Pharmacy Health Information Technology Collaborative

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

September 24, 2018

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1695-P
7500 Security Boulevard
Baltimore, MD 21224-1850

Re: [CMS-1695-P] Medicare Program; Proposed Changes to Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

Dear Sir/Madam:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative (Collaborative), we are pleased to submit comments for the *Medicare Program; Proposed Changes to the Hospital OPPS and RFI on Promoting Interoperability and Electronic Health Care Information, et al* proposed rule.

Pharmacists are users of health IT and are supportive of interoperability standards, especially those utilizing certified EHR technology (CEHRT). The Collaborative supports the use of particular standards which are important to pharmacists for working with other health care providers, transitions of care, allergy reactions, immunization (historical and administered), immunization registry reporting, medications, medication allergies, patient problems, 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), developing the national health information technology (HIT) framework since 2010.

The following are our comments for proposed measure removal, RFI questions regarding new or revised CoPs/CfC/RfPs for the electronic exchange of health information, and barriers to interoperability.

Proposed Removal of OP-12: The Ability of Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data (page 541)

The Collaborative does not fully support removing measure OP-12 beginning in CY 2021. CMS cites Factor 2, performance or improvement on a measure does not result in better patient outcomes, as its reason for removing this measure, stating that "OP-12 is a process measure that tracks the transmittal of data, but does not directly assess quality or patient outcomes." Rather than remove OP-12, the Collaborative suggests that the measure be restructured to assess the quality of care provided rather than only assessing HIT functionality. As CMS notes in its overview and rationale for removing OP-12, commenters expressed this concern about how the measure is structured in the CY 2011 OPPS/ASC final rule. Restructuring this measure would make it more meaningful and useful in helping to improve patient outcomes.

Pharmacists are a part of the health care management teams providing Medicare services to patients, which includes receiving laboratory data electronically into EHRs.

A. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicaid-Participating Providers and Suppliers (pages 627-38)

Requiring Use of 2015 Edition CEHRT

The Collaborative supports aligning the Medicare and Medicaid Promoting Interoperability Programs and requiring the use of the 2015 Edition certification criteria.

Trusted Exchange Framework and Common Agreement (TEFCA)

The Collaborative supports the six core principles of the Trusted Exchange Framework and Common Agreement (TEFCA) by which Qualified HINs, as well as HINs, and other data sharing arrangements are used for the exchange of electronic health information and to facilitate interoperability. Although the Collaborative is supportive of these principles, we have concerns that adherence is voluntary and all participant agreements for permitted purposes may not support all of the HIPAA permitted purposes. Adherence to the core principles should be required for participating in TEFCA. Voluntary adherence could decrease success of the goals set by TEFCA, especially, for achieving interoperability. The Collaborative also recommends that all TEFCA participant agreements for permitted purposes be compliant with HIPAA and support HIPPA permitted purposes. The privacy and security of patients is paramount.

If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?

Developing a new standard may help, provided such a new standard bans any form information blocking. There are also other aspects that CMS needs to look at that may not necessarily be resolved by a new CoP/CfC/RfP standard. The Collaborative supports exchanges operating openly and transparently. Critical to achieving open and transparent exchanges is ensuring that information blocking is discouraged and does not occur with vendors or health care providers, including removing barriers that may constitute or be perceived as information blocking. The existence of information blocking currently is a concern of the Collaborative and its members. As users of health information technology, pharmacists in all practice settings need unhindered access to the exchange and use of electronic health information.

We recommend that CMS identify and analyze gaps and make available the best solutions to curtail information blocking, including looking further at the Trusted Exchange Framework and Common Agreement (TEFCA). The Collaborative also believes it may be necessary to rethink the HIPAA Privacy Rule, which is often misunderstood and used as a justification to block information sharing.

Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?

The Collaborative believes every effort should be made to ensure a patient's or resident's, et al, right and ability to electronically access their health information without undue burden. Without knowing what existing portals or other electronic means are currently in use by many hospitals, the Collaborative cannot provide comment.

Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?

The Collaborative believes that new or revised CMS CoPs/Cfcs/RfPs would improve the routine electronic transfer of health information if CMS required the use of Certified EHR Technology (CEHRT) for interoperability and implemented safety protocols.

Under new or revised CoPs/CfCs/RfPs, should non-electronic forms of sharing medically necessary information (for example, printed copies of patient/resident discharge/transfer summaries shared directly with the patient/resident or with the receiving provider or supplier, either directly transferred with the patient/resident or by mail or fax to the receiving provider or supplier) be permitted to continue if the receiving provider, supplier, or patient/resident cannot receive the information electronically?

The Collaborative recommends that the non-electronic forms of sharing medically necessary information, as noted in the question, continue to be used, particularly if the recipient cannot receive the information electronically. At this stage, interoperability and electronic exchanges of information are not universally in place and being used. This is especially critical for patients, many of whom may not have computers or access to computers.

Are there any other operational or legal considerations (for example, HIPAA), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?

As discussed in our first comment, the Collaborative recommends that CMS analyze gaps and identify and make available the best solutions to curtail information blocking, including looking further at TEFCA. The Collaborative also believes it may be necessary to rethink the HIPAA Privacy Rule under this new paradigm. The HIPAA Privacy Rule is often misunderstood and used as a justification to block information sharing.

What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements, should be allowed under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP including CEHRT hardship or small practices be extended to new requirements? Would extending such exceptions impact the effectiveness of these requirements?

The Collaborative continues to support exceptions under the QPP, including CEHRT hardship for small practices.

Communication Between Hospitals and Their Patients and Caregivers

As noted previously, it may be necessary to rethink the HIPAA Privacy Rule. HIPAA is often used as a way to block information sharing. Additionally, the Collaborative also encourages CMS to begin looking at new technologies that are evolving and one day may replace technology that is currently being used. One technology that is now being touted as a possible solution to some interoperability issues in health care is blockchain. Although currently making its way into the financial industry (Bitcoin is one of its earliest and larger

users), recent reports state that blockchain has strong applicability for health care and health information.

e. Regulatory Barriers and Transparency Issues (page 662)

What specific barriers that limit sharing data with model vendors or manufacturers? What safeguards should be in place regarding sharing data with potential model participants?

The Collaborative supports exchanges operating openly and transparently. Critical to achieving open and transparent exchanges is ensuring that information blocking is discouraged and does not occur with vendors or health care providers, including removing barriers that may constitute or be perceived as information blocking. The existence of information blocking currently is a concern of the Collaborative and its members. As users of health information technology, pharmacists in all practice settings need unhindered access to the exchange and use of electronic health information. Establishing trust in any framework will be vital to its success. There will need to be true accountability in this regard.

The Collaborative wants to ensure that electronic health care data flows as it should and that pharmacists have appropriate access to health care information needed to provide necessary person-centered care and manage patients' health conditions, particularly when transitioning from the hospital to other points of care, including home care.

Pharmacists' clinical management of medications through person-centered care requires access to the complete patient records and information. Data should not be limited. The Collaborative's members support ensuring that patient data is protected as required by federal and state law but advocate that privacy and safeguards are balanced with reasonable measures to allow transmission, use, and access patient health care data.

We recommend, as we have to ONC, that CMS also identify and analyze gaps and make available the best solutions to curtail information blocking. As noted previously, the Collaborative also believes it may be necessary to rethink the HIPAA Privacy Rule. HIPAA is often used as a way to block information sharing.

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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 ten 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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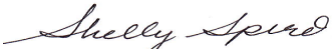
On behalf of the Pharmacy HIT Collaborative, thank you again for the opportunity to comment on the *Medicare Program; Proposed Changes to the Hospital OPPS and RFI on Promoting Interoperability and Electronic Health Care Information, et al* proposed rule.

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

Respectfully submitted,



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