Management and Budget
Executive Office of the President
U.S. General Services Administration
725 17th St., NW
Washington, DC 20503

Re: CMS-10396 (Medication Therapy Management Improvements): Agency Information Collection Activities: Submission for OMB Review; Comment Request

Dear Director Young:

The Pharmacy Health Information Technology (PHIT) is pleased to submit comments, on behalf of our members, regarding *CMS-10396: Agency Information Collection Activities: Submission for OMB Review*.

PHIT 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, including comprehensive medication reviews (CMRs). Additionally, pharmacists are users of telehealth and health IT, and in particular, e-prescription (eRx) and electronic health record (EHR) systems. PHIT 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) for patient electronic information, state 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 comments concern the second part of the request pertaining to *CMS-10396: Medication Therapy Management Improvements – Standardized Format*.

2. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Medication Therapy Management Program Improvements

With advances in technology used for data collection, PHIT encourages the Office of Management and Budget (OMB) and the Centers for Medicare and Medicaid Services (CMS) to examine and consider the [Pharmacist eCare Plan](#)¹ for use in Medicare Part D's Medication Therapy Management (MTM) program, especially for comprehensive medication reviews (CMRs). Pharmacists perform CMRs and provide summaries to Medicare beneficiaries.

In our April 6, 2020 [comments](#)² submitted to CMS regarding CMS-4190-P, we suggested that CMS revisit its rationale for the CMR 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.

PHIT supported the policies in the CMS proposed rule that encouraged the use of Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR)-based APIs to make health information more widely accessible, including the CMR. FHIR can be leveraged for CMRs, making the summaries interoperable. 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 eCare Plan and the Office of the National Coordinator's (ONC) demonstration grant to make the eCare Plan interoperable using FHIR.

For pharmacy, PHIT recommends the eCare Plan using HL7 CDA R2 Implementation Guide: C-CDA Templates for Clinical Notes R1, which incorporates United States Core Data for Interoperability (USCDI) v1 and FHIR Release 4 for interoperable exchange of medication-related clinical data captured by pharmacists.

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 Medicare beneficiaries receiving services.

An updated CDA and FHIR R4 Pharmacist eCare Plan Implementation Guides version is

¹ <https://www.ecareplaninitiative.com/>

² https://www.pharmacyhit.org/pdfs/collaborative-outreach/FINAL_PHIT_CMS-4190-P_Comments_4-6-20.pdf

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.”³ 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.”⁴


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 for Prescription Drug Programs, and 11 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-centered 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.

On behalf of the Pharmacy HIT Collaborative, thank you again for the opportunity to comment on the *CMS-10396: Agency Information Collection Activities: Submission for OMB Review*.

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

Respectfully submitted,



Shelly Spiro, RPh, FASCP
Executive Director, Pharmacy HIT Collaborative

³ <http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=1232>

⁴ Ibid.

shelly@pharmacyhit.org