



Via Electronic Submission to: <http://www.regulations.gov>

June 24, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1716-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1716-P: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals

Dear Ms. Verma:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative (Collaborative), we appreciate the opportunity to submit comments on proposed *CMS-1716-P: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Rates, et al.*

Pharmacists provide essential pharmacy and health-related services to patients. Additionally, pharmacists are users of health IT, and in particular, e-prescription and 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 Collaborative has been involved with the federal agencies, including the Office of the National Coordinator (ONC) and the Centers for Medicaid and Medicare Services (CMS) in developing the national health information technology (HIT) framework and standards since 2010.

Our comments focus solely on Section VIII.D: Proposed Changes to Medicare and Medicaid Promoting Interoperability of the proposal.

Section VIII.D.3: Proposed Changes to Measures Under the Electronic Prescribing Objective

The Collaborative supports incorporating integration between Prescription Drug Monitoring Programs (PDMPs) and certified EHR technology (CEHRT) by eligible hospitals and CAHs to advance access and usability of PDMP data by health care providers. While the Collaborative supports this integration, and technological advances have been made, PDMP is still maturing in development and use and faces challenges with regard to interoperability, particularly accessing data across states.

PDMPs could be an integral component for opioid use disorder (OUD) prevention and improve pain management. The Collaborative believes CMS, along with ONC, has a critical role in helping to resolve the insufficient interoperability issues that exist. Primary among the issues creating challenges and barriers to interoperability within the 49-state PDMPs (Missouri does not have a state PDMP) are: no single integrated access to data among states; no real-time interoperable data among states; no real-time response for validating accurate data; and different standard sets being used. For PDMPs to become fully interoperable and integrated with current electronic exchanges of health information, these barriers and challenges need to be solved. One possible approach that has been discussed in the Trusted Exchange Framework and Common Agreement (TEFCA) is to move in the direction of integrating access to data by establishing a single “on ramp” to the states’ PDMPs. Although a single on ramp may not necessarily resolve all issues, and it would require buy-in from all states, it would be a first step and one that CMS could help to bring to fruition.

In addition, the Collaborative encourages CMS to consider barriers health care practitioners, including pharmacists, may have related to electronic prescribing and PDMPs regarding confidentiality of substance use disorder patient records. In recent rulemaking pertaining to 42 CFR Part 2, SAMHSA decided not to address electronic prescribing and state PDMPs.¹

Section VIII.D.6.b: Proposed Additional CQMs for Reporting Periods Beginning with CY 2021

The Collaborative supports adding the two, proposed, opioid-related CQMs to the Promoting Interoperability Measure set beginning with the reporting period in CY 2021: Safe Use of Opioids – Concurrent Prescribing CQM and Hospital Harm – Opioid-Related Adverse Events eCQM.

¹ Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, “Confidentiality of Substance Use Disorder Patient Records,” 82 Federal Register 6052, February 17, 2017.

Section VIII.D.6.e(1): Requiring EHR Technology to be Certified to all Available CQMs

The Collaborative supports continuing to require EHRs to be certified to all available CQMs adopted for the Medicare Promoting Interoperability Program for CY 2020 and subsequent years.

Section VIII.D.7.a: Request for Information on Potential Opioid Measures for Future Inclusion in the Promoting Interoperability Program

The Collaborative supports the use of SNOMED CT, LOINC, RxNorm, and ICD 10 or CPT for OUD prevention and treatment measures. These standards align with clinical workflows.

Section VIII.D.7.b: Request for Information on NQF and CDC Opioid Quality Measures

The Collaborative supports the use of the following NQF-endorsed quality measures, stewarded by the Pharmacy Quality Alliance (PQA), for inclusion in the Promoting Interoperability Program:

- *Use of Opioids at High Dosage in Persons Without Cancer (OHD) (NQF #2940)*
- *Use of Opioids from Multiple Providers in Persons Without Cancer (OMP) (NQF #2950)*
- *Concurrent Use of Opioids and Benzodiazepines (COB) (NQF# 3389)*

These measures align with the *CDC Opioid Prescribing Guideline* and published evidence that demonstrates an association between these prescribing patterns and an increased risk of opioid misuse and overdose. They also relate to activities likely to be successful in combatting the opioid epidemic and can be supported using CEHRT. In addition to the example provided related to the *OMP (NQF #2950)* measure, the *COB (NQF #3389)* measure could include using health IT to electronically prescribe the opioid medication, to query a PDMP, and to identify where naloxone co-prescription may be appropriate based on information received through health information exchange with other health care providers and recording key health information in a structured format.

Although PQA's composite measure, *Use of Opioids at High Dosage and from Multiple Providers in Persons Without Cancer (OHDMP) (#2951)*, is also NQF-endorsed, the individual measures (OHD #2940 and OMP #2950) may be most useful for the Medicaid Promoting Interoperability Program. In addition to recent adoption into the Medicare Shared Savings Program, PQA opioid measures are used in the Medicare Part D Quality Program, Medicaid 1115 Substance Use Disorder Waivers, and the OHD and COB measures are included in the Medicaid Adult Core Set, creating alignment of opioid measures across programs.

Clinical Quality Language and Fast Healthcare Interoperability Resources compliant versions of the opioid measures would be needed. An additional consideration is identifying appropriate exclusions for the measures, including hospice, cancer, and sickle cell disease to mitigate potential unintended consequences.

The Collaborative supports the use of the *Implementing the CDC Prescribing Guideline for Prescribing Opioids for Chronic Pain, among other sources as a way to help* opioid quality measure development. The Collaborative encourages monitoring and reviewing quality measurement implementation, particularly for unintended consequences. Of the 16 CDC measures, the following would be particularly beneficial in the management and coordination of short- and long-term opioid therapy, especially if linking them to EHRs:

- Measure 2: The percentage of patients with a new opioid prescription for chronic pain with documentation that a PDMP was checked prior to prescribing.
- Measure 11: The percentage of patients on long-term opioid therapy who had documentation that a PDMP was checked at least quarterly.
- Measure 16: The percentage of patients with an opioid use disorder who were referred to or prescribed medication-assisted treatment.

Although evidence shows PDMPs as an effective tool in reducing “negative health outcomes associated with the medically unnecessary use of controlled substances,” the actual use of PDMPs by physicians and in clinical care is low.² Including these particular CDC measures as part of CMS’ CQMs may help improve PDMP usage and support integration of pharmacists on care teams given their familiarity with PDMP. Integrating PDMP information into EHRs would also make it easier for clinicians to check a patient’s PDMP record.³ The Collaborative also encourages CMS to support sharing information, beyond that which is needed for quality measure purposes, with health care practitioners to support more informed clinical decisions.

Section VIII.D.7.d: Request for Information on including Medicare Promoting Interoperability Program Data on the *Hospital Compare Website*

(1) Immediate Access

The Collaborative supports ONC’s 21st Century Cures Act proposed rule to move to an HL7 FHIR-based API under 2015 Edition certification. Although the ONC proposed rule is not finalized, the Collaborative would be supportive of a possible bonus under the Promoting Interoperability for early adoption of FHIR-based API in the intermediate time before ONC’s final rule’s compliance date.

(3) Available Data

With regard to ONC proposing to adopt a new 2015 Edition certification criterion for electronic health information (EHI) export, the Collaborative believes incorporating an alternative measure under the Provider to Patient Exchange Objective that would require health care providers to use technology certified to the EHI criteria to provide patients their

² <https://www.healthit.gov/playbook/opioid-epidemic-and-health-it/>

³ Ibid.

complete electronic health data contained within an EHR would be effective in encouraging the availability of all data stored in health IT systems.

The Collaborative also believes that CMS should include a health IT activity that promotes and encourages bidirectional exchange of health information and bidirectional communications across the care continuum.

(g) Request for Information on Engaging Activities that Promote the Safety of the EHR

One critical area regarding safety risks arising from technology implementation that is not being fully addressed in this and other proposed rules is cyber attacks. Most proposals appear to focus on such elements as disrupting workflows, increase errors in records, etc., that may be perceived as posing safety risks and harm to patients.

Because of the increased sophistication that cyber attackers employ, the Collaborative believes better approaches to user identity verification and authentication would be especially useful, particularly for those using patient portals. Traditional approaches to authentication are no longer adequate;⁴ better approaches are needed. Protecting patient information is paramount. Cybercrime, which is a fast-growing challenge, needs to be kept at the forefront of discussions on certified health IT and the use of EHRs. Some of the largest cyber attacks and data breaches to date have been in the health care industry.⁵

The Collaborative recommends establishing more sophisticated, common identity proofing practices and requiring multi-factor authentication for all patient and provider access to any trusted exchange framework and health IT systems, particularly with regard to the various means of accessing health IT systems and electronic health information. Access to health IT systems via mobile phones, email, online services, and other electronic avenues is becoming more commonplace, thereby increasing the potential of putting patient data more at risk.

If CMS is considering offering points towards the Promoting Interoperability Programs score, ensuring systems are as secure as possible from cyber attacks should be one of the areas included in attestation for such points.

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

⁴ "Patient Portal Identity Proofing and Authentication," Guidance from the HIMSS Identity Management Task Force. https://www.himss.org/sites/himssorg/files/Patient_Portal_Identity_Proofing_and_Authentication_Final.pdf (accessed October 5, 2018).

⁵ <https://www.hipaajournal.com/largest-healthcare-data-breaches-2017/> (accessed October 5, 2018).

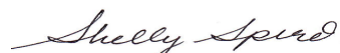
nine associate members encompassing e-prescribing, health information networks, transaction processing networks, pharmacy companies, system vendors, pharmaceutical manufacturers, and other organizations that support pharmacists' services.

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.

On behalf of the Pharmacy HIT Collaborative, thank you again for the opportunity to comment on *CMS-1716-P: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Rates, et al.*

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

Respectfully submitted,



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