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Dr. Donald Rucker
National Coordinator
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Mary E. Switzer Building
330 C Street SW
Washington, DC 20201

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

Dear National Coordinator Rucker:

Thank you for soliciting comments on the Office of the National Coordinator for Health Information Technology's (ONC's) regulations implementing bipartisan provisions from the 21st Century Cures Act (Cures) passed in 2016. These regulations have the potential to improve the effectiveness and use of health information technology by: 1) equipping patients and clinicians with better information to inform care decisions, and 2) addressing limitations in the design of electronic health records (EHRs) that contribute to both medical errors and physician burden. While many provisions in the regulations take strides toward achieving those goals, ONC could make several enhancements to better fulfill that vision. The Pew Chartiable Trusts also submitted comments to regulations on health data access from the Centers for Medicare & Medicaid Services (CMS) published in conjunction with ONC's rules.

The Pew Charitable Trusts is a non-profit research and policy organization with several initiatives focused on improving the quality and safety of patient care, facilitating the development of new medical products and reducing costs. Pew's health information technology initiative focuses on advancing the interoperable exchange of health data and improving the safe use of EHRs. Pew also develops and supports state and federal policies that expand access to effective treatment for substance use disorders (SUDs).

These regulations implement certain provisions in Cures intended to improve the ability of different institutions to efficiently exchange health information—a concept also known as interoperability—and otherwise address barriers in the use of EHRs. Pew's comments will focus on provisions in the regulations and corresponding requests for information that strive to:

- Enable easier extraction and use of health data from EHRs via application programming interfaces (APIs), which let different technologies communicate;
- Enhance the export of additional electronic health information (EHI)—which includes information not available via APIs;
- Address information blocking, where health care providers or technology developers restrict access to patient data;

- Expedite adoption of these new capabilities by EHR developers and health care providers;
- Improve care for patients with opioid use disorders;
- Establish voluntary criteria for EHRs used in pediatric settings;
- Solicit ways to improve patient matching rates, which refers to the ability to link records for the same individual across different sites of care;
- Streamline data exchange between EHRs and registries; and
- Support the sharing of information, such as screenshots, to improve system safety and usability.

Summary of Pew's focus and key recommendations

In responding across the regulation, Pew's comments address four main factors in the use of health information technology: extraction of data from EHRs; patient matching; the safe use of technology; and other opportunities to leverage health data to improve care.

Extraction of data from EHRs via APIs

These regulations establish a fundamental requirement: patients and clinicians must have access to data in EHRs. Currently, many health care providers face challenges extracting data from EHRs, exchanging information with other organizations, and finding relevant data in the records they review. These challenges lead to patients and clinicians having an incomplete picture of individuals' medical history, which can, for example, contribute to medication errors and costly duplicative testing.[1]

To address that challenge, Congress in Cures required ONC to develop new criteria for EHRs to make "all data elements" available via APIs, which are software tools that allow systems to request and deliver information to other systems. APIs are the backbone of the modern internet. These tools allow websites to aggregate flight information, track personal financial habits, and display social media posts in real time. APIs operate in the background, connecting and transferring information between different systems. In Cures, Congress also banned "information blocking," which constitutes efforts by EHR vendors or health care providers to interfere, restrict, or prevent data exchange. These regulations further define information blocking, and the associated exceptions.

By identifying a common standard for APIs, ONC rightly provides a foundation for EHR data exchange, which will allow hospitals to better communicate with one another, clinicians to use new decision support tools, and patients to access their information. As ONC implements the API provision, ONC should maintain its commitment to the use of standards and extraction of more data, such as clinical notes, which provide narrative context and information not otherwise captured in a patients' records. ONC should also finalize its proposal regarding information blocking, where the agency clarifies that failure to enable the use of APIs to exchange information and implement common standards would constitute information blocking.

Better patient matching to foster interoperability

Patients receive care in a variety of settings—including in primary care offices, emergency departments, and specialty care facilities. To exchange medical data across these different sites of care, health organizations must know that they are communicating about the same person. Patient matching refers to the ability to accurately link a patient's record from multiple doctors' offices or hospitals where that individual seeks care. Presently, up to half of the information exchanges made by health care organizations may fail to accurately match records for the same patient.[2]

In the proposed regulations, ONC issued a request for information (RFI) on steps the agency can take to address inadequate patient matching. Pew urges ONC to take two steps toward improving match rates. First, ONC should standardize address to the standard used by the U.S. Postal Service, which Pew research—in conjunction with Indiana University—showed improved match rates by 3 percent. An organization with a match rate of 85 percent, for example, could reduce the number of unlinked records by 20 percent with standardizing address alone. One health information technology developer indicated that broad use of the U.S. Postal Service standard for address would help match an additional tens of thousands of records per day. The research also indicated that match rates could increase further with standard formats for both addresses and last names used simultaneously.[3] Second, ONC should require the availabiluty of more data for matching—such as email address, which is already collected in half of patient records.[4] These recommendations will help ensure that clinicians and patients have access to more complete, accurate, and up-to-date medical information—thus improving safety and reducing costs.

Enhancements to EHR usability can reduce burden, improve safety

These regulations also afford an opportunity to address another challenge with EHRs: subpar system usability that hampers these technologies from meeting their full potential in delivering more efficient and safer care. Usability refers to how EHRs are designed, implemented, and used by clinicians. Usability-related safety problems can emerge due to confusing interfaces, the need to develop workarounds to complete tasks, an overabundance of unnecessary alerts, and many other issues given the central role that EHRs increasingly have in helping clinicians order procedures, review health information, and obtain decision support. Pew research, in collaboration with MedStar Health's National Center for Human Factors, examined 9,000 safety events in three hospitals, finding that EHR usability contributed to approximately one-third of those errors.

In Cures, Congress required ONC to develop recommendations for the voluntary certification of EHRs used in pediatric settings, given the differences in the health care needs of children and adults. In implementing this provision via the proposed regulations, ONC identifies 10 clinical priorities where care differs, such as for EHRs to support medication dosing based on pediatric patients' weight.

While ONC rightly identified those clinical priorities, the agency can take additional steps to improve safety and usability. For example, for health information technology products to obtain the pediatric-focused certification, ONC should clarify that system developers involve appropriate end users, such as pediatricians and pediatric nurses, to test the system. In addition,

ONC should require use of pediatric-focused scenarios and mock pediatric data to conduct these assessments.

In these regulations, ONC also eliminates the use of restrictive nondisclosure and intellectual property clauses in EHR vendor contracts (often referred to as "gag clauses"). These clauses can inhibit clinicians from discussing or disclosing EHR usability issues that pose risks to patient safety.[5] For example, ONC indicates that clinicians can now share screenshots of the system (so long as they still protect patient privacy). By enabling the sharing of this information, clinicians, developers, and researchers can better identify systemic problems with EHR designs and implementations to improve usability and safety.

Use of health information technology to further improve patient care

Health information technology provides new tools to clinicians, hospitals, and researchers to understand care and address deficiencies. ONC further advances the use of this technology to improve care in several ways.

First, ONC seeks information on how to support data exchange between EHRs and registries, which collect data on patients with similar conditions—such as heart failure or joint replacement—to support quality improvement efforts, public health, and conformance with requirements from health plans to measure physician performance. Many registries collect the same basic information, such as birth date, smoking status, and address, but use a range of standards to record these data elements. Congress tasked ONC with issuing new criteria to ease the exchange of data from EHRs directly to registries. Pew-funded research conducted by the Duke Clinical Research Institute can provide guidance to ONC on how to facilitate EHR-registry data exchange, such as how to transmit information on vital signs.[6]

Second, EHRs can help equip clinicians and patients with new tools to address a growing public health policy priority: the opioid epidemic. ONC should draw on stakeholder feedback to fully consider how the proposed certification criteria and future ONC work could complement the spectrum of existing state and federal efforts to advance opioid use disorder (OUD) prevention and treatment through: 1) increased uptake of EHRs by behavioral health providers; 2) integration of tools to refer patients for substance use treatment within EHRs; 3) integration of prescription drug monitoring programs (PDMPs) into EHRs; and 4) development and integration of clinical decision support tools for opioid prescribing and OUD screening into EHRs.

Pew's more detailed comments on these four topic areas are below.

Standards-based API provisions can improve interoperability, patient care

In the proposed rule, ONC strives to address a critical challenge to the effective, interoperable exchange of data: the ability to extract information from electronic health records in a manner that other systems can easily understand. ONC, in response to Cures, identifies APIs based on widely adopted standards to address that challenge. Many industries—including banking, social media, and online retail—use APIs to aggregate data from dispersed systems, yet health care has not broadly deployed these tools in an effective way to access and compile patient records.

Currently, EHRs often either don't enable the use of APIs, or only implement these tools in a proprietary way that inhibits their use by other organizations. When EHRs use different standards for APIs, each third-party technology must change its systems to reflect every variation. Recognizing this limitation, Congress in Cures required ONC to introduce new criteria for EHRs to have APIs—colloquially referred to as "open APIs"—that other technologies could use "without special effort" to access "all data elements" within the system. These proposed regulations implement that provision from Cures.

Underpinning ONC's approach in the regulations, ONC seeks standardization of APIs across EHRs; this standardization would, for example, enable third-party software to more easily sync with different systems without additional or EHR-specific interfaces. Achieving standardization across APIs requires standards for both how information can be accessed and how the data elements are depicted. ONC accomplishes part of that goal by requiring use of the Fast Healthcare Interoperability Resources (FHIR) standard for how information is exchanged.

FHIR, alone, though permits the depiction of data elements in different ways and considers the inclusion of some data as optional. As that variation and optionality within FHIR can inhibit interoperability, ONC proposes to require the use of an implementation guide developed by the Argonaut Project—a collaboration among technology developers and health care providers—that provides constraints on how to implement FHIR.[7] The combination of both FHIR and the constrained implementation (contained in the Argonaut Data Query Implementation Guide) will reduce the barriers to API use so that patients and clinicians are more easily able to access data contained in EHRs. Should ONC seek to adopt implementation specifications formally balloted through a standards development organization, the agency could instead use the U.S. Core Implementation Guide from Health Level 7 (the standards organization that oversees FHIR), which based its work on the Argonaut guidance.[8] Either approach could meaningfully support ONC's efforts to reduce optionality in the implementation of FHIR.

Data elements exposed via APIs

In implementing the API provisions in Cures, ONC provides guidance on what information constitutes "all data elements" that systems would make available. In prior regulations, ONC has required EHRs to have APIs that make certain information—referred to as the Common Clinical Data Set (CCDS)—available for patient access, such as through a smartphone application.[9] The CCDS contains some critical information—such as medications, laboratory tests run, and problem lists.

ONC proposes to expand and adjust the CCDS to meet the statutory requirement of making "all data elements" available. This expanded data set would be renamed the U.S. Core Data for Interoperability (USCDI). Specifically, ONC proposes to expand access to the following data through APIs:

- *Clinical notes*: First, ONC proposes to add different types of clinical notes to APIs via the USCDI. These clinical notes include both free text entered by clinicians as well as structured data, such as selections from a list. Pew supports the addition of notes to the

USCDI as they can give patients and other clinicians key information on observations and treatments that may not be captured effectively via other means. For example, patients have indicated that access to notes helps them better understand their care, and makes them more likely to follow through on tests and referrals.[10] When patients received access to their physician's clinical notes, some individuals—particularly those who are older, less educated, non-English speaking, and non-white—reported the greatest benefit.[11]

ONC requests comment on which clinical notes to include in the USCDI. The agency includes three options:

1) All notes;
2) Eight note types identified by the Argonaut Project (Discharge Summary note; History & Physical; Progress Note; Consultation Note; Imaging Narrative; Laboratory Report Narrative; Pathology Report Narrative; and Procedures Note); or
3) Eleven types of clinical notes that would build on document types identified by Health Level 7.

Given that clinical notes can contain critical observations and information relevant to patients and their care team, ONC should adopt the first option—the release of all notes. In doing so, though, ONC should ensure that, where available, notes should be released in accordance with refined implementation guidance (e.g. for the note types identified through the Argonaut Project). Argonaut is also developing a guide to access all notes for a patient; ONC should leverage that effort to further foster standardization.[12]

- *Provenance*: Second, ONC proposes to add provenance—which indicates the author, the author's organization, and a time stamp—associated with each data element in the USCDI. The inclusion of provenance would encode each piece of data with the necessary information so that users—such as patients or clinicians—can understand its origin (e.g. whether a medication was entered by a primary care physician or at a hospital). In addition, the time stamp will allow applications to chart or order information, such as by listing patients' medications starting with the most recent.

  Pew supports the addition of provenance to the USCDI, as both clinicians and applications that access records require this information to provide much needed context for the data released via APIs. However, the industry may lack consistent guidance on how to implement provenance for each of these elements. For example, does the "author" of an allergy refer to the patient that reported this information, or the medical assistant or clinician that recorded it in the EHR? ONC should ensure that sufficient guidance exists—either from the agency, a standards organization, a private sector collaborative (like the Argonaut Project), or another group—to implement provenance across the USCDI. In the final rule, ONC should indicate from where the guidance will emerge—such as a standards development organization or public-private collaboration. Should ONC elect to prioritize data elements for the addition of provenance, the agency should focus on those elements where having this information provides the greatest utility—such as clinical notes and medications.

- *Pediatric vital signs*: Third, ONC proposes to include pediatric vital signs in the USCDI. While vital signs—such as blood pressure, heart rate, and temperature—were already part of the CCDS, ONC proposes to now include body-mass-index percentiles for children; weight for age, sex, and length; and head circumference for patients less than 3 years old.

  Pew supports the addition of pediatric vital signs to the USCDI, as this information would enable more precise care for children. For example, the inclusion of these vital signs will enable different applications to model the growth of a child according to biologic reference ranges, and enable the proper dosing of drugs based on patients' weight.

  However, ONC should further assess whether to require only the exchange of the raw data (e.g. head circumference) but not the associated percentiles, as guidance from the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) may change over time.[13] ONC should also coordinate with CDC and WHO to examine whether they can make a standard API available to provide up-to-date information on growth chart recommendations. EHR developers could then use these APIs to convert the raw data into percentiles based on the most current guidance.

- *Patient matching data*: Fourth, ONC proposes to add patients' addresses and phone numbers to the list of demographic data exchanged as part of the USCDI, which already includes patients' names, dates of birth, and other demographic data.

  The availability of addresses and phone numbers will better enable systems to match patient records across systems. However, ONC should further advance the use of the U.S. Postal Service (USPS) standard for address. This standard, for example, indicates the appropriate street suffixes to use. Pew-funded research at Indiana University revealed that use of the USPS standard for address can improve the accuracy of matching records by approximately 3 percent.[14] An organization with a match rate of 85 percent, for example, could see its unlinked records reduced by 20 percent with standardizating address alone. The research further revelaed that standardizing last name in conjunction with address could improve match rates from approximately 81 to 91 percent, which would reduce the number of unmatched records by half.

  Software that automatically converts addresses to the USPS standard after they are entered into the system is available in the commercial market; it is the reason many websites, for example, automatically make format changes to addresses at the time consumers place online orders. Use of this standard would not necessarily require workflow changes at the point of patient registration, and would meaningfully help to link records using the general processes that providers already employ. ONC should coordinate with the USPS to evaluate the use of its API, which converts addresses into this standard, for use by health care organizations to improve patient matching.[15] In addition, if necessary, ONC could limit address standardization to the USPS format for only domestic addresses.

  The effects of address standardization are further described in Pew's response to the patient matching RFI included herein.

- *Allergy expansion*: Finally, ONC requests comments on whether to expand the "medication allergies" list to also encompass reactions for other substances, such as food. ONC indicates that this transition would also include listing both the substance and reaction in the Systematized Nomenclature of Medicine—Clinical Terms standard.

  Pew supports the transition of this data element to "substance reactions" so that APIs can extract both the medications and other substances to which patients have allergies or adverse reactions. This capability could, for example, enable clinical decision support tools to alert clinicians when patients are allergic to substances from which medications are made, such as eggs or pigs, or specific foods served to hospitalized patients.[16] As a result, this expansion of the medication allergies category could improve patient safety.

Constrained use of FHIR critical for interoperability without special effort

To exchange the data in the USCDI, ONC proposes to require use of FHIR and associated implementation guidelines for the data. However, ONC requests input on which release of the FHIR standard to include in the regulations. ONC offers four choices: 1) adopt FHIR Release 2, which is currently broadly in use;[17] 2) adopt FHIR Release 2 and 3; 3) adopt FHIR Release 2 and 4, the latter of which was recently released and is the first normative version of the standard, meaning it will not change for an extended period of time;[18] or 4) adopt FHIR Release 4.

Regardless of which FHIR release ONC selects, the agency should keep two principles in mind. First, the agency should not incorporate multiple versions of FHIR in the regulations. The inclusion of two FHIR releases could introduce differences in implementations, thus undermining the agency's efforts for standard APIs. Second, the agency should ensure that the version of FHIR selected is paired with the appropriate implementation guidance that reduces variation and optionality in how the standard is implemented. ONC should not sacrifice the implementation guidance to implement a newer FHIR release.

To that end, Pew recommends the use of FHIR Release 4 coupled with implementation guidance, such as from the Argonaut Project. As FHIR Release 4 will already have been available for a few years by the time these ONC regulations take effect, the selection of any other release of the standard would codify older implementations with known deficiencies into regulations. Instead, ONC should leverage the latest efforts, especially given that FHIR is not expected to significantly change from Release 4 for some time given that it is a normative version of the standard. While Argonaut has currently developed implementation guidance for FHIR Release 2, ONC should work with that organization and Health Level 7 to make adjustments to reflect changes in FHIR Release 4.

However, the timing of updates to the implementation specifications may prohibit ONC from referencing FHIR Release 4 along with the final implementation guidance. Pew urges ONC to not select a version of FHIR for implementation if an associated implementation guidance cannot also be required in the regulations. If an implementation guidance for FHIR Release 4 is not available by the time ONC finalizes the rule, the agency should select FHIR Release 2 with the associated Argonaut or HL7 implementation guide.

Availability of documentation, transparency essential to effective APIs

For technology developers to use APIs to access data in EHRs, they require access to documentation on how to use those interfaces and the associated business or legal requirements. Some vendors currently make this information public, while others require third-party developers to agree to different legal terms or other restrictions in order to view the documents. In addition, the use of APIs may incur different fees.

In the proposed rule, ONC includes several requirements that would reduce barriers to the use of APIs for the exchange of data. Specifically:

- *Documentation*: ONC indicates that the technical and business documentation must be made available via a public hyperlink without any requirements, including login screens or agreement to terms and conditions.

  Pew supports these provisions that would provide open accessibility to key documentation for the use of APIs. These documents will give third-party application developers the information they need to use APIs to effectively extract information while also being aware of any restrictions (such as terms and conditions) that different EHR developers employ.

  The public availability of this documentation should also not introduce an undue burden on EHR developers. Organizations in many other industries make API documentation, which is much like an instruction manual, publicly available.[19] The documentation instructs third-party vendors how to request information and how the information they'll receive is coded. As a result, for APIs to be used, the documentation would need to be developed regardless of whether it's made public. Therefore, EHR developers will already create this documentation, and making it available will not add significant burden.

- *Fees*: ONC also generally prohibits EHR developers from charging fees for the implementation and use of APIs that expose the USCDI elements, as these costs could introduce "special effort." Despite the overall prohibition, ONC outlines three categories of permitted fees that EHR developers may charge health care facilities, but not end users, such as patients. First, ONC permits EHR developers to charge "reasonably incurred" fees for developing, deploying, or upgrading the API technology. Second, ONC permits fees to recover incremental costs associated with the use of APIs, such as additional server capacity. Finally, ONC permits fees for value-add services associated with data access. These value-add services may include training, integration testing, the addition of write capabilities to the API (discussed in more depth below), and numerous other services.

  ONC rightly recognizes that exorbitant fees can introduce barriers to the use of APIs for data exchange. By generally prohibiting fees and allowing them only for reasonably incurred expenses, ONC removes cost as a barrier to hospitals and health care facilities using APIs for interoperability. In addition, ONC permitting fees for value-add services—including ones that can promote better interoperability of data—ensures that EHR

developers still have incentives to innovate and compete on ways to better exchange information. ONC should clarify that EHR developers can charge these value-add fees without triggering information blocking provisions (described in more depth below) in the regulation. ONC should also clarify whether EHR developers can charge fees for other uses of APIs unrelated to the USCDI, such as for scheduling applications offered to customers.

- *FHIR endpoints*: ONC also proposes to require EHR system developers to make the FHIR server's endpoints (referred to as the FHIR Service Base URL) publicly available. These FHIR server endpoints enable applications that use APIs to know where to target their queries, much like websites' URLs. ONC proposes that EHR developers publicly make available the FHIR server's endpoints regardless of whether the vendor or the health care provider manage those endpoints. In situations where health care providers locally manage their FHIR servers, EHR developers would be required to obtain the endpoints from their clients.

  Pew supports requirements to ensure that FHIR endpoints are publicly available. These requirements will give application developers vendor-specific directories for how to sync with EHRs to extract data.

  However, because each EHR developer will release the FHIR server's endpoints individually, there will not be a single, cross-vendor repository of this information. Pew also supports ONC's suggestion that EHR developers, health care providers, and advocacy organizations create a single public resource or repository to house all vendors' FHIR server's endpoints, which would make it easier for technology developers to locate these URLs.

Considerations for future API capabilities

As part of the proposed rule, ONC recognizes that API capabilities and associated standards will emerge over time. ONC address these future capabilities in several ways.

- *Standards Version Advancement Process (SVAP)*: ONC indicates that standards—including FHIR—may emerge with new capabilities or benefits beyond existing versions. However, EHR developers may not be able to adopt those newer standards absent ONC rulemaking permitting the change. Given that these standards updates may occur faster than regulations can support, ONC proposes to develop the SVAP wherein the agency could permit the adoption of a newer version of a standard on a voluntary basis.

  Pew supports this approach to give ONC flexibility to permit the use of updated standards. However, ONC should ensure that this approach does not introduce unneeded optionality. For example, enabling the use of FHIR Release 2 and 4 simultaneously via the SVAP process could introduce differences that would undermine the agency's efforts to advance standardization among APIs. When ONC permits updated standards through the SVAP process, the agency should expeditiously conduct rulemaking to formally adopt the newer version and provide a process for sunsetting older versions of the standard.

- *Adding the write capability*: ONC currently proposes that APIs have the ability to only read—or extract—information from EHRs. However, some applications—such as decision support tools—may also be able to provide additional benefits to clinicians by entering, or writing, data into EHRs.[20] In the draft rule, ONC indicates that the agency may consider that "write" capability in future rulemaking.

  As FHIR further develops and API adoption increases, ONC should advance the use of these write capabilities for the bidirectional exchange of information out of and into EHRs by third-party applications. For example, patients could use this capability to update their address, which would enhance patient matching.[21] In doing so, ONC should ensure that robust cybersecurity practices—and, if applicable, new policies—exist to ensure that the addition of write capabilities do not introduce security risks.

- *Other data in FHIR profiles*: In the proposed regulations, ONC also provides guidance on the documentation that must be made available for data exposed via APIs that are not part of the USCDI. For example, ONC indicates that FHIR and the Argonaut implementation guide permits the transmission of patient' photos via APIs. ONC states that if an EHR developer makes this information available via an API, then documentation for how to obtain these optional elements must also be made available.

  The availability of these optional data elements can further improve patient care. For example, the availability of patient photos can support patient identification and matching efforts, especially if common standards are used for the information.

EHI export functionality would help patients obtain all their data

Along with requirements for EHRs to make some data available via APIs, ONC also proposes in the regulations to facilitate the extraction of a broader group of data—referred to as electronic health information (EHI)—from health information technology systems. This export criterion would support two uses of the information: a) delivery of the information to a patient upon his or her request; and b) the download of all information in a system to allow health care providers to change EHRs without burdensome processes to transfer the data.

Under the proposed regulations, ONC would require EHRs to enable the export of the technology's "entire database," including clinical, claims, billing, and administrative information. Further, ONC proposes to require that technologies export data stored in separate data warehouses that the system "produces and electronically manages."

Unlike the API provisions in the draft regulations, ONC does not propose to require that technologies make this information available via any specific standards or format. Instead, ONC indicates that the information should be extracted and remain computable wherever possible. Eventually, ONC states, it expects that EHRs would increasingly facilitate the extraction of EHI via APIs.

Revisions to EHI requirements would enhance the provision's utility

Pew supports ONC's efforts to increase the information extracted from health information technology via the EHI export functionality. Several revisions to the proposed requirements would enhance the utility of EHI to equip patients and clinicians with usable data while ensuring that technology developers can effectively meet the new requirements.

- *Require use of APIs for data*: Congress required ONC to issue new criteria for EHRs to make "all data elements" available via APIs. However, ONC's proposed API requirements would only expose a subset of data—the USCDI—via APIs. In parallel, ONC proposes to make all data from certified health information technology exportable via the EHI provision, which does not require developers to utilize APIs.

  To address the gap between Congress' requirements in Cures and ONC's proposal for APIs, the agency should require certified EHRs to make EHI available via APIs wherever possible. However, unlike the USCDI data, much of the EHI data may not have widely adopted standards or associated profiles via FHIR. Indeed, no such standard exists to describe all possible data elements across all EHRs.

  Therefore, to the greatest extent possible, ONC should require EHR vendors to support an API-based export capability for EHI while not requiring any particular standard for data that are not part of the USCDI. Eventually, 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.

  In addition, ONC already indicates that documentation on how to use the EHI export functionality should be publicly available on the internet. If adopting a requirement for vendors to make EHI available via APIs, ONC should adopt the same provisions on the accessibility of documentation—such as ensuring that developers make the documentation freely available to the public without any login or other associated requirements.

- *EHRs may not have access to all EHI*: Pew supports ONC's efforts to ensure that all patient data held by health systems should be easily made available to individuals upon their request, and transferable when facilities switch technology vendors. The EHI provision—which describes health data as both the information contained in EHRs and in databases accessible to the system—would ensure the extraction of all relevant data to meet that goal.

  While laudable, some health technologies—while having some abilities to access data in different systems—may not have the ability to effectively remove data from those other databases via an API. For example, images are often stored outside the EHR. As a result, they may not be able to make data from all third-party systems available via an EHI export functionality. Given that limitation, ONC should clarify the definition of EHI, and that the export function applies only in cases where the health technology can access, manage, and *extract* the data.

- *Timeframe to use for EHI export*: ONC requests comment on whether to set a timeframe for the EHI export capability, such as only from the past month or two years.

  In principle, patients should be able to access all of their information upon request, regardless of when the information was documented in the record. However, some information may be coded differently (e.g. with the use of one standard versus another) based on when it was entered in the system. ONC should, to the greatest degree possible, encourage the release of all longitudinal data, only providing exceptions for when technological challenges exist to prevent the release of information.

Information blocking implementation advances standards-based APIs

Cures also prohibits EHR developers and health care providers from "information blocking," which the law generally defines as efforts to interfere, restrict, or prevent data exchange. Cures authorizes fines of up to $1 million per violation. In the proposed rule, ONC both provides guidance on what constitutes information blocking and identifies a series of permitted practices that would restrict data exchange. For example, ONC indicates that EHR configurations that prevent the sending of referrals to unaffiliated health care providers would constitute information blocking. On the other hand, ONC provides exceptions to this policy if the sharing of information would put patient data or safety at risk.

In better defining information blocking and the associated exceptions, ONC further advances the use of standards-based APIs in several ways. For example, ONC indicates that health systems' failure to publish and enable the use of API server endpoints would constitute information blocking. The availability of these endpoints is critical for any third-party application to gain access to the data to, for example, allow patients to use the applications of their choice to download health records. Additionally, ONC indicates that the failure to use widely-adopted standards—whether or not they are explicitly referenced in regulation—would constitute information blocking. Defining information blocking in this way will discourage EHR developers from using proprietary standards for the purposes of creating barriers to data exchange.

In finalizing the regulations, ONC should maintain these and other provisions that further reflect the expectation that EHR developers enable, and health care providers effectively implement, standards-based APIs to support data exchange.

ONC should provide certainty on implementation timeline

ONC's proposed rule would establish a timeline for both EHR developers to add new capabilities and health care providers to implement those functionalities. This occurs because of the intersection between ONC's certification requirements for EHRs and payment policies from CMS that require the use of systems that meet the ONC criteria.

As part of CMS' payment policies for fiscal year 2019, the agency has required hospitals and health care providers to use EHRs that meet ONC's 2015 edition certification criteria as part of its quality improvement and measurement policies. In this proposed rule, ONC makes changes to the 2015 criteria but does not create a new edition of the requirements. Instead, ONC requires EHR

developers to upgrade their systems to meet the new criteria within two years of its rule taking effect. After two years, hospitals and health care providers that have not implemented EHRs that meet the new criteria will no longer be using systems that meet the newly revised 2015 criteria. As a result, those facilities would no longer be in compliance with CMS requirements to use EHRs that adhere to the 2015 criteria. In effect, even absent CMS action, under existing and proposed regulations, hospitals and other health care facilities will be required to upgrade to EHRs that meet the criteria in these proposed regulations.

Given the meaningful improvements that ONC proposes to require of EHRs via the updated criteria, such as for APIs, Pew supports both the establishment of new functionality and provisions to encourage timely adoption by hospitals and health care providers.

ONC should consider two factors in finalizing the development and adoption timelines in the regulations.

- First, ONC and CMS should encourage health care providers to test systems once they are deployed. This testing can identify safety concerns that arise due to facilities' unique workflows, third-party technologies that also interact with the EHR, and many other factors. Post-implementation testing with a specific focus on safety can help detect problems before patients are harmed. ONC should emphasize the importance of post-implementation usability and safety testing in the final regulations.

- Second, ONC, in collaboration with CMS, should not shift the implementation timeline once finalized in the regulations. In the past, CMS has adjusted implementation timeframes after hearing from health care providers that they have not taken steps in a timely fashion to implement EHRs that meet ONC's revised certification criteria. The possibility of delays creates uncertainty in the industry and for EHR vendors on when to complete development and testing of new functions in time for deployment at health care facilities. Therefore, ONC should commit to adhering to the timeline—currently two years—established in the final regulations.

Opportunities to advance care for patients with opioid use disorder

Pew supports ONC's efforts to determine how health information technology functionalities and standards can support the effective prevention and treatment of opioid use disorder (OUD) across patient populations and care settings.

As Pew has worked with states to improve access to treatment for people with substance use disorders, two central challenges related to health information technology have emerged. First, there has been relatively low adoption of EHRs by addiction medicine specialists and other behavioral health care providers. This inhibits the exchange of relevant patient health information between providers and coordination of care. Second, even in cases where a patient's primary health care provider does have an EHR, he or she may face challenges referring patients to behavioral health providers for treatment due to the lack of referral tools within EHRs. ONC should explore how it could use its authorities and coordinate with other federal agencies to

advance uptake of EHRs by behavioral health providers and facilitate the integration of tools to refer patients for substance use treatment within the EHR.

In addition to addressing these overarching challenges, Pew has identified a number of other opportunities where health information technology could advance prevention and treament for OUD. Prescription drug monitoring programs (PDMPs) can improve patient care, but they are often time consuming and cumbersome for clinicians to access. There are two ways PDMPs could be better leveraged to inform care. First, better integrating PDMPs and EHRs, such as through a single sign-on that allows a provider to access both the PDMP and patient health record, can facilitate more efficient workflow and increase prescriber use of PDMP data. Second, more user-friendly presentation of PDMP data in the EHR could help prescribers more easily interpret this information. Online focus groups of PDMP administrators that we conducted found that many shared a belief that there is great potential to implement enhancements to PDMPs via EHRs.[22] Enhancements could include allowing a provider to tailor risk asssesment thresholds based on PDMP data, allowing, for example, a pain clinic to set a higher risk threshold for total morphine equivalent dosage than a general practice care setting.

There is also potential for health information technology to give clinicians needed tools to address OUD prevention and treatment through better prescribing and screening for OUD. Facilitating the development and integration of clinical decision support tools—based on guidelines such as the Centers for Disease Control and Prevention's *Guideline for Prescribing Opioids for Chronic Pain*—that work with the EHR could help drive more appropriate prescribing decisions. Similarly, clinical decision support tools linked to the EHR could allow clinicians to more efficiently screen patients for OUD. ONC should continue to explore how emerging standards could help advance these clinical decision support tools. One example of such an emerging standard is the clinical decision support (CDS) Hooks specification (an open, vendor-agnostic specification) discussed in the Request for Information. CDS Hooks could enable the EHR to automatically prompt relevant decision support tools based on the clinician's workflow. For example, as a clinician is writing a prescription, CDS Hooks could generate a notification that gives the clinician the option to launch a support tool that draws on the CDC *Guideline for Prescribing Opioids for Chronic Pain*. Similarly, the CDS Hooks specification could prompt OUD screening tools in certain situations based on certain EHR workflow.

Health information technology can also boost delivery of evidence-based treatment for OUD. Medication-assisted treatment (MAT)—a combination of psychosocial therapy and U.S. Food and Drug Administration-approved medications—is an underutilized form of treatment for OUD. ONC should explore how it could facilitate the development and uptake of clinical decision support tools that could increase provider comfort and use of these evidence-based therapies.

We encourage ONC to draw on stakeholder feedback to fully consider how the proposed certification criteria and future ONC work could complement the spectrum of existing state and federal efforts to advance OUD prevention and treatment through: 1) increased uptake of EHRs by behavioral health providers; 2) integration of tools to refer patients for substance use treatment within EHRs; 3) integration of PDMPs into EHRs; and 4) development and integration of clinical decision support tools for opioid prescribing, OUD screening and delivering MAT.

ONC can further improve safety in criteria for EHRs used in the care of children

In Cures, Congress directs ONC to establish voluntary criteria for EHRs used in the care of children. Through this provision, Congress recognized that EHRs designed for use in adult populations may overlook differences when caring for children and introduce the opportunity for medical errors. For example, unlike adults, children often receive medication doses based on their weight.

These errors can occur, in part, due to poor system usability—which refers to how the layout, customization, configuration, and implementation of EHRs affects their use by clinicians. Inadequate usability has two major consequences. First, ineffective usability can contribute to clinician burden and burnout, which can make them more susceptible to making errors.[23] Second, poor usability can contribute directly to patient harm through errors that occur when clinicians interact with the EHR.

Pew collaborated with MedStar Health's National Center for Human Factors in Healthcare to examine the contribution of EHR usability to medication safety events in three health care organizations that treat pediatric patients. The research, published in *Health Affairs* last year, revealed that EHR usability contributed to medication errors in 3,243 of 9,000 safety events examined.[24] Of those usability-related events, more than 80 percent involved an inappropriate drug dose, and 609 of the usability-related events reached patients. In one case, a transplant patient missed days of medication that would help prevent organ rejection. In another case, the blood transfusion for a newborn in critical condition was delayed due to the inability to create a record. These findings, along with other research conducted by MedStar Health, indicate a clear link between the usability of EHRs and patient safety.[25]

The new pediatric-focused criteria required by Cures provides ONC with an opportunity to improve usability and the safety of EHRs used to care for children.

To implement that provision in Cures, ONC identified 10 clinical priorities for pediatric care drawn in large part from the Children's Electronic Health Record Format—a resource developed by the Agency for Healthcare Research and Quality to assist with the design of EHRs.[26]

These priorities include functions that are distinct or common for pediatric care, such as weight-based drug dosing, using biometric norms to monitor growth, and age- and weight-specific single-dose medication range checking. In the proposed rule, ONC rightly identified those areas where additional pediatric focus in EHR design could improve care. ONC selected provisions in its existing and newly proposed criteria that can support these clinical priorities, and developed worksheets to demonstrate how they would apply to pediatric care.

Overall recommendations to enhance the program

ONC should consider the following recommendations that can improve the overall program for EHRs used in the care of children.

- *Require All Use Cases*: ONC should clarify that only those technologies that meet all the required criteria can obtain the pediatric-focused certification. Otherwise, technologies may receive certification for some of the clinical priorities, and health care facilities may inadvertently believe that the system supports all 10 clinical priorities.

- *Develop Specific Guidance*: ONC should further develop detailed guidance or implementation specifications for each proposed pediatric clinical priority to assist EHR developers and testing organizations in assessing conformance with the pediatric clinical priorities. ONC has developed this type of guidance for certification in the past (e.g. the Certification Companion Guide).

- *Use Pediatric and Usability Expertise*: ONC should involve pediatric and usability experts in the development of implementation guides and test procedures for the pediatric clinical priorities. For example, ONC should involve pediatricians, pediatric nurses, and human factors experts in developing those resources.

Additional opportunities to map the criteria to pediatric care

In the proposed rule, ONC aligns the technical worksheets for each of the 10 clinical priorities with certification criteria from ONC's 2015 edition and changes made to the criteria through these regulations. ONC should extend that approach—mapping criteria from existing requirements—to other aspects of the pediatric-focused criteria in several ways.

- *Specify use of pediatric-focused test scenario:* Under current regulations, EHR developers must use testing scenarios to show that they comply with ONC's 2015 edition certification requirements.[27] These testing scenarios mirror real clinical events and workflows to demonstrate the functionality of their systems and compliance with ONC's criteria. For the pediatric-focused requirements, ONC should clarify that some of the testing scenarios used be EHR developers should involve pediatric patients and pediatric-specific factors.

- *Include pediatric end-users*: As part of those testing scenarios, EHR developers must involve at least 10 end users—such as doctors or nurses—to conduct the assessments under current regulations. As the proposed rule is currently drafted, pediatric end-users are not required to be involved in the testing of a product for pediatric-focused criteria. Recognizing the unique aspects of pediatric care, ONC should require the involvement of at least five pediatric-focused clinicians—such as pediatricians and pediatric nurses—among the 10 required for end-user testing for those technologies that are also meeting pediatric-focused criteria. Recognizing that some EHR developers may not have access to additional end-users for testing, the pediatric clinicians could be included within the minimum 10 end-user requirement, and not as an additional requirement.

- *Require use of simulated pediatric patient data*: EHR developers use data on simulated patients to demonstrate that their technologies meet ONC's certification program. ONC supplies some test data for those assessments.[28] For pediatric-focused criteria, ONC should supply test data for simulated pediatric patients and clarify that the test data used must involve simulated data of children

Improving medication safety for children

As part of the clinical priority for weight-based drug dosage for children, ONC proposes use of the National Council on Prescription Drug Programs SCRIPT Version 10.6 and optional Structured and Codified Sig Format—a standard to enable the efficient and safe exchange of prescribing information between clinicians, pharmacies, payers, and others involved in the patient's care.

Pew supports this provision as the optional Structured and Codified Sig Format provides more consistency in the way that drugs are prescribed (e.g. by specifying the dosage units of a liquid medications) and can support weight-based drug dosing calculations. This consistency can prevent confusion when filling a prescription.

ONC can take steps to advance patient matching

ONC's rule includes an RFI on patient matching to obtain input on steps the agency can take to address this challenge. In issuing this RFI, ONC correctly recognizes that to achieve interoperable exchange of medical data, health organizations must also know that they are communicating about the same person. Presently, up to half of the information exchanges made by health care organizations may fail to accurately match records for the same patient.[29] Congress, in Cures, also recognized that ineffective patient matching can inhibit interoperability by commencing a Government Accountability Office (GAO) study, which was released in January of this year.[30]

Ineffective patient matching can have patient safety and cost ramifications. Patients may receive inappropriate care and face the possibility of medical errors if information used for treatment is missing or inaccurate; one in five hospital chief information officers surveyed said that patient harm occurred within the last year due to a mismatch.[31] In an extreme example, the care for an 11-month-old twin was documented in her sister's record, resulting in the failure of the health system to recoup $43,000 in costs from the insurer.[32]

To accurately match records held at different health care facilities, organizations typically compare patients' names, dates of birth, and other demographic data to determine if records refer to the same individual. Health care facilities use algorithms to conduct these matches, and also employ staff to manually review records. This process often fails to accurately link records because of typos entered into the system; similarities in names, birth dates or addresses among different patients; changing information, such as when individuals move or get married; and many other reasons.[33]

While some private sector technologies—such as referential matching, wherein third-party data are used to support matches—show promise, market forces have been unable to solve the patient matching problem for decades. In fact, patient matching requires collaboration between unaffiliated organizations, even competitors, that lack the incentives to agree to a set of standards or develop systems that seamlessly exchange information.

Pew conducted two years of research—including interviews with health care providers, focus groups with patients, and contracted studies—to examine different ways to address matching challenges. This research revealed two critical ways that ONC can improve patient matching.

Standardize certain demographic data already collected

First, ONC should require the use of standards for certain demographic data elements—an approach long recommended by many other organizations, including Audacious Inquiry in a report contracted by ONC.[34]

In Pew-funded research published recently in the *Journal of the American Medical Informatics Association*, experts at Indiana University studied whether the standardization of different data elements improves patient matching rates.[35] Researchers attempted to match records in four databases, standardized the data in those databases, and then retried matching the records to determine whether that standardization yielded better results. The researchers culled tens of thousands of records from the Indiana Health Information Exchange; a county public health registry; Social Security's Death Master file; and a newborn screening laboratory. Each of these databases had already been reviewed to ensure that the record matches were accurate, which allowed researchers to understand the number of correct and inaccurate matches both before and after the standardization of select demographic data.

The research revealed that the standardization of address to the standard employed by USPS, which details the preferred abbreviations for street suffixes and states, for example, would improve match rates by approximately 3 percent. An organization with a match rate of 85 percent, for example, could see its unlinked records reduced by 20 percent with standardization of address alone. One technology developer indicated that this would help their system match an additional tens of thousands of records per day. Separately, standardizing last name to the standard used by the Council for Affordable Quality Healthcare—while showing limited utility on its own—would further improve match rates when coupled with address standardization. The research indicated that standardizing last name in conjunction with address could improve match rates from, for example, approximately 81 to 91 percent, which would reduce the number of unmatched records by half.

As mentioned earlier, ONC's recent regulations already propose embedding address in the USCDI, but the agency could further improve match rates by requiring use of the USPS standard. To further promote the use of this standard, ONC should also coordinate with USPS to ensure that health care organizations can use the postal service's online, API-based tool—or another easily accessible mechanism—to convert addresses to the USPS standard. There may also be scenarios—such as for military personnel stationed abroad—where the use of the USPS standard is not feasible. ONC could restrict use of the USPS standard to domestic, non-military addresses if challenges arise in the broader use of the standard.

Adopt additional data elements for patient matching

Second, ONC should advance the use of regularly collected demographic data elements for patient matching. ONC currently requires EHRs to make some demographic data—such as

name, birth date, and sex—available, and proposes to add address and phone number to the USCDI. However, health records contain other demographic data routinely collected that aren't typically used or made available to match records.

For example, research published in 2017 showed that email addresses are already being captured in more than half of patient records.[36] The documentation of email is likely higher today, given the adoption of patient-facing tools, like portals, that often require emails to register.

ONC could improve match rates by identifying and including in the USCDI readily available data elements—such as email address, mother's maiden name, or insurance policy identification number—that health information technologies could use for matching.

Specific responses to questions in patient matching RFI

ONC seeks input on various approaches to address patient matching, minimum data requirements, and measures to assess performance of different solutions.

First, ONC requests input on the potential effect that data collection standards may have on the quality of health data that is captured and stored. ONC also requests input on solutions that may increase the likelihood of accurate data capture, including the implementation of technology that supports the verification and authentication of certain demographic data. As mentioned above, use of the USPS standard for address would improve match rates, and does not require the capture of information in this format given the availability of online tools to conduct the conversion.

Second, ONC solicits information on additional attributes that could aid patient matching, and new data that could be added to the USCDI or further constrained within it to support patient matching. As previously mentioned, ONC should examine additional data routinely collected in EHRs to also use for matching—such as email address, health insurance ID, mother's maiden name, and others.

Third, ONC seeks comments on potential solutions that involve patients in the capture, update and maintenance of their own demographic and health data. Pew collaborated with the RAND Corporation to examine patient involvement in record matching.[37] The research revealed two key ways for patients to support record matching. For one, patients could validate their demographic information by verifying their mobile phone number and other data. In addition, EHRs could support smartphone applications that use standard APIs to allow patients to update their demographic data. ONC and the technology industry could pilot these patient-led approaches.

Fourth, ONC requests input on other innovative approaches to address patient matching. Pew research revealed a promising approach to patient matching that has not yet been widely used in health care: biometrics, such as fingerprint or facial recognition scans. In Pew-led focus groups on patient matching, patients overwhelmingly preferred the use of biometric over other options.[38] Patients in the focus groups indicated that they already use biometrics in other aspects of their lives—such as to unlock smartphones or board airplanes—and should be able to use the same approach for record matching. Pew intends to conduct further research on how the health care

system could use biometrics to match records across different organizations while protecting patient privacy and the security of data.

Finally, ONC seeks input on performance measures and indicators that can be used to evaluate patient matching algorithms. Benchmarking different approaches would help shed a spotlight on matching deficiencies and the wide variation in quality across different algorithms. Technology developers could then use that information to improve their algorithms, and health care providers could adopt the most promising approaches. ONC should work with CMS to determine how to benchmark different matching approaches; this likely requires the identification of a large, real-world data set to test different algorithms. The use of real-world data, rather than synthetic data, is essential given that some innovative approaches—such as referential matching—use third-party databases to support their algorithms. This benchmarking could assess duplicate creation rates, the number of records correctly matched, and the frequency with which records are incorrectly merged.

Pew-funded research can inform approach to EHR-registry data exchange

ONC also includes another RFI on how to implement a section of Cures that requires EHRs to be able to send data to and—where applicable—receive data from clinical registries. Registries collect data on patients with similar conditions—such as heart failure or joint replacement—to support quality improvement efforts, public health, and conformance with requirements from health plans to measure physician performance.

However, clinicians and hospitals may report to multiple registries, which may use a range of standards for data elements. Even when registries collect similar clinical concepts—like whether the patient uses tobacco products—that information can be depicted in different formats or standards. As a result, health care providers may have to transform data collected in EHRs into the specific requirements of each registry—which is often accomplished through employing additional personnel or hiring a contractor. That variability both inhibits interoperability and introduces burdens on health care providers. Recognizing this challenge of data submission to registries, Congress tasked ONC with issuing new criteria to ease the exchange of data from EHRs directly to registries.

Duke-led research provides a framework for registry data exchange

To explore these challenges, Pew funded the Duke Clinical Research Institute (DCRI) to provide data on the variability in data elements and standards among registries. DCRI collected case report forms, data dictionaries, and other documentation from 38 registries across various clinical domains, including cardiology, ophthalmology, obstetrics, and gastroenterology. DCRI then identified data elements that the registries have in common and the standards used to record common information. Building on that information, DCRI developed recommendations for a data model and baseline standards—based on FHIR—that registries should use. DCRI then convened the registries and other experts to discuss the findings and develop adoption strategies for the recommendations. The full research findings are available on DCRI's website.[39]

DCRI's findings include:

- *Lack of common data elements*: Generally, registries collect few common data elements. Some of the more commonly collected data elements include: name, sex, tobacco use, weight, height, and blood pressure. However, even some of the more regularly collected information was not ubiquitously included. For example, approximately half of registries collect height and weight.
- *Varying standards used:* Even for those data elements collected with a higher frequency, registries obtain the information in different ways. For example, some registries collect information on care team members via National Provider Identifiers, while others did not.
- *Non-conformance with ONC requirements*: Registries also did not uniformly use standards already required by ONC for EHRs as part of the certification program. For example, ONC's 2015 certification requirements include specific standards for depicting tobacco use via the Systematized Nomenclature of Medicine (SNOMED) standard, though registries generally used a different approach for that information.

Given the analysis conducted by DCRI, ONC should incorporate many of the data-driven, FHIR-based recommendations borne from this research into its requirements for EHRs. DCRI created an implementation guide to support implementation of the recommendations; ONC could reference this guide, such as via the API Resource Collection in Health proposal. Other organizations—including a group of registries convened by the Food and Drug Administration—are already incorporating the DCRI recommendations into their approach; complementary action by ONC could fuel adoption among EHRs.

Greater alignment—such as through the adoption of DCRI's recommendations—between the requirements for EHRs and the way registries collect data can fuel more efficient interoperability and reduce the burden on health care providers to report data for public health and quality improvement programs.

Health IT communications sharing of screenshots can improve usability, safety

In 2012, the Institute of Medicine reported on restrictions in EHR developer contracts—such as nondisclosure or intellectual property clauses, often referred to as "gag clauses"—with health care providers that prohibit the sharing of information on the system.[40] These clauses have inhibited the ability of health care providers and researchers to share information—including screenshots—on EHRs to identify common problems in the design or implementation of systems that can contribute to usability and patient safety problems.

Congress in Cures sought to address this barrier to improving EHRs by banning the use of these clauses. In implementing this provision, ONC limits the use of clauses that restrict the sharing of information on EHRs, including via dissemination of screenshots, social media posts, written reviews, peer-reviewed statements, online forum posts, and other modes of communicating information. ONC provides some exceptions to this policy, such as to protect EHR developers' trade secrets or communications related to unreleased products.

Pew supports ONC's proposal to enable the sharing of information on EHRs. The availability of screenshots and other data can foster collaboration among EHR developers, health care providers,

and researchers to better understand systemic challenges associated with the use of health information technology. For example, the sharing of screenshots can help different health care facilities understand whether a proposed customization or implementation of an EHR has introduced safety-related challenges at other facilities. The sharing of information can also foster the identification of solutions to common problems, such as whether certain facilities successfully addressed a common usability challenge.

Conclusion

The bipartisan passage of Cures launched a new era for improving EHR interoperability and patient safety. Now, with these proposed regulations, ONC has an opportunity to fulfill that promise. In these regulations, ONC proposes critical steps to better equip patients and clinicians with data, and address deficiencies in the safety and use of EHRs. In finalizing the regulations, ONC should:

- Support the implementation of secure, standard API access to a wide range of health data;
- Facilitate the export of all EHI so patients and health systems can obtain and control their information;
- Advance information blocking rules to promote data exchange across systems;
- Expeditiously advance adoption of these new capabilities by both EHR developers and health care provides;
- Consider how the new criteria and future ONC work could complement existing strategies to address the opioid epidemic;
- Focus on patient safety and EHR usability throughout the implementation of certification for EHRs used in pediatric settings;
- Address patient matching via better data standards;
- Adopt best practices recently developed to facilitate data exchange between EHRs and registries; and
- Enable the sharing of EHR screenshots to promote the identification of systemic usability challenges and solutions that can improve safety.

Aside from this rule implementing Cures, ONC also has indicated its intention to begin rulemaking to implement other aspects of the law, including the EHR reporting program to collect and make public data on different systems. As ONC implements that aspect of Cures in future rulemaking, we urge ONC to make safety a central tenet of the usability criteria of that program.

Thank you for the opportunity to provide comments on this proposed rule. Should you have any questions or if we can be of assistance, please contact me at 202-540-6761 or jrising@pewtrusts.org.

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