



May 3, 2019

The Honorable Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-9115-P, Mail Stop C4-26-05,
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act;
Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed
Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers
of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers

Attention: CMS-9115-P

Submitted electronically to <http://www.regulations.gov>

Dear Administrator Verma:

The Sequoia Project is pleased to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed rule *Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers*. We appreciate CMS's demonstrated commitment to consider thoughtfully the comments that it receives from stakeholders in response to such proposed rules.

The Sequoia Project is a non-profit, 501(c)(3) public private collaborative that advances interoperability for the public good. The Sequoia Project previously served as a corporate home for several independently governed health IT interoperability initiatives, including the eHealth Exchange health information network and the Carequality interoperability framework. The eHealth Exchange health information network and Carequality now operate under their own non-profit corporations.

The Sequoia Project currently supports the RSNA Image Share Validation Program, the Patient Unified Lookup System for Emergencies (PULSE) and Interoperability Matters. Our comments on the proposed rule are based on our organization's significant experience supporting large-scale, nationwide health data sharing initiatives, including assessments of interoperability and security capability of exchange participants. Through these efforts, we serve as an experienced, transparent and neutral convener of public and private-sector stakeholders to address and resolve practical challenges to interoperability, including in-

depth development and implementation of trust frameworks and associated agreements. This work extends to several crosscutting projects, including patient matching, improving the quality of clinical documents exchanged, information blocking, and other matters prioritized by these stakeholders, such as health IT disaster response.

Our deep experience implementing national-level health IT interoperability, including our track record of supporting and operationalizing federal government and private sector interoperability initiatives provide a unique perspective on interoperability-related provisions of the proposed rule.

In this letter, we provide priority high-level comments intended to help CMS strengthen the ultimate final rule. We share an overall aim to improve the health and health care of patients and our nation through more seamless patient and provider access to patients' health information.

Overview

The Sequoia Project supports CMS's focus on interoperability and patient access to data. We provide comments based on our experience. In these comments, we highlight:

- The Sequoia Project agrees with CMS's goals and general approach to advance interoperability and patient access to health information. We strongly support CMS's work with the private sector, including the Da Vinci project and Health Level 7 (HL7®). We also suggest that CMS take an approach that decouples the semantics of interoperability from specific transport approaches, a model that seems to be increasingly used in CMS incentive program requirements in recent years and reflected in the focus by both ONC and CMS on interoperable data sets backed by standards for specific data elements.
- The Sequoia Project strongly supports effective public and private-sector efforts to address potential information blocking. As part of these comments, we are conveying to CMS the perspectives of the Information Blocking Workgroup of The Sequoia Project's Interoperability Matters Cooperative, attached as Appendix 2.
- We agree that effectively addressing patient privacy concerns and refinements to current HIPAA implementation approaches are important to more effective interoperability. In February 2019, we provided suggestions in this area in response to a recent request for information from the HHS Office of Civil Rights (OCR). We indicated support for OCR's desire to evaluate potential revisions to provisions of HIPAA regulations that may impede value-based or coordinated care.
- The Sequoia Project generally supports CMS's proposed approach for health plans to use open APIs and the use by reference of ONC standards rather than CMS defining standards in its own rules. At the same time, we have concerns about CMS's proposed timing and associated burdens for health plans and providers. For example, we believe that the plan adoption timetable proposed by CMS is overly aggressive given when this proposed rule was released, especially given the need for coordinated timing with ONC

on implementation of standards-based open APIs across ONC and CMS regulatory requirements. We believe that CMS must provide adequate time for implementation and testing, which is typically at least 18 months from publication of a final rule.

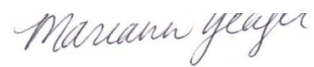
- We strongly support the proposal for health plans to participate with existing trusted exchange networks, which have proved their value in enabling and scaling standards-based interoperability at a national scale. We also support CMS's plans to test ways to promote interoperability across the health care spectrum through models tested by the Center for Medicare and Medicaid Innovation (CMMI) and proposal to require that Innovation Center model participants may, where appropriate, be required to participate in a trusted exchange network that meets the criteria outlined above for health plans.
- In general, we do not believe that a new Condition of Participation (CoP) to require electronic exchange of specified information is necessary given other current and forthcoming policies, including ONC's parallel efforts on information blocking as required under the 21st Century Cures Act, and may also create new burdens on hospitals. In contrast, we believe hospitals and facilities should be incentivized to participate in a broader set of exchange activities through trust exchange networks, as CMS proposes for health plans. We recognize that the initial focus on admission, discharge, and transfer (ADT) messages reflects a laudable intent to be focused and prioritized but at the same time, think that a focus on ADT exchange using the messaging standard referenced in the proposed rule (i.e., HL7® Messaging Standard Version 2.5.1), is too narrow given the broad scope and need for exchange. Moreover, there are a variety of current and emerging approaches to event notification that can be used by hospitals to meet the intent of the proposal. We believe therefore that referencing a specific data transport standard is premature. If CMS proceeds with this proposal to use CoPs for event notification, we suggest a focus on the functional need to send event notification rather than specific mechanisms or standards. We also urge that CMS be mindful of comments from the hospital community and others on the feasible timing to implement such a new CoP, which should likely be at some point after the effective date of the final rule.
- In its Request for Information on Advancing Interoperability Across the Care Continuum, CMS outlines the lack of adoption/use of certified health IT among post-acute care (PAC) providers and its efforts to increase standardization of data in this area. We agree with the importance of this issue. We note recent positive signs in this area, including a significant increase in connectivity in this community.
- In its Request for Information on Policies to Improve Patient Matching, CMS asks how it can leverage its program authority to support those working to improve patient matching. We agree with CMS on the importance of accurate patient matching and provide detailed comments to CMS, including a review of our own work and the need for private sector-led efforts with strong federal government support. We highlight the Sequoia Project's *A Framework for Cross-Organizational Patient Identity Management*.¹

¹ <https://sequoiaproject.org/resources/patient-matching/>

Conclusions

We thank CMS for providing the opportunity to comment on this proposed rule. We strongly support CMS's focus on interoperability and are eager to assist in advancing a national agenda.

Most respectfully,

A handwritten signature in cursive script that reads "Mariann Yeager".

Mariann Yeager
CEO, The Sequoia Project

cc: Mark Roche, M.D.
Alex Mugge

Appendix 1: Detailed Comments

CMS Goals and Approach

CMS seeks to advance interoperability and patient access to health information using available authority, including its authority over various health plans. It states: “[w]hen a patient receives care from a new provider, a *complete record* of their health information should be readily available to that care provider, regardless of where or by who care was previously provided. When a patient is discharged from a hospital to a post-acute care (PAC) setting there should be no question as to how, when, or where their data will be exchanged. Likewise, when an enrollee changes health plans or ages into Medicare, the enrollee should be able to have their claims history and encounter data follow so that information is not lost.”

The CMS proposal focuses on:

- Enabling *patients* to access their health information electronically *without special effort* by requiring payers subject to this proposed rule to make data available through an *application programming interface (API)* to which third party software applications connect to make the data available to patients;
- Ensuring that *providers* have ready access to health information about their patients, regardless of where the patient may have previously received care; and
- Proposing requirements to ensure specified *payers* make enrollee electronic health information held by the plan available through an API such that, with use of software it expects payers and third parties to develop, the information becomes easily accessible to the enrollee, and that the data flows seamlessly with the enrollee as they change providers, plans, and issuers. CMS proposals would also seek to ensure that payers make it easy for enrollees to identify which providers are in a plan’s network.

Comment: The Sequoia Project wholeheartedly agrees with CMS’s goals and general approach. We also strongly applaud and support CMS’s work with the private sector, including the Da Vinci project and Health Level 7 (HL7®).

Challenges and Barriers to Interoperability (p. 7614)

Patient Identifier and Interoperability

CMS provides a summary discussion of the extent to which challenges in accurate patient identification and matching can be a barrier to interoperability.

Comment: The Sequoia Project agrees with CMS on the importance of accurate patient matching. We provide detailed comments below to CMS’s request for information on this issue, including a review of our own work and the need for private sector-led efforts with strong federal government support.

Lack of standardization

CMS discusses the importance of standards for effective interoperability and the role of standards-based application programming interfaces (APIs).

Comment: The Sequoia Project agrees with CMS on the importance of standards and standards-based APIs to augment existing, proven interoperability standards and approaches. We also agree with its intent to incorporate by reference several standards and implementation specifications proposed in a companion proposed rule by the Office of the National Coordinator for Health IT (ONC).

Information Blocking

In sections VIII.B. and C. of this proposed rule CMS proposes to publicly report the names of clinicians and hospitals who submit a “no” response to certain attestation statements related to the prevention of information blocking in order to deter health care providers from engaging in conduct that could be considered information blocking.

Comment: The Sequoia Project does not have comments on this CMS proposal but does strongly support effective public and private-sector efforts to address potential information blocking. In addition, as part of these comments, in Appendix 2 we are conveying to CMS the approach taken and findings of the Information Blocking Workgroup of the Sequoia Project’s Interoperability Matters Cooperative of the Sequoia Project’s Interoperability Matters Cooperative. We urge CMS to give careful consideration to these perspectives. The central goals of Interoperability Matters are to:

- *Prioritize interoperability matters that benefit from national-level, public-private collaboration;*
- *Focus on solving targeted, high impact interoperability issues;*
- *Engage the broadest group of stakeholders and collaborators;*
- *Coordinate efforts into cohesive set of strategic interoperability directions with an implementation focus;*
- *Channel end user needs and priorities;*
- *Bring forward diverse opinions;*
- *Support transparent public forums;*
- *Provide feedback based upon real world implementation to standards organizations and policy makers; and*
- *Deliver work products and implementation resources*

Lack of Adoption/Use of Certified Health IT Among Post-Acute Care (PAC) Providers

CMS outlines issues associated with lack of adoption/use of certified health IT among post-acute care (PAC) providers and its efforts to increase standardization of data in this area.

Comment: We agree with the importance of this issue. We note recent positive signs in this area, including a significant increase in connectivity for this community through Carequality and eHealth Exchange, even in the absence of government incentives, and a new initiative sponsored by ONC and CMS to identify/execute on opportunities to apply FHIR to PAC interoperability topics.

Privacy Concerns and HIPAA

CMS outlines issues related to patient privacy and HIPAA as they relate to interoperability.

Comment: We agree that effectively addressing patient privacy concerns and refinements to current HIPAA implementation approaches are important to more effective interoperability. In February 2019, we provided several suggestions in this area in response to a recent request for information from the HHS Office of Civil Rights (OCR). We indicated support for OCR's desire to evaluate potential revisions to provisions of HIPAA regulations that may impede the ongoing transformation to value-based care or interfere with coordinated care without meaningfully protecting the privacy or security of protected health information (PHI).

The Sequoia Project and its related initiatives are committed to efficient and useful electronic exchange of health care information and agree with the need to strike an optimal balance between privacy and security and access to PHI to meet the range of legally and contractually permitted purposes for such information. We have seen first-hand how uncertainty about what is permitted or required under HIPAA has impeded organizational and individual willingness to share information and to engage with health information exchange initiatives, especially for allowed purposes other than treatment.

Summary of Major Provisions (p. 7617)

The Sequoia Project organizes our comments using the approach taken by CMS in its Summary of Major Provisions. Overall, CMS proposes multiple initiatives to enhance patients' access to their electronic health care information.

- CMS proposes to create and implement new mechanisms for patients to access and direct the use of their health care information.
- CMS proposes to require that specified information be made accessible to patients via "open" APIs.

- CMS proposes to require several types of health plans over which it has jurisdiction to implement open APIs consistent with API technical standards proposed by ONC for adoption as well as adopted and proposed content and vocabulary standards. CMS also asks if it should separately specify standards for some of these areas in its own rules. CMS, like ONC in its companion proposed rule, addresses when updated standards may be used and must be used. Finally, CMS proposes that subject payers must make data available within one day of receiving data, while also acknowledging that this requirement will create pressures on capitated providers to provide information timely to support this as their receipt of data seem to count towards the one day.

Comment: The Sequoia Project generally supports CMS's proposed approach, including the definition of open, standards-based APIs and the incorporation by reference of ONC standards rather than CMS defining standards in its own rules. In this regard, we recommend that CMS continue to keep in mind the need for vocabularies and/or value sets used for quality measure reporting to be aligned with the vocabularies used for the clinical data.

We do have concerns about two aspects of CMS's proposed timing. First, we believe that the plan adoption timetable proposed by CMS is overly aggressive given when this proposed rule was released; we suggest that CMS finalize a timetable based on when the final rule is effective, using an approach and timing similar to that used by ONC, while also being mindful of comments received from the health plan community on timing. Secondly, although we strongly support rapid and timely patient access to their data, we believe that the "one day" requirement may prove impractical in the context of the complex organizational structures involving health plans and their capitated or contracted providers.

- CMS proposes to require payers to support beneficiaries in coordinating their own care via payer to payer care coordination.
- CMS proposes that a plan must, if asked by the beneficiary, forward his or her (USCDI data set) information to a new plan or other entity designated by the beneficiary for up to 5 years after the beneficiary has disenrolled with the plan.
- CMS proposes a requirement for specified health plans to coordinate care between plans by exchanging, at a minimum, the data elements in the United States Core Data for Interoperability (USCDI) standard at enrollee request at specified times.

Comment: We support this general approach, including the baseline requirement for use of USCDI. We also ask that CMS define more clearly what it intends to require by "forward" (as used in the preamble) or "send" (in the regulatory text), addressing, for example, the need for such information to be accessible to the receiving plan and to encourage use of a trusted exchange network in making such information available.

In general, we agree with the specific elements of Version 1 of the USCDI, including addition of Clinical Notes as a Data Class, the initial set of note types selected, and ONC's stated intention to expand this list over time. With respect to clinical notes, we draw CMS's attention to a 2018 joint Carequality/CommonWell document "Concise Consolidated CDA: Deploying Encounter Summary CDA Documents with Clinical Notes,

February 2019^[1]. This white paper defines a path to improve the content in C-CDA exchange, including recommendations for including notes in C-CDAs.

- CMS is proposing to require that several specified types of health plans must participate in a trusted health information exchange network meeting CMS-specified criteria by 1/1/2020. CMS also discusses and requests comments on an approach to payer-to-payer and payer-to-provider interoperability which leverages such existing trusts networks. A trusted exchange network would need to meet the following criteria:
 - The trusted exchange network must be able to exchange PHI, defined in 45 CFR 160.103, in compliance with all applicable state and federal laws across jurisdictions.
 - The trusted exchange network must connect both inpatient EHRs and ambulatory EHRs.
 - The trusted exchange network must support secure messaging or electronic querying by and between patients, providers and payers

Comment: We strongly support this proposal to focus on trusted exchange networks and networks which interconnect through trusted exchange frameworks that are in production now and have proved their value in enabling standards-based interoperability. We agree that ONC's proposed TEFCA Draft 2 has significant promise but also agree with CMS that health plans can add significant capabilities now, including enhanced payer-to-payer and payer-to-provider interoperability through existing trusted exchange networks.

- To address information blocking, CMS is proposing to publicly post information about negative attestations on appropriate CMS websites.

Comment: As indicated previously, The Sequoia Project does not have comments on this specific CMS proposal but does strongly support effective public and private-sector efforts to address potential information blocking. The first project of our Interoperability Matters Cooperative has been a workgroup on information blocking; the work of that workgroup relevant to this proposed rule is attached as Appendix 2. We urge CMS to give careful consideration to these perspectives.

- CMS is proposing to publicly identify clinicians who have not submitted digital contact information to the applicable CMS system and is proposing to align program requirements for specified health plans to make provider directory information publicly available via an API.

Comment: We support the proposal to align program requirements for specified health plans to make provider directory information publicly available via an API and emphasize the importance to interoperability of accurate and complete digital contact information and provider directories.

^[1] https://s3.amazonaws.com/ceq-project/wp-content/uploads/2019/04/11013830/20190201_Improve_C-CDA_Joint_Content_WG_IHE_v1.1_Final.pdf

- CMS is proposing to revise the conditions of participation (CoPs) for hospitals (including short-term acute care hospitals, long-term care hospitals (LTCHs), rehabilitation hospitals, psychiatric hospitals, children’s hospitals, and cancer hospitals) and CAHs to require that these entities send patient event (ADT) notifications to another health care facility or to another community provider. CMS proposes to limit this requirement to only those Medicare- and Medicaid-participating hospitals and CAHs that possess EHRs systems with the technical capacity to generate information for electronic patient event notifications.

Comment: As we communicated to CMS in our comments on the 2019 IPPS proposed rule, in general, we do not believe that a new CoP to require electronic exchange of specified information is necessary in the context of other current and forthcoming policies. We are concerned that compliance concerns and costs could hinder investments and actions to enhance interoperable data exchange. Duplicative or overlapping simultaneous requirements in incentive programs and CoPs could be counterproductive. In contrast, we believe that hospitals and facilities should be incentivized to participate in a broader set of exchange activities through trust exchange networks, as CMS has proposed for health plans.

At the same time, we recognize that the initial focus on patient event notification (i.e., ADTs) reflects the high value of such notification as well as a laudable intent to be focused and prioritized in such a policy but at the same time, we think that a focus on ADT exchange using the ADT Messaging standard incorporated by reference at 45 CFR 170.299(f)(2) (i.e., HL7® Messaging Standard Version 2.5.1—HL7® 2.5.1), is too narrow given the broad scope and need for exchange. (Note that the regulatory text in the Federal Register version of the proposed rule references the standard at 45 CFR 170.205(a)(4)(i) whereas the “display copy” and the Federal Register preamble reference 45 CFR 170.299(f)(2). We ask CMS to clarify its intentions on the standard intended to be referenced.)

Although it is generally true that hospitals have HL7® Version 2 ADT interfaces already in place, these interfaces tend to be highly customized and often focused on internal notifications, and the messages they exchange are not mutually comprehensible (by sender and external receiver) without intermediation. More generally, as indicated by CMS in the preamble, there are a variety of current and emerging approaches to event notification that can be used by hospitals to meet the intent of the proposal and convey the indicated data elements. For example, current initiatives are exploring use of the HL7® FHIR® standard for notifications. We believe that referencing a specific data transport standard, particularly without associated implementation guidance for this use case that can scale at a national level, is premature.

If CMS proceeds with this proposal to use CoPs for event notification, we suggest that it focus on the functional need to send external event notification rather than specific mechanisms or standards, including explicitly allowing use of trusted exchange networks and frameworks. We also urge that CMS be mindful of comments received from the

hospital community and others regarding the feasible timing to implement such a new CoP, which should likely be at some point after the effective date of the final rule.

- CMS plans to test ways to promote interoperability across the health care spectrum through models tested by the CMMI. It also proposes to require that Innovation Center model participants may, where appropriate, be required to participate in a trusted exchange network that meets the criteria outlined above for health plans.:

Comment: We support such tests as part of CMMI activities as well as the required engagement with trusted exchange networks, in line with our prior comments.

- CMS considered but did not include in this proposed rule a proposal to make updates to the Promoting Interoperability Program to encourage eligible hospitals and CAHs to engage in certain activities focused on interoperability. This concept was initially in a request for public comment in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20537 through 20538). CMS discussed a possible strategy in which it would create a set of priority health IT or “interoperability” activities that would serve as alternatives to measures in the Promoting Interoperability Program. It offered three examples of activities that might be included under such an approach, including:
 1. Participation in, or serving as, a health information network which is part of the Trusted Exchange Framework and Common Agreement (TEFCA);
 2. Maintaining an open API which allows persistent access to third parties which enables patients to access their health information; and
 3. Participating in piloting and testing of new standards that support emerging interoperability use cases.

CMS states that it expects to introduce a proposal for such “interoperability activities” in the FY 2020 IPPS/LTCH PPS and invites comments on this concept.

Comment: We generally support CMS’s consideration of a shift from performance-based measurement to one focused on provider engagement with priority health IT activities. At the same time, CMS should carefully evaluate the implications of the specifics of such a shift on the incentives faced and likely resulting activities of providers and other stakeholders. In addition, we agree that active participation in sharing networks and agreements based on the TEFCA or other such exchange-related trusted agreements (as introduced and defined in this proposed rule) could eventually qualify for such an approach. At the same time, because the TEFCA has not been completed or implemented, we suggest that CMS await enough experience with the TEFCA before it finalizes any such approach focused on the TEFCA. We do believe that CMS could move more quickly in adding participation in an existing trusted exchange network as an activity, distinct from a connection to the TEFCA.

Requests for Information

XI. Request for Information on Advancing Interoperability Across the Care Continuum (p. 7653)

CMS is soliciting comment on several potential strategies for advancing interoperability across care settings to inform future rule-making activity in this area.

- CMS is seeking input on how HHS can more broadly incentivize adoption of interoperable health IT systems and use of interoperable data across settings such as long-term and PAC, behavioral health, and those settings serving individuals who are dually eligible for Medicare and Medicaid and/or receiving home and community-based services. CMS invites comment on specific policy strategies HHS could adopt to deliver financial support for technology adoption and use in these settings.

Comment: As noted above, we have observed significant strides in both the LTPAC and behavioral health communities, particularly the former. Much of this momentum is relatively recent. By no means do we suggest that all challenges will solve themselves in the short term without CMS assistance or action; rather, we believe the recent progress by early adopters likely makes the timing right for action by CMS that focuses on incentives to adopt interoperable technology and participate in trusted exchange networks in the short to medium term.

- CMS is seeking comment on whether to move toward the adoption of PAC standardized data elements through expansion of the USCDI process. It is interested in whether the standardized patient assessment data elements implemented in CMS PAC assessment instruments in satisfaction of the IMPACT Act would be appropriate. If the full set of such standardized patient assessment data elements is not appropriate, it is seeking comment on whether a subset of these standardized items would be appropriate, and input on which data elements should be prioritized as part of a subset.

Comment: This proposed approach would be a good place for CMS to start, especially as the PAC data elements were originally implemented in 2014, but we are not certain how much of this data is now collected electronically. We suggest that CMS pay careful heed to comments from implementers to assess the appropriate nature and pace of inclusion in the USCDI. We also believe that some of these data elements are of sufficiently general relevance and maturity for inclusion in the USCDI (e.g., functional status information) but other data elements such as information on pressure ulcers, although very important within the PAC community, may be too specific for the broader USCDI as it is currently conceived. Perhaps one alternative approach to immediate addition to the full data set would be to first develop FHIR implementation guides for the exchange of PAC assessment data elements (involving a CMS and ONC-led process for PAC use of FHIR® that we believe to be underway). These guides, once developed, could be adopted voluntarily right away by those who are more advanced, and phased into the USCDI and CMS requirements as appropriate, based on that initial experience. More generally, we suggest that the USCDI might move to a model where there is an ability to segment data

classes and elements based on the capabilities of specific health IT, the data contained in that health IT, and the needs of specific users and exchange partners.

XIII. Request for Information on Policies to Improve Patient Matching (p. 7656)

CMS seeks comments on how it can leverage its program authority to support those working to improve patient matching.

General Comments: In our detailed comments below, we address the questions CMS poses in its request for information (RFI) and agree with CMS on the importance of this issue and the role of the private sector, with federal government support, in improving match rates. We highlight the Sequoia Project's "A Framework for Cross-Organizational Patient Identity Management," first published in 2016 and updated in 2018.² We commend this report to CMS and point to ongoing work in this area by the Sequoia Project Patient Identity Management Work Group. We emphasize that much of the focus in accurate patient matching has been intra-organizational but that true interoperability and data liquidity will require accurate cross-organizational matching.

More generally, although federal agencies are restricted to patient matching approaches instead of use of a unique identifier, the private sector should not be subjected to that restriction. We urge ONC to support and enable a competitive marketplace for secure identity solutions from commercial third-party enterprises. In addition, it is important to note that identity requirements for Payment and health care Operations are fundamentally different than identity requirements for Treatment. Financial transactions are reversible, and reports can be corrected, but patient care actions are often permanent. Accordingly, in our experience, providers have lower tolerance for false positives, and the different purposes of use should not be subjected to a lowest- common- denominator patient matching approach.

1. Should CMS require Medicare FFS, MA Plans, Medicaid FFS, Medicaid managed care plans (MCOs, PIHPs, and PAHPs), CHIP FFS, CHIP managed care entities, and QHP issuers in FFEs (not including SADP issuers), use a patient matching algorithm with a proven success rate of a certain percentage where the algorithm and real world processes associated with the algorithm used are validated by HHS or a 3rd party?

Comment: We strongly support use of matching algorithms as part of an overall patient matching strategy. At the same time, we believe that such a specific mandate is premature and that the state of the art does not support valid and reliable cross-organizations comparison at a level to support such an approach. We do suggest that CMS consider the cross-organizational patient matching maturity model included in the above report for consideration as a baseline to build on as it seeks to improve both provider and health plan patient matching accuracy.

2. Should CMS require Medicare FFS, the MA Plans, Medicaid FFS, Medicaid managed care plans, CHIP FFS, CHIP managed care entities, and QHP issuers in FFEs to use a

² <https://sequoiaproject.org/resources/patient-matching/>

particular patient matching software solution with a proven success rate of a certain percentage validated by HHS or a 3rd party?

Comment: We believe that such a mandate would be overly prescriptive.

3. Should CMS expand the recent Medicare ID card efforts by requiring a CMS-wide identifier which is used for all beneficiaries and enrollees in health care programs under CMS administration and authority, specifically by requiring any or all of the following:
 - That MA organizations, Part D prescription drug plan sponsors, entities offering cost plans under section 1876 of the Act, and other Medicare health plans use the Medicare ID in their plan administration.
 - That State Medicaid and CHIP agencies in their FFS or managed care programs use the Medicare ID for dual eligible individuals when feasible.
 - That QHP issuers in FFEs use the Medicare ID for their enrollees in the administration of their plans.

Comment: Wider plan use of the Medicare Beneficiary ID could enhance matching accuracy. The above-referenced Sequoia report concluded that substantially increased patient match rates (i.e., above 95%) may require a supplemental identifier in addition to the required fields. A supplemental identifier could be a national or regional shared identifier, such as a driver's license number or the Medicare Beneficiary ID number, and/or validated cell phone number. High data quality of such an identifier at the point of capture is essential for acceptable patient match rates.

4. Should CMS advance more standardized data elements across all appropriate programs for matching purposes, perhaps leveraging the USCDI proposed by ONC for HHS adoption at 45 CFR 170.213.

Comment: Additional data elements to improve patient matching efforts may include: Maiden Name, Multiple Birth Indicator, Birth Order, Telephone Number types (we note the high value of the validated cell phone number), and Email Address(es). More generally, data collection standards and their consistent application by health plans, providers and exchange organizations are a critical determinant to matching accuracy. The above-referenced Sequoia Project document addresses this issue in detail, including, notably, a maturity model for intra-organizational and cross-organizational organization processes to enhance patient matching accuracy, including rigorous information governance. Overall, the biggest opportunity to immediately enhance matching rates is standardized formats for demographic data among data sharing participants.

5. Should CMS complement CMS data and plan data in Medicaid managed care plans (MCOs, PIHPs, and PAHPs), CHIP managed care entities, MA Plans, and QHP issuers in an FFE (not including SADP issuers) with one or more verifying data sources for identity proofing? What potential data source should be considered? What are possible

restrictions or limitations to accessing such information?

Comment: CMS should not dictate specific solutions.

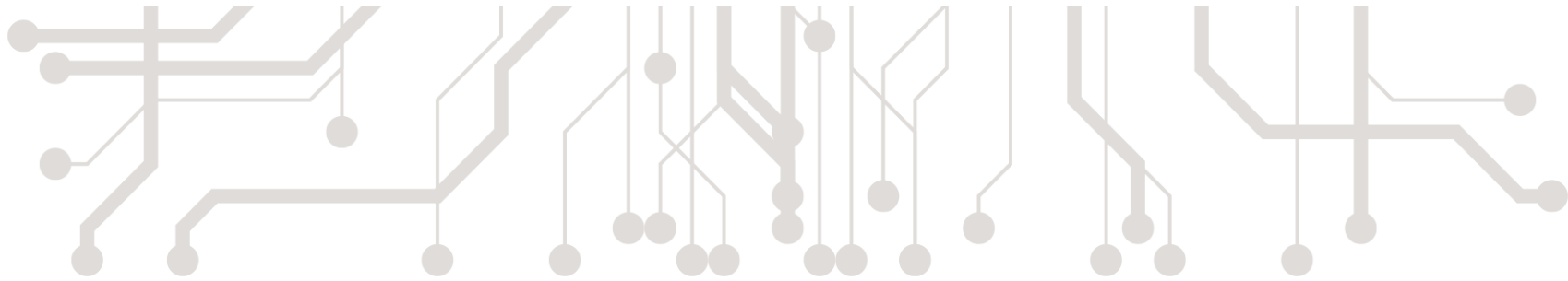
6. Should CMS support connecting EHRs to other complementary verifying data sources for identity proofing? What potential data source should be considered? What are possible restrictions or limitations to accessing such information?

Comment: CMS should not dictate specific solutions. In addition, EHRs will not always be the primary way in which health care organizations manage patient matching and identify so a focus on EHR-based approaches is likely not warranted.

7. To what extent should patient-generated data complement the patient-matching efforts?

Comment: Involving the patient in data entry, correction, and maintenance can maintain and enhance patient data integrity over time. This approach includes making it a practice to ask the patient at every visit whether their address or phone number has changed and also having the patient review their demographic information to ensure its correctness. Patient portals and other self-service applications can also help patients understand the extent of their identity completeness and how it can be increased. More generally, we recognize that more complete demographic data will only get us so far and we should increasingly look to approaches like biometric data, that rely on data that is “patient inherent” rather than simply “patient-generated”.

Appendix 2: Recommendations of the Information Blocking Workgroup of the Interoperability Matters Forum



Information Blocking Workgroup

Final Report on ONC March 2019 Proposed Rule: Information Blocking Provisions

Interoperability Matters

4/30/2019

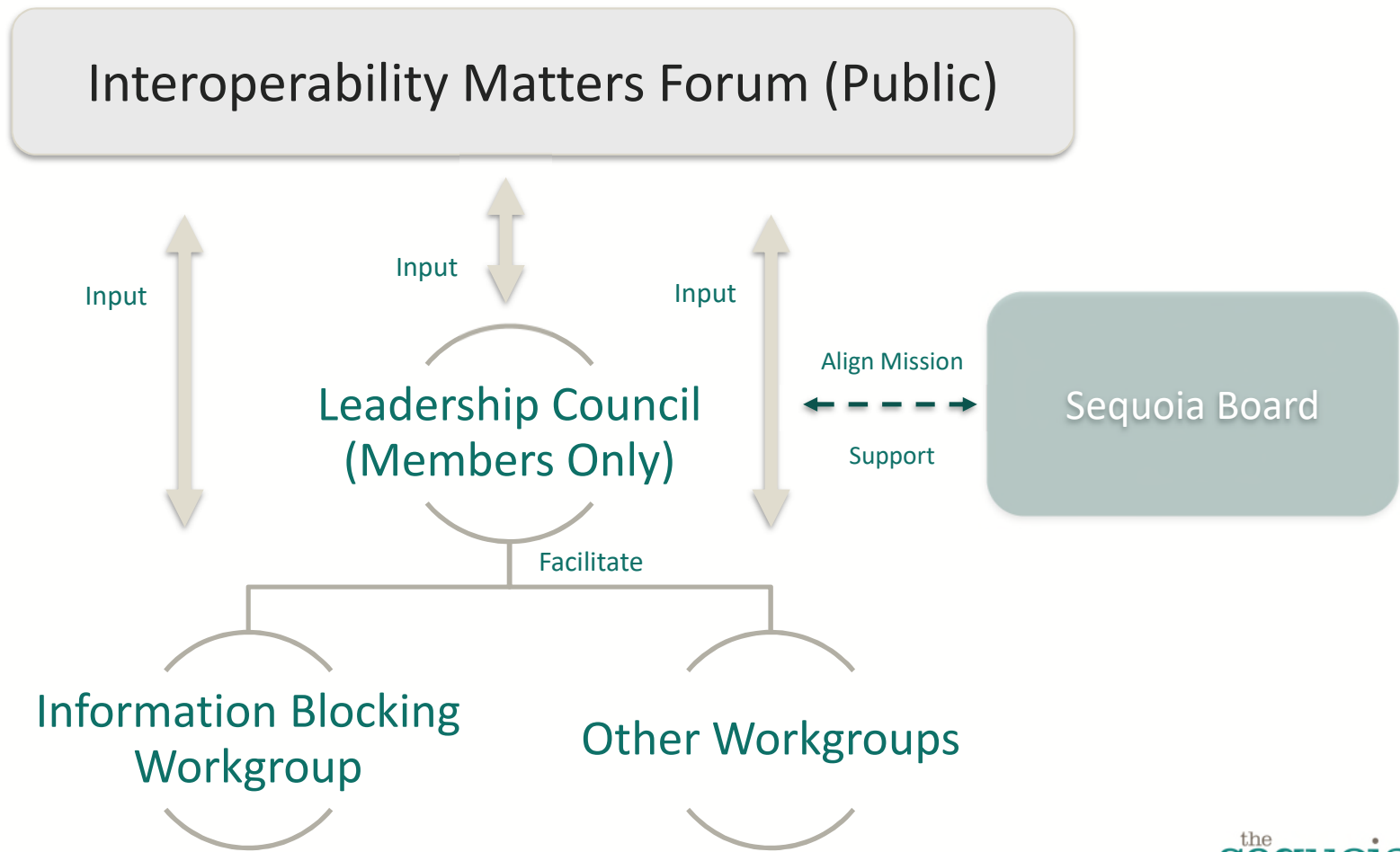
Organization of the Report

- Background on the Workgroup
- Findings
 - Actors and Other Definition
 - Information Blocking Practices
 - Exceptions
 - Preventing Harm
 - Privacy
 - Security
 - Recovering costs reasonably incurred
 - Declining to provide access, exchange, or use of EHI if request is infeasible
 - Licensing technologies or other interoperability elements
 - Making health IT unavailable to perform maintenance or improvements
 - Request for Information: Disincentives for Providers
- Next Steps

Interoperability Matters Cooperative: Function

- Prioritize matters that benefit from national-level, public-private collaboration
- Focus on solving targeted, high impact interoperability issues
- Engage the broadest group of stakeholders and collaborators
- Coordinate efforts into cohesive set of strategic interoperability directions
- Channel end user needs and priorities
- Bring forward diverse opinions, which may or may not result in consensus
- Facilitate input and develop work products, with implementation focus
- Support public forum for maximum transparency
- Provide feedback based upon real world implementation to policy makers
- Deliver work products and implementation resources

Interoperability Matters: Structure



Interoperability Matters Advisory Forum (Public)

- Provides open, public forum to provide input and assure transparency
- Serves as listening session for staff, workgroup and Leadership Council
- Represents diverse private / public stakeholder and end user perspectives
- Provides input into the priorities and work products
- Enables community to share tools, resources and best practices
- Provides venue for policy makers to hear diverse perspectives in real-time

Information Blocking Workgroup: Purpose

- Identify practical, implementation-level implications of proposed and final information blocking rules, which may or may not be consensus positions
- Provide input into Sequoia comments to ONC on proposed rule
- Facilitate ongoing discussions to clarify information blocking policies and considerations prior to and after the Final Rule

Information Blocking Workgroup: Scope and Focus of Review

- Primary: *Information Blocking* part of ONC proposed rule
 - Definitions (including Information Blocking Practices and Actors)
 - Identify implications and suggest revisions
 - Information blocking practices with examples
 - Add, revise, delete
 - Reasonable and Necessary Exceptions
 - Add, revise, delete
 - Activities that are info blocking, but are reasonable and necessary according to ONC criteria
 - Specific ONC comments sought
 - ONC RFI: disincentives for providers and price transparency
 - Complaint process and enforcement
- Secondary:
 - Information Blocking elements of Conditions and Maintenance of Certification, including enforcement

Workgroup Representatives

Associations and Orgs - health IT community

- Mari Greenberger, HIMSS
- Matt Reid, AMA
- Lauren Riplinger, AHIMA
- Scott Stuewe, DirectTrust

Consumers

- Ryan Howells, CARIN Alliance
- Deven McGraw, Ciitizen

Federal Government

- Steve Bounds, SSA
- Margaret Donahue, VA

Health Information Networks and Service Providers

- Angie Bass, Missouri Health Connect
- Dave Cassel, Carequality
- Laura Danielson, Indiana Health Information Exchange
- Paul Uhrig, Surescripts, Co-Chair

Healthcare Provider

- David Camitta, Dignity, Co-Chair
- Eric Liederman, Kaiser Permanente

Legal, Technology, Standards, and Policy Subject Matter Experts

- Jodi Daniel, Crowell & Moring, LLP
- Josh Mandel, Microsoft
- Micky Tripathi, MaEHC

Payers

- Nancy Beavin, Humana
- Danielle Lloyd, AHIP
- Matthew Schuller, BCBSA

Public Health

- John Loonsk, APHL

Vendors

- Brian Ahier, Medicity / Health Catalyst
- Aashima Gupta, Google
- Cherie Holmes-Henry, EHRA / NEXTGEN
- Rob Klootwyk, Epic
- Josh Mast, Cerner

Informatics

- Doug Fridsma, AMIA

Safety net providers / service provider

- Jennifer Stoll, OCHIN

Release of Information Company

- Rita Bowen, MROCorp

The Sequoia Project Team

Lindsay Austin, Troutman Sanders Strategies

Didi Davis, VP, Informatics, Conformance & Interoperability

Steve Gravely, Gravely Group - Facilitator

Shawna Hembree, Program Manager

Mark Segal, Digital Health Policy Advisors - Facilitator

Dawn VanDyke, Director, Marketing Communications

Mariann Yeager, CEO

Deliverables

- Perspectives on ONC 21st Century Cures proposed rule that inform industry and Sequoia Project regulatory comments
- Assessments of proposed rule implications to the community
- Assessments of ONC proposed rule, with identified follow-up actions needed by federal government and private sector

7424 Federal Register / Vol. 84, No. 42 / Monday, March 4, 2019 / Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary
45 CFR Parts 170 and 171
RIN 0955-AA01
21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).
ACTION: Proposed rule.

SUMMARY: This proposed rule would implement certain provisions of the 21st Century Cures Act, including conditions and maintenance of certification requirements for health information technology (Health IT) developers under the ONC Health IT Certification Program (Program), the voluntary certification of Health IT for use by pediatric health care providers, and reasonable and necessary activities that do not constitute information blocking. The implementation of these provisions would advance interoperability and support the access, exchange, and use of electronic health information. The proposed rule would also modify the 2015 Edition Health IT certification criteria and Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs.

DATES: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, no later than 5 p.m. on May 3, 2019.

ADDRESSES: You may submit comments, identified by RIN 0955-AA01, by any of the following methods (please do not submit duplicate comments). Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

• **Federal eRulemaking Portal:** Follow the instructions for submitting comments. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word. <https://www.regulations.gov>.

• **Regular, Express, or Overnight Mail:** Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule, Mary E. Switzer Building, Mail Stop: 7033A, 230 C Street SW, Washington, DC 20201. Please submit one original and two copies.

• **Hand Delivery or Courier:** Office of the National Coordinator for Health Information Technology, Attention: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule, Mary E. Switzer Building, Mail Stop: 7033A, 230 C Street SW, Washington, DC 20201. Please submit one original and two copies. (Because access to the interior of the Mary E. Switzer Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

Enhancing the Public Comment Experience: To facilitate public comment on this proposed rule, a copy will be made available in Microsoft Word format on ONC's website (<http://www.healthit.gov>). We believe this version will make it easier for commenters to access and copy portions of the proposed rule for use in their individual comments. Additionally, a separate document ("public comment template") will also be made available on ONC's website (<http://www.healthit.gov>) for the public to use in providing comments on the proposed rule. This document is meant to provide the public with a simple and organized way to submit comments on proposals and respond to specific questions posed in the preamble of the proposed rule. While use of this document is entirely voluntary, we encourage commenters to consider using the document in lieu of unstructured comments, or to use it as an addendum to narrative cover pages. We believe that use of the document may facilitate our review and understanding of the comments received. The public comment template will be available shortly after the proposed rule publishes in the *Federal Register*. This short delay will permit the appropriate citation in the public comment template to pages of the published version of the proposed rule.

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. Such information includes, but is not limited to: A person's social security number; date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered proprietary. We will post all comments that are received before the close of the comment period at <http://www.regulations.gov>.

Backlist: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> or the Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Mary E. Switzer Building, Mail Stop: 7033A, 230 C Street SW, Washington, DC 20201 (call ahead to the contact listed below to arrange for inspection).

FOR FURTHER INFORMATION CONTACT: Michael Lipinski, Office of Policy, Office of the National Coordinator for Health Information Technology, 202-690-7151.

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Key Concepts for Workgroup Review

Actors

- Health Care *Providers*
- *Developers* of Certified Health IT
- Health Information *Exchanges*
- Health Information *Networks*

Blocking Practices

- *Restrictions on access, exchange, or use* of EHI through formal means (e.g., contractual restrictions) or informal means (e.g., ignoring requests to share EHI)
- *Limiting or restricting the interoperability of health IT* (e.g., disabling a capability that allows users to share EHI with users of other systems)
- *Impeding innovations and advancements* in access, exchange, or use of health IT-enabled care delivery (e.g., refusing to license interoperability elements to others who require such elements to develop and provide interoperable services)
- *Rent-seeking and other opportunistic pricing practices* (e.g., charging fees to provide interoperability services that exceed actual costs incurred to provide the services)
- *Non-standard implementation practices* (e.g., choosing not to adopt relevant standards, implementation specifications, and certification criteria)

Exceptions

1. Engaging in practices that prevent harm
2. Engaging in practices that protect the privacy of EHI
3. Implementing measures to promote the security of EHI
4. Recovering costs reasonably incurred
5. Declining to provide access, exchange, or use of EHI if a request is infeasible
6. Licensing technologies or other interoperability elements that are necessary to enable access to EHI
7. Making health IT unavailable to perform maintenance or improvements

Criteria for Workgroup Review

- *ONC basis* for selecting exceptions:
 - Each is limited to certain activities that *clearly advance the aims* of the information blocking provision
 - Each addresses a *significant risk that regulated actors will not engage in these beneficial activities* because of uncertainty concerning the breadth or applicability of the information blocking provision
 - Each is *subject to strict conditions* to ensure that it is limited to activities that are reasonable and necessary
- *Impact* of a practice and exception
- *Likely benefit* per Congressional intent and by actor/party
- *Implementation: feasibility & complexity, cost & burden: by actor/party*
- *Compliance: challenges, uncertainties, potential best practices*
- *Unintended consequences*



Actors and Other Definitions

Actors and Other Definitions: Findings

§171.102

- The definition of an *actor* is critical because it exposes organizations to penalties and the regulatory implications of defined *practices* and *exceptions*.
- The proposed definition of an *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 *EHI*, and standards developing organizations (SDOs) or organizations that develop recommended interoperability policies are not networks and could, inappropriately, be included in the proposed definition.
 - Should receipt of health IT incentive program payments or federal stimulus payments be a determinant of whether an organization is an HIE or an HIN?
- The definition of an *HIE* includes *individuals*, which is difficult to understand, and, as with the *HIN* definition, could sweep in individuals or organizations that are not actually HIEs.
- The distinction between HIEs and HINs is unclear; HIEs should be viewed as a subset of HINs; ONC should therefore consider combining the two types of actors into one combined definition.
- The HIT *developer* definition needs more clarity on whether its application includes all *interoperability elements* under the control of the developer.
 - In addition, the definition is too broad as it could bring in companies that only have one product certified against one or a very few criteria, for example a quality reporting module.
 - The definition would also seem to inappropriately include organizations like value-added resellers in its focus on “offers” certified health IT.
- ONC should consider defining EHI to equal PHI as defined by HIPAA.



Information Blocking Practices

Practices: Findings

§171.103 and p. 76165

- The definition of *interoperability elements* is very broad (beyond certified health IT) and interacts with the identified information blocking practices and actors (and other aspects of the information blocking requirements) to create a very broad and complex web of compliance risk.
- Although part of the Cures statute, the term “likely” in the regulatory definition of information blocking, without a commonly understood definition or one in the proposed rule is problematic.
 - It could lead to an ongoing a large number of commercially motivated allegations of information blocking, even without any actual blocking.
 - Actions and capabilities associated with patient matching might trigger the “likely” level of risk.
 - ONC should define “likely” as “highly probable,” backed up with examples of actual information blocking.
- There is a need to allow for due diligence as distinct from simply delaying access and such diligence should not need an exception (e.g., the security exception) to avoid implicating or being judged as information blocking. The need to vet external locations of exchange includes but is not limited to apps (e.g. networks).
 - In lieu of a focus on “vetting” of apps and other points of exchange by providers, CARIN Alliance suggests a focus on apps needing to be “centrally registered” by an EHR or a health plan. This approach allows a light 'vetting' process of the app but also allows the app to gain access to all client end points following registration without providers needing or wanting to vet every app. https://www.carinalliance.com/wp-content/uploads/2019/02/CARIN_Private-and-Secure-Consumer-Directed-Exchange_021019.pdf
 - It would be desirable if there can be a central point where apps are certified/vetted to achieve efficiencies for plans/providers/Vendors/app developers. If organizations want to do other vetting, that would be permitted of course, but at minimum CMS and ONC should release a White List for apps that they have vetted, and preferably also a Black List from the FTC if there is not a full fledged certification process. There is concern from some participants that being simply “registered” with a plan will not determine if it is a legitimate request, from a legitimate organization, with a legitimate scope of data elements.

Practices: Findings

§171.103 and p. 76165

- The focus on non-standard implementations, combined with the broad definitions of actors, could pose challenges for certain organization, such as clinical registries, which have historically needed some non-standard implementations to achieve their intended purpose. In addition, we ask ONC to provide additional examples of non-standard implementations beyond those on p. 7521, for when applicable adopted standards exist and when they do not.
- There should be “safe harbor” provisions for some practices without the need to use an exception with all of its specificity.
- The nature of this rule and the underlying issue being addressed is leading ONC to assume actors have bad intent, and to err on the side of ensuring that there are no loopholes for these bad actors to exploit. This approach is understandable, but it casts such a wide net that there is a strong chance of collateral damage and pulling in those who are acting in good faith. It should be possible to relax some of the language in the practices and exceptions (e.g., “all things at all times and if no alternatives”), perhaps language that references acting in good faith and an allowance for “one off” cases in a gray area.



Exceptions

Preventing Harm: Findings

§171.201

- This is an important exception. The example of domestic abuse (p. 7525) is apt and reinforces the importance of this exception. We urge ONC to ensure that the exception as finalized fully addresses relevant examples, included those that may be suggested in comments (e.g., is the focus on physical harm too restrictive?). ONC should also provide additional examples in the Final Rule. It should especially consider the challenges that will be faced in tailoring exceptions to specific threats of harm.
- The proposed burden of proof is unreasonable and the need to demonstrate that a policy is sufficiently tailored is likely to create a costly compliance burden.
- ONC should be explicit in recognizing the need for deference to other state and federal laws, including consideration of implications from the recently enacted Support Act.
- ONC and OCR must rapidly develop detailed guidance for the field, especially in the absence of a body of case law that can guide compliance.
- Will available technology (e.g., EHRs) enable actors, such as providers, to document compliance with this and other specific exceptions and their detailed components, including “and” and “or” scenarios. Will compliance tracking technology need to be validated?

Protecting Privacy: Findings

§171.202

- Despite the OCR guidance on the HIPAA right of access and apps, there is a broad view that providers and developers will feel a need and obligation for some due diligence regarding apps and points of exchange.
 - A recent 2019 Manatt and eHealth Initiative Issue Brief *Risky Business? Sharing Data with Entities Not Covered by HIPAA* highlights existing international, federal and state laws, regulation and guidance and the highly complex and confusing environment that healthcare-related organizations face with respect to privacy and security related rights and obligations.
- ONC needs to be more realistic about the complexities and challenges of separating out 42 CFR Part 2 data from other EHI, especially but not only when the information is contained in clinical notes.
- There are important overlaps between privacy and security that must be recognized. There is concern that the proposed exceptions do not sufficiently recognize the kinds of bad actors that are present in the environment. For example, organizations that employ security-related attacks on other organizations vs. those that may have received authorization to access data but may collect more than authorized or use the information in unauthorized ways. It is essential that the exception enables actors to address the range of such security threats, including those posed by state actors.
- HHS should clarify when existing contractual obligations (as opposed to the decision to enforce such a provision), notably via BAAs, supersede Information Blocking provisions or provide a basis for an exception. We expand on this issue in comments in the “infeasible requests” exception.

Protecting Security: Findings

§171.203

- APIs employed using appropriate standards and technologies and operational best practices can be very secure. In the final rule, ONC should be clear on this point as well as the necessary technologies and practice to achieve such security.
- ONC should confirm that cross-organizational sharing (e.g., provider to provider) of security information, regarding a state-sponsored threat or other “bad actor,” is permissible and does not implicate information blocking or could fall within the indicated exception.
- ONC should confirm that an organization can use security policies that exceed what is required by law or regulation based on their assessment of the threat environment, without violating this exception.
- ONC should recognize the valid need to allow for due diligence as distinct from simply delaying access and such due diligence should not need the security exception to avoid implicating or being judged as engaged in information blocking. The need for vetting of external locations of exchange includes but is not limited to apps. (e.g. networks).

Protecting Security: Findings

§171.203

- Despite the OCR guidance on the HIPAA right of access and apps, there is a broad view that providers and developers will feel a need and obligation for some due diligence regarding apps and points of exchange.
 - A recent 2019 Manatt and eHealth Initiative Issue Brief *Risky Business? Sharing Data with Entities Not Covered by HIPAA* highlights existing international, federal and state laws, regulation and guidance and the highly complex and confusing environment that healthcare-related organizations face with respect to privacy and security related rights and obligations.
- The security exception has a safety valve for cases where there is no written policy (171.203(e)). The exception calls for not only a determination that the practice is necessary, but that effectively there exists no other way of having protected your security that might have been less likely to interfere with information access. This requirement is asking a lot of the network engineers who may be trying to fight off a sustained attack at 3:00 am. We suggest that 171.203(e)(2) should therefore have a further safety valve for short-lived actions that are taken in good faith while a situation is being evaluated and understood.
- ONC should address the extent to which actions by an actor to address legal liability not mitigated by HHS Office of Civil Right (OCR) HIPAA-related policies can support use of this exception, including potential liability that can come with exchange that is not covered by OCR guidance relating to the HIPAA patient right of access. Such liability could arise from such sources as state laws, FTC regulations, or contractual obligations.

Recovering Costs Reasonably Incurred: Findings

§171.204

- There was strong support for ONC's proposal to provide free API access to an individual who requests access to their EHI through a consumer-facing application and ONC should consider whether this approach could be extended to public health access.
- There were varying views regarding prohibition of fees for patient access:
 - Some noted that prohibition on any fees that do not meet this very detailed exception is too complex (both preamble and regulatory text) and interferes too much with market operations and could reduce investment in needed interoperability solutions. They suggest that ONC revise the exception to shift from an emphasis on cost recovery to a focus on the shared goal, central to 21st Century Cures, that pricing should not be a deterrent to information sharing.
 - Some also were concerned with the breadth of the prohibition on fees “based in any part on the electronic access by an individual or their personal representative, agent, or designee to the individual’s electronic health information.,” particularly the reference to “designees.” They noted that data accessed in this way by commercial “designees” (e.g., apps) has economic value with costs associated with its provision. Prohibiting any such fees to designees (as opposed to the individual) as part of the information blocking provision, beyond API certification requirements, could reduce investment in interoperability capabilities and overall availability of information. In addition, this issue has important interaction effects with the companion CMS interoperability proposed rule if payers, who are required and encouraged to create APIs are unable to recover costs because they have been defined as HIEs or HINs as part of this rule.
- There was concern with a high burden for hospitals to comply with this exception.

Recovering Costs Reasonably Incurred: Findings

§171.204

- We ask ONC to clarify what individuals and entities are subject to the prohibition of fees for individual access and how to determine if an entity is actually an individual's designee for data sharing. More generally we ask ONC to clarify whether consent to share information to be interpreted as equivalent to actual patient direction to share?
- Many terms in this exception are subjective (e.g., "reasonable). We ask ONC to provide clear definitions in the final rule and associated guidance.
 - In particular, we ask ONC to provide more guidance on the allowance for "reasonable profit" in the preamble (p. 7538) and to explicitly include such an allowance in the regulatory text.
- ONC states that the method to recover costs "[m]ust not be based on the sales, profit, revenue, or other value that the requestor or other persons derive or may derive from the access to, exchange of, or use of electronic health information, including the secondary use of such information, that exceeds the actor's reasonable costs for providing access, exchange, or use of electronic health information." The preamble (p. 7539) further states that "such revenue-sharing or profit-sharing arrangements would only be acceptable and covered by the exception if such arrangements are designed to provide an alternative way to recover the costs reasonably incurred for providing services." *The term "alternative" is confusing and could be read to imply that this method is an alternate to another simultaneously offered method of cost recovery, which we do not believe is ONC's intent; we ask ONC to clarify.*

Recovering Costs Reasonably Incurred: Findings

§171.204

- The disallowance for costs that are “due to the health IT being designed or implemented in non-standard ways that unnecessarily increase the complexity, difficulty or burden of accessing, exchanging, or using electronic health information” requires further clarification. In particular, ONC should recognize that there are often multiple actors and actor-types involved in an implementation. A given actor could face higher costs as a result of non-standard implementations by another actor (e.g., a provider, a developer or vice versa). Such costs incurred as a result of non-standard design or implementation by another actor should be able to be reflected in fees.
- This exception should be expanded to clarify that costs associated with research, including costs from non-standard implementations due to research needs, should be able to be reflected in fees.
- There was interest and uncertainty as to how rapidly useful pricing information can be included in this exception.

Infeasible Requests: Findings

§171.205

- We are very concerned that this exception is too vague, with many undefined terms (e.g., timely, burdensome, etc.). This vagueness will create uncertainty as to whether claiming this exception will ultimately be validated by regulators and therefore lessen the benefit of this important exception.
- We ask ONC to address potential conflicts between valid contracts, such as HIPAA Business Associate Agreements, and requests for data access that are inconsistent with these contracts. To what extent does the need to honor (as opposed to the desire to enforce) contractual obligations meet the infeasibility exception? ONC indicates in multiple places that actors cannot enforce certain contracts that are contrary to the provisions in this rule but does not address corresponding contractual obligations to honor contracts; this gap is very problematic, especially as application of these provisions will often require case-by case, fact-based evaluations.
- We ask ONC to recognize that infeasibility can come from the *scale effects* of requests for access as opposed to the marginal cost of meeting any given request (e.g., not tens of requests but tens of thousands of requests). Organizations may need to develop and uniformly apply policies to reflect the feasibility of types of requests and development and application of such policies should meet this exception so long as they meet criteria such as being non-discriminatory.

Infeasible Requests: Findings

§171.205

- We ask ONC to recognize that honoring specific requests for information can be infeasible if the cost to meet that request, for example researching whether a patient has provided consent, are prohibitive.
- We ask ONC to confirm that infeasibility could include not having the technical capability in production to meet a request (e.g., not having APIs or other technical means to support a specific type of exchange, access, or use, for example to enable write access to the EHR), when the cost of acquiring such capabilities are excessive and could reduce the ability to meet other project plans and customer commitments.
- We ask ONC to consider whether a request can be deemed infeasible if there is another widely accepted alternative for performing the same or comparable action?
- We do not believe that this exception should need to be invoked, or information blocking implicated, if, per the regulatory language, the actor works “with the requestor in a timely manner to identify and provide a reasonable alternative means of accessing, exchanging, or using the electronic health information”.
- We ask ONC to confirm lack of backwards compatibility of standards could be a basis for invoking this exception, for example if ONC finalizes its proposal to allow both FHIR DSTU 2 and FHIR Release 4.

Reasonable and Non-Discriminatory Terms (RAND) Licensing: Findings §171.206

- Overall, we ask ONC to simplify this exception and its scope and to provide more guidance on RAND licensing and its implementation.
- We request that ONC address the potential for unintended consequences; for example, some health IT delivery models might have fees eligible for the RAND licensing exception and others would only be eligible for 171.204, with the potential for higher net financial returns under one model or the other, a preference that is not intended (and should not be) as a matter of public policy.
- The preamble discussion of this exception is complex and will require very technical and fact-specific steps by actors, including establishment of “reasonable” royalties.
- We ask ONC to consider the combined implications and timing to assess feasibility, licensing implications and enter a negotiation for licensing within a 10-day timeframe.

Reasonable and Non-Discriminatory Terms (RAND) Licensing: Findings §171.206

- In addition, given the extensive use of licenses as one element of commercial health IT software offerings, we ask ONC to clarify which software licenses would need to (be revised to) meet this exception to avoid information blocking (i.e., will *all* software licenses need to be converted to RAND terms or only those that focus on specific intellectual property rights, and in what timeframe?). For example, would licenses for EHRs presented to providers be subject to this provision or only licenses for specific IP (e.g., code sets) or APIs licensed by an EHR developer to an application developer? We also ask ONC to recognize that this exception, if it requires changes to virtually all health IT software licenses, is likely to have far reaching and very disruptive impacts on the market for health IT software, including a high compliance and documentation burden.
- We ask ONC to clarify its definition of “royalty” and which fees associated with licenses software would be consider a royalty and which would not, and hence only eligible for the exception at 171.204.

Reasonable and Non-Discriminatory Terms (RAND)

Licensing: Findings §171.206

- We ask ONC to clarify whether, *in all cases*, fees that might be associated with software are also eligible for the alternate exception under 171.204. The preamble (p. 7549) states that “[f]inally, the actor must not condition the use of interoperability elements on a requirement or agreement to pay a fee of any kind whatsoever unless the fee meets either the narrowly crafted condition to this exception for a reasonable royalty, or, alternatively, the fee satisfies the separate exception proposed in § 171.204, which permits the recovery of certain costs reasonably incurred”.
- We also ask ONC to clarify whether an actor that licenses an interoperability element, and chooses to use the exception at 171.204 for fees, would also need to use this exception, as there are many non-monetary aspects of this exception.
- We ask ONC to address an actor’s obligation to license intellectual property that they do not yet have and to clarify that inability to honor such a request could be met by the feasibility exception and would not require use of this one as well.

Health IT Performance: Findings

§171.207

- We ask ONC to recognize that it is unlikely that actors would make a system unavailable as part of deliberate information blocking and we question whether such downtime should be considered a practice that implicates information blocking and hence, whether this exception is needed.
 - Providers have strong incentives to keep systems up and to respond quickly to unplanned outages
- We recognize that system unavailability due to prevention of harm or security risks would fall under those exceptions and not this one. At the same time, subjecting urgent system downtime needs to the far-reaching requirements associated with *any* of these exceptions seems unwarranted.
- The language in this exception (preamble and regulation) is not sufficiently clear.
 - For example, what if only one part of a system goes down, such as the gateway for inbound queries?

Health IT Performance: Findings

§171.207

- In general, unplanned *maintenance* would not occur. We ask ONC to recognize that unplanned downtime will almost always only occur when the actor initiating the downtime is unable to control such situations.
- Scheduling downtime is very complex even within an organization; the need to gain the assent of external parties affected by the downtime is impractical and infeasible.
 - Consider a cloud-based system that is used by hundreds or thousands of users. Would the actor be unable to initiate needed maintenance if even one of these users did not agree?
 - We agree that it is desirable for service level agreements (SLAs) to address maintenance downtime but requiring agreement by users for *any* downtime should not be required.
 - If ONC makes needed system maintenance and upgrades more difficult to accomplish, overall system quality will be threatened.

Requests for Information—Disincentives for Health Care Providers: Findings (p. 7553)

- We do not believe that additional provider disincentives are needed given those already in place.

Next Steps

- The Information Blocking Workgroup will continue its work following submission of comments to ONC.
- This ongoing work will include:
 - Assessments of proposed rule implications to the community; and
 - Discussions to clarify information blocking policies and considerations, including follow-up actions needed from the federal government and private sector, prior to and after the Final Rule.