

May 20, 2019

Don Rucker, MD
National Coordinator
Office of the National Coordinator for Health Information Technology
US Department of Health and Human Services
Attn: RIN-0955-AA01
Mary E. Switzer Building
330 C Street, SW
Washington, DC 20201

RE: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program [RIN-0955-AA01]

Dear National Coordinator Rucker:

On behalf of our more than 100,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) is pleased to submit the following comments on the Office of National Coordinator for Health Information Technology's (ONC) proposed rule, *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program*. The mission of APTA is to build a community to advance the physical therapy profession to improve the health of society. Physical therapists play a unique role in society in prevention, wellness, fitness, health promotion, and management of disease and disability by serving as a dynamic bridge between health and health services delivery for individuals across the age span. While physical therapists are experts in rehabilitation and habilitation, they also have the expertise and the opportunity to help individuals improve overall health and prevent the need for avoidable health care services. Physical therapists' roles may include education, direct intervention, research, advocacy, and collaborative consultation. These roles are essential to the profession's vision of transforming society by optimizing movement to improve the human experience.

APTA appreciates the opportunity to submit comments. Please find our detailed comments below.

Introduction

APTA agrees with and supports the ONC's proposed definition of interoperability with a focus on semantic interoperability that allows access, exchange, and use of electronically accessible data, as well as native data capture that supports the export of standardized data between entities. Integrated technology plays a vital role in a provider's ability to function in a value-based care system. To date, ONC, as well as the Centers for Medicare and Medicaid Services (CMS) have been very exclusive in their development of policies related to electronic health records (EHRs), interoperability, and more, focusing primarily on physicians and hospitals, to the exclusion of physical therapist private practices, postacute care organizations, and other provider types. It is disappointing that "smaller" providers, who do not have the same leverage and market share as health systems and large organized provider groups do, are left out of many policy discussions. We recommend that greater attention be focused on the "end-game," which is better performance by all health care providers and improved health outcomes.

Financial and Technical Barriers Preventing Nonphysicians from Adopting Certified EHR Technology

Physicians and hospitals were afforded EHR incentive funding and multiple stages to adopt EHRs and learn how to successfully exchange patient information using certified electronic health record technology (CEHRT), whereas physical therapists in private practice, other nonphysician health care professionals, and long-term and postacute care facilities were ineligible to participate in the Meaningful Use EHR Incentive Program (now the Promoting Interoperability category within the Merit-based Incentive Payment System, or MIPS) and have received little to no direction, as well as time and resources, to adopt and implement comprehensive, interoperable EHR systems that promote care coordination and improve patient outcomes.

Moreover, while large provider groups/health systems may be on a compatible EHR system, most independent practices use EHRs that are not standardized, making it that much more imperative that these providers, and their specific needs, are front and center in the discussions. In fact, many of these providers use and rely upon on an electronic medical record (EMR), as opposed to an EHR, which has significant differences in capability. As noted by ONC, EMRs are "a digital version of the paper charts in the clinician's office... But the information in EMRs doesn't travel easily out of the practice." Whereas, "EHRs focus on the total health of the patient... EHRs are designed to reach out beyond the health organization that originally collects and compiles the information."¹ Providers who continue to rely on an EMR face significant financial and administrative barriers that are preventing them (and their vendors) from transitioning from an EMR to even a basic EHR system. Thus, requiring providers who use an EMR, as well as those who have adopted a basic EHR, to upgrade to an EHR system that satisfies the certification criteria and promotes interoperability, without any form of assistance from the federal government, is not only unjust but nearly impossible.

To ensure the future health care system is one that is patient-centric and dedicated to improving care quality and increasing patients' access to their information, all relevant parties

¹ ONC Health IT blog, <https://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/emr-vs-ehr-difference>. Accessed May 1, 2019.

across the continuum, need, and deserve, financial and administrative support to help them implement CEHRT and adopt measures that give patients the ability to manage their health information. It is critical that patient information can flow between various sectors of the care continuum, including physicians, hospitals, physical therapists in private practice, postacute care and long-term care providers, and other health care providers.

Applicability of Certification Criteria for Nonphysician EHR Vendors

The ONC certification process has established standards and other criteria for structured data that EHRs must use. However, vendors that develop and offer EHRs for physical therapists and other nonphysician providers do not understand how to satisfy the 2015 Edition Health IT Certification criteria, given that several of the criteria are inapplicable to these health care professionals. For example, while APTA supports the adoption of the US Core Data Interoperability Standard (USCDI), as it would establish a set of data classes and constituent data elements that would be required to be exchanged in support of interoperability nationwide, there are several data elements included in USCDI that are not practical to include in typical physical therapist practice, including: laboratory tests, laboratory values/results, immunizations, and unique device identifiers for a patient’s implantable devices. Due to the lack of guidance for these vendors and nonphysician professionals, only a limited number of EHRs have been certified by ONC and encompass the necessary components for the documentation and transmission of information regarding physical therapy services.

As is a common theme throughout our comments, modifying and building upon the existing technological structure to satisfy future CEHRT requirements requires significant financial investment, is time-consuming, and is disruptive to workflow. As such, to better leverage health IT functionality in the short-term, as well as to incentivize physical therapist and other nonphysician provider participation in the Quality Payment Program (QPP) and other value-based models in the future, we recommend that ONC allow EHRs used by physical therapists and nonphysician providers to become certified by satisfying a subset of the certification criteria adopted by the US Department of Health and Human Services (HHS) Secretary in 45 CFR 170.315, unless and until ONC releases other guidance.

Alternatively, APTA encourages ONC to consider modifying the requirements of the 2015 Edition Health IT Certification Criteria for nonphysician EHR vendors. APTA has reviewed the CEHRT categories and identified criteria that may not apply to physical therapist practice:

CEHRT Category	CEHRT Criteria
Clinical Processes	<ul style="list-style-type: none"> • Computerized provider order entry (CPOE) medications (<i>prescribing</i>) • CPOE laboratory • Drug-drug, drug allergy interaction checks for CPOE • Drug-formulary and preferred drug list checks (<i>CPOE</i>) • Implantable device list

Care Coordination	<ul style="list-style-type: none"> • Electronic prescribing* (for medications)
Public Health	<ul style="list-style-type: none"> • Transmission to immunization registries • Transmission to public health agencies—syndromic surveillance • Transmission to public health agencies—reportable laboratory tests and values/results • Transmission to cancer registries • Transmission to public health agencies – electronic case reporting • Transmission to public health agencies – antimicrobial use and resistance reporting • Transmission to public health agencies – health care surveys
*Electronic prescribing may be utilized for referrals and DME	

While recognizing that some certification criteria are not applicable to physical therapists, it is critical that technology used by physical therapists affords them the ability to receive a medication list. EHR technology must allow physical therapists to receive data from multiple encounters that include the dosage, frequency, and administration of the medicines, as well as potential drug interactions. The physical therapist also must be able to document patient comments related to medication use. Additionally, it is important that physical therapists have technology that enables them to access laboratory and diagnostic imaging values and results, as well as record, change, and access diagnostic imaging orders.

Unintended Consequences of Excluding Rehabilitation Providers from Meaningful Use
 APTA supports rehabilitation providers being able to fully participate in QPP – both MIPS and Advanced Alternative Payment Models (APMs). However, CEHRT requirements are designed for prescribing professionals and do not capture tasks performed by nonphysician professionals using different types of EHRs (or EMRs). Consequently, barring any regulatory or policy changes to address the numerous technical and financial barriers associated with adopting and using CEHRT, physical therapists will be unable to meet the definition of CEHRT required for purposes of the Advanced APM minimum CEHRT use threshold. Further, without any guidance on how physical therapy EHR vendors may certify their rehabilitation-specific products, the ability of the physical therapy profession to succeed in future value-based care models is impeded.

The repercussions associated with excluding physical therapists from Meaningful Use, leaving them without guidance (or funding) to adopt CEHRT, are mounting. For example, now that physical therapists are included in MIPS, but lack CEHRT, physicians are less inclined to refer patients to physical therapists. Under MIPS, physicians are being scored on the Promoting Interoperability category transition measure, which requires that the referring provider use

CEHRT to create a summary-of-care record and electronically transmit it to a receiving health care provider. However, physical therapy EHRs are not equipped to receive such information, thus requiring the physician to fax the referral, which the physician prefers not to do, as such practice detracts from their scoring under the Promoting Interoperability category. Physicians and other MIPS-eligible providers expect other eligible providers to have CEHRT and be participating in all 4 categories; however, the newly eligible MIPS providers, including physical therapists, do not presently have the capability to participate in the Promoting Interoperability category.

CMS has acknowledged that most nonphysician providers do not have CEHRT; as such, CMS is reweighting the Promoting Interoperability category for physical therapists and other newly eligible MIPS providers in 2019. However, CMS states in the 2019 Medicare Physician Fee Schedule Final rule that its “intention is not to continue the proposed policy in perpetuity.”² CMS believes “that for increased interoperability and health information exchange it is important for all types of MIPS eligible clinicians to use CEHRT.” CMS further states it intends to adopt measures for the Promoting Interoperability performance category that are available and applicable to all types of MIPS eligible clinicians.³ Moreover, the Medicare Access and CHIP Reauthorization Act of 2015 mandates that APM Entities participating in Advanced APMs must require eligible clinicians to use CEHRT. In 2019, to participate in a Medicare Advanced APM, each APM entity must require at least 75% of eligible clinicians to use CEHRT to document and communicate clinical care with patients and other health care professionals. In 2020, this threshold will increase to 100%. As of January 1, 2020, CMS requires that to qualify as an Other-Payer Advanced APM, 75% of eligible clinicians participating in the other payer arrangement must use CEHRT. This threshold will increase to 100% in future years.

Over the last several years, APTA has reiterated the concerns outlined above in numerous comment letters and in meetings with ONC and CMS staff, with little to no response. Within the 2019 Physician Fee Schedule Final Rule, however, CMS responded to our concerns, stating, “the Advanced APM minimum CEHRT use threshold applies to APMs and the requirements they impose on participating APM Entities, not to the individual APM Entities participating in APMs...“the Advanced APM minimum CEHRT use threshold does not mean that all eligible clinicians in each participating APM Entity are required to use CEHRT, and that the methods used in the Advanced APM to ascertain whether the required percentage of CEHRT use is met may be unique to each APM. This means there can be a percentage of eligible clinicians participating in an APM Entity who are not using CEHRT and the APM Entity will still follow the APM’s terms and conditions. Understanding this may have a greater effect on non-physician or non-prescribing eligible clinicians, moving forward, we will monitor this issue for new APMs and will consider possible solutions to facilitate participation in Advanced APMs by non-physician or non-prescribing eligible clinicians that may not use CEHRT due to lack of certified systems for that specific specialty.”⁴

² CY 2019 Physician Fee Schedule Final Rule. <https://www.govinfo.gov/content/pkg/FR-2018-11-23/pdf/2018-24170.pdf>. Accessed March 8, 2019.

³ CY 2019 Physician Fee Schedule Final Rule. <https://www.govinfo.gov/content/pkg/FR-2018-11-23/pdf/2018-24170.pdf>. Accessed March 8, 2019.

⁴ CMS 2019 Medicare Physician Fee Schedule. <https://www.federalregister.gov/documents/2018/11/23/2018-24170/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions>. Accessed May 7, 2019.

We appreciate that CMS has begun to acknowledge these serious concerns, but action on the part of ONC and CMS is required. To move to a more standardized and interoperable environment, facilitate nonphysicians' participation in MIPS and Advanced APMs in the future, and promote increased interoperability and care coordination, it is critical that ONC work with CMS to: 1) develop guidance for nonphysicians and their EHR vendors on how to adopt and implement CEHRT; and 2) offer financial and administrative assistance to help providers adopt this new technology. Moreover, to ensure that the CEHRT adoption process is equitable and fair for all parties, we recommend that ONC set a date by which it expects all EHRs to comply with certification criteria. To that end, we request that ONC allow EHR vendors and health care providers a transition period of 3-5 years to develop, adopt, and integrate certified products. We also recommend that ONC work with CMS to educate providers on the certification process in a manner that clearly conveys what providers need to know, what they need to do now and in future years, and the anticipated costs associated with adopting and implementing certified technology.

International Classification of Functioning, Disability, and Health

APTA recommends that ONC recognize the need to adopt classification of health and health-related domains within CEHRT, specifically International Classification of Functioning, Disability, and Health (ICF). ICF was officially endorsed by all 191 WHO member states in the 54th World Health Assembly in 2001 as the international standard to describe and measure health and disability. The ICF is operationalized through the WHO Disability Assessment Schedule (WHODAS 2.0).⁵ It describes health and health-related domains using standard language; it is used by physical therapists, among other rehabilitation professionals, and promotes the delivery of coordinated, collaborative care. Different approaches and technical solutions exist for integrating the ICF in EHRs, such as combining the ICF with other existing standards for EHRs or selecting ICF codes with natural language processing.⁶ Adopting ICF terminology within EHR systems could advance data sharing and reuse by EHRs and advance the practice of physical therapy and research. Moreover, this would allow physical therapists to contribute their unique clinical perspective to other health care providers in a more meaningful fashion.⁷

Again, APTA strongly recommends that ONC include the use of ICF as the documentation terminology to represent patient problems in future editions of certified EHR technology. The Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT) and LOINC taxonomy are insufficient to describe patient problems as it relates to mobility, activities and participation, and associated environmental factors. In short, SNOMED CT does not accurately represent physical therapist practice. Additionally, LOINC terms currently are a broader grouping of ICF terms. Incorporating ICF into CEHRT will help to facilitate communication between health care providers as well as better enable physical therapists and

⁵ International Classification of functioning, Disability and Health. <http://www.who.int/classifications/icf/en/>. Accessed May 1, 2019.

⁶ Martiz R, Aronsky D, Proding B. The International Classification of Functioning, Disability and Health (ICF) in Electronic Health Records. A systematic literature review. *Appl Clin Inform.* <https://www.ncbi.nlm.nih.gov/pubmed/28933506>. Accessed April 1, 2019.

⁷ Vreeman, DJ, Richoz, C. Possibilities and implications of using the ICF and other vocabulary standards in electronic health records. *Physiother Res Int.* <https://www.ncbi.nlm.nih.gov/pubmed/23897840>. Accessed May 1, 2019.

other rehabilitation professionals to better describe an individual's health, function, and disability.

Implementation Timeline

APTA has serious concerns that the implementation timeline within the ONC rule may be untenable. ONC will need to ensure that health IT developers and other entities can comply with the standards, and that additional time (and resources) is afforded to health care providers to adopt and integrate this new technology into their practice. It is imperative that ONC offer financial assistance to providers, including physical therapists, who did not receive financial incentives to adopt and demonstrate meaningful use of CEHRT and whose salary is much lower than that of providers included in the Medicare EHR Incentive Program. For example, according to the Bureau of Labor Statistics Occupational Outlook Handbook, a physical therapist's median pay in 2017 was \$86,850 per year, compared with \$208,500 for physicians and surgeons and \$158,120 for dentists.⁸ Before mandating the use of CEHRT for physical therapists in private practice and other nonphysician providers, we recommend that ONC and CMS afford nonphysician providers, including physical therapists in private practice, ample opportunity to develop and adopt certified technology.

Greater Consideration for Providers Across Care Continuum

APTA strongly urges ONC to expand the scope and focus of its work and prioritize the implementation and dissemination of semantically interoperable, standards-based health IT systems that can be used by nonphysician providers, including physical therapists in private practice, and long-term and postacute care facilities, as well as by physicians, hospitals, and other health care providers. Seamless, effective, and secure information exchange practices enabled by such standards-based systems will improve health outcomes and enhance efficiency. To support a more standardized and interoperable environment, we recommend that: 1) ONC modify the 2015 Edition Health IT Certification Criteria for physical therapy and other nonphysician EHR vendors; 2) prior to finalizing the modified certification criteria, ONC collaborate with broad multi-stakeholder groups on the development and implementation of modified health IT certification criteria to better understand how to incentivize adoption of health IT that can generate and exchange standardized data and supporting documentation; and 3) ONC provide financial and administrative implementation assistance for physical therapists in private practice, postacute care providers, and other provider types during this transition.

Please find below our more detailed comments and recommendations on the proposed rule.

Proposed Deregulatory Actions

Removal of Certain ONC Health IT Certification Program Requirements

APTA supports ONC's proposed deregulatory actions.

Limitations Disclosures

APTA supports ONC's proposal to add as a complementary Condition of Certification that developers would be prohibited from taking any action that could interfere with a user's ability

⁸ BLS Occupational Outlook Handbook. <https://www.bls.gov/ooh/>. Accessed March 28, 2019.

to access or use certified capabilities for any purpose within the scope of the technology's certification.

Updates to 2015 Certification Criteria

Standards and Implementation Specifications

APTA supports ONC's proposal to remove the Common Clinical Data Set (CCDS) definition and effectively replace it with USCDI, Version 1(v1).

Revised and New 2015 Certification Criteria

USCDI

APTA supports ONC's proposal to remove the CCDS and replace it with USCDI. APTA also supports the replacement of applicable data elements within the USCDI with natively interoperable data elements developed and vetted through a standards development organization (SDO) such as HL7. This consensus-based approach encompasses real-world use cases while the balloting process invites critique and input from a varied pool of stakeholders.

As ONC is aware, in 2017 APTA launched the [Physical Therapy Outcomes Registry](#), which captures relevant data from EHRs and billing information, and can transform this data into meaningful, intuitive, and actionable feedback for providers on the frontline of patient care. The combination of clinical and quality measurement expertise is essential to ensure that professional registries can be facile and evolve over time with practice. That same expertise is also required to create and maintain clinical practice guidelines and corresponding quality measures for the patient populations served by clinician specialties.

APTA's registry team worked on the "Improving Healthcare Data Interoperability" project sponsored by The Pew Charitable Trusts.⁹ The objective of the project was to position registries as "interoperability ready" at the database/physical level. Clinical concepts were abstracted from the data collection forms and data model representations provided by 38 registries, and the common clinical concepts found across multiple registries were identified for further analysis. Concordance of these common concepts was evaluated across registries, with the USCDI.

In conjunction with the HL7 Clinical Interoperability Council's Common Clinical Registry Framework (CCRF), a project within the HL7 Clinical Interoperability Council dedicated to advancing efforts to achieve standardization and interoperability between clinical registry operators, we recommend that ONC consider the collective focus, impact, and shared objectives that clinical registries have concerning the CCDS with USCDI and the Proposed Expansion Process. Through a collaborative public consensus process using data collected from registry case report forms, data dictionaries, and the existing USCDI, we have identified and defined key data elements that are universal across clinical registries to create common data elements. Ultimately, these data elements will be balloted through HL7, mapped to existing terminology standards (such as SNOMED Clinical Terms), and incorporated into the HL7 Fast Healthcare Interoperability Resources (FHIR) standard.

⁹ The final report, recommendations and work products are available at <http://dcric.org/registry-data-standards/>. Accessed April 15, 2019.

We are encouraged by ONC’s dedication to standardization and alignment as demonstrated in the Draft USCDI Version 1 dataset rule. While it is understood that ONC has moved forward with the use of the 2015 Edition CCDS as set out in the 2015 Edition Health IT Certification Criteria final rule, we have identified several inconsistencies within the CCDS and offer our recommendation to assist in harmonization of data classes to create a more comprehensively useable data set:

Recommendation Related to *Smoking*

APTA supports the use of Smoking Status/Tobacco Use as a proof of concept for the consensus-driven process. Requiring health IT developers to abide by this core data set will promote efforts to expand interoperability. Through the [“Improving Healthcare Data Interoperability”](#) work, completed by the Duke Clinical Research Institute and PCPI, data elements from 38 registries were requested to create a harmonized, natively interoperable data set that includes existing ontology and FHIR reference bindings. Specifically, in this work, the “Tobacco Use” data element use case was highlighted. This was originally derived from the “Smoking Status” data element within the USCDI. This data element has been rigorously reviewed by subject matter experts within clinical, public health, and informatics realms and harmonized with existing quality measurement value sets.

To that end, we wish to bring to your attention the data class “Representing Patient Tobacco Use” (Smoking Status). After collection of data from 11 different registries regarding tobacco-related questions, it was determined that the term “Smoking Status” does not accurately capture the clinical information needed to classify Tobacco Use. The current value set for “Smoking Status” is not well structured, nor is it clinically relevant. Existing science has been organized around tobacco use. Smoking and the correlation between number of cigarettes smoked over duration (defined as pack-years) is well documented in medical literature and therefore should support any definition. Other tobacco use, such as smokeless tobacco and pipe smoking, has been correlated with an increased incidence of oral cancer, limiting its usefulness in determining outcomes related to tobacco use and abuse. Current electronic clinical quality measures (eCQMs) stewarded by PCPI articulate this concept as “Tobacco User” and the converse “Tobacco Nonuser” with an intentionally robust value set intended to quantify the spectrum of tobacco use and abuse. The concepts set forth are harmonious with existing eCQMs and adequately capture clinically relevant data regarding tobacco use. Therefore, we recommend that ONC deprecate the data class “Smoking Status” in favor of the clinically accurate concept of “Tobacco Use” as discussed in the description below.

Use Case: Tobacco Use

The use case for Tobacco Use demonstrates how information would clinically be asked of a patient, captured in a documentation system, and sent to registries. It is assumed that this process does not involve manual chart abstraction. This example is intentionally both granular and parsimonious, including only detailed questions regarding cigarette use/abuse, rather than comprehensive questions about secondhand smoke or other tobacco nicotine use/abuse. Data collected in this manner can be combined to derive other commonly asked questions regarding tobacco use. To reduce data collection burden, additional detail should be justified by need; specifically, there should be a scientific or clinical rationale behind data collected.

USCDI 2015 Edition Certification Criteria

As discussed in further detail below, due to APTA's efforts to develop and grow its Physical Therapy Outcomes Registry, we now recognize that the clear majority of rehabilitation-specific EHRs are not certified. Further, although many vendors have 2015 Edition compliant products on the market, they do not certify rehabilitation-focused products. We strongly urge ONC to consider this and address the health IT needs of nonphysician providers, including physical therapists, as the agency drafts the final rule.

APTA also recommends that ONC clarify in final rulemaking the timeline by which a health IT developer must comply with the new Condition and Maintenance of Certification requirements after there is a change in ownership, merger or acquisition, or consolidation.

USCDI Standard - Data Classes Included

Pediatric Vital Signs

In 2005, the US Preventive Services Task Force (USPSTF) found adequate evidence that body mass index (BMI) is an acceptable measure for identifying children and adolescents with excess weight. Later, in 2013, USPSTF issued a final recommendation that clinicians screen for obesity in children and adolescents 6 years and older and offer or refer them to comprehensive, intensive behavioral interventions to promote improvements in weight status.¹⁰ Given that 39.8% of US adults and 18.5% of children and adolescents are obese, there is a significant need to screen children and adolescents who are at risk for obesity.¹¹ Therefore, in addition to pediatric vital signs, APTA recommends that ONC add BMI and related health risks in children to the USCDI.

Clinical Notes

Although APTA supports ONC's proposal to include a new data class titled Clinical Notes, we encourage the agency to ensure that these clinical notes are standardized across all health care professionals. For example, the care plan should be consistent across professionals, recognizing that the tests and measurements being performed and data collected will vary by provider type and specialty; clinical notes also should follow LOINC standards. Further, we recommend ONC add data elements that support functional ability.

Provenance

APTA supports the delineation of the Provenance data class into three data elements. The data provenance elements could be helpful to registries in validating the origination of data they receive.

¹⁰ USPSTF Recommendation Statement.

<https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/obesity-in-children-and-adolescents-screening>. Accessed April 19, 2019.

¹¹ Centers for Disease Control and Prevention. <https://www.cdc.gov/obesity/data/adult.html> and <https://www.cdc.gov/obesity/data/childhood.html>. Accessed April 19, 2019.

USCDI Standard – Relationship to Content Exchange Standards and Implementation Specifications

Clinical Notes C-CDA Implementation Specification

APTA supports ONC's proposal to adopt the HL7 C-CDA Templates for Clinical Notes R1 Companion Guide. We appreciate that ONC intends to begin with a baseline, and there is a level of standardization that is even at the line item level, and then just free text.

Electronic Prescribing Standard and Certification Criterion

While APTA supports ONC's efforts to revise the 2015 Edition Certification Criteria and harmonize with relevant CMS program timelines, we strongly urge ONC to acknowledge that rehabilitation-specific EHRs do not include any of the electronic prescribing criterion. Moreover, while we appreciate ONC's proposals regarding voluntary certification, we expect that most providers will not comply with certification until required to do so. Because nonphysician providers have not been required to adopt CEHRT, there has been little drive for adoption on the part of the EHR vendors and/or the providers. Unless and until ONC puts forth certification guidance for vendors who develop rehabilitation-specific EHRs and makes adoption mandatory, providers will not require vendors to incorporate such criteria, and vendors will do nothing.

Further, although many EHR vendors have 2015 Edition compliant products on the market, vendors do not include the same certification modules within their rehabilitation-specific products for numerous reasons:

- It is unclear how rehabilitation-specific products can comply with the certification criteria, due to the number of criteria that are inapplicable to rehabilitation providers;
- Even if guidance existed, there is a significant cost associated with developing specialty products that satisfy the certification criteria;
- ONC and CMS are not pressuring these vendors to develop certified products for rehabilitation providers; and
- Rehabilitation providers were not included within Meaningful Use and are not currently required to participate in the Promoting Interoperability category within MIPS; as such, these providers are not mandating their EHR vendors to develop such products.

APTA requests ONC discuss in final rulemaking how it intends to address the lack of certified products for rehabilitation providers and compel EHR vendors (that have 2015 Edition compliant products on the market) to include the certification modules within their rehabilitation-specific products in the future.

Clinical Quality Measures – Report Criterion

APTA supports ONC's proposal to remove HL7 QRDA standard requirements from the 2015 Edition CQMs – report criterion in §170.315(c)(3) but require that health IT certified to the criterion support the CMS QRDA IGs. We agree this would reduce burden on health IT developers and indirectly on health care providers as they would no longer have to, in practice, develop (health IT developers) and support (both developers and providers) two forms of the QRDA standard (i.e., the HL7 and CMS forms).

Electronic Health Information (EHI) Export

APTA supports ONC's proposal to adopt a new 2015 Edition certification criterion for EHI export. The ability to export data on both individuals and groups of patients will aid data transfer to registries. To ensure EHI can be accessed, exchanged, and used across health IT systems, we recommend ONC adopt an export criterion that is standardized across systems. To guarantee all data exported can be imported and readable by other systems, the export criterion also must support semantic interoperability. Additionally, we caution against ONC affording health IT developers significant flexibility in determining export standards, as this may undermine the purpose of the export criterion.

Patient Access – Export Functionality

APTA supports ONC's proposal but encourages the agency to clarify in final rulemaking what constitutes "timely" and "no longer than reasonably necessary." Without defined terminology, health IT developers may take advantage of the flexibilities afforded by the agency regarding the export criterion. We also seek clarification from ONC regarding the penalties it will impose if there is a delay in exporting data in response to a user's (health care provider or patient) request and how it will monitor a health IT developer's compliance with exporting data in a timely manner. To that end, we recommend ONC issue subregulatory guidance in easily understandable language that describes how a patient or provider may issue a complaint if a health IT developer refuses to comply with the request.

Further, we request that ONC discuss in final rulemaking how health IT developers may be permitted to limit the type of users able to access and initiate EHI export functions and provide examples of permissible versus non-permissible behavior.

Scope of EHI

APTA supports ONC's efforts to render patient data more accessible. Given the health care system's current evolution to one that is more patient-centered and focused on team-based care and coordination of services, there is a greater need for the exchange of and access to patient information. EHRs must be able to share images, text, clinical, administrative, claims, and billing data. Affording patients and providers a greater capability to transport data will facilitate a more seamless experience for patients and maximize care delivery. Unfortunately, agreements with EHR vendors often are written in a manner that hinder patient and provider access to their EHI, which in turn negatively impacts a provider's ability to deliver high-quality care. We are hopeful the agency's information blocking regulations will prevent this from occurring in the future.

Moreover, because EHI has not yet been defined and standardized, much of this data has not been incorporated within the USCDI. Therefore, APTA recommends ONC consider and put forth the additional data elements that must be incorporated into the USCDI to better facilitate exchange of EHI. Moreover, given that EHI data cannot be easily exchanged via FHIR, we recommend that ONC require EHR vendors to support an API-based export capability for *all* data elements (information beyond the USDCI). As standards are more widely adopted for different data elements that are made available via the EHI provision, ONC should expand the USCDI to encompass more of this information. Finally, APTA recommends that ONC work with APTA and other professional societies to help determine what data are critical to share for clinical use.

Export Format

APTA supports ONC's proposal to require developers to provide instructions to patients and/or providers on how to access, download, and move their information. We also support ONC's proposal to require that the developer's export format be made publicly available via a hyperlink as part of certification to the EHI export criterion. We recommend, however, that ONC provide guidelines on the export format, to ensure that each developer's export format is not widely variable, thereby further promoting seamless exchange.

Timeframes

APTA recommends that the EHI export criterion require health IT systems to be developed in such a way that allows a health care provider to set timeframes for EHI export.

Replaces the 2015 Edition "Data Export" Criterion in the 2015 Edition Base EHR Definition

APTA supports ONC's proposal to include the proposed EHI export criterion in the 2015 Edition Base EHR Definition.

Privacy and Security Transparency Attestations

APTA supports ONC's modifications to the 2015 Edition privacy and security certification framework, including its proposals related to encryption and multi-factor authentication.

Modifications to ONC Health IT Certification Program

Record Retention

Given the variability of record retention requirements, to minimize confusion, APTA recommends that ONC adopt record retention timeframes that align with other record retention timelines whenever is feasible. For example, CMS's record retention requirement for providers that submit cost reports is 5 years; Medicare managed care program providers must retain their records for 10 years; and the HHS Office of Civil Rights' (OCR) HIPAA-related documents policy requires providers to maintain their policies and procedures implemented to comply with HIPAA for a minimum of six years from when the document was created or the date when it was last in effect, whichever is later.

Health IT for Care Continuum

Health IT for Pediatric Setting

Recommendations for the Voluntary Certification of Health IT for use in Pediatric Care

Children's health care needs differ from those of adults, which includes specialized equipment and different sets of expertise. While APTA appreciates that ONC identified clinical priorities for pediatrics and put forth recommendations for pediatric health IT voluntary certification criteria, we strongly recommend that ONC also include developmental activity milestones within the certification criteria. Physical therapists help children develop their gross motor skills. These skills are required to control the large muscles of the body for walking, running, sitting, crawling, and other activities. At certain ages, children should reach specific gross motor skill milestones. If this is recognized in one setting but not communicated to another, collaborative treatment may be missed or delayed, resulting in negative outcomes. Limited standards and communication among providers must be addressed.

We also recommend that activity and participation be included in the certification criteria.¹² Additionally, ONC should incorporate the International Classification of Functioning, Disability and Health for Children and Youth (ICF-CY), derived from the International Classification of Functioning, Disability and Health (ICF) (WHO, 2001), which is designed to record the characteristics of the developing child and the influence of its surrounding environment.¹³ The ICF-CY provides a framework and standard language for the description of health and health-related states in children and youth. The ICF-CY can be used by providers, consumers, and all those concerned with the health, education, and well-being of children and youth. It provides a common and universal language for clinical, public health, and research applications to facilitate the documentation and measurement of health and disability in children and youth.

Further, APTA recommends that ONC state in final rulemaking that an EHR developer seeking certification for pediatric functionalities should test the system using pediatric-focused clinicians, including pediatric physical therapists, who work in neonatal intensive care units, schools, outpatient treatment centers, hospitals, rehabilitation facilities, and in children's homes. ONC also should require EHR developers to use pediatric-focused scenarios and mock pediatric patients when testing the functionality of their systems.

Health IT and Opioid Use Disorder Prevention and Treatment – Request for Information

APTA recommends ONC examine how clinical decision support can be used within EHRs to address opioid use disorder prevention and treatment.

USCDI

While we appreciate ONC's real world testing proposals, as ONC pursues establishment of a minimum set of data classes, we encourage the agency to collaborate with professional societies that represent different areas of clinical focus. This will help to better ensure health data classes and data elements represent the full care spectrum.

Conditions and Maintenance of Certification

Provisions

Information Blocking

Generally, APTA supports ONC's proposed Condition and Maintenance of Certification related to information blocking and we agree that this provision allows for data liquidity for registries. However, APTA seeks clarification from ONC regarding the HHS Office of Inspector General's authority to investigate claims of information blocking if conducted by health information exchanges, health information networks, or health care providers. We also seek clarification from ONC regarding the penalties the agency might impose if an EHR developer prevents a clinical data registry from providing interfaces to clinicians who use the EHR technology and wish to submit EHI to the registry.

¹² CDC Milestones. <https://www.cdc.gov/ncbddd/actearly/milestones/index.html>. Accessed March 8, 2019.

¹³ ICF-CY.

https://apps.who.int/iris/bitstream/handle/10665/43737/9789241547321_eng.pdf;jsessionid=0DC43422465E77B3DEF1BDF30A814B04?sequence=1. Accessed March 8, 2019.

Assurances

APTA supports ONC's proposal to require that a health IT developer provide assurances to the HHS Secretary that it will not take any action that constitutes information blocking.

Certification to the "Electronic Health Information Export" Criterion

APTA supports ONC's proposal that a health IT developer that produces and electronically manages EHI must certify health IT to the 2015 Edition "electronic health information export" certification criterion. It is critical that a health IT developer provides assurances that it is not taking actions that constitute information blocking or any other action that may inhibit the appropriate exchange, access, and use of EHI.

Records and Information Retention

As previously stated, APTA recommends that whenever feasible, ONC should adopt record retention timeframes that align with other record retention timelines. We also recommend that ONC clarify and/or provide examples of the types of records and information that would be necessary to demonstrate compliance with the requirements of the Health IT Certification program.

Trusted Exchange Framework and the Common Agreement (TEFCA) – Request for Information

APTA believes that participation in TEFCA should be encouraged, as this can potentially increase data liquidity by reducing the risk associated with data exchange.

Communications

APTA supports ONC's class of communications that would receive unqualified protection from developer prohibitions or restrictions.

Application Programming Interfaces (APIs)

APTA supports FHIR-based APIs and the decentralization of promoting interoperability via these APIs. However, the development and focus on FHIR APIs does not mean that existing standards (v2, CDA) will no longer be of use; existing standards are meant to be used in conjunction with FHIR. Moreover, while we support FHIR as an interface standard and recognize the need to include APIs as a required part of EHR certification, to improve interoperability, we again urge ONC to recognize that many EHRs do not support the use of APIs for data exchange. For instance, physical therapists in private practice and other nonphysician providers may be relying on EHRs without API functionality. We recognize that APIs reflect the future of data exchange in health care; APIs enable patients to access their health records; hospitals to better exchange data with other organizations; and health care facilities to build and implement new decision support tools in addition to their EHRs. However, instituting API standards and requirements without first addressing the needs of health care providers using EHRs that do not support the use of APIs will only further isolate these health care providers, hindering their capabilities to communicate and share information with other health care professionals, suppliers, providers, and patients.

Therefore, before expanding certification requirements to encompass required APIs, it is critical that ONC provide financial and administrative assistance, as well as ample time, for providers

who are relying on technology without API functionality to adopt and implement certified technology that can overcome barriers to API use.

Options for Adoption of FHIR

APTA supports the use of HL7 FHIR standards and implementation specifications. This is a standard format that allows for the decentralization of regulating standard data. While we defer to other HL7 workgroups with more expertise on FHIR versioning, we recommend that ONC adopt releases 2 and 3 and eventually release 4 by the time the rule is finalized. The common data elements put forth by the [Improving Healthcare Data Interoperability](#) project are based on FHIR Version 3.0.1, US Core Implementation Guide 2.0.0, and we wish to retain compatibility with that standard. Many organizations are still working on implementing FHIR Version 4, but to date, there are no implementation guides of which we are aware. By the time this rule is finalized, release 4 will likely be implemented and we will need to evaluate our data elements accordingly. Therefore, APTA would support releases that support the set of common data elements put forth by the data interoperability project.

App Registration

APTA supports ONC's proposal that health IT presented for testing and certification must be capable of enabling apps to register with an "authorization server."

Condition of Certification Requirements

Record-Keeping Requirements

As previously stated, APTA recommends that, whenever feasible, ONC adopt record retention timeframes that align with other record retention timelines.

Non-Discrimination

While APTA supports ONC's proposal to prohibit nondiscrimination regarding the provision of API technology, we recommend that ONC discuss in final rulemaking how it intends to enforce a nondiscrimination policy.

Real World Testing

While APTA appreciates and supports ONC's real world testing proposal, we strongly encourage ONC to consider how it may incentivize health IT developers to test certified health IT in rehabilitation settings, including physical therapist private practices and postacute care facilities.

Attestations

APTA supports ONC's proposal related to attestations. We also agree with ONC's intention to subject health IT developers to direct review, corrective action, and enforcement procedures under the program if developers fail to comply with the attestation to all Conditions and Maintenance of Certification requirements.

Certification Ban and Termination

APTA supports ONC's proposal that if a health IT developer under ONC direct review for noncompliance with a Condition of Certification failed to work with ONC or was otherwise noncompliant with the requirements of the CAP and/or CAP process, ONC could issue a certification ban for the health IT developer (and its subsidiaries and successors). We appreciate

however, that ONC will consider on a case-by-case basis the appropriateness of termination of a health IT module's certification(s) based on the specific circumstances of the noncompliance with the Condition of Certification.

Appeal

APTA supports ONC's proposal to enable a health IT developer to appeal an ONC determination to issue a certification ban and/or termination resulting from non-conformity with a Condition of Certification and would follow the processes specified in §170.580(g).

Suspension

APTA supports ONC's proposal to include a process for suspending the certification of a health IT module at any time if ONC has a reasonable belief that the certified health IT module may present a serious risk to public health and safety.

Proposed Termination

APTA supports ONC's proposal to proceed immediately to a certification ban and/or termination of the affected certified health IT modules' certificates if a developer does not take appropriate and timely corrective action. A certification ban and/or termination are appropriate disincentives for noncompliance with the Conditions and Maintenance of Certification.

Public Listing of Certification Ban and Terminations

APTA supports ONC's proposal to publicly list health IT developers and certified health IT modules that are subject to a certification ban and/or have been terminated, respectively, for noncompliance with a Condition of Certification or for reasons already specified in §170.581.

Information Blocking

Relevant Statutory Terms and Provisions

Health Care Providers

To better ensure alignment across regulatory programs, APTA recommends that ONC adopt the broad definition of health care provider to encapsulate all individuals and entities covered by the HIPAA health care provider definition. As the health care system evolves to a value-based system, a greater number of health care professionals are being recognized as "health care providers," and this number will only continue to grow. While we acknowledge the current health care system may not recognize some health care professionals as "providers," it is critical that the health care system of the future acknowledge *all* health care professionals who may engage or be the subject of information blocking.

Health IT Developers of Certified Health IT

APTA recommends that ONC expand the definition of "health IT developer" to include health IT developers with products that are certified under the program in addition to health IT developers that, at the time they engaged in a practice that is the subject of an information blocking claim, **do not** have technology certified under the program. All health IT developers should be compelled not to engage in information blocking. As previously stated, many of the EHR products used by physical therapists and other nonphysician providers are not certified under the program (although we expect that they will be in the future). Until that time, however, we do not

recommend “allowing” the software developers of these products to engage in information blocking. These developers are contracted with a significant portion of this nation’s health care providers; excluding this swath of developers for the purposes of interpretation and enforcement of the information blocking provisions seems contrary to the intent of ONC’s rule and would effectively disrupt ONC’s efforts to expand the access to, exchange of, and use of EHI. To better ensure that ONC does not create an information blocking “loophole” while also inadvertently incentivizing health IT developers *not* to produce certified products, APTA strongly recommends that ONC expand the definition of health IT developers to include developers who may not have certified products.

EHI Definition

APTA supports ONC’s proposed definition of EHI. We believe the proposed definition would support both foundational and structural interoperability.

Price Information

APTA supports ONC’s assertion that price information is becoming more important with the increase in high deductible health plans and surprise billing, which have increased out-of-pocket health care spending, and that transparency in the price and cost of health care would help address these concerns by allowing patients to make informed health care decisions. Before undertaking any price transparency initiatives, we recommend that ONC first evaluate the impacts of similar policies currently being implemented in the states. There has been a recent wave of state legislation and rulemaking regarding health care price transparency, and the benefits of many of these policies have yet to be assessed. At least 28 states have passed legislation related to health care price transparency or disclosure.¹⁴ Laws include those that require health care providers to give patients an estimate of the costs of treatment, that require hospitals to provide charge data to state regulators, and that create websites intended to educate consumers about average prices in their area. We recommend that ONC weigh the relative successes of these models against the burden they create upon providers.

Questions

Should prices that are included in electronic protected health information (electronic protected health information and health information that is created or received by a health care provider and those operating on their behalf; health plan; health care clearinghouse; public health authority; employer; life insurer; school; or university):

1. *Reflect the amount to be charged to and paid for by the patient’s health plan (if the patient is insured) and the amount to be charged to and collected from the patient (as permitted by the provider’s agreement with the patient’s health plan), including for drugs or medical devices?*

True price transparency does not exist unless the actual cost of services as well as the out-of-pocket costs for the patient are clear. The amount patients will be responsible for must be easily understandable for such information to be valuable. Otherwise, clinicians will

¹⁴ National Conference of State Legislatures. Transparency and Disclosure of Health Costs and Provider Payments: State Actions. <http://www.ncsl.org/research/health/transparency-and-disclosure-health-costs.aspx>. Accessed May 13, 2019.

be required to take time away from direct patient care to instead discuss pricing with patients.

2. *Include a reference price as a comparison tool such as the Medicare rate and, if so, what is the most meaningful reference?*

Adding a reference price could be helpful for less-savvy consumers; however, it also could lead to confusion for consumers with less understanding of health care pricing. If a reference price is used, it should be the Medicare price, as insurance companies and providers frequently negotiate rates based on Medicare prices (example: reimbursement at 150% of Medicare rates, rather than setting prices for each individual service).

For the purpose of informing referrals for additional care and prescriptions:

1. *To the extent that patients have a right to price information within a reasonable time in advance of care, how would such reasonableness be defined for:*
 - a. *Scheduled care, including how far in advance should such pricing be available for patients still shopping for care, in addition to those who have already scheduled care?*

While this may depend on the complexity of the service—for instance, prices for routine services should be available well in advance of scheduling—we recommend that, generally, pricing should be available for patients at least 90 days in advance of the scheduled care.

- b. *Emergency care, including how and when transparent prices should be disclosed to patients and what sort of exceptions might be appropriate, such as for patients in need of immediate stabilization?*

When emergency care is required, it often is necessary to preserve life; accordingly, price is less of a concern at the time of the emergency. While the prices of items or services may be made available in real time, disclosing pricing information for emergency care may inadvertently prevent patients from seeking the service. Therefore, we recommend adopting an exception to price transparency when life-sustaining care/stabilization is immediately necessary. For example, providers should be allowed to provide care without offering a price quote if the health of the patient is at risk. With that said, prices for emergency care could be made available within 24 hours of patient stabilization. Although the charge has already been incurred, such information will help patients and their families/caregivers inform their future care decisions.

- c. *Ambulance services, including air ambulance services?*

Ambulance services should be exempt from price transparency when life sustaining care/stabilization is immediately necessary.

- d. *Unscheduled inpatient care, such as admissions subsequent to an emergency visit?*

Unscheduled inpatient care should be exempt from price transparency requirements when life sustaining care/stabilization is immediately necessary.

2. *How would price information vary based on the type of health insurance and/or payment structure being utilized, and what, if any, challenges would such variation create to identifying the price information that should be made available for access, exchange, or use?*

Each payer, employer, and benefit package may differ; as such, the information that is provided should reflect the nuances of each patient's evidence of coverage.

3. *Should price information be made available on public web sites so that patients can shop for care without having to contact individual providers, and if so, who should be responsible for posting such information? Additionally, how would the public posting of pricing information through API technology help advance market competition and the ability of patients to shop for care?*

Pricing information is necessary for consumers to make informed care decisions. However, there is significant variability in pricing, as the price of a procedure/visit/treatment will vary based upon setting, geography, type of provider, etc. Accordingly, requiring every provider to make their pricing available for every procedure/visit/treatment would be difficult to maintain, and likely would have little utility for patients and caregivers.

Moreover, requiring providers to offer pricing information without also offering information regarding the quality of care renders the pricing information relatively meaningless, as the lowest cost provider may also have the worst outcomes. If providers will be required to post price information then providers also should be required to collect and share standardized outcomes and data on patient experience and satisfaction; otherwise, providers are merely competing on price, rather than price *and quality*. As discussed in a recent Health Affairs article, “various initiatives have encouraged Americans to consider quality when choosing clinicians, both to enhance informed choice and to reduce disparities in access to high-quality providers. The literature portrays these efforts as largely ineffective.” The article recommends that “public policy respond to emerging trends in information exposure, establish standards for rigorous elicitation of narratives, and assist consumers’ learning from a combination of narratives and quantified metrics on clinician quality.”¹⁵

¹⁵ Health Affairs.

https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2018.05006?utm_source=Newsletter&utm_medium=email&utm_content=Bill+Frist+and+Margaret+Hamburg+On+Health+Care+Spending+Growth%3B+Vaccine+Exemptions%3B+Americans++Growing+Exposure+To+Clinician+Quality+Information&utm_campaign=HAT+3-21-19

Accessed March 21, 2019.

If HHS determines that price information should be made available on public websites, we recommend that providers only be required to offer average or benchmark pricing for patients to use for comparison. Moreover, we recommend the development of resources that help patients understand how to comparison shop and how to recognize provider specialization and credentialing. For instance, specialty practices are likely to have higher pricing profiles; however, consumers are unlikely to understand why the differences in price exist.

Finally, it is important to recognize that many providers treat patients during an *episode* of care; as such, if price information is to be incorporated into EHI, it will be important to clarify whether the prices displayed are indicative of “price per code,” “average per visit,” or “average per episode.” Additionally, it is unclear whether HHS intends that the prices displayed would include average out-of-pocket costs incurred for patients, along with the duration. To that end, we suggest that HHS consider requiring only that providers publish the basic fees associated with the most commonly billed codes.

4. *If price information that includes a provider’s negotiated rates for all plans and the rates for the uninsured were to be required to be posted on a public web site, is there technology currently available or that could be easily developed to translate that data into a useful format for individuals?*
 - a. *Are there existing standards and code sets that would facilitate such transmission and translation?*

Although there are codes with relative value, there is significant variability in the valuation of codes by individual payers and plans and in the list of approved codes available to providers. Also, the application of reduction methodology to a system that was intended to be standardized has become anything but standardized.

- b. *To the extent that some data standards are lacking in this regard, could developers make use of unstandardized data?*

Taking the existing standards and sets and adopting a standardized methodology would be a more mindful solution.

5. *What technical standards currently exist or may be needed to represent price information electronically for purposes of access, exchange, and use?*

There are existing infrastructures and taxonomy for price information. The challenge lies in the organizational and payer variability.

6. *Would updates to the CMS-managed HIPAA transactions standards and code sets be necessary to address the movement of price information in a standardized way?*

Gag clauses or nondisclosure agreements in provider and insurer contracts prevent insurers from sharing providers’ prices on their online price look-up tools for plan

members. Enabling providers to include prices in a patient's EHR will require modifications to the HIPAA transaction actions. We encourage HHS to examine the feasibility of incorporating price estimation for a patient's visit or episode of care within the same system that is used to check ability eligibility electronically (ASC X12 270/271) for every health insurer.

7. *How can price transparency be achieved for care delivered through value-based arrangements, including at accountable care organizations, demonstrations and other risk-sharing arrangements?*

Providing patients with cost estimates ahead of their visit or episode of care can be achieved using tools during pre-registration. Presenting patients with an estimate of their out-of-pocket costs *before* they receive care can help patients prepare for the financial impact of that care. Moreover, linking the price estimator to online resources, such as financial assistance and online bill pay, will further improve the payment process, reducing the burden on both patients and providers.

8. *What future requirements should the Department consider regarding the inclusion of price information in a patient's EHI, particularly as it relates to the amount paid to a health care provider by a patient (or on behalf of a patient) as well as payment calculations for the future provision of health care to such patient?*

We recommend that ONC work with CMS to provide greater consumer education before imposing additional burdens on providers, health IT developers, and third-party vendors. Unless consumers know what questions to ask and to whom, there is a significant likelihood they will not find the answers they need. We suggest that any public information on price be accompanied by basic information on copayments, deductibles, network issues, and visit limitations that will alter any information a consumer may receive. The information incorporated within the EHI must be accompanied by the appropriate explanations; otherwise, ONC risks making the task of navigating the health care system more ambiguous. Patients will over-rely on data without considering their situation; consequently, they will be left with surprise financial responsibilities not initially anticipated.

Moreover, the development of user interfaces and analytics is needed that would allow providers or their staff to structure simple queries to obtain and track actionable reports related to specific patients, peer comparisons, provider-level resource use, practice patterns, and other relevant information.

9. *If price information is included in EHI, could that information be useful in subsequent rulemaking that ONC may consider in order to reduce or prevent surprise medical billing, such as requirements relating to: The provision of a single bill that includes all health care providers involved in a health care service, including their network status.*

While we support the intent of this idea and believe patients would greatly benefit from such a bill, we are concerned that providers would have to bear the financial and

administrative burden of explaining the pricing and policies to patients. We note, however, that even if a consumer obtains an accurate quote of their out-of-pocket costs, this would not reflect the quality of care they will receive. In most retail exchanges, consumers expect the quality of an item or service to be reflected in the price. However, because of the history of convoluted payment systems in health care, market forces have been unable to keep price tethered to outcomes. With the trend toward better aligning payment with quality, progress is being made to end this discrepancy. Unless and until quality is incorporated into the price of services, consumers will not truly be able to make informed decisions about their care. Therefore, we recommend that ONC establish a process to ensure that beneficiaries receive benefits at in-network levels in circumstances when there is no available provider to provide covered benefits or when covered benefits cannot be provided without unreasonable delay.

Practices That May Implicate the Information Blocking Provision

Examples of Practices Likely to Interfere With Access, Exchange, or Use of EHI

APTA appreciates that a practice that seems to implicate the information blocking prohibition may not necessarily violate it, and each situation requires careful consideration of the specific facts. Although not discussed in the proposed rule, we recommend that in final rulemaking, ONC formally recognize that EHR vendors that refuse to share data with registries interfere with the access, exchange, or use of EHI, thus implicating the information blocking prohibition.

Applicability of Exceptions

Treatment of Different Types of Actors

As previously stated, APTA recommends that ONC finalize the definition of health care provider that is consistent with the HIPAA definition and expand the definition of health IT developer to include developers that have not had products yet certified.

Proposed Exceptions to the Information Blocking Provision

In addition to the recommendations outlined below, APTA recommends ONC establish a mailbox or other reporting process by which a provider, patient, or third-party vendor can report instances of information blocking.

(1) Preventing Physical Harm to Patients and Others

APTA supports Information Blocking Exception #1.

(2) Promoting Privacy of EHI

APTA has concerns that allowing a non-HIPAA covered entity to rely on the ONC information blocking privacy exception, sub-exception 2 (practices not regulated by HIPAA, but which implement documented, transparent privacy policies) could create a significant burden on providers and patients if patients are blocked from accessing their information by non-HIPAA covered entities. Given that ONC has expressed that one of its priorities is to relieve clinician burden, we recommend that ONC clarify in final rulemaking that non-HIPAA covered entities are **not** permitted to use this or any other information blocking exception. Allowing non-HIPAA covered entities to engage in information blocking by relying on the second exception could create significant havoc for all parties.

For example, a non-HIPAA covered entity may have an arrangement to share data with certain EHRs, but not others. If a provider needs data for information or monitoring, a provider may need to pay more to have a relationship with this non-HIPAA covered entity or be cut off from the information completely. Or, a non-HIPAA covered entity, which is a repository of health-related data, may collect data that is later deemed to fall into the definition of social determinants of health (SDOH). This entity may refuse to share this data with a hospital in City A and instead set up an ‘exclusive’ contract with a different hospital in City B. In such instance, it would be inappropriate for the non-HIPAA covered entity to invoke this information blocking exception as the reason why they are not required to share information. We strongly recommend that ONC clarify in final rulemaking that non-HIPAA covered entities are not permitted to rely on the second information blocking exception, particularly sub-section 2; it is imperative there is no loophole for entities not subject to HIPAA.

(3) Promoting Security of EHI

HIPAA compels the protection of patient information that is created, received, used, or maintained by a covered entity, and HIPAA-covered entities will often err on the side of caution in their internal policies to ensure HIPAA compliance. HIPAA-covered entities frequently adopt organizational policies and unduly restrictive or even incorrect interpretations of HIPAA or state privacy law that then lead to a lack of interoperable movement of information. While we appreciate that ONC is allowing organizations to follow internal policies when determining whether it can or should share information, we have concerns that the privacy and security exceptions to information blocking will be misapplied and/or inappropriately relied upon. For example, an organization may rely on this exception as a pretext for a business decision not to share such information. As the exception is currently proposed, providers and third parties can use Exception #3 to justify their inappropriate actions and be protected from potential penalties.

ONC clearly seeks to compel sharing of EHI to facilitate coordinated care. Therefore, we encourage ONC to modify the security exception to ensure that the security of information is not used as a pretext for information blocking. APTA also recommends that ONC and OCR provide more education to providers and other HIPAA covered entities to ensure there is appropriate understanding of the application of HIPAA privacy and security laws.

(4) Recovering Costs Reasonably Incurred to Provide Access, Exchange or Use of EHI:

APTA appreciates that ONC has included an exception to information blocking that discusses recovering costs reasonably incurred to provide access, exchange, or use of EHI. However, we have concerns that without additional guidance, ONC’s expectation that the amount charged may only include a reasonable profit may be wildly misconstrued, much to the detriment of the patient and/or provider. APTA recommends that ONC provide additional clarity regarding ONC’s proposal to allow recovery of costs that an actor reasonably incurs to provide access, exchange, or use of EHI.

To avoid causing confusion among the industry, we recommend that ONC clarify in final rulemaking what constitutes objective and verifiable criteria and provide recommendations for harmonizing this exception with HIPAA’s regulations that govern the charging of fees for electronic copies of medical records. We also request that ONC provide additional clarification

regarding what constitutes a “reasonable profit” and provide examples of what fees would or would not be reasonable when providing EHI to a patient.

(5) Responding to Infeasible Requests to Provide Access, Exchange or Use of EHI

APTA supports the infeasible request exception; however, we recommend that ONC provide examples of what would be considered infeasible (or not infeasible), including what the agency believes would constitute a substantial burden. Without additional guidance from ONC, it is likely that some actors will broadly interpret this exception to the detriment of the patient, provider, or other third party and engage in a form of information blocking that is not protected by the agency. We do appreciate, however, ONC’s proposal that for infeasible requests, stakeholders must respond in a timely manner to those making requests and work with them to provide a reasonable, alternative way to access the data.

(6) Licensing Interoperability Elements

APTA supports Information Blocking Exception #6.

(7) Maintaining and Improving Performance of Health Information Technology

APTA supports Information Blocking Exception #7.

Requests for Information

Complaint Process

We strongly advise ONC to substantially expand its information blocking proposal to ensure that it encapsulates all parties who may engage in information blocking and/or be subjected to information blocking. To that end, we recommend that ONC develop an action strategy for patients, providers, and vendors who believe they are being subjected to information blocking that outlines how they can alert ONC to concerns of information blocking, such as establishing a mailbox to receive feedback from public stakeholders; how ONC will investigate and address complaints of information blocking; and penalties it will impose on providers, vendors, or health IT developers that engage in information blocking. Establishing a mechanism to receive feedback on potential instances of information blocking will help ONC understand how problematic and widespread the practice is and whether the parameters put forth by ONC are appropriate.

Disincentives for Health Care Providers

To ensure all entities better understand what constitutes information blocking and what is permitted under the law, we encourage ONC to provide education and training for health care providers and consumers. The policies included within this proposed rule are complex and full of intricacies that even the savviest or most educated consumers and providers fail to understand. In addition, we encourage ONC to address in final rulemaking how it will assess whether the actor “knows or should know that the actions are likely to cause interference.” Finally, we caution against imposing severe penalties on health care providers, as it is likely that some health care providers may engage in information blocking for clinical care purposes, not realizing it constitutes information blocking under the law.

Registries

Development of professional registries has been spurred by the need to create meaningful quality measures to assist providers in the shift to value-based payment and models of care. These registries will be critical to the success of innovative payment models in the future, as they are able to deliver real-time data to providers for monitoring, assessing, and responding to new and dynamic models of care delivery. APTA has serious concerns that lack of standardization across electronic infrastructure on the data element, definition, and value-set level has made it difficult to implement health IT within registries. More work needs to be done to encourage the originators of data to adhere to standards to promote bidirectional data exchange. For example, supporting a widely used, consensus-based standard such as FHIR reduces burden on health IT implementers. USCDI was not developed with an eye toward public health or registry reporting, and this needs to be kept in mind as a use case for future development of the USCDI. Having this work originate in an SDO would help alleviate this problem. As we move toward outcomes-based payment and advanced quality-reporting structures that will rely heavily on electronic data submission, it is critical that ONC continue to support the development and success of professional registries.

As payment reform moves from process-oriented performance metrics (eg, checklists) to outcome-oriented performance metrics (eg, how patients feel and function based on their self-report), EHRs need to keep pace. Currently, very few EHRs can collect patient-reported outcome (PRO) questionnaires of how patients feel and function. They also lack meaningful ways to display this information to clinicians and patients (eg, graphs of symptoms over time). APTA recommends that ONC require certified EHRs to be interoperable and able to share information with professional societies' registries. We also recommend ONC require EHRs to transmit movement-related issues to registries, such as falls history, levels of function, and community activities and participation.

As previously discussed, to assess the current state of clinical data interoperability with respect to registries, APTA participated in a project termed "Improving Health Data Interoperability" sponsored by the Pew Charitable Trusts. The hypothesis was that data liquidity had not been achieved in the registry domain, and that native data interoperability shared by both clinical documentation and registry database systems would provide the best pathway to accomplishing data liquidity. The primary conclusion from the project was that the registry community is not aligned with national interoperability initiatives and is not incentivized to contribute to interoperability efforts. With "swivel chair interoperability" being the primary mechanism for data submission to registries, this misalignment is a national burden costing billions of dollars. The opportunity exists for the registry community to facilitate and catalyze native data interoperability as a key demonstration of health care data interoperability, with many of the clinical concepts already in the USCDI serving as the proving ground.

APTA supports the recommendations put forth in Duke Clinical Research Institute's comment letter. We reiterate the recommendations put forth by Duke Clinical Research, including:

- ONC should further develop the USCDI to include technical (both clinical application and database developer) specification of common data elements for capture of information as interoperable data. The technical output of the project is a recommended implementation of core common clinical data elements. Our technical implementation

specification could serve as a model for accomplishing the same across the USCDI. Should all parties conform to the implementation, data liquidity with native data interoperability will be naturally accomplished for the selected clinical concepts.

- An authoritative process to identify, define, and specify standards for common clinical data elements and an agreed-upon process for its governance is needed. Also necessary is a common data element repository or common clinical data element library to support the technical adoption of standard common data elements. Similarly, common data element, model tooling, and terminology repositories for candidate data elements are needed.
- A program focused on registries to define domain-specific core clinical concepts as data elements. While the project did not develop domain-specific clinical concepts, it was clear that the key kernel of clinical information needed to assess quality, performance, and outcomes is well-represented by the data requested through registries. The registry community can be leveraged to capture clinically relevant information as data at the point of care to serve the needs of care delivery, outcomes evaluation, quality and performance measurement, and medical product evaluation and surveillance. Doing so increases the availability of data for real-world evidence, knowledge generation, and translation of that knowledge into practice to improve public health.

Patient Matching

APTA recognizes that effective patient matching is necessary to achieve interoperability. To effectively exchange medical data, health care providers must know that they are communicating about the same person. Unfortunately, many of the information exchanges made by health care providers and organizations fail to accurately match records for the same patient, as there are significant issues with linking medical records to individual patients. For example, although many providers have transitioned from paper records to EMRs or EHRs, a significant number of patient records are incomplete due to their records not being accurately linked to them. Efforts to expand interoperability and records sharing will compound the patient matching problem by increasing the volume of data that must be matched to the correct patients. Further, new sources of data are emerging that will need to be integrated into the patient profile, including the patient-generated health information submitted through websites and wearable technology. Correlating official medical records with this additional information will be incredibly difficult, if not impossible for some providers. As patients gain access to their records, patients may find that their health record is missing information, or, worse, that it may have included incorrect information from another patient.

Improving patient matching rates will require a multifaceted approach. For example, ONC could require the adoption of a unique patient identifier system. The agency also could identify and include in the USCDI readily available data elements, including email address, mother's maiden name, or insurance policy identification number, that health information technologies may use for matching. Further, we are aware that the US Government Accountability Office (GAO) published a report in January 2019 highlighting ideas offered by stakeholders to improve the ability to match patients' records. Examples discussed in the report include implementing common standards for demographic data, developing a data set to test the accuracy of matching methods, implementing a national unique patient identifier, and developing a public-private

collaboration to improve patient record matching.¹⁶ We encourage ONC to consider the recommendations included within GAO's report, as it is critical that ONC pursue multiple mechanisms to improve patient record matching.

Conclusion

APTA thanks ONC for the opportunity to provide comments on the Interoperability and Information Blocking proposed rule and applauds the agency for continuing to take steps to improve interoperability and access to, and the quality of, information that Americans need to make informed health care decisions. While we support many of ONC's proposals, we continue to have concerns that many of the current and proposed reforms to improve interoperability fail to recognize the nonphysician community, including physical therapists. Moreover, it is difficult for such providers, particularly small and rural providers, to invest in health IT while also facing the pressures of changing Medicare payment methodologies, forcing providers to evaluate whether they have the financial capabilities to continue to operate in this space. Due to their exclusion from the former Meaningful Use process and ineligibility for EHR adoption incentives, physical therapists have unique concerns that often are overlooked. Therefore, as ONC undertakes the development of policy reforms, we strongly recommend ONC afford greater deference to the needs of physical therapists and other nonphysician providers and the valuable role they play in this nation's health care system.

Should you have any questions, please contact Kara Gainer, Director of Regulatory Affairs, at karagainer@apta.org or 703/706-8547 or Matt Elrod, Lead Practice Specialist, at mattelrod@apta.org or 703/706-8596. Thank you for your consideration.

Sincerely,



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SLD: krg

¹⁶ GAO Report to Congressional Committees. Health Information Technology: Approaches and Challenges to Electronically Matching Patients' Records Across Providers. <https://www.gao.gov/assets/700/696426.pdf>. Accessed April 5, 2019.