Dr. Don Rucker
Office of the National Coordinator for Health IT
330 C Street SW
Washington, DC 20416

Dear. Dr. Rucker:

On behalf of the membership of DirectTrust, we appreciate the opportunity to submit comments in response to the *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs (Strategy)*. We believe it is critically important that health care providers and the health IT community work together to reduce burdens that affect care delivery.

Background on DirectTrust

The DirectTrust community has developed a single "on-ramp" for health care stakeholders to participate in nationwide health information exchange for "push" transactions via Direct messaging and attachments. Since its inception just over 6 years ago, Direct exchange is now available to over 1.8 million clinicians and 248,000 patients/consumers in over 139,000 health care organizations in the United States. Nearly 274 million Direct messages were transacted in 2018. To physician-users, the Direct exchange experience varies greatly and many systems lack the level of simplicity others have come to expect. Whether Direct Messaging functions as an automated process or a clinical messaging mechanism, usability and consistency should be the expectation for users. The lack of clear workflow requirements and standardized EHR functionality has led to increased provider burdens that make the exchange of electronic health information more onerous than it should be.

There are numerous use cases widely adopted and appropriate for securely "pushing" electronic health information via Direct. Focusing on care coordination in particular:

- Real time acute care facility discharge messages to the patient's ambulatory care team.

- "Closed loop referrals" (when placing a referral to another healthcare provider or service, followed by the return of the results from the service or encounter to the referring provider).

- Ad-hoc communication among individual providers, other health care team members, patients, and caregivers.

These multi-lateral communications are critical components of an agile, coordinated and patient-centered healthcare system, a great clinical workflow tool, and the best solution to eliminating the need for the fax for sharing health information. Increasingly, health care providers are using a combination of electronic "push" messaging with document and/or data element "query" technology to provide the full range of interoperability between clinical information systems.

Below, we discuss how ONC should provide additional clarity in the Health IT Certification regulation regarding workflow requirements, as well as the need for consistent functionalities in

EHR systems to improve interoperability and the flow of information between clinicians. We believe it is important for ONC to address both of these issues in order to implement its strategy to improve health IT usability and the user experience.

Workflow Requirements: Improved Usability Through Better Alignment with Real-World Workflows, Harmonized User Actions, and Increased End User Engagement and Training

The Direct Standard ™ and DirectTrust were designed to support the goal of optimizing health information exchange among providers and others in order to better coordinate patient care. Direct messaging allows a clinician to exchange information electronically with others within their normal workflow while improving efficiencies over paper and fax. While Direct messaging has achieved considerable adoption by clinicians and health care organizations, many providers have not yet realized seamless Direct interoperability as a result of EHR usability barriers.

As ONC noted in the *Strategy* there is a disconnect between clinician workflows and health IT system design, that is reducing the usability of EHRs and other tools. In the health IT usability and the user experience draft strategy, ONC notes that provider burden would be reduced via improved usability through better alignment of EHRs with clinical workflow. Recommendation one in this strategy states that EHR system design should be better aligned with real-world clinical workflows. In addition, ONC recommends that harmonized user actions for basic clinical operations across EHRs and increased end user engagement and training will improve end user efficiency, experience, and satisfaction.

While ONC has required that Certified Health Information Technology supports Direct messaging, ONC should clarify in future certification program rulemaking the steps health IT developers must take to ensure their products are aligned with real-world clinical workflows including those that interact with external systems. In order to be a Certified Health IT Product, health IT developers should demonstrate that they have met certain criteria to improve usability and end-user experience. These criteria should not be overly prescriptive, to allow further innovation, but should reflect industry-standard guidelines for EHR optimization for clinical workflows. The criteria should include, but may not be limited to:

- Documentation regarding the testing of the product by end-users. This should include the clinical settings the product was tested in, the types of users included in the testing, the amount of time spent testing, and the number of testing iterations the product went through during development;

- Consultation or consideration of user-centered design subject matter experts in the development process;

- Use-case examples of standardized and customized workflows. This should provide ONC with examples of any anticipated end-user customizations and demonstrate how customizations will impact the clinical workflow. This information should also be provided to end-users prior to the installation of a customized Certified Health IT Product; and

- Development of clinical role-based workflow resources, training, and support mechanisms to be provided to end-users before, during, and after installation.

By capturing workflow requirements in the certification rule, ONC can ensure that health IT vendors are fully considering usability in their development efforts. These requirements also have the added benefit of improving interoperability and will allow DirectTrust to implement functionality improvements that will further reduce provider burden, such as enhanced messaging features to make Direct as functional and easy to use as email and automation upgrades that will assist with clinician prioritization.

Consistent Functionality: Improved Clinical Documentation Functionality and Presentation of Clinical Data within EHRs, Improved User Interface Design Standards, and Standardized Clinical Content Entry and Display

It is important for ONC to consider the types of functionality that providers need, to inform future editions of the EHR Certification Program and to better understand the limitations of existing certified functionality and how they impact provider burden. Throughout ONC's health IT usability and user experience strategies, ONC recommends increased consistency of functionalities within EHRs. This includes recommendations that aim to improve clinical documentation functionality, enhance presentation of clinical data within EHRs, improve user interface optimization recommendations, and harmonize surrounding clinical content in health IT.

Currently, EHR functions may work well within a particular system, but as users try to exchange information with other clinicians, differences in systems, versions, and workflows lead to failures. ONC should ensure that certain aspects of clinical workflow in health IT products are standardized and consistent across systems and versions. Standardized workflows should be required for:

- How data is sent and received by a system – Clinicians need basic messaging functionality in addition to background processes to safely and efficiently utilize Direct messaging to support clinical care. Enabling both of these functionalities in full should be the primary focus of health IT vendors for current development to assure that all applications satisfy these basic requirements;

- How receiving systems handle delegation – allowing for incoming messages to be handled by others than the recipient to allow for routine tasks to be handled by appropriate resources;

- What triggers sending data– Eliminating batching of transition of care (ToC) push messages to near real-time push of information at the time of patient transition and enhanced automation, specifically associated with both user and system actuated event triggers to send Direct messages; and

- What content or payloads can be sent and received – Systems must allow the recipient to send (outbound) and open, view and store (inbound) a wide variety of content types received as message attachments including structured data, unstructured data, and

images. Patient-context information contained in the message attachment should be visible or accessible to the clinical user.[1] Differences between EHRs for these capabilities mean that not all exchange partners can perform all possible use-cases.

Consistency is a fundamental requirement for easing provider burden. Incomplete or unusable data leads to increased documentation time and burden. For example, systems interacting with specialty EHRs experience significant challenges in information exchange. A specialty EHR for an oncology practice may have a completely different workflow and data interface; when data is sent from that system to another clinician, the data provided may be unusable given the context of the patient's visit. ONC should work with EHRs and other health IT vendors to ensure that data is delivered in a context-driven manner and with standardized workflows for effective data exchanges.

Conclusion

We appreciate ONC's efforts to reduce clinician burden related to the use of health IT and EHRs. DirectTrust and its membership look forward to further collaboration with ONC and other industry stakeholders to ensure that workflow requirements and functionality recommendations are implemented to ease clinician burden. We encourage ONC to review our Consensus Statement on how to optimize clinician usability and Interoperability through Direct exchange and to support the recommendations of our clinician steering group to better improve the usability, workflow, and clinician efficiency to support interoperability and improvements in healthcare delivery.

Sincerely,

Scott Stuewe
President and CEO, Direct Trust

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[1] Consensus Statement: Feature and Function Recommendations to Optimize Clinician Usability of Direct Interoperability to Enhance Patient Care, available at: https://www.thieme-connect.com/products/ejournals/html/10.1055/s-0038-1637007#OR170165ra-11