June 19, 2023

Dr. Micky Tripathi
National Coordinator for Health Information Technology
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Washington, DC 20201

Submitted electronically at http://www.regulations.gov

In reference to: *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing* (HTI-1)– RIN 0955–AA03

Dear National Coordinator Tripathi:

Point-of-Care Partners (POCP) appreciates the opportunity to respond to the above referenced Office of the National Coordinator for Health Information Technology (ONC) proposed rule.

POCP brings a perspective that is unique to those held by providers, payers, and health IT vendors. As healthcare management consultants since 2003, we have led the development of standards and transactions that have evolved since the adoption of the Health Insurance Portability and Accountability Act (HIPAA) and Medicare Part D. We have frequently been called upon by healthcare regulators and supporting organizations to provide expert testimony at hearings involving health IT standards.

For over two decades, as members of the National Council for Prescription Drug Programs (NCPDP), POCP has helped shape the standards for prescription benefit Claims (Telecommunication), ePrescribing and ePA (SCRIPT), Formulary and Benefit (F&B), and Real-Time Prescription Benefit Standard (RTPB). Our familiarity with the implementation requirements of these standards, and perspective as health IT management consultants, allows us to consider impacts of regulations for diverse stakeholders, including patients, providers, payers, life sciences companies, and health IT vendors.

General Comments

Point-of-Care Partners commends the ONC effort to address health data, technology, and interoperability and more specifically focusing on advances for pharmacy interoperability. Information sharing is crucial for advancing medical research, public health initiatives, and personalized patient care. The proposed rule encourages health IT systems to share relevant data in a standardized and secure manner. We are especially pleased to see in this proposed rule ONC's focus on pharmacy interoperability. Pharmacy interoperability plays a crucial role in improving patient care, enhancing medication management, and promoting better health outcomes. Advancing pharmacy interoperability offers numerous benefits, ranging from reducing medical errors to enabling comprehensive medication histories and facilitating coordinated care. When patients receive care from multiple providers or transition between different healthcare settings, such as hospitals, clinics, and pharmacies, interoperability becomes essential. Full scale interoperability between all healthcare clinicians, including pharmacists, will enable all healthcare professionals to access comprehensive patient information, leading to better diagnosis, treatment, and prevention of diseases. The commitment shown by the ONC in fostering collaboration, standardization, and interoperability is paving the way for enhanced care coordination, improved patient outcomes, and increased efficiency in healthcare delivery.

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We have assessed the considerations set out in this proposed rule and share our observations and recommendations detailed below.

Pharmacy Interoperability

As previously detailed, POCP has extensive subject-matter expertise and real-world experience in interoperating in the pharmacy services arena and therefore we offer the following comments for consideration by the ONC as you contemplate next steps in this process.

It is crucial to establish and adhere to standardized formats for data exchange to ensure seamless interoperability. Commonly used standards in pharmacy interoperability include the NCPDP and Health Level Seven (HL7) dually balloted NCPDP eCarePlan, the specialty medication enrollment implementation guide and the CARIN Consumer Realtime Pharmacy Benefit Check. These standards are just a few examples of collaboration amongst these two standards bodies. Consent is another area of collaboration between the two standards bodies which is another focus area for ONC in this proposed rule. The technical infrastructure and capabilities of the systems involved in pharmacy interoperability need to be compatible. This includes ensuring support for secure communication protocols, data encryption, authentication mechanisms, and data integrity verification.

As Pharmacists continue to meet the needs of patients via the expansion of the clinical services they provide, we need to ensure interoperability of the data necessary for treatment and reimbursement as well as the clinical data originating in the pharmacy. Clinical data like vaccinations, blood pressure or other data that originates in the pharmacy will need to follow the patient as they travel through the healthcare ecosystem whether back to their general practitioner, to a specialist or to the emergency room. To ensure this data can flow across care settings, it will be increasingly important to consider certification of the systems that support these efforts. Pharmacy systems certification to meet specific standards and criteria defined by ONC could be a catalyst to improve interoperability between certified Health IT Modules and other relevant systems which is essential to enable smooth data exchange and ensure compatibility.

Related to pharmacy interoperability, it is important to note that regulatory frameworks like the 21st Century Cures Act and subsequent rulemaking from Centers for Medicare and Medicaid (CMS) have been catalysts for interoperability advances. Provisions within the 21st Century Cures Act and CMS regulatory pillars have accelerated improvement in interoperability between provider EHRs, payers and patients, setting up data-sharing capabilities between these stakeholders, and should be reviewed when considering certification criteria related to pharmacy interoperability and data fluidity amongst all stakeholders who care for and advance patient care.

Relative to how developers of certified health IT may be able to support drug price transparency and patient choice, and meet other market demands while ensuring reliable and trusted performance, POCP recommends ONC consider the following:

- Current and future Developers of certified health IT can leverage the technical expertise to inform future standards modifications, develop and enhance systems that provide accurate drug pricing information, facilitate informed decision-making, and deliver seamless experiences to patients and healthcare providers.
- Developers can integrate features that enable real-time access to pricing information from various sources, such as pharmacy benefit managers, government databases, and pricing transparency initiatives. By incorporating these functionalities into certified health IT systems, providers including pharmacist can provide patients with transparent cost information as well as for future consideration information on other resources such as community resources for those that are dealing with health disparities, empowering them to make

informed choices and better manage not only the cost of their care but access to other support services, as needed.

- Developers can focus on enhancing patient choice by building patient-facing tools within their certified health IT systems. These tools can enable patients to compare medication costs, explore alternatives, and consider factors such as formulary coverage and therapeutic options. By providing comprehensive and personalized information, developers empower patients to actively participate in their treatment decisions, fostering a patient-centered approach to healthcare.
- Developers should continually assess and understand the evolving needs of the healthcare landscape. By actively engaging with stakeholders, such as pharmacists, providers, payers, and regulatory bodies, developers can identify emerging requirements and incorporate them into their certified health IT systems. These demands may include functionalities related to medication adherence, medication therapy management, or integration with emerging healthcare technologies.
- To ensure reliable and trusted performance, developers must prioritize system stability, accuracy, and data security. Rigorous testing, performance monitoring, and adherence to regulatory guidelines are essential. Robust security measures, including data encryption, access controls, and audit logs, are critical to safeguarding patient health information and maintaining trust in the system's performance.

Section III.G.2.d Broader Electronic Prescribing Ecosystem for Pharmacy Interoperability

In general, most electronic health record (EHR) and prescribing systems provide a considerable level of configurability to accommodate the needs of different customers or practice sites. However, it's important to note that the availability of certain features or functionalities at a product level doesn't guarantee a uniform experience for every practice or provider. This aspect should be taken into consideration when conducting workflow or user experience tests, as different systems often offer a variety of options, requiring consistent implementation.

POCP supports additional certification criteria that support real world electronic prescribing workflows. Certification of workflows, including the demonstration of a prescriber going through the entire process of drug selection, eligibility checks, prescription writing, RTBC, and transmission could be pivotal for validating user experience, ensuring comprehensive evaluation, detecting, and preventing errors, assuring interoperability, and promoting standardized practices. In addition, certification would ensure that data exchange between various components is smooth and accurate. This promotes interoperability and enables healthcare providers to access essential information at each step of the prescribing process. Lastly, a very important issue relative to certification is the user experience. Certification of workflows allows for the validation of the user experience from start to finish. It ensures that the entire process is intuitive, efficient, and aligns with best practices, leading to improved user satisfaction and reduced workflow disruptions.

When considering workflow testing for ePrescribing and other pharmacy interoperability areas, it is essential that ONC prioritize in your considerations the development and adoption of NCPDP standards that enable seamless information exchange, accurate medication reconciliation, and effective decision support, ultimately benefiting both healthcare providers and patients.

Pharmacy Interoperability within the ONC Health IT Certification Program including Real-Time Prescription Benefit (RTPB) Capabilities - RFI Response

POCP supports ONC establishing a certification criterion utilizing the NCPDP RTPB Standard. The NCPDP RTPB Standard Version 12 (Version 12) was published in October of 2021. Since that time, there have been new enhancements added

to the NCPDP RTPB Standard which are needed by the industry resulting in RTPB Standard Version 13 (Version 13). Enhancements to Version 13 include:

- Added Coverage Status Message to assist in communicating coverage information at a product level which is not codified. By adding this field, the payer will be able to communicate important information regarding coverage and provide clarifying or additional information.
- Added values to the Coverage Restriction Code and data elements to the RTPB Standard to codify information communicated in the Message to reduce the number of free text messages on the response.
- Added next available fill date to communicate when the patient is eligible to receive a prescription refill in a discrete field instead of via a free text message.
- Added fields to communicate formulary status and preference level. This allows for the communication of the formulary status of both submitted product and alternative products to help understand pricing on the response.
- Added data elements to convey the patient's address, state/province, zip/postal code, and country on the request transaction to aid in coverage determination.

POCP recently submitted comments to CMS-4201-P in response to CMS's proposal for the adoption of Version 12. In its comments, POCP supported the adoption of the RTPB Standard but recommended adoption of RTPB Version 13 due to the benefits of the enhancements outlined above. Similarly, should ONC propose to establish criterion utilizing the NCPDP RTPB Standard, POCP suggests utilizing Version 13 now, instead of in the future, as it will help in future migrations and will enable immediate use of the enhancements.

Real-time prescription benefit certification has the potential to improve medication adherence, reduce costs, and enhance patient satisfaction. By providing prescribers with accurate and up-to-date information on formulary coverage, prior authorization requirements, and cost-sharing details, they can make informed decisions regarding medication selection that aligns with a patient's insurance coverage and financial capabilities. This process can help reduce delays in prescription processing, increase transparency, and potentially lower out-of-pocket costs for patients.

It's worth noting that the implementation of real-time prescription benefit certification may involve technical challenges and coordination among different stakeholders, including electronic health record (EHR) vendors, pharmacies, payers, PBMs and health information exchanges. However, as the healthcare industry continues to move toward increased interoperability and data exchange, real-time prescription benefit certification could be a valuable tool in optimizing medication therapy and enhancing patient outcomes.

Requirements for Use of XML or EDI Format

The RTPB Standard enables the exchange of patient eligibility, product coverage, and benefit financials for a chosen product and pharmacy, and identifies coverage restrictions, and alternatives when they exist, facilitating the ability for pharmacy benefit payers/processors to communicate to providers. The RTPB standard contains two different syntaxes for the exchange of real-time prescription benefit information (XML and EDI). The RTPB standard does not require implementers support both syntaxes and allows for implementers to use intermediaries to facilitate the translation between the two syntaxes. Therefore, POCP recommends ONC provide test tools allowing systems to certify using the format(s) they have chosen to implement, and that the certification criterion should only require testing against one format, if ONC were to require RTPB.

Request for comment on whether a potential RTPB certification criterion should require demonstration of compliance with both NDC and RxNorm

Pharmacy claims using the NCPDP Telecommunication Standard use the code sets defined by the NCPDP Product Identifier Standard which includes National Drug Code (NDC), Universal Product Code (UPC), National Health Related Item Code (NHRIC), and Unique Device Identifier (UDI), but does not include RxNorm. RTPB integration closely mimics the pharmacy claims submission process, so if pharmacy benefit managers (PBM) do not process claims using RxNorm codes it is unclear if there is any benefit to EHRs supporting RxNorm if the PBM will not use the data.

On the questions of the ability for either NDC or RxNorm alone to provide sufficient information for applications to provide reliable, accurate clinical decision support, such as dosing guidance, drug interaction or drug allergy checks, *USCDI V3 Allergies and Intolerances class Substance (Drug Class)* element uses the SNOMED CT code system. Thus, regardless of whether the RTPB feature used NDC or RxNorm it would also need the ability to check using SNOMED CT. This means a mapping between code systems as well as ontology.

POCP opposes replacing the use of National Drug Code (NDC) with RxNorm values due to the disruptive impact such a change would have on the pharmacy industry. While RxNorm is useful for communication of clinical data for clinical care, the NDC is critical for specific product identification in research, dispensing and administrative workflows. The NDC is the key unique product identifier and is the standard of practice used throughout the pharmacy industry to identify the specific product. The industry heavily relies on the NDC in all aspects of its business, including, but not limited to, drug ordering, medication dispensing, reporting, billing, and patient safety.

RxNorm lacks the specificity required to uniquely identify a product and utilizing it as the single source terminology set would compromise patient safety but would also impact the ability for a PBM to send back an accurate patient price during a RTPB transaction, unnecessarily increasing healthcare administrative burden and cost.

POCP supports the use of both RxNorm and NDC without replacing NDC for RxNorm as the single source of clinical data for clinical care, research, and administrative workflows.

Request for comment - Should ONC propose a new certification criterion that would enable a user to use a Health IT Module to obtain formulary and benefits information using a more recent NCPDP Formulary and Benefit Standard

The Formulary and Benefit Standard (F&B) has been updated to Version 60 to meet industry needs and current usage. F&B Version 60 Updates from Version 3.0 include the following:

- All files (lists) have been normalized, which allows for smaller files and reusability, and have expiration dates.
- The alternative and step medication files have been redesigned to reduce file sizes and to include support for reason for use (diagnosis)
- The step medication files now support a more complex step medication program.
- Coverage files have been updated to include support for electronic prior authorization and specialty drugs.
- The copay files have been updated to allow a minimum and maximum copay range without a percent copay.

POCP suggests that Version 60 be the adopted new version of the Formulary and Benefit Standard.

Regarding the consideration to require support for the patient identity segment to be included in the certification criterion as a part of a real-time prescription benefit, the Formulary and Benefit Standard does not include a patient segment; furthermore, the patient segment in the NCPDP SCRIPT standard cannot be interchanged into the RTPB standard nor the Formulary and Benefit Standard. These are each unique standards with individual schema that cannot be intermingled and would therefore not be feasible. As for the consideration of ONC to require alternative or additional demographic data elements or sets of demographic data elements as part of a real-time prescription benefit certification criterion to further improve patient matching, it would be unreasonable to require the full USCDI V3

Patient Demographics/Information data class for this purpose because some data elements such as "Related Person's Name" and "Occupation" are irrelevant to this use case. However, ONC should consider requiring a minimum subset of relevant Patient Demographics/Information data elements which would be useful for accurate patient matching.

The RTPB standard supports sending a primary and secondary diagnosis, and for each of those diagnoses only one code/qualifier can be sent. ICD-10 is the preferred code set by pharmacies and pharmacy benefit managers, so requiring EHRs to send SNOMED codes could lead to interoperability problems if the pharmacy benefit managers do not support that code set.

Requesting comment on whether a real-time prescription benefit certification criterion should require conformance to the Patient Segment specified in NCPDP SCRIPT standard version 2022011 (replacing the NCPDP RTPB standard version 12 Patient (Demographic) Segment) to support the identification and linkage of records needed to support the successful exchange of patient-specific benefit information.

How should ONC address alignment of a real-time prescription benefit criterion to the electronic prescribing criterion in § 170.315(b)(3)?

Approaches should involve input and collaboration from healthcare providers, EHR vendors, industry experts, and other stakeholders to ensure the certification criteria effectively support real-world electronic prescribing workflows while considering the challenges and benefits of each approach.

ONC should encourage the integration of RTPB and ePrescribing functionalities within electronic health record (EHR) systems. This integration would allow healthcare providers to access real-time prescription benefit information directly within their existing ePrescribing workflows, eliminating the need for separate systems and reducing potential errors or delays.

ONC should prioritize education and training initiatives to familiarize healthcare providers with the integration of RTPB and ePrescribing criteria. This would include providing resources, conducting webinars, and offering guidance documents that explain the benefits, functionalities, and best practices associated with aligning these criteria.

ONC should collaborate with key stakeholders, including EHR vendors, RTPB solution providers, pharmacies, payers, and healthcare providers, to gather input and insights during the development and implementation of alignment strategies. Engaging stakeholders will ensure that the criteria address their specific needs and challenges, leading to greater adoption and success.

Requesting comments on whether a real-time prescription benefit criterion should also require demonstration of support for products that are not defined as medications but may also be included in a RTPB transaction, namely vaccines and medical devices or supplies. Should ONC require conformance to the NCPDP Formulary and Benefit Standard for devices? The NCPDP Formulary and Benefit Standard supports the exchange of UDIs for devices, and adoption of this standard may support other critical RTPB processes.

NCPDP membership to continue to meet the needs of the industry is actively considering items that ONC mentions such as vaccines, medical devices and supplies and even professional pharmacy services. NCPDP's RTPB standard does support medical devices. From a structural perspective, there is capability to support and a means to communicate various product identifiers; however, the implementation levels currently vary based on current system functionality or business need. Should ONC move forward with exploring products that are not identified as medications, adequate time needed for industry-wide system changes and implementation should be taken into consideration before the expanded use and/or requirement of multiple, alternate product identifiers. Additionally, ONC should be mindful of

current rulemaking in progress by the U.S. Food and Drug Administration (FDA) to revise the NDC format and drug product barcode label requirements that could affect current identifiers for medications and drug products.[1]

Seek information on formulary and benefit management and electronic prior authorization capabilities that work in tandem with real-time prescription benefit functionality in the context of electronic prescribing workflows.

Prior authorization is a significant challenge. NCPDP's SCRIPT Standard, adopted by CMS for the Med D Program can be utilized to automate and expedite the prior authorization process for the patient, provider, and health plan. Facilitated through the ePrescribing workflow the use of the SCRIPT standard expedites the determination process, leading to improved access for patients to their needed medications. While the Formulary and Benefit standard is helpful in determining medications covered or not covered by a health plan, it is not patient-specific to coverage and therefore not as successful as needed to determine patient specific detail. RTPB functionality provides real-time access to patient-specific medication coverage information, cost-sharing details, and therapeutic alternatives. It allows healthcare providers to view a patient's drug formulary, benefit coverage, copayment information, and any prior authorization requirements while they are in the process of prescribing medications. ePA functionality integrated into electronic prescribing workflows and integrated into the RTPB workflow can reduce delays in treatment and improve patient care.

Could a bundled approach to testing more than one pharmacy interoperability criterion in a single testing event address testing and other challenges?

A bundled approach to testing multiple pharmacy interoperability criteria in a single testing event has the potential to address testing and other challenges effectively. However, it is important to consider the complexity and feasibility of bundling specific criteria together such as how to logically group criteria. Additionally, careful planning, clear documentation, and effective coordination among stakeholders are essential to ensure the success of a testing approach, including a bundled testing approach.

What additional burden would requiring the Patient Segment identified in NCPDP SCRIPT standard version 2022011 as part of a real-time prescription benefit certification criterion impose on health IT developers seeking to certify Health IT Modules to this criterion?

The NCPDP Formulary and Benefit Standard does not include a patient segment. Furthermore, the patient segment in the NCPDP SCRIPT standard cannot be interchanged into the RTPB standard nor the Formulary and Benefit Standard. These are each unique standards with individual schema that cannot be intermingled and would therefore not be feasible. We therefore do not recommend this path by ONC.

SVAP

RTPB is a standard that enables real-time access to prescription benefit information. By including RTPB as a certification criterion, the ONC promotes interoperability between different healthcare systems and facilitates the seamless exchange of prescription benefit information among providers, pharmacies, and other relevant stakeholders.

By including RTPB as a certification criterion, the ONC encourages the adoption and implementation of a widely recognized industry standard. Standardization promotes consistency and compatibility among different health IT

[1] U.S. Food and Drug Administration. Proposed Rule on Revising the National Drug Code Format. December 27, 2022. Available at https://www.fda.gov/drugs/drug-approvals-and-databases/proposed-rule-revising-national-drug-code-format.

systems and supports the seamless flow of information across the healthcare ecosystem. It also fosters competition and innovation in the development of RTPB-related solutions.

The SVAP process allows for the continuous improvement and advancement of health IT standards. By naming NCPDP RTPB as a certification criterion, the ONC acknowledges the evolving nature of the healthcare landscape and the need to stay current with emerging technologies and standards. It provides an avenue to incorporate future enhancements and updates to RTPB as they are developed by NCPDP and vetted through the SVAP process, ensuring that certified systems align with the latest industry requirements.

POCP supports naming NCPDP RTPB as a certification criterion within the ONC's SVAP process as it is important to promote interoperability, patient-centered care, medication adherence, cost savings, industry standardization, and alignment with evolving healthcare standards and technologies.

Clinical Decision Support Hooks and FHIR CDS Hooks RFI Response

POCP supports the use and adoption of CDS Hooks. CDS Hooks are a valuable technological advancement in healthcare that significantly enhance clinical decision support and improve patient care outcomes. By providing a standardized approach to integrating clinical decision support (CDS) systems with electronic health records (EHRs), CDS Hooks enable real-time delivery of context-specific, evidence-based recommendations directly to healthcare providers at the point of care. Furthermore, CDS Hooks can streamline the clinical workflow by seamlessly integrating CDS functionalities into existing EHR systems.

Another significant advantage of CDs Hooks is their flexibility and extensibility. They allow for the integration of various CDS services and vendors, enabling healthcare organizations to choose and implement the solutions that best suit their needs. This promotes interoperability and facilitates the exchange of data between systems, fostering collaboration and knowledge sharing across healthcare settings.

Through our experiences working with vendors and EHRs as HIT consultants and via the HL7 FHIR Accelerators (Da Vinci, *FAST*, CodeX, Gravity), not all of these entities are fully ready to execute and implement CDS Hooks; however, with further efforts, focus and incentives adoption of this modern technology will further advance interoperability, reduce burden, create synergies across stakeholders and improve patient care. Regarding the CDS Hooks RFI, the CDS Hooks Standards for Trial Use (STU) STU2 specification is published and is the most relevant version. In alignment with HL7's recommendation, POCP suggests that until a more recent normative specification is published, STU2 be the version that is referenced in guidance and required for adoption and use. As newer versions become available, POCP recommends that the ONC consider updating the version of the specification to reference.

A fully normative specification for CDS Hooks is currently planned for ballot in the next six (6) months to a year, including a normative specification for CDS Hooks. When these fully normative specifications become available, POCP recommends these versions be referenced in guidance.

We do note that for purposes of certification, the HL7 CDS Hooks specification is not fully describing the specific data requirements and use in context of particular workflows, e.g., Appropriate Use Criteria or Prior Authorization. Therefore, where ONC is considering referencing HL7 CDS Hooks as part of certification criteria --which aim to drive wide adoption of consistent interoperability capabilities using standards such as HL7 CDS Hooks -- ONC should focus on the specific implementation guides for the workflows of interest which include use of HL7 CDS Hooks and fully describe how to use HL7 CDS Hooks in that context. This will further advance consistent use of HL7 CDS Hooks for use cases that are deemed critical enough to advance through certification.

To achieve greater adoption of CDS Hooks, we recommend that HHS continue to explore opportunities to incentivize utilization.

Decision Support Interventions and Predictive Models

As part of this NPRM, ONC is proposing to revise the name of the CDS criterion to “decision support interventions” reflects the various and expanding forms of decision support that certified Health IT Modules enable or interface with. These interventions would include evidence based DSIs, linked referential DSIs, and predictive DSIs. The proposed DSI criterion is a revised certification criterion as it serves as both an iterative and replacement criterion for the “clinical decision support (CDS)” criterion.

We are pleased to see ONC's commitment to addressing this crucial, influential, and complex healthcare technology matter. We fully endorse additional initiatives aimed at fostering collaboration and enhancing transparency concerning DSI and Predictive Models' advancement.

On a positive note, DSIs and predictive models provide healthcare professionals with evidence-based insights and recommendations to support their clinical decision-making. These tools analyze vast amounts of data, including patient health records, medical literature, and treatment guidelines, to provide tailored recommendations, improving the accuracy and effectiveness of diagnosis and treatment plans. By leveraging DSIs and predictive models, healthcare organizations can optimize resource allocation and improve operational efficiency. These tools can help identify patients at higher risk for certain conditions, enabling proactive interventions and resource allocation to prevent adverse events or unnecessary hospitalizations leading to cost savings and more efficient use of healthcare resources.

However, there are also unintended consequences that need to be considered. DSIs can have adverse, or negative impacts on patients, patient populations, or communities due to a range of factors related to model risk. Predictive models heavily rely on historical data to make future predictions. If the data used for training the models is incomplete, biased, or not representative of the diverse patient population, it can lead to inaccurate or biased predictions. This can result in inappropriate treatment decisions or disparities in healthcare outcomes. Additionally, and as referenced through this NPRM, some predictive models operate as "black boxes," meaning their inner workings are not easily understandable or explainable to healthcare professionals. This lack of transparency can raise concerns about the validity and trustworthiness of the predictions, making it challenging to assess the model's reliability and potential biases.

Considering these advantages and the risks and the work by the ONC Health Information Technology Advisory Committee (HITAC) to evaluate these perspectives, POCP supports the following recommendations from the HITAC:

- ONC should collaborate with DSI and other HIT developers, the FDA, and other stakeholders to implement a standards-based approach for sharing both machine-readable and human-readable tables/lists of DSI attribute information. As a first phase of this effort, ONC should produce a document format for DSI developers to use in conveying information to EHR developers and interface specialists.
- ONC collaborate with the FDA to require that DSI developers include the ability for clinicians and patients to provide feedback to developers about potential risks for using the DSI in special sub-populations of patients, such as patients with specific rare conditions, who may have not been sufficiently represented in the DSI development or testing data sets.
- ONC limit the interfacing or incorporation of "large language models" of AI/DSI into certified HIT unless the DSI developer can clearly articulate the data sources and logic used to produce outputs, until such time when these

new models are better understood, and the industry/government develops better insight into how to mitigate potential risks.

TEFCA Condition for Manner Exception Response

Overall, POCP commends the ONC on its proposal for an updated manner exception that provides various protections and incentive for organizations to participate in the Trusted Exchange Framework and Common Agreement (TEFCA), which is currently voluntary. However, it is difficult to predict how this exception will function in practice due to the variations in the flow down agreements from Qualified Health Information Networks (QHINs) to their participants and sub-participants and the potential for participants and subparticipants to exchange with each other across different QHINs.

The use of the phrase "required to be supported" could be more explicitly defined, as TEFCA employs other terms such as "permitted," "allowed," or "authorized," and further specifies the initial exchange purposes that necessitate a response. It would be beneficial if the ONC provided further clarification as to what might constitute "attempting to fulfill," as it appears vague.

Additionally, it would be helpful if the ONC explicitly addressed the example regarding the exemption from conforming to the fee or license requirements. Is ONC stating that the fee exception and license exception are not applicable under the TEFCA manner exception? In other words, can the responding organization charge any amount they wish or require a license fee under any conditions they desire? TEFCA does not explicitly address fees outside of QHIN-to-QHIN exchanges (where they are prohibited), but this exception would seemingly grant QHINs perhaps too much flexibility in determining fees for their participants, beyond the usual reasonableness constraints imposed by information blocking rules. And what about fees that participants or sub-participants could charge each other if part of different QHINs (e.g., using TEFCA as the transport network). Regarding the potential requirement to check a directory, it seems reasonable to perform such checks, although the NPRM indicates that the accuracy of the check is not mandated. However, it would be beneficial for the ONC to include language specifying the frequency with which directory checks should be conducted. For example, should the directory be checked for every request, or should the frequency align with the update frequency of the directories themselves?

By addressing these points, the ONC can provide further clarity and guidance, ensuring a more comprehensive understanding of the proposed updates and their practical implications.

***New* Patient Requested Restrictions Criterion in § 170.315(d)(14)**

POCP applauds ONC's recognition of the need for additional tools related to patient privacy restrictions and the recognition of the complexity involved with capturing and sharing data as it relates to marginalized communities. Point-of-Care Partners (POCP) believes the complex issues connected with informed consent are more important than is often recognized.

POCP supports the inclusion of the new certification criterion ''patient requested restrictions'' in § 170.315(d)(14) and supports the initial approach that this restriction remains standards agnostic.

However, we do recommend that ONC consider going one step further when it comes to consent and health equity.

One of the most difficult parts when it comes to consent is educating providers, patients and their caregivers about consent and building trust in marginalized communities around data sharing. Outside of certification criteria, POCP recommends ONC work with other agencies under HHS to create education campaigns for providers, patients and their

caregivers related to consent best practices. This education material should cover what, why, how, and what if I change my mind.

Other Comments

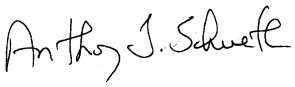
Moving forward, Point-of-Care Partners encourages continued collaboration between the ONC, healthcare organizations, technology vendors, and other stakeholders to drive further advancements in health data, technology, and interoperability. By working together, we can unlock the full potential of health information exchange, enabling healthcare providers to make well-informed decisions, empowering patients to actively participate in their care, and ultimately leading to a more efficient and effective healthcare system for all.

Conclusion

Point-of-Care Partners is pleased to offer comments on the proposed regulation and welcomes any further inquiries. Please reach out to me at tonys@pocp.com if we can provide clarification or additional information.

Thank you for the opportunity to comment.

Sincerely,



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