PREMIER TRANSFORMING HEALTHCARE TOGETHER®

June 3, 2019

Donald Rucker, MD
Office of the National Coordinator for Health Information Technology
330 C Street SW
Washington, D.C. 2020

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

Submitted Electronically: https://www.regulations.gov/comment?D=HHS-ONC-2019-0002-0001

Dear Dr. Rucker,

On behalf of the 4,000 U.S. hospitals and health systems and more than 165,000 other providers and organizations in the Premier healthcare alliance, we are pleased to submit these comments in response to the Office of the National Coordinator for Health Information Technology (ONC) proposed rule on 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program. The Premier healthcare alliance, a 2006 Malcolm Baldrige National Quality Award recipient, maintains the nation's most comprehensive and largest healthcare databases in the industry. Premier works with its members on utilizing informatics, analytics, and data to improve care quality and patient safety, while achieving cost efficiencies. With integrated data and analytics, collaboratives, supply chain solutions, and advisory and other services, Premier enables better care and outcomes at a lower cost. Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. In the comments below, we provide general comments about ONC's overall approach and strategy and then offer comments and recommendations about specific proposed provisions.

GENERAL COMMENTS

ONC's proposed rules along with the CMS Proposed Patient Access and Interoperability proposed rules are a good start to further advance nationwide interoperability. We strongly support the overall intention and direction of the proposed rules and believe they will be an important step forward in creating a more dynamic, competitive and innovative healthcare information technology (IT) ecosystem. The proposed rules begin to address technical, business and behavioral issues that impede health IT market competition as well as interoperability and data access.

It is essential to address ongoing interoperability challenges so that providers can improve care delivery, patient safety and performance, and to drive operational efficiencies. Premier continues to advocate for, develop and implement innovative solutions to achieve open data access across health IT systems and technologies to support the industry's value-based care transition across the care continuum. Interoperability will enable systems to move beyond simply recording data in electronic health records (EHRs) toward integrating and combining data to streamline analytics on supply chain, financial, public and population health and clinical care for evidence-based decision-making. Without connectivity across the care continuum, data collection is fragmented and does not provide the total picture necessary for healthcare providers to deliver informed, coordinated care. Premier's overarching comments focus on the following aspects of the proposed rules:

- Ensuring increased provider data access and availability at the point of care and within workflow
- Reducing provider burdens
- Clarifying terms and terminology
- Considering privacy and security issues

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Provider Data Access and Availability at the Point of Care and within Workflow

We are concerned that the proposed rules do not adequately ensure that providers have access to real time information on their patients at the point of care. Providers need robust, scalable, and interoperable health IT systems and EHRs to improve clinical decision making and deliver safe, coordinated and effective care and to improve outcomes. **ONC should focus additional attention on the ongoing need for providers to have real time access to data at the point of care and within workflow**. Data are essential to achieve the vision of a patient/consumer-centered and healthcare provider-driven healthcare system. Premier wholeheartedly supports expanding patients' access to their healthcare data. We are concerned, however, that the proposed rules emphasize data access to patients and consumers without ensuring that providers have unfettered access to their patients' health data.

The inability to access and integrate timely and complete data across the care continuum from multiple sites of service, diverse providers and various data sources threatens quality of care, patient safety and efficiency. The lack of access to complete and timely data adds inefficiencies and costs to the healthcare system and hampers population health efforts, public health surveillance and reporting.

The movement towards value-based care and alternative payment models has created an even greater imperative for health information exchange and interoperability. Advanced payment models such as accountable care organizations (ACOs) and bundled payments involve participation by multiple providers, suppliers and payers who are at risk for coordinating the care of patients, requiring the ability to access and aggregate information from different EHRs, health IT applications and across multiple facilities and care settings.

Healthcare providers (especially under risk-based care and advanced payment models) have inadequate and limited access to timely and complete Medicare, Medicaid, Children's Health Insurance Program (CHIP), Veteran's Affairs (VA) and Tricare data. Missing and lagged data prevent providers from treating and managing care for individuals, populations and communities.

We urge ONC to adopt standards and related implementation guides for the transmission of data to and from EHRs (read-write capabilities) and ensure that applications of the providers' choosing can be successfully used within the clinical workflow. In its Request for Information (RFI) about registries, ONC seems to suggest it is considering read-write capabilities to and from EHRs and third-party applications. We urge ONC to consider other use cases beyond registries, such as clinical surveillance, clinical decision support and electronic prior authorization. We also urge ONC to focus additional attention on improving EHR usability.[1] [2]

Reducing Provider Burdens

We are pleased that CMS and ONC continue to articulate their commitment to reduce unnecessary regulatory data collection, documentation and reporting burdens and to reduce related costs for providers. Nevertheless, we believe that the proposed rules will likely result in greater burdens and costs. For example, the proposed ONC information blocking rule creates conflicting requirements, such as those under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Substance Abuse Confidentiality Regulations (42 CFR Part 2 regulations) that will require additional provider due diligence to ensure compliance. **We urge the agencies to undertake additional efforts to further align federal programs to reduce provider burden and eliminate redundant and unnecessary reporting.** Furthermore, we strongly recommend that the agencies more closely coordinate their rulemaking to avoid duplicative, ambiguous or conflicting requirements**.**

[1] G Talley Holman, Steven E Waldren, John W Beasley, Deborah J Cohen, Lawrence D Dardick, Chester H Fox, Jenna Marquard, Ryan Mullins, Charles Q North, Matt Rafalski, A Joy Rivera, Tosha B Wetterneck; Meaningful use's benefits and burdens for US family physicians, Journal of the American Medical Informatics Association, Volume 25, Issue 6, 1 June 2018, Pages 694–701, https://doi.org/10.1093/jamia/ocx158

[2] MGMA Regulatory Relief Survey, October 2018, Available at https://www.mgma.com/getattachment/0dcef899fe2c-4225-ac94-5820df6475cf/MGMA-Regulatory-Relief-Survey-2018.pdf.aspx?lang=en-US&ext=.pdf

CMS' proposed requirements for the hospitals' Conditions of Participation (CoPs) will create additional burdens on providers. CoPs create an extreme penalty (i.e. potential exclusion from Medicare). The proposed CoP would require hospitals to demonstrate that their EHRs are generating patient event notifications. It is important, therefore, for **ONC to incorporate requirements for event notifications within the U.S. Core Data for Interoperability (USCDI), the base EHR definition criteria, and the certified health information technology program (CEHRT).**

Implementation Timeline

We urge ONC to re-consider the effective date of these rules for providers. While 24 months may be enough for health IT developers to create, test, and certify the new functionality, it is not feasible for providers to implement the vast number and type of changes proposed in these rules within the same 24-month time period. ONC should ensure that providers have additional time (for example, a minimum of an additional 12-24 months from the date they receive the "new EHR" from their vendors) to test and implement the new system along with adequate time to train staff. Additional time beyond the proposed time period in these rules, is needed for providers to work with their EHR vendors on contact modifications. Furthermore, a **period of non-enforcement is needed to allow providers** to adjust to the new requirements, especially those related to EHI and information blocking. ONC needs to work with CMS to harmonize the timelines with associated CMS Program requirements.

Clarifying Terms and Terminology

The ONC proposed rule presents and defines various terms and terminology in overly broad, vague and potentially ambiguous and inconsistent ways that will result in unintended consequences. Premier believes that there are significant technical, logistical, practical, operational, and legal concerns about the proposed definitions, terms and terminology and their applicability, including how the terms relate to each other and to the potential implication of the information blocking rule. In the sections below, we identify concerns with ONC's proposed terms, definitions and their use and we **recommend actions that ONC should take to reduce the likelihood of misinterpretations and unintended consequences**.

Considering Privacy and Security Issues

ONC's proposed rule assumes that existing privacy and security laws, regulations and guidances are adequate and appropriate. However, we believe that ONC understates the privacy and cybersecurity risks and potential liabilities[3] by requiring patient access to health data via third-party applications. These third-party application developers are typically not covered by HIPAA because they offer their applications directly to consumers and not on behalf of a healthcare provider or health plan. ONC and HHS should take additional steps to ensure a more thoughtful approach to how providers, who are covered by HIPAA as covered entities or business associates, share electronic health information (EHI) with non-HIPAA entities, and should require such third party applications to appropriately safeguard protected health information (PHI).

ONC ignores concerns about the potential privacy and security risks created by allowing patients to choose third-party applications to connect to EHRs via open application programming interfaces (APIs). We are concerned that ONC's proposed rule may apply the information blocking prohibition too broadly and establish privacy and security exceptions to information blocking too narrowly. As we further discuss in these comments, we **recommend that ONC further narrow the definition of EHI in the final rule**. As the definition of EHI plays an important role in determining whether an activity triggers information blocking restrictions or conditions of certification requirements, the breadth of this definition as currently proposed could lead to unintended consequences, especially pertaining to privacy and security of health data.

We are concerned that ONC does not recognize the complexities of patient access to data and the need for additional privacy and security safeguards. ONC should acknowledge and pro-actively address the

[3] Health Care Industry Cybersecurity Task Force (HHS), Report on Improving Cybersecurity in the Health Care Industry (2017), https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf .

complexities and implications for privacy and security, especially related to data access that occurs outside or beyond the scope of HIPAA.[4] We urge **ONC to work with CMS to develop and align criteria and tolerable risk levels appropriate to assessing risk of an API for allowing third party applications selected by the patients to access their health data.**[5] [6]

We note that the Office for Civil Rights (OCR) has recently issued new FAQs (frequently asked questions) to address how HIPAA Rules apply to covered entities and their business associates with respect to the right of access, applications and APIs. The OCR FAQs explicitly pertain to electronic protected health information (ePHI) from the "electronic health record (EHR) system", whereas ONC refers to electronic EHI. Therefore, we are concerned that the recent OCR FAQs are not applicable to the provisions of the ONC or CMS proposed rules. We urge ONC and CMS to work with OCR to develop focused informational materials (such as FAQs and guidances) about information blocking and patient access to ensure that stakeholders are more fully informed once these rules are finalized and implemented.

The Federal Trade Commission's (FTC) Health Breach Notification Rule[7] is also relevant to ONC's rules requiring patient access to health data and should be used to help further educate patients. We recommend that CMS and ONC work with OCR to harmonize the use of terms (i.e., health IT; EHRs; PHI; ePHI; EHI; health IT systems) within the final rules and with existing privacy and security legislation and regulations. Premier strongly believes that providers need access to patients' information to provide safe and effective care. We believe that **HHS should harmonize state and federal privacy policies so that providers can exchange and share all PHI for treatment, payment and operations purposes**.

We believe that **ONC understates concerns that unscrupulous actors could use direct-to-consumer applications to profit from obtaining and using or disclosing PHI without the individual's authorization**.[8] The proposed fee structure (free data access for patients) may result in additional unintended consequences such as compromised or bogus efforts to obtain data "on behalf of patients." Furthermore, we note that CMS has established specific processes for third-party application developers to access patient data under CMS' Blue Button 2.0 initiative and to register a beneficiary-facing application[9]; however, ONC does not appear to contemplate a similar process for third-party applications accessing patient data under these proposed rules. According to the proposed rule, an Actor cannot conduct "verification" checks on individual third-party applications before allowing the application to connect to its API, but rather must conduct such "verification" on the developers themselves and must complete the process within five business days. Although ONC provides some examples of acceptable "verification" processes in the proposed rule, the permissible scope and purpose of "verification" is still unclear given that the Actor is not permitted to seek additional information about the third-party developer's application or its security readiness. **We recommend that ONC provide further guidance on the types of "verification" that will be permitted and permit providers to undertake some form of review of third-party applications themselves before permitting them to connect to their APIs**.

We recommend that ONC consider additional steps to help ensure the quality and reliability of the applications used by patients to access their data.[10] [11] HHS should consider the need for a more robust comprehensive vetting or registration process beyond what is depicted in these proposed rules, for

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[4] Risky Business? Sharing Data With Entities Not Covered by HIPAA https://www.manatt.com/Insights/White-Papers/2019/Risky-Business-Sharing-Data-With-Entities-Not
[5] Grundy Quinn, Chiu Kellia, Held Fabian, Continella Andrea, Bero Lisa, Holz Ralph et al. Data sharing practices of medicines related apps and the mobile ecosystem: traffic, content, and network analysis BMJ 2019; 364 :l920
[6] Huckvale K, Torous J, Larsen ME. Assessment of the Data Sharing and Privacy Practices of Smartphone Apps for Depression and Smoking Cessation. JAMA Netw Open. 2019;2(4):e192542. doi:10.1001/jamanetworkopen.2019.2542
[7] https://www.ftc.gov/tips-advice/business-center/guidance/complying-ftcs-health-breach-notification-rule
[8] Fougerouse PA, Yasini M, Marchand G, Aalami OO. A Cross-Sectional Study of Prominent US Mobile Health Applications: Evaluating the Current Landscape. AMIA Annu Symp Proc. 2018; 2017:715–723. Published 2018 Apr 16.
[9] https://bluebutton.cms.gov/
[10] de la Vega R, Miró J. mHealth: a strategic field without a solid scientific soul. a systematic review of pain-related apps. PLoS One. 2014;9(7):e101312. Published 2014 Jul 7. doi:10.1371/journal.pone.0101312
[11] https://xcertia.org/the-guidelines/

third- party applications.[12] [13] We propose that ONC and OCR work with the private sector to develop a privacy and security trust or certification framework for third party applications seeking to connect to APIs of certified health IT. Once established, ONC should permit developers of certified health IT and healthcare providers to limit the use of their APIs to third party applications that have agreed to abide by the framework.

ONC should take proactive steps to ensure that patients, beneficiaries, enrollees and their caregivers will be able to understand the nuances of privacy and security of their health data, especially when such data is shared with third-party health applications. We recommend that HHS develop and launch a broad educational and outreach campaign to advise stakeholders, especially patients and their caregivers, about privacy and security of their health information, especially focusing on the risks and challenges when connecting to third-party applications that are beyond the scope of current federal regulations, such as HIPAA and 42 CFR.

Privacy and Security Transparency*.* ONC proposes two new privacy and security attestation requirements for developers of certified health IT to indicate whether the certified health IT supports encrypting authentication credentials and/or multi-factor authentication. Premier believes that certification to these required attestations will help increase transparency and potentially motivate health IT developers to encrypt authentication credentials and support multi- factor authentication.

Premier notes that under HIPAA, covered entities and business associates may evaluate whether it is reasonable and appropriate to implement both encryption of authentication credentials and multi-factor authentication. We ask ONC to clarify that its decision to list these attestations on the Certified Health IT Product List (CHPL) does not create new requirements for healthcare providers to implement multi-factor authentication or encryption of user credentials unless their security risk analysis determines that the implementation of these safeguards is reasonable and appropriate to mitigate potential risk.

Data Segmentation for Privacy and Consent Management Certification Criteria*.* ONC proposes to modify the Data Segmentation for Privacy certification criterion to permit metadata tagging at the section and entry level. We are concerned with this proposed granular approach to data tagging for health information exchange, primarily due to our concerns that the proposed metadata tagging tools are not yet mature enough for release. In the proposed rule, ONC references studies and publications, but we believe these are insufficient to justify the proposed wide-scale implementation of data segmentation tools.

In the sections below, we offer comments about specific proposed provisions.

DEREGULATORY ACTIONS

Premier appreciates ONC's intentions to reduce provider burdens by proposing deregulatory actions but is not convinced that these actions will reduce provider burdens. Surveillance of certified health IT ensures the continued conformance of the functionalities and standards specifications required by certification. Surveillance activities can include randomized and reactive complaint-based surveillance. The purpose of surveillance is to ensure that certified health IT capabilities meet certification requirements, not just in a controlled testing environment, but also when they are used "in the field." We are particularly concerned about and **do not support the proposed removal of required randomized surveillance which we believe are needed to ensure continued conformance to certification requirements**.

ONC proposes to remove several certification criteria from the 2015 Edition that are included in the 2015 Base EHR definition. ONC includes reasons for the removal of criteria, such as "no longer needed for

[12] Larson RS. A Path to Better-Quality mHealth Apps. JMIR Mhealth Uhealth. 2018;6(7):e10414. Published 2018 Jul 30. doi:10.2196/10414
[13] Marceglia S, Fontelo P, Rossi E, Ackerman MJ. A Standards-Based Architecture Proposal for Integrating Patient mHealth Apps to Electronic Health Record Systems. Appl Clin Inform. 2015;6(3):488–505. Published 2015 Aug 5. doi:10.4338/ACI-2014-12-RA-0115

CMS' Promoting Interoperability programs"; "widely used, essential to clinical care, would be in EHRs if criterion did not exist"; "functionality widely adopted and does not facilitate interoperability; would be captured in an interoperable form by USCDI"; "may be constraining innovation"; and "little market demand, significant overlap with "transitions of care" criterion". Premier is concerned that prior and ongoing modifications to the definition of the base EHR will have unintended consequences when trying to track and assess effects of any edition's "new," "revised," and "unchanged" certification requirements. Furthermore, we believe that ONC overestimates the cost savings in the cost impact analysis in the proposed rule.

RECOGNITION OF FOOD AND DRUG ADMINISTRATION (FDA) PRECERTIFICATION PROCESSES

ONC proposes to establish processes that would provide health IT developers that can document successful certification under the Food and Drug Administration (FDA) Software Pre-Certification Pilot Program with exemptions to the ONC Health IT Certification Programs requirements for testing and certification of its health IT to the 2015 Edition "quality management systems" criterion and the 2015 Edition "safety- enhanced design" criterion, as these criteria are applicable to the health IT developer's health IT presented for certification. ONC requests input on whether it should establish its own new regulatory processes that are based primarily on evaluating the health IT developers rather than their health IT products. **Premier believes that it is premature for ONC to contemplate adoption of the FDA-Precertification Pilot program.** The proposed rules contain significant changes to the certification criteria as well as the conditions and maintenance of certification requirements. Further, **we recommend that ONC re-visit possible changes to ONC's certification methods, criteria and processes (such as establishing organization-level rather than product level certification after finalizing these rules and obtaining experience with their implementation**. We also recommend that ONC consider conducting its own pilot test to evaluate its proposed adoption of the FDA's approach.

UPDATING AND MAINTAINING THE 2015 EDITION CERTIFICATION CRITERIA

ONC proposes significant changes and modifications to the 2015 Edition Certification Criteria and proposes to modify rather than retire and replace the 2015 Edition Certification Criteria with a new Edition. We are concerned that by not updating to a new Edition, stakeholders and users will be confused about which version of 2015 Edition is referenced or discussed. **Premier recommends that ONC consider introducing a new Edition of Certification rather than propose changes to and retain the title of the current 2015 Edition.** Additionally, we urge ONC to adopt and publicly disseminate a predictable and visible schedule and timeline for potential CEHRT modifications and changes so that stakeholders can better anticipate and adequately plan for potential requirements.

It is also important that ONC develop, maintain and widely disseminate detailed information about the differences between certification criteria editions and offer stakeholder education. Contributing to potential confusion is ONC's proposal to update code sets for several 2015 Edition certification criteria as part of USCDI v1 adoption. Over time, the health IT certification process and program are used for other purposes beyond the CMS Promoting Interoperability program, including HHS delivery of reform and clinical transformation programs that seek to leverage health IT certification.[14] While the Promoting Interoperability Programs continue to require the use of certified health IT, the use of certified health IT has expanded to other government and non-government programs.[15]

Also contributing to potential misunderstanding is that ONC once again is proposing to make changes to certain certification criteria, including criteria such as: "problem list"; "smoking status"; "medication list"; "medication allergy list" ; and "drug formulary and preferred drug list checks;" and others that are not currently included in the 2015 Edition Base EHR definition (at §170.102.) to the definition of the base

[14] ONC Fact Sheet: Voluntary 2015 Edition EHR Certification Criteria ("2015 Edition") Proposed Rule
[15] https://www.healthit.gov/topic/certification-ehrs/programs-referencing-onc-certified-health-it

EHR (Patient-specific education resources; Common Clinical Data Set Summary (CCDS) Record – Create; Common Clinical Data Set Summary (CCDS) Record – Receive; and Secure Messaging). Therefore, over time the description of what constitutes a "base EHR" evolves.

ADOPTING THE USCDI STANDARD

ONC proposes to replace the CCDS definition with the USCDI standard and to remove the CCDS definition and all its references from the 2015 Edition. ONC further proposes to include in the USCDI v1 the newest versions of the CCDS "minimum standard" code sets that are available at the time of publication of a subsequent final rule. **Premier recommends that ONC provide additional details, including a specific timeline and schedule, about planned process for future USCDI expansion that would be predictable, transparent, and open to stakeholder participation.**

ONC proposes to add Address & Phone Number, Pediatric Vital Signs, Clinical Notes, and Provenance to the current CCDS data classes and elements as part of USCDI v1; and proposes revisions to two data classes: Unique Device Identifier (UDI) and Medication. **Premier suggests that ONC consider specifying use of the United States Postal Service (USPS) and clarifying which phone number(s) to include (such as cell phone number)**. We believe that additional specification will help address ongoing patient data matching challenges.

ONC proposes to adopt for the USCDI v1 the 8 clinical note types identified by Argonaut Project participants: (1) Discharge Summary note; (2) History & Physical; (3) Progress Note; (4) Consultation Note; (5) Imaging Narrative; (6) Laboratory Report Narrative; (7) Pathology Report Narrative; and (8) Procedures Note. **Premier recommends that ONC provide additional clarification about each of the proposed clinical note types to help ensure consistency and understanding of each note type**. For example, it is not clear if "Procedures Note" includes "Operative Report".

We believe that ONC's cost estimates do not accurately reflect additional provider implementation costs, including those related to ensuring compliance with HIPAA, 42 CFR and other federal and state privacy laws." Furthermore, Premier is concerned that the inclusion of eight new categories of clinical notes present significant complexities and challenges related to separating out 42 CFR Part 2 data. Many EHRs cannot segregate sensitive data from other data. Thus, we urge ONC to re-consider its information blocking (especially the privacy and patient harm) exceptions to explicitly address these practical considerations.

Medication

ONC seeks comment on removing the Medication Allergies element from the Medication data class and creating a new Substance Reactions data class having two elements within it – Substance and Reaction. ONC further proposed that medication allergies would be reported under Substance Reactions and non-medication substances would be reported using SNOMED CT©. Premier supports ONC proposed changes to separating out the allergen and the reaction.

Revising the Electronic Prescribing ("e-Rx")

ONC proposes to align health IT certification criteria with CMS' Medicare Part D e-Rx standards by adopting NCPDP SCRIPT 2010771 as the new standard beginning January 1, 2020. Premier supports adoption of the updated NCPDP SCRIPT standard for e-prescribing. However, ONC's proposal does not require use of the NCPDP electronic prior authorization (ePA) standard. Premier supports the adoption of the ePA standard approved by NCPDP to improve efficiencies in the prior authorization process, improve patient outcomes, reduce point-of-sale rejections, and improve the Medicare Part D member experience. Therefore, Premier recommends that ONC also adopt the NCPDP ePA standard.

Electronic Health Information (EHI) Export

ONC proposes to add a new certification criterion for "EHI export" to the 2015 Edition and to the 2015 Edition Base EHR definition. Our comments about the EHI export function are related in part to our concerns about ONC's proposed definition of EHI. **We believe that ONC's proposed definition of EHI is overly broad and expansive and will be burdensome and extremely costly to implement**. Furthermore, we recommend that ONC implement a transition period between the "data export" and "EHI export" criteria as part of the final rule.

ONC's proposed rule states that the scope of the criterion would encompass all EHI that a **health IT system** *produces and electronically manages* for a patient or a patient group and applies to that *health IT product's entire database*, including clinical, administrative, and claims data and data stored in separate data warehouses and *those outside of EHRs*. ONC's proposed definition of EHI also includes data that ranges from the oldest to the most recently available for the patient or patient group regardless of electronic format (e.g., includes PDFs). **We recommend that ONC consider the array of technical, technological, logistical, practical, economic and legal barriers to operationalizing their proposed definition of EHI and the proposed EHI export function before finalizing these rules.** Furthermore, as we discuss elsewhere in these comments, providers need to be able to adhere to applicable federal and state laws concerning release of information and conduct appropriate due diligence before providing data access.

ONC should clarify the scope of the EHI export in the 2015 Edition certification criteria and the related condition of certification. Premier believes that the proposed definition of EHI should be harmonized with existing definition of the legal medical record and designated record set and that the related EHI export function and implication of information blocking refer to data collected and maintained within the EHR, and specifically to the (standardized data elements within the) USCDI. As ONC implements updates to the USCDI, the definition of EHI would include the additional data. Additionally, ONC should clarify the definitions of several terms relevant to their discussion of EHI and EHI export, including "health IT system"; "timely," "unreasonable burden," "health IT product"; and "produces and electronically manages" and provide examples of each. We also request that ONC further explain "A health IT developer that manages electronic health information must certify health IT to the certification criterion in § 170.315(b)(10)." Additional clarity is needed to stipulate that this criterion refers to certified EHRs and NOT to all certified heath IT.

ONC notes that the minimum requirement of the new criterion would be a discrete data export capability rather than persistent, real-time EHI access, "although refusal to provide persistent or real-time access where a developer could reasonably do so might raise information blocking concerns." Premier is concerned about the disparity between the new requirement and the potential to implicate the information blocking rule. We urge ONC to harmonize the required functionality of the certification criterion with the information blocking rule (if the requirement is for a discrete data export capability then failure to provide discrete (but not persistent) data access should implicate information blocking). **We also ask ONC to clarify to what extent the EHR vendor or the provider using the EHR might implicate information blocking.**

ONC notes that the new criterion is intended to support two specific use cases: exporting a single patient's entire EHR upon request by the patient (patient access) and exporting the entire health IT database for a patient group upon request by a provider (system transition). ONC's rules should allow providers to perform the necessary due diligence in accordance with existing federal and state privacy laws (such as HIPAA) to confirm the patient's identify when responding to requests to provide access to data via the export function. ONC needs to further clarify the "EHI export" criterion as related to a provider's request for the data for all patients (when migrating to a new EHR). Additionally, **Premier believes that providers should be able to implement and use the EHI export function (and the FHIR-based API within the USCDI and base EHR) for additional provider-facing use cases (such as quality improvement, care coordination and population health analytics).**

ONC 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, there are currently insufficient standards 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 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 similar provisions on the accessibility of documentation—such as ensuring that EHR developers make the documentation freely available to the public without any login or other associated requirements.

Clinical Quality Measures – Report

ONC details the history of its endeavors to support electronic reporting of clinical quality measures (CQMs) by providers to CMS programs (e.g., end-to-end reporting). These have entailed adoption of the Category I and Category III Quality Reporting Document Architecture (QRDA) standards along with their related HL 7 and CMS implementation guides. ONC invites comment on whether to allow health IT modules certified to the "CQM–report" criterion to be tailored only to the standard (QRDA I or III) that matches the care setting targeted by the module's developers. ONC notes that the emerging FHIR standards combined with APIs are likely to prove more efficient for quality reporting than current approaches, and ONC seeks comment on the potential replacement of QRDA-based reports by FHIR-enabled APIs. **We are concerned that the proposed removal of HL7 QRDA standards from 2015 Edition CQMs may not achieve the envisioned burden reduction of multiple standards for developers and providers**. Premier suggests that consolidation of standards would more likely result in reducing provider burdens. The Joint Commission (TJC) and CMS hospital submission programs in 2018 had variations in the QRDA-1 submission validations and processing. For example, TJC implemented additional validations to ensure QRDA-1 files utilized the data template IDs specified in the current HL7 standard but CMS did not validate the template IDs. Removing the HL7 standards from the CMS Implementation Guide, unless also adopted by The Joint Commission, may increase the variation between hospital reporting programs and increase the burden on developers and providers to support multiple solutions for various submission programs.

Premier supports the adoption of FHIR v4-enabled APIs as a replacement for QRDA-based reports, but believes that published documentation aligning HL7 C-CDA, QRDA, and/or FHIR standards to the Quality Data Model used for eCQM calculation will allow for more consistent eCQM reporting and improved interoperability in clinical quality feedback between health systems and data registries.

Standardized API for Patient and Population Services

ONC proposes to adopt a new "Standardized API for Patient and Population Services" certification criterion (§170.315(g)(10)) to replace the current "application-access–data category request" criterion" (§170.315(g)(8)). Premier supports the proposed Standardized API for Patient and Population Services and its inclusion in the 2015 Edition Base EHR definition. However, Premier asks ONC to further clarify the relationship between this certification criterion (§170.315(g)(10)) and the proposed EHI export function since ONC notes that the standardized API would also support the two "EHI export" criterion use cases (i.e., patient access and system transition). **We urge ONC to continue its efforts to accelerate the development and adoption of standards for bulk data queries (requests for multiple patients' data) and the adoption of a FHIR-based population-level data API.**[16]

[16] The Intersection of Technology and Policy: EHR Population Level Data Exports to Support Population Health and Value https://www.healthit.gov/sites/default/files/page/2018-03/Population%20Level%20Data%20Export%20Meeting%20Summary%20Report_0.pdf

ONC proposes to require certified developers of health IT that are seeking certification under the API criterion to demonstrate functionality that would allow an organization (such as a case management vendor for a health plan) to query and receive data from the API concerning multiple patients. Given that there is not yet a consistent, standardized specification for FHIR servers to handle searches for multiple patients, ONC clarified that the developer may approach searches for multiple patients in the manner it deems most efficient to meet this proposed certification criterion. Although ONC's proposed EHI export criterion does not specify a content standard for the EHI export, as we have stated previously, **we believe that ONC should specify options for how the exported information is to be made available.**

We are concerned that the current lack of a standard for implementing population-level queries could result in implementation of solutions that raise privacy and security concerns as well as data quality and integrity shortcomings. We are concerned that certified health IT developers will implement different methodologies of varying maturity to match patients within the certified health IT to the patients listed in the population-level query. Each incorrect patient match represents a potential breach of protected health information, which could expose the healthcare provider implementing the API to potential liability under HIPAA.

We ask that ONC clarify that healthcare providers who choose not to implement the population-based query functionality would not be engaged in information blocking. We also ask that ONC clarify that healthcare providers that do elect to implement population-based queries have leeway under the privacy and security exceptions to information blocking to deny population-level queries if there are issues in matching patients within the system to the list of individuals that the querying party requested, or other security concerns.

Standards Version Advancement Process (SVAP)

As part of the proposed rule, ONC recognizes that API capabilities and associated standards will emerge over time. ONC notes that new and/or refined 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 to allow ONC to permit the adoption of a newer version of a standard on a voluntary basis. Premier supports this approach to give ONC flexibility to permit the use of updated standards.

Emerging Standards and Innovation

To inform future health IT policy, ONC invites comments about emerging standards as part of future ONC policymaking. ONC poses specific questions about Clinical Decision Support (CDS) Hooks and FHIR-based care plans. **Premier supports efforts to develop, adopt and implement CDS Hooks for real-time clinical decision support and to improve clinical workflow.** CDS Hooks can support clinicians during their decision-making process, ensuring appropriate information is provided at the point of care. Premier believes that CDS Hooks has applicability to other third-party clinical decision support services use cases beyond opioid prescribing and OUD prevention and treatment. We recommend that ONC prioritize CDS Hooks as a future certification criterion and as part of the base EHR definition.[17] [18]

A shared care plan is a critical concept for managing an individual's health across a continuum that includes both clinical and non-clinical settings, and ONC requests comment on the current maturity of existing and forthcoming technical specifications to support care plans and care plan data, as well as specific information that could be prioritized within a future USCDI data class focused on care plans.

[17] http://docs.smarthealthit.org/fhir-bulk-data-docs/export.html
[18] https://cds-hooks.org/

Premier supports ONC accelerating standards develop and adoption and implementation specifications for care plans and encourages ONC to prioritize this for future certification criterion and as part of the base EHR definition.

CONDITIONS AND MAINTENANCE OF CERTIFICATION

ONC proposes several requirements for Conditions and Maintenance of Certification; they involve information blocking; appropriate exchange, access, and use of EHI, communications regarding health IT; APIs; real world testing for interoperability; attestations regarding certain requirements and submission of reporting criteria under the EHR reporting program. **Premier recommends that ONC further clarify that these provisions pertain specifically to EHR vendors.**

Request for Comment on the Trusted Exchange Framework and Common Agreement (TEFCA)

In January 2018, ONC released a draft Trusted Exchange Framework and Common Agreement (TEFCA) for public comment. The first Draft TEFCA described a high-level proposed network of networks. However, it was difficult to determine to what extent the proposed architecture was reasonable and scalable across use cases, permitted uses and stakeholders. In previous comment letters, Premier urged ONC to further clarify and address the multiple dimensions of and approaches to data access, exchange and sharing and describe how the TEFCA will accommodate currently envisioned and future stakeholders, health IT technologies, public policies, permitted purposes, queries and use cases. ONC released TEFCA 2.0 in April 2019 and comments are due June 19, 2019.

ONC seeks comment on whether certain health IT developers should be required to participate in the TEFCA as a means of providing assurances to their customers and ONC that they are not taking actions that constitute information blocking or any other action that may inhibit the appropriate exchange, access, and use of EHI. **We believe that it is premature for ONC to make this a regulatory requirement until these proposed 21st Cures Act rules and the TEFCA is finalized.** We are cautiously optimistic that, once finalized, the TEFCA will help achieve nationwide interoperability as envisioned by the 21st Century Cures Act.

Communication

ONC proposes a condition of certification barring a health IT developer from prohibiting or restricting certain protected communications. Premier is generally supportive of ONC's proposal that a health IT developer may not prohibit or restrict the communication regarding: usability of its health IT; interoperability of its health IT; security of its health IT; users' experiences when using its health IT; and business practices of developers of health IT related to exchanging electronic health information.

Conditions and Maintenance of Certification: Application Programming Interfaces

ONC proposes initial requirements for health IT developers and their certified Health IT Module(s) as well as ongoing requirements that must be met by both health IT developers and their certified Health IT Module(s) under the Program. To implement the Cures Act's API Condition of Certification, ONC proposes new standards, new implementation specifications, and a new certification criterion as well as detailed Conditions and Maintenance of Certification requirements. The Base EHR definition would also be modified. In this rule, ONC proposes to adopt standards, implementation specifications, and a new API certification criterion to implement the technical requirements associated with the Cures Act's API Condition of Certification.

ONC proposes and defines several "Actors": "API Technology Supplier," "API Data Provider," and "API User." **Premier urges ONC to provide greater clarity in the final rule about actors to distinguish them from one another and to eliminate any overlap or situations where an entity could exist in more than one category**. We also recommend that ONC provide additional information (and examples)

of acceptable business practices and interactions between the API Technology Supplier, the API Data Provider and the API User, to clarify what activities are permitted to occur between them and under what circumstances.

API Condition of Certification Requirements

Under the proposed rule, the use of an application developer verification process would be optional. Premier has previously expressed our concerns about the potential challenges regarding third-party applications access to patient health data. We urge ONC to review the level and scope of vetting that may be necessary. We note that ONC's rules state that separate from this provision, API Technology Suppliers may establish additional mechanisms to vet application developers and that such mechanisms could fit into the "value-added services" permitted fee and result in the application being acknowledged or listed by the health IT developer in some special manner (e.g., in an "app store," "verified app" list). We are concerned that EHR vendors who choose to vet third-party applications would be able to charge for such vetting as a "value-added service" under the proposed rules.

ONC notes that an API Technology Supplier would be permitted to charge fees to an API Data Provider to recover the costs reasonably incurred by the API Technology Supplier to develop, deploy, and upgrade API technology for the API Data Provider. ONC proposes that any fees under this category of permitted fees could be charged only to the data provider(s) for whom the capabilities are deployed. We recommend that ONC further clarify why it believes it is inappropriate to pass such costs on to API Users (under the definitions proposed at 170.102, an API User creates software applications that interact with the APIs developed by the API Technology Supplier, and an API Data Provider is the organization that deploys the API technology (e.g., a health care provider)).

Proposed permissible and non-permissible fees

Premier supports ONC's proposal to limit the fees that health IT developers of certified health IT may charge to support the access, exchange or use of EHI, however ONC should clarify the nature and extent of some of the permissible fees – particularly the permissible fees unique to API technology and interoperability elements.

ONC proposes to permit API Technology Suppliers to impose fees equal to the "incremental costs reasonably incurred by the API Technology Supplier" to support the use of API technology deployed by or on behalf of an API Data Supplier. We ask ONC to provide further guidance on the types of costs that a developer could charge to permit API Data Suppliers to offer population-level queries to API Users. For example, we understand based on the proposed rule that an API Technology Supplier may charge "usage-based" fees for API usage for purposes other than patient access, exchange and use – which would include population-level queries. ONC notes, however, that the "usage-based" fees would need to be limited to the recovery of "incremental costs" directly attributable to "supporting API interactions at increasing volumes and scale within established service levels."

We request that ONC clarify that such usages fees must relate to the costs associated with actual hardware (e.g., server space) needed to support the increased volume of queries for non-patients and not the cost of implementing the population-level query functionality itself. As ONC proposed requiring health IT developers that certify to the API functionality to demonstrate the ability to perform population-level queries, we do not believe it would be appropriate for API Technology Suppliers to charge usage fees in order to recover the cost of developing this capability. We urge ONC to provide additional guidance on the permissible types of usage fees for population-level queries.

ONC also proposed to permit certified developers of health IT to charge royalty fees based on the "independent value" of the developer's "interoperability element" to a licensee's technology. ONC should provide further clarification on these two terms– "interoperability element' and "independent value" - to

ensure that this permitted royalty fee is not used to charge exorbitant fees to healthcare providers and others.

We understand from the proposed rule that ONC is hesitant to provide an exhaustive list of what constitutes an interoperability element, but it would be helpful if ONC could provide examples of technologies that would and would not fit into the broad definition it has offered for "interoperability elements." We are concerned that health IT developers could classify many different types of "technologies, services, policies and other conditions" as necessary means by which EHI can be accessed, exchanged or used. For example, some health IT developers currently charge royalty fees in order for alerts from third party clinical decision support application to be embedded into the developer's EHR, because the developer considers the EHR's code to be proprietary (and for the signaling of an alert to be a use of the proprietary code). We seek clarification on whether the code of an EHR itself could be considered a "means" by which EHI can be accessed, exchanged or used.

We also seek further guidance on calculating the "independent value" of an interoperability element to a licensee. ONC has indicated that health IT developers are prohibited from basing any fee on the revenue generated by a requestor based on access, exchange or use of EHI. It would seem difficult to calculate the independent value an actor's technology to a licensee without taking revenue into account. We ask that ONC provide guidance on how requestors and health IT developers should calculate the "independent value" and consider additional restrictions on the royalty that a health IT developer may charge. We suggest that cost recovery fees commensurate with the cost of designing and offering the interoperability element, along with "incremental costs" associated with higher levels of traffic through the interoperability element, would be enough.

Real World Testing

The Cures Act requires health IT developers to successfully test the real-world use of the technology for interoperability in the type of setting in which that technology would be marketed; this requirement is imposed as a Condition and Maintenance of Certification. Premier recommends that ONC provide more clarity around the care settings and venues that test plans must cover. For example, ONC needs to **clarify the minimum expectations regarding applicable care settings and venues** (such as types and numbers of settings, for the health IT product). Additionally, we recommend that ONC provide additional clarity and examples around several of the terms used in this section of the proposed rule (such as, "*scenario*"; "*use case*"; and "*workflow*").

For purposes of the Condition of Certification, ONC proposes that successful real-world testing includes that the certified health IT is exchanging EHI in the care and practice settings for which it is intended for use; and EHI is received by and used in the certified health IT. Elsewhere in our comments, Premier expresses our concerns about ONC's proposed extremely expansive and overly broad definition of EHI and related challenges about the EHI export function.

ONC proposes to limit the applicability of this Condition of Certification to developers with health IT modules certified to one or more 2015 Edition certification criteria focused on interoperability and data exchange. **ONC should provide clarity around how successful real-world testing can be met and reported for each of the proposed criteria**. We further recommend that ONC provide additional guidance about what will constitute a minimally acceptable testing plan with explicit content depicting the minimum requirements for each component of the testing plan

Premier supports ONC's proposal to require developers to submit publicly available annual prospective real-world testing plans as well as annual retrospective real-world testing. We believe that ONC needs to provide additional clarity around their requirement for "at least one measurement or metric associated with the real-world testing". Premier supports ONC's proposal that 2020 be considered as a pilot year in order to provide health IT developers enough time to develop and submit plans for a full year of real-world testing in 2020.

ONC needs to further clarify the extent to which health IT developers need to involve stakeholders (such as providers, users and clinicians) in the real-world testing. ONC should also provide guidance on real-world testing using simulated data. Additionally, ONC should adjust its estimates in the cost impact analysis to reflect provider involvement in real-world testing.

EHR Reporting Program (Criteria Submission)

The Cures Act requires developers to submit reporting criteria on certified health IT in accordance with the EHR reporting program. **Premier is concerned that ONC has not yet established the EHR Reporting Program and urges ONC to accelerate its development and implementation.** Although ONC issued a request for information (RFI) about the program in late 2018, ONC has not provided any updates or status reports about their plans and progress. Congress anticipated that providers would benefit from having comparative information to help make EHR acquisition and replacement decisions. Such information would be especially helpful to smaller hospitals and clinical practices and safety net providers. Frustration and disappointment with EHRs continue as evidenced by clinicians' ongoing concerns about EHRs such as: added paperwork; increased documentation; entering data during the patient encounter; lack of interoperability with other systems; and system failures.[19] [20] [21] Other indicators of dissatisfaction include the growing number of outpatient organizations looking to replace EHRs.[22] [23] Enabling providers and physicians to be more informed consumers of EHRs is critical to improving the selection, purchasing, implementation and replacement of EHRs and enhancing EHR vendors' accountability for product performance. It is important for ONC to continue efforts to publicly disseminate information about certified health information technology products—including information about usability, costs, security, interoperability, and compliance with standards.

Information Blocking Terms, Terminology and Definitions

ONC proposes definitions for several terms and concepts contained in the information blocking provision (Information Blocking (§171.103)). As we have stated previously, several proposed definitions and explanation for these terms and terminology are broad, vague, and/or potentially ambiguous and are therefore subject to misuse and/or misinterpretation and will likely result in unintended consequences. Premier offers comments and recommendations about definitions and terms and **we are especially concerned about how the application of terms and their definitions expose entities to penalties and the regulatory implications of defined practices and exceptions.**

- We urge ONC to develop mutually exclusive categories of *entities and actors*, to clarify roles and responsibilities so that entities can understand if and how specific provisions of the final rules will apply to them;
    - The proposed definition of a *health information network* (*HIN)* is too broad and could include organizations that are not networks; it should be more narrowly focused: For example, health plans, technology companies that handle health data and health information, and standards developing organizations (SDOs) or organizations that develop recommended interoperability polices are not networks but could, inappropriately, be included in the proposed definition. Within the rules, ONC notes that under certain circumstances providers, hospitals and health

[19] Need for EHR Reporting Program Physicians, Nurses Give Mixed Reviews on EHRs Improving Care Quality https://www.hcinnovationgroup.com/clinical-it/electronic-health-record-electronic-medical-record-ehr-emr/news/21078776/physicians-nurses-give-mixed-reviews-on-ehrs-improving-care-quality
[20] Stanford Medicine's 2018 National Physician Poll https://med.stanford.edu/content/dam/sm/ehr/documents/EHR-Poll-Presentation.pdf
[21] G Talley Holman, Steven E Waldren, John W Beasley, Deborah J Cohen, Lawrence D Dardick, Chester H Fox, Jenna Marquard, Ryan Mullins, Charles Q North, Matt Rafalski, A Joy Rivera, Tosha B Wetterneck; Meaningful use's benefits and burdens for US family physicians, Journal of the American Medical Informatics Association, Volume 25, Issue 6, 1 June 2018, Pages 694–701, https://doi.org/10.1093/jamia/ocx158
[22] https://www.healthcaredive.com/news/more-than-third-of-outpatient-providers-want-to-replace-ehrs-it-tools/553619/
[23] Outpatient EHR Replacement https://www.reactiondata.com/wp-content/uploads/2019/04/OutpatientEHRReplacementReactionDataFreemium.pdf

systems could be considered HINs, which presents significant additional challenges and concerns.
    - The proposed definition of a *health information exchange* (*HIE)* is also too broad and includes individuals, which seems incongruous. Furthermore, based on the definition, organizations that are not networks could be included. The definition needs greater clarity.
    - The distinction between *HIEs and HINs* is unclear.
    - The distinction between *EHR vendors and other health IT developers* is not clear. ONC should explicitly indicate when a requirement relates to EHRs and EHR developers and when requirements pertain to products certified to the base EHR definition
- The *health IT developer* definition is too broad and could include entities that only have one product certified to only one or a very few focused criteria, for example a quality reporting module;
- As part of its definition of *health IT developer of certified technology*, ONC notes that the information blocking rule is not limited to practices related only to certified health IT; it would apply to any practice by an individual or entity that develops or offers certified health IT that is likely to interfere with access, exchange, or use of EHI, including practices associated with any of the developer's or offeror's health IT products that have not been certified under the Program. Premier recommends that ONC re-consider its proposed inclusion of non-certified technology as this approach will be extremely burdensome and costly to providers and health IT developers and will stifle innovation;
- The proposed definition *of electronic health information* (EHI) is overly broad and expansive and will present significant challenges to implement as proposed. As we have stated before, we recommend a more focused definition of EHI to equal PHI. The current proposed definition is beyond Congressional intent (as expressed within 21st Century Cures). ONC needs to clearly depict specific data types and technologies that ware included within the definition. For example, to what extent and how would data captured by medical devices be considered EHI? Pertaining to information blocking, ONC should consider that the exchange of data elements contained within the USCDI serve as the basis for any implication of information blocking;
- ONC proposes to clarify that "*required by law*" specifically refers to any interference with access, exchange, or use of EHI that is explicitly required by state or federal law. However, this definition fails to address potential tensions between laws and/or regulations such as data relating to substance abuse disorder data and its regulation under HIPAA and 42 CFR;
- ONC's proposed definition of *likelihood of interference* seems especially subjective and subject to (mis) interpretation. Also contributing to the challenge and confusion is ONC's assertion that where there is a *reasonably foreseeable risk* that a practice will interfere with access, exchange, or use of EHI, it may violate the information blocking rule even if harm does not actually materialize. We urge ONC to further define *reasonably foreseeable risk* and provide examples*;*
- ONC presents and discusses another term within the rules --*observational health information* ("information created or maintained during the practice of medicine or the delivery of patient care, such as patient information in an EHR or other clinical information management systems when it is clinically relevant, directly supports patient care, or facilitates delivery of healthcare to consumers"). The definition is cumbersome and confusing and contains terms that need to be clarified ("clinical information management systems" and "clinically relevant");
- ONC needs to clarify that *data created through analysis, aggregation or algorithms* (such as population trends, quality measures and risk scores) are not electronic heath information subject to information blocking rules;
- ONC use of the term "*affiliated entities*" is unclear, vague and needs greater clarity;
- ONC notes that its definition of *interoperability element is intentionally broad to be able to* capture all potential means by which EHI may be accessed, exchanged or used for any relevant purpose, both now and as conditions evolve. ONC states that the means of accessing, exchanging, and using EHI are not limited to functional elements and technical information but also encompass technologies, services, policies, and other conditions necessary to support the many potential uses of EHI. We urge ONC to re-consider its use of "interoperability element" and to more narrowly focus the term;
- In earlier parts of this comment letter, we expressed concerns about the definitions of several terms relevant to ONC's discussion of *EHI* and *EHI export*, including "*health IT system"; "timely,"*

"unreasonable burden," "health IT product"; and "produces and electronically manages" and we urge ONC to provide examples of each; and

- We previously requested that ONC clarify "*A health IT developer that manages electronic health information* (must certify health IT to the certification criterion in § 170.315(b)(10))." ONC needs to stipulate that this criterion refers to certified EHRs.

RFI ON PRICE INFORMATION

ONC seeks comment on the parameters and implications of including price information within the scope of EHI for purposes of information blocking. ONC also notes that there is HHS-wide interest in understanding the technical, operational, legal, cultural, environmental and other challenges to creating price transparency within health care. Although ONC notes that it has chosen not to define price information, we urge ONC to do in the context of potential rulemaking. Premier supports price transparency for patients and providers. However, price information should not be included in the definition of EHI. Elsewhere in these comments, Premier has expressed our concerns about ONC's proposed expansive definition of EHI. We again **urge ONC to narrow its definition of EHI and not include price information.** ONC's proposed rules include changes that if adopted as proposed will add layers of significant complexities and potential unintended consequences. We do not support adding price information to EHI as there are other available mechanisms and policy levers to achieve some price transparency currently.

We urge ONC and CMS to undertake a more systematic and evidenced-based approach and leverage prior and ongoing efforts as they consider making price information available to patients and consumers beyond this RFI.[24] [25] [26] **We recommend that ONC work with CMS other federal agencies to convene and engage directly with public and private sector stakeholders**, including, hospitals and health systems, patient groups, payors, plans, insurers, standards development organizations (SDOs), clinicians, health services researchers, professional and trade associations, and medical specialty societies **to address issues about price transparency.** We believe that CMS and ONC should leverage CMS' proposed rules requiring payers to share data with patients via APIs and the requirement for payers to share data with providers to help achieve the price transparency contemplated in ONC's RFI. Additionally, we urge ONC and CMS to recognize the importance of health literacy and help ensure that patients understand price information and recognize the limitations and challenges of providing pricing information to patients.[27] [28] [29] In addition to considering price transparency for patients, it is essential that price information be made available to hospitals, health systems, physicians and other providers.

Premier recommends that ONC and CMS work with payers to identify approaches and establish methods for payers to make price information more accessible to patients and providers. CMS is currently making patients' claims data available to patients via the Blue button 2.0. Payers could provide real time data (such as cost estimates prior to and during the delivery of care) via APIs. Furthermore, ONC should work with CMS and other payers to ensure that price and payment information is

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[24] Gourevitch, R. A., Desai, S., Hicks, A. L., Hatfield, L. A., Chernew, M. E., & Mehrotra, A. (2017). Who Uses a Price Transparency Tool? Implications for Increasing Consumer Engagement. Inquiry : a journal of medical care organization, provision and financing, 54, 46958017709104. doi:10.1177/0046958017709104

[25] Berkman ND, Sheridan SL, Donahue KE, Halpern DJ, Viera A, Crotty K. The Challenge of Understanding Health Care Costs and Charges Vineet Arora, MD, MAPP, Christopher Moriates, MD, and Neel Shah, MD, MPP AMA J Ethics. 2015;17(11):1046-1052. doi: 10.1001/journalofethics.2015.17.11.stas1-1511.

[26] Understanding Healthcare Prices: A Consumer Guide https://www.aha.org/system/files/2018-04/14transparency-consumerguide.pdf

[27] Procedure Price Lookup: A step toward transparency in the health care system https://www.brookings.edu/blog/techtank/2019/01/30/procedure-price-lookup-a-step-toward-transparency-in-the-health-care-system/

[28] Desai S, Hatfield LA, Hicks AL, Chernew ME, Mehrotra A. Association Between Availability of a Price Transparency Tool and Outpatient Spending. JAMA. 2016;315(17):1874–1881. doi:10.1001/jama.2016.4288

[29] Price Transparency in Health Care: An Introduction Issue Brief 2014. http://familiesusa.org/sites/default/files/product_documents/HSI%20Price%20Transparancy%20Brief_final_web.pdf

standardized (and interoperable) across payers so that the information can be presented in a usable way and easily understood by patients and can be implemented by providers with little additional burden.[30]

ONC poses several questions suggesting that ONC contemplates requiring price information be included in EHRs. ONC also seeks comment on several types of price information, each with potential limitations and challenges. For example, reflecting charges paid for by the patient's health plan and the amount paid by the patient; including deductibles, copayments and coinsurance would place a huge burden on providers to update and reconcile this information after claims processing. Providers give patients initial estimates based on information provided by payers or insurers, but the amounts can change, in part due to whether a patient has met applicable deductibles. Additionally, it would be hard to determine how and what price information could be captured in the EHR. Multiple providers may interact with a clinician for an episode of care, in addition to any facility charges. It's unclear which charges, all or a portion, would be most beneficial to include as "price information". Regardless of the price information that may be most useful, most providers' billing systems remain separate from the EHR. Incorporating price information would require interoperability between billing and/or practice management systems and EHRs, a capability currently not widely deployed. We believe that **patients need to engage directly with payers or health insurers to determine accurate information about their potential financial responsibility for any given health care service**. A patient's responsibility will vary depending on payment plans negotiated with individual health insurers and unique circumstances based on each patient's experience.

Another type of price information considered by ONC is the charge master price, negotiated prices, pricing based on CPT codes or DRGs, bundled prices, and price to payer. This information would be difficult to incorporate into the EHR because it is not linked to an individual patient but rather is global information that varies by payer. Moreover, gross level costs are not useful to patients in that it does not consider contractual allowances, plan coinsurance structures, charity care policies and mission driven expenses such as teaching programs. It is difficult to identify the actual costs associated with care because the components such as staffing, overhead, and materials costs are accounted for inconsistently across the healthcare system and there is a lack of price transparency for underlying materials costs.

EXCEPTIONS FOR REASONABLE AND NECESSARY ACTIVITIES THAT DO NOT CONSTITUTE INFORMATION BLOCKING

ONC proposes seven exceptions that would apply to certain activities that do in fact interfere with the access, exchange, or use of EHI (i.e., constitute information blocking) but that are reasonable and necessary if certain conditions are met. For all the proposed exceptions, we believe that the proposed burden of proof for the exceptions is unreasonable and will likely result in additional provider administrative, reporting and compliance burdens and costs. We do not believe that ONC sufficiently recognizes the existing complexities and challenges of complying with various federal (such as HPAA and 42 CFR) and state laws and regulations. These complexities will become more difficult with the need for stakeholders to consider ONC's information blocking rules in addition to existing rules and regulations and will create excessive administrative burden. As we have previously stated, we recommend that ONC

[30] Berkman ND, Sheridan SL, Donahue KE, Halpern DJ, Viera A, Crotty K, Holland A, Brasure M, Lohr KN, Harden E, Tant E, Wallace I, Viswanathan M. Health Literacy Interventions and Outcomes: An Updated Systematic Review. Evidence Report/Technology Assessment No. 199. (Prepared by RTI International–University of North Carolina Evidence based Practice Center under contract No. 290-2007-10056-I. AHRQ Publication Number 11- E006. Rockville, MD. Agency for Healthcare Research and Quality. March 2011.

and HHS address ongoing and heightened cybersecurity risks faced by the healthcare stakeholders.[31][32] [33] [34] [35] The descriptions of the exceptions are complex and technical, and we urge ONC to simply them and to provide additional descriptions and examples in the final rules. The information blocking rules and related exceptions are overly complex, and if adopted as proposed, would create unnecessary administrative complexity and burdens. We recommend that ONC:

- Develop and conduct a broad outreach and educational program about the final information blocking provisions;
- Work with other agencies (including CMS, OIG, FTC and OCR) to develop and widely disseminate additional and more comprehensive informational materials, such as guidances and FAQs about information blocking;
- Provide more guidance on RAND licensing and its implementation;
- Align information blocking privacy and security exceptions with HIPAA and other existing federal regulations and laws;
- Allow hardship exceptions for providers' compliance with state-level health data privacy and security laws and regulations;
- Allow hardship exemptions for providers who did not qualify for HITECH's EHR incentives, especially those who do not currently have certified EHRs;
- Clarify why ONC proposes to define "individual" in a more expansive manner than the term is defined under the HIPAA Privacy Rule or in section 3022 of the PHS Act;
- Further clarify why ONC proposes to define EHI beyond ePHI;
- Provide explicit examples of health IT developers of certified health IT not covered by HIPAA and how/why such entities are not subject to these rules; and
- Provide additional clarification and examples of acceptable circumstances and actions when providers can respond to an individual's request not to share some of their health data information.

Privacy exception

Premier supports ONC's inclusion of an exception to information blocking that recognizes actors' interest in maintaining the privacy of PHI and complying with HIPAA and state privacy laws. We are concerned, however, that given the limited nature of the sub-exceptions and stringent documentation requirements for meeting them that actors will be understandably concerned about inadvertently triggering a penalty. To avoid doing so, actors may be unintentionally incentivized to overshare EHI without satisfying privacy-protective pre-conditions established by HIPAA and other laws, such as the verification requirements at 45 C.F.R. § 164.514(h). **We recommend that ONC clarify in the final rule that actors do not face penalties under the information blocking provisions when they elect to not disclose information in a good faith effort to comply with HIPAA, 42CFR and state privacy laws**. While it is possible that some actors may inappropriately seek to use privacy laws as a shield against disclosing EHI, the requirement that Actors decline disclosures only in good faith should significantly reduce this possibility, such that it is outweighed by the gained privacy and security protections for individuals by broadening the privacy exception.

As currently defined in the proposed rule, the privacy exception would require significant administrative complexity to implement. For example, in order to meet the "pre-condition not satisfied" sub-exception,

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[31] At the Nexus of Cybersecurity and Public Policy: Some Basic Concepts and Issues. Editors Committee on Developing a Cybersecurity Primer: Leveraging Two Decades of National Academies Work; Computer Science and Telecommunications Board; National Research Council; Clark D, Berson T, Lin HS, editors. Washington (DC): National Academies Press (US); 2014 Jun
[32] Cybersecurity in Hospitals: A Systematic, Organizational Perspective. J Med Internet Res. 2018 May 28;20(5):e10059. doi: 10.2196/10059.Jalali MS, Kaiser JP.
[33] Kruse CS, Frederick B, Jacobson T, Monticone DK. Technol Health Care. Cybersecurity in healthcare: A systematic review of modern threats and trends. 2017;25(1):1-10. doi: 10.3233/THC-161263.
[34] https://www.independent.co.uk/news/business/news/healthcare-is-now-top-industry-for-cyberattacks-says-ibm-a6994526.html
[35] https://www.himss.org/sites/himssorg/files/u132196/2018_HIMSS_Cybersecurity_Survey_Final_Report.pdf

the Actor not only needs to have written policies and procedures in place concerning the federal or state privacy pre-condition, but must also do "all things reasonably necessary within its control to provide the individual with a meaningful opportunity to provide" a consent or authorization to share the information.

Premier supports ONC's proposal that when individuals are directing the disclosure of their data, an Actor should be required to engage in the level of effort provided for in this proposed rule to try to satisfy a privacy pre-condition. For other use cases, however, we believe that Actors should be permitted to decide that it would be too burdensome to seek multiple consents or authorizations to share data at the request of a third party. **We urge ONC to provide examples or case studies to illustrate the application of this exception**. For example, if a case management service requests access data pertaining to multiple patients' substance use disorder treatment, the healthcare provider should not be penalized for deciding that it would be too difficult to seek consent or authorization from each applicable patient to share data with the case management service provider.

Premier believes that the key to unlocking information protected by state or federal laws that are more stringent than HIPAA is to harmonize state and federal laws to the HIPAA standard – thereby removing any preconditions to sharing the information for treatment, payment and healthcare operations purposes. Penalizing Actors for not engaging in "all things reasonably necessary within its control" to obtain consents or authorizations only stands to further aggravate the burdensome nature of more stringent privacy laws.

Given the existing patchwork of state privacy laws, however, Premier encourages ONC to adapt its proposal to permit Actors who operate across multiple states to implement the pre-conditions of state laws that are the most stringent for purposes of this sub-exception. It is often too difficult for organizations operating across state lines to develop different consent workflows for each state, and ONC is right to recognize that organizations instead will implement the most stringent state law. As long as Actors implement a state-mandated pre-condition consistently when responding to requests, we believe Actors should be permitted to select which portions of a state law to implement globally across states rather than being required to provide "all privacy protections afforded by that law across its entire business." It may be impossible to implement some aspects of a state law, such as data retention requirements, across state lines without violating the laws of another state. As a result, we believe **ONC should give Actors leeway to select which state law requirements they wish to apply globally as opposed to just the residents of the applicable state.**

Security exception

Security threats to EHI are constantly increasing, and any organization that transmits EHI must continue to exercise vigilance to ensure the security of the transmission. Premier supports ONC's proposal to establish an exception to the information blocking prohibition when an Actor denies access to information due to a tailored, non-discriminately implemented security practice directly related to safeguarding the confidentiality, integrity and availability of EHI.

Premier also appreciates that ONC provides two methods of denying access, exchange or use of EHI on security grounds: 1) on the basis of a written organizational security policy; or 2) on a case-by-case, facts and circumstances basis when the security practice is necessary to mitigate the security risk to EHI, and there are no reasonable and appropriate alternatives to the practice that are less likely to interfere with the access, exchange or use of EHI. While organizational security policies and procedures often provide strong processes for evaluating and mitigating risks, it can be difficult in a written organizational policy and procedure to address specific parameters for establishing differing levels of access to various systems that contain EHI. As a result, it is helpful that ONC has provided Actors an option to evaluate requests on a case-by-case basis to address potential security risks in a reasonable and appropriate manner. We believe ONC should **clarify in the final rule that Actors may apply the steps established**

by the security exception when "verifying" third party application developers prior to permitting them to connect to the API.

Additional Exceptions—Request for Information Re: Common Agreement

ONC is considering whether it should propose in future rulemaking a narrow exception to the information blocking rule for practices that are necessary to comply with the requirements of the Common Agreement. This would be intended to support adoption of the Common Agreement and encourage other entities to participate in trusted exchange. The exception would provide protection for practices expressly required by the Common Agreement or necessary to implement those requirements. ONC expects that its proposed exception would apply only to contract terms, policies and other practices that are strictly necessary to comply with the Common Agreement, and the exception would apply to practices that are no broader than necessary under the circumstances. **Premier believes that it is premature for ONC to make this a regulatory requirement until these proposed 21st Cures Act rules and the TEFCA is finalized.** We urge ONC to accelerate efforts to launch the TEFCA.

COMPLAINT PROCESS

Section 3022 of the PHS Act requires ONC to implement a standardized process for the public to submit reports on claims of health information blocking. ONC indicates that it will implement the process by building on existing mechanisms, including the current complaint process. ONC seeks comment on this approach. We support ONC's intent to build on existing mechanisms and recommend that **ONC develop a revised proposed complaint approach based on the final rules for public comment and to widely disseminate information about the compliant process.**

DISINCENTIVES FOR HEALTHCARE PROVIDERS REQUEST FOR INFORMATION

Section 3022(b)(2)(B) of the PHSA provides that any healthcare provider determined by the OIG to have committed information blocking will be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable federal law, as the Secretary sets forth through notice and comment rulemaking. ONC is requesting information on whether updates to disincentives or the modification of disincentives already available under existing HHS programs and regulations would provide for more effective deterrents.

Existing Disincentives

Providers currently face penalties for noncompliance in CMS programs. For example, the Promoting Interoperability program utilizes a performance-based scoring methodology inclusive of measures such as, support electronic referral loops by sending health information and provider to patient exchange of health information. Hospitals must meet the Promoting Interoperability requirements in order to receive their full market basket adjustment for payment. **Premier believes ONC should leverage existing mechanisms for provider disincentives for sanctioning those providers who are confirmed to be information blocking**. **We strongly urge the ONC to avoid layering additional disincentives on providers and instead utilize existing and more appropriate levers within existing programs to discourage information blocking**.

EHR Barriers

ONC should ensure requirements reflect the nature of current EHR functionality and capabilities and that disincentives are not in place for anything that is not possible within the functionality of CEHRT. Legacy EHR platforms impede and/or do not allow real time data flow between EHRs and the clinical workflow. Furthermore, data is locked in proprietary software systems at times preventing providers from being able to connect and exchange information. We recommend that the ONC oversight include monitoring EHR

systems and understanding the barriers that clinicians face in implementing EHR functions that support interoperability when assessing whether information blocking occurred.

Non-duplication of Penalty Structures in 21st Century Cures

The 21st Century Cures Act includes a subsection giving the Secretary the authority to ensure that penalties do not duplicate penalty structures that would otherwise apply with respect to information blocking. **Premier firmly believes that the existing penalties for noncompliance in the CMS programs are enough and the appropriate lever to hold providers accountable for information blocking.** Under no circumstances should providers be subjected to civil monetary penalties set aside for vendors, HIEs, or HINs, which can be as high as $1 million per violation. It is clear that Congress set up a distinct penalty structure specifically reserved for providers. The statute clearly articulates that providers charged with information blocking "shall be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rulemaking."

REGISTRIES REQUEST FOR INFORMATION

ONC discusses its activities related to implementation of sections 4005(a) and (b) of the Cures Act, which pertain to interoperability and bidirectional exchange between EHRs and registries and describes several public reporting requirements for which a lack of standardization has contributed to slow adoption of health IT systems among registries.[36] ONC seeks information on how IT solutions and the proposals in this rule can aid bidirectional exchange with registries for various purposes including public and population health, patient safety, quality reporting, and quality improvement. Premier appreciates ONC's request for stakeholder input to identify use cases where an API using FHIR Release 4 might support improved exchange between an EHR and a registry. **We support exploring the use of FHIR Release 4**.

Interoperability between EHRs and registries requires accurate and consistent data exchange and syntactic and semantic data and interoperability standards.[37] [38] [39] [40] EHR vendors, payers, and registries, however, often maintain different data, using various logic models, implementation profiles, and standards. There is a need to consider ways to better harmonize data, measures, standards and implementation guides, particularly when there are multiple different implementation specifications for the same measures across different reporting programs, with subtle nuances and differing results. The lack of consistency across a measure hampers the ability of providers to capture and report the necessary data. An example of this is NQF # 2372, Breast Cancer Screening: Percentage of women 50-74 years of age who had a mammogram to screen for breast cancer. The CMS eCQM requires a HCPCS, LOINC, or SNOMED code to indicate that a screening was performed whereas the registry CQM requires that a screening was performed AND evidence that results were documented and reviewed. Since the only code provided is a HCPCS G-code, it is up to registries to interpret what other codes or documentation may be acceptable.

We recommend that ONC convene and engage directly with public and private sector stakeholders, including other federal agencies (i.e., CDC and CMS), registry developers, payors, standards development organizations (SDOs), clinicians (registry users), EHR vendors, measure developers, professional and trade associations, public health entities and medical specialty societies). ONC needs to identify the potential common and unique requirements, needs and characteristics of different types of registries (i.e., clinical data registries; medical device registries; quality measurement,

[36] *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs*. December 2018. https://www.healthit.gov/topic/usability-and-provider-burden/strategy-reducing-burden-relating-use-health-it-and-ehrs
[37] Registries for Evaluating Patient Outcomes: A User's Guide [Internet]. 3rd edition. https://www.ncbi.nlm.nih.gov/books/NBK208625/
[38] Blumenthal S. (2018). Improving Interoperability between Registries and EHRs. AMIA Joint Summits on Translational Science proceedings. AMIA Joint Summits on Translational Science, 2017, 20–25.
[39] EHR and Registry Interoperability http://blog.ajrr.net/ehr-and-registry-interoperability
[40] https://www.apta.org/PTinMotion/2017/11/Feature/Registries/

reporting, and improvement; cancer registries; device registries; patient reported outcome registries; public health reporting registries). In addition, it is important to identify the common priority issues, current challenges and potential solutions. We recommend the following action items:

- Leverage ONC's ongoing efforts to adopt data standards and implementation guides for certified EHRs (such as the USCDI);
- Build on CMS' efforts to base measures and calculations (numerators/denominators) on data within certified EHRs;
- Advance private sector efforts to develop common data elements and systems interoperability[41]
- Explore the feasibility of shorter- and longer-term options. For example, in the shorter term, to the extent that registries currently collect and use standardized data from certified EHRs, consider adoption of an open API to allow registries to connect to and access data directly from EHRs;
- Transition to measures based on more well-defined clinical concepts that can be represented by available vocabularies (such as SNOMED CT, LOINC, RxNorm, ICD-10, and CPT);
- Harmonize use of standardized data classes and elements;
- Expand access to publicly available value sets defining clinical conditions, medications, patient characteristics, and care delivery that account for multiple data source types (e.g. EHR, billing, claims) that may be used to populate registries;
- Maximize electronic data collection, reporting and measures calculations;
- Leverage and expand on existing research relevant to the technological challenges in accessing, extracting, and aggregating electronic health record data;[42] [43]
- Assess the feasibility and use of controlled clinical vocabularies and aligned common data models and use of consistent units of measurement across measures, programs, and data stewards, registries;
- Address and assess various operational, technical and business case considerations pertinent to current clinical data collection methods and approaches as well as ongoing registry viability. It is critical to consider existing data collection, workflow, and reporting challenges and burdens for providers and clinicians;
- Fund and conduct pilot projects to deploy and evaluate various approaches to data sharing and exchange between providers' EHRs and registries; and
- Consider factors (i.e., technical, technological, logistical, resources) unique to smaller and/or under-resourced clinical practices and providers.

PATIENT MATCHING REQUEST FOR INFORMATION

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. ONC seeks comment on additional opportunities for patient matching. To accurately match records held at different healthcare facilities, organizations typically compare patients' names, dates of birth, and other demographic data to determine if records refer to the same individual. Healthcare 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.

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[41] https://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=1391
[42] Innovative Approaches to Accessing, Extracting, and Aggregating Electronic Health Records Data. https://avalere.com/insights/innovative-approaches-to-accessing-extracting-and-aggregating-electronic-health-records-data
[43] The Pew Charitable Trusts. [Online]. 2016. Available from: http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2016/11/next-steps-to-encourage-adoption-of-data-standards-for-clinical-registries .

While some private sector technologies—such as referential matching, wherein third-party data are used to support matches—show promise, market forces have thus far been unable to solve the patient matching challenge. Ongoing and recent efforts, however, do offer some potential insights and strategies to improve patient matching.[44] [45] [46] [47] [48] [49] [50] **Premier urges ONC to consider additional refinement of adoption of standardized data elements within the USCDI**. ONC proposes to embed address in the USCDI. We believe that 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 healthcare 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.

We recommend that ONC advance the adoption of other regularly collected demographic data elements (useful 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 often contain other demographic data routinely collected that aren't typically used or made available to match records. ONC could improve match rates by adding other standardized data elements to the USCDI (such as email address, mother's maiden name, or insurance policy identification number).

CONCLUSION

In closing, the Premier healthcare alliance appreciates the opportunity to submit these comments on the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program. Premier shares the vision of achieving interoperability and the establishment and adoption of standards and functions of health IT that will enable an interoperable, learning health ecosystem. Premier hopes our comments are helpful as you continue this important work. If you have any questions regarding our comments or need more information, please contact Meryl Bloomrosen at Meryl_bloomrosen@premierinc.com or 202.879.8012.

Sincerely,

Blair Childs
Senior vice president, Public Affairs
Premier healthcare alliance

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[44] Government Accountability Office, "Health Information Technology: Approaches and Challenges to Electronically Matching Patients' Records across Providers" (2019), https://www.gao.gov/products/GAO-19-197
[45] Genevieve Morris et al., "Patient Identification and Matching Final Report" (2014), https://www.healthit.gov/sites/default/files/patient_identification_matching_final_report.pdf.
[46] College of Healthcare Information Management Executives, "Summary of CHIME Survey on Patient Data-Matching" (2012), https://chimecentral.org/wpcontent/uploads/2014/11/Summary_of_CHIME_Survey_on_Patient_Data.pdf
[47] Beth Haenke Just and Karen Proffitt, "Do You Know Who's Who in Your EHR?" Healthcare Financial Management 63, no. 8 (2009): 68-73, https://www.justassociates.com/application/files/2514/9124/7591/HFM_August_2009_Do_You_Know_Whos_In_Your_EHR.pdf .
[48] Shaun J Grannis et al., "Evaluating the effect of data standardization and validation on patient matching accuracy," Journal of the American Medical Informatics Association 26, no. 5 (May 2019): 447–456, https://doi.org/10.1093/jamia/ocy191
[49] Adam Culbertson et al., "The Building Blocks of Interoperability: A Multisite Analysis of Patient Demographic Attributes Available for Matching," Applied Clinical Informatics 8, no. 2 (2017): 322-336, https://doi.org/10.4338/ACI-2016-11-RA-0196 .
[50] Robert S. Rudin et al., "Defining and Evaluating Patient-Empowered Approaches to Improving Record Matching," RAND Corp., accessed Aug. 27, 2018, https://www.rand.org/pubs/research_reports/RR2275.html .