Coppersmith Briefs

Making Improvements?: ONC's Proposed Enhancements to the Information Blocking Rule (HTI-1)

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Introduction

The Information Blocking Rule (IBR) is changing. On April 18, 2023, the Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS), published a notice of proposed rulemaking (NPRM): "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing" or "HTI-1." ONC proposes to:

- Reimagine the ONC Health IT Certification Program (Program)—which consists of Certification Criteria and Assurances Condition and Maintenance of Certification Requirements—as edition-less, such that health information technology (health IT) developers can utilize new and updated standards and their customers will be provided with timely technology updates;
- Establish new Conditions and Maintenance Certification requirements for health IT developers under the Program, including a new Electronic Health Record (EHR) Reporting Program (referred to as the Insights Condition) and requirements for certified health IT to support patient restrictions on the use and disclosure of specific data elements;
- Update certification criteria, implementation specifications and standards for the Program, including revised criteria for clinical decision support (CDS), patient demographics and observations, electronic case reporting (ECR), and application programing interfaces (APIs) for patients and population services;
- Adopt the United States Core Data for Interoperability (USCDI) version 3 (v3) as a standard for the Program by January 1, 2025; and
- **Update and enhance the IBR, including clarifying the definition of health IT developer of certified health IT and expanding the Content and Manner and Infeasibility Exceptions.**

ONC is also:

- Requesting information on a wide range of topics, including pharmacy interoperability, electronic prior authorization, lab data interoperability, technology standards, and additional IBR exclusions or exceptions; and
- Proposing new policies in collaboration with other federal agencies—including the Food and Drug Administration (FDA), HHS Office for Civil Rights (OCR), U.S. Department of Veterans Affairs (VA), and Federal Trade Commission (FTC)—to promote trust in predictive decision support interventions (DSIs) and algorithmic transparency.

ONC's intent with HTI-1 is to:

- Continue to implement the 21st Century Cures Act of 2016 (the "Cures Act"), including establishing the EHR Reporting Program, APIs for electronic health information (EHI) for use without special effort, and IBR exceptions for reasonable and necessary activities that interfere with the access, exchange and use of EHI;
- Achieve the goals of the Biden-Harris Administration's Executive Orders (EOs), including EO 13994 (Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats), EO 13985 (Advancing Racial Equity and Support for Underserved Communities Through the Federal Government) and EO 14091 (Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government); and
- Leveraging health IT to advance interoperability.

This Coppersmith Brief puts the proposed IBR enhancements in context to provide actors with the basic information they need to understand the proposed changes to IBR. This Coppersmith Brief does not cover the proposed changes to the ONC Program, certification requirements, or policies for DSI and algorithmic transparency. **Comments on the NPRM are due no later than June 20, 2023,** and can be submitted electronically here. ONC recommends using the public comment template.

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IBR Background

The Information Blocking Rule or IBR (collectively, 42 U.S.C. § 300jj-52 and 45 C.F.R. Part 171) prohibits health care providers, health IT developers of certified health information technology, and health information networks and exchanges (HIN/HIEs) from engaging in practices that are likely to interfere with the access, exchange or use of electronic health information (EHI), unless the practice is required by law or a regulatory exception applies. The compliance deadline for IBR took effect on April 5, 2021. On October 6, 2022, the option for limiting compliance to EHI identified by the data elements in the USCDI v1 expired. IBR regulatory enforcement is delayed pending issuance and finalization of the enforcement rules. In the meantime, ONC proposes to clarify and enhance IBR applicability and exceptions.

Summary of Proposed IBR Enhancements

Proposed Changes to IBR Definitions

ONC proposes to materially narrow the scope of the types of individuals and entities that qualify as a "health IT developer of certified health IT." The IBR currently defines "health IT developer of certified health IT" as:

> An individual or entity, other than a health care provider that self-develops health IT for its own use, that develops or offers health information technology (as that term is defined in 42 U.S.C. 300jj(5)) and which has, at the time it engages in a practice that is the subject of an information blocking claim, one or more Health IT Modules certified under a program for the voluntary certification of health information technology that is kept or recognized by the National Coordinator pursuant to 42 U.S.C. 300jj–11(c)(5) (ONC Health IT Certification Program).[1]

ONC proposes to change this definition by:

- Clarifying that it does ***not*** apply to a health care provider "that self-develops health IT not offered to others" in place of "for its own use"; and
- Introducing a definition of "offers health information technology" or "offer health IT."

Under the current regulations, an offeror of certified health IT could be any individual or entity, including a health care provider, that licenses access to certified health IT through contractual terms or practices undertaken to operate or maintain health IT used by another individual or entity. ONC's original intent with including offerors was to hold accountable those individuals and entities that might develop the certified health IT but could engage in information blocking practices through their control over the health IT. In a December 16, 2020 blog post, ONC wrote that the "resale or other arrangement potentially including donation of software or services" could qualify an individual or entity as a health IT developer of certified health IT.[2] This led to considerable industry concern that engaging in EHR donation and subsidiary arrangements to provide community health care providers with access to otherwise financially

unattainable use of certified EHRs would trigger IBR liability or increased IBR liability for those individuals and entities engaged in such arrangements.

To address these concerns and provide further clarification in the regulatory text, ONC has proposed to define "offer health IT" as "to hold out for sale, resale, license, or relicense; or to sell, resell, license, relicense, or otherwise provide or supply health information technology [that includes one or more certified modules] for use by other individual(s) or entity(ies) under any arrangement other than the following:"[3]

- Donation and subsidized supply arrangements, so long as the donation or subsidy is made without any conditions limiting the interoperability or use of the technology to access, exchange or use EHI for a lawful purpose either explicitly in the written contract or through oral statements or patterns of conduct.

- The following implementation and use activities:
    - Issuing user accounts and/or login credentials for employees (including 1099 contractors) in the course of their employment or contractual engagement;
    - Making available production instances of API technology or portals that are used to query or transmit EHI from or across a health information network or exchange (HIN/HIE), such as a patient, provider, payer or public health portal;
    - Issuing user accounts and/or login credentials to public health authorities for public health purposes, such as syndromic surveillance;
    - Issuing user accounts and/or login credentials to providers who need to access health IT systems to document/bill for care provided at the health care facility; and
    - Certain consulting and legal service arrangements, including outside legal counsel and consultants, as well as practice management or other provider administrative or operations management organizations where the organization stands in the shoes of the provider in dealings with the health IT developer or commercial vendor and/or in managing the day-to-day operations and duties for the health IT developer as part of a comprehensive array of ***predominantly*** non-health IT administrative and operational functions that would otherwise fall on the clinician practice or other health care provider's partners, owners, or staff. ONC proposes to use a factors test for distinguishing between: (1) practice/operational arrangement that includes health IT as a necessity to operate as a provider; as compared to (2) an arrangement to supply health IT that happens to include additional service.[4] The former arrangement (scenario 1) being an excluded arrangement; the latter arrangement (scenario 2) constituting an offer of health IT. Under the former arrangement (scenario 1), the health care provider actor would be accountable for any information blocking committed on the provider's behalf, but that arrangement would not trigger application of the health IT developer definition for the management organization. ONC seeks comment on whether this particular exclusion is too confusing or if different or additional criteria should be considered.

Importantly, none of these exceptions constitute a categorical exclusion of particular classes or types of individuals or entities from qualifying as an offeror of health IT and thus a health IT developer of certified health IT. Rather, whether

the arrangement is excluded depends on the facts and circumstances of the arrangement. For example, ONC explains that for an entity that operates multiple business lines—one that would qualify for an exclusion (such as consulting services) and another that would meet the definition of "offers health IT" (such as reselling a license to a certified EHR)—the business line that meets the definition would result ***in the entire entity*** being considered a health IT developer of certified health IT for ***all its practices***, including the business line that provides the typically excluded services.[5]

ONC's intent with this proposed change is to explicitly exclude from developer IBR liability:

- Those beneficial arrangements that expand provider access to and use of certified EHR technologies;
- Those circumstances in which a provider only implements the features and functionality of their EHR systems, such as engaging patient access APIs; and
- The furnishing of certain legal, health IT expert consulting or management consulting services to providers or others who are interested in obtaining or using health IT.

ONC also proposes to:

- Add a definition of "business associate," as defined by HIPAA, see 45 CFR 160.103;
- Add a definition of "provide," as defined by the ONC Program, see proposed 45 CFR 170.102;[6] and
- Revise the definition of "information blocking" to remove the period for which actors could limit compliance to the data elements represented in the USCDI v1 because that time period expired as of October 6, 2022.

The proposed addition of the "provide" definition to the general definitions section is perplexing because, if finalized, it may have the unintended effect of making whole conditions of the IBR exceptions non-sensical because "provide" will mean "the action or actions taken by a health IT developer of certified Health IT Modules to make the certified health IT available to its customers."[7] ONC does not explain why it proposes to include this definition in the IBR, but presumably ONC intends it to be used in connection with the new infeasibility condition for "manner exception exhausted," discussed below. As such, ONC should consider limiting its application to that condition of the Infeasibility Exception.

Contraction and Expansion of the Content and Manner Exception

It is not information blocking for an actor to limit the content of its response to an EHI request or the manner in which it fulfills an EHI request to access, exchange, or use of EHI, provided certain conditions are met. The Content and Manner Exception (45 CFR 171.301) exists to support innovation and competition by allowing actors to first attempt to negotiate market rates and terms for the access, exchange or use of EHI, without having to comply with the requirements of the Fees and Licensing Exceptions to have certainty that the fees and other terms imposed on the access, exchange or use of EHI is not information blocking. An actor bears the burden of proving that the actor satisfies all applicable requirements and conditions of the Content and Manner Exception at all relevant times.[8]

Removal of "Content" from the Content and Manner Exception

ONC proposes to rename the "Content and Manner Exception" (45 CFR 171.301) the "Manner Exception" and to limit its use to negotiations and agreements over ***how*** EHI is accessed or exchanged (and not including ***what*** EHI is accessed or

exchanged). Currently, the "Content and Manner Exception" may be used in circumstances where an actor engages in a "practice of ***limiting the content of its response*** to ***or the manner in which it fulfills a request***" for EHI.[9] ONC proposes to remove safe harbor protection for limiting the content of the response and to narrow the exception to apply only in circumstances where the actor is technically unable or cannot reach agreeable terms with the requestor to fulfill the request ***in the manner requested***. ONC proposes deletion of the content element because an actor's ability to limit compliance to only that EHI identified by the data elements represented in the USCDI v1 expired on October 6, 2022.

However, this proposed rule change overlooks that often an actor may only be able to provide some of the EHI requested in the manner it is requested; that is, an actor may limit the content of its response while otherwise fulfilling the EHI request in the manner in which it is requested. For example, because certified APIs are currently tied to the USCDI v1, these APIs often can only support the access, exchange and use of data elements represented in the USCDI v1. Thus, an actor may be able to satisfy the Manner Exception with respect to some, but not all, of the EHI requested. The proposed rule changes create uncertainty as to whether the Manner Exception may be utilized in these circumstances.

The TEFCA Expansion: Trusted Exchange Framework and Common Agreement

ONC further proposes to expand the Content and Manner Exception (45 CFR 171.301) to create a safe harbor protection for actors who are Qualified Health Information Networks (QHINs), Participants or Subparticipants (as those terms are defined by the Common Agreement) (collectively, "TEFCA Actors").

TEFCA refers to the Trusted Exchange Framework and Common Agreement. The Cures Act required ONC to develop TEFCA—that is, a set of non-binding but foundational principles for nationwide EHI exchange and a legal contract that advances those principles. It is not itself a technology, platform, network or standards body. Rather, TEFCA is a data sharing framework that establishes the minimum requirements to support nationwide data exchange. ONC designated the Sequoia Project as the Recognized Coordinating Entity (RCE) to be responsible for developing the Trusted Exchange Framework (TEF), Common Agreement, minimum technical standards and standard operating procedures, including the permitted exchange purposes. The RCE is also responsible for vetting and designating the QHINs that will provide the technical networks and connections to facilitate TEFCA-based data exchange. QHINs will enter into the Common Agreement with the RCE and QHINs, which, in turn, are required to flow down contractual obligations to their Participants and Subparticipants through the framework agreements. Participants and Subparticipants could be hospitals, physician practices, pharmacies, HIEs and other HINs, individual access service providers (*e.g.*, third party applications that provide services to individuals), electronic health record vendors, other technology vendors, public health authorities, governmental departments and agencies, and more. As of the date of this briefing, the RCE has not approved any QHINs and there is no live data sharing occurring on any networks operating under TEFCA. Nevertheless, the ONC is proactively proposing a TEFCA exception to IBR to encourage actors to participate in TEFCA.

Under the NPRM, if TEFCA Actors ***offer*** to fulfill an EHI request from any other QHIN, Participant or Subparticipant for any purpose permitted under TEFCA (*i.e.*, treatment, payment, health care operations, individual access services (IAS), and more) using any technical service provided by a QHIN or the specified technical services in the applicable TEFCA framework agreement available to both parties, then such actors are entitled to:

- Refuse to offer the EHI in any alternative manner, even if the EHI being requested goes beyond the minimum data classes and elements required by the Common Agreement;
- Charge any fee related to fulfilling the EHI request without satisfying the requirements of the Fees exception (see 45 CFR 171.302), even if the requestor does not want to access, exchange or use the EHI through the TEFCA connection or by the TEFCA technical specifications; and
- Impose any licensing terms for the interoperability elements used in connection with the request without satisfying the requirements of the Licensing Exception, again without regard to whether the requestor desires to use the TEFCA connection for the requested EHI access, exchange or use.

If finalized as proposed, this exception may give individuals and entities that offer TEFCA connections (*i.e.*, TEFCA Actors, including QHINs) the ability to engage in wide scale information blocking practices with respect to other networks, exchanges and technologies that EHI requestors may prefer to use for data sharing activities that overlap with TEFCA's broad permitted exchange purposes—including common treatment, payment, health care operations and public health activities—if those requestors also participate in TEFCA-based exchange. These practices may range from the outright refusal to provide the EHI requested to exorbitant fees for access to a TEFCA connection or use of technologies specified TEFCA, as well as licensing provisions that inhibit competition and innovation. Because TEFCA also requires that any Participant or Subparticipant in TEFCA be assigned to a single QHIN, this rule change may have the unintended effect of monopolizing data exchange in a handful of entities who can use fees and licensing provisions to inhibit innovation, stifle competition and divert requestor resources away from interoperability solutions that would be better suited and scaled to meet their needs.

Notably, this proposed exception also goes well beyond ONC's earlier discussions of the potential scope of a TEFCA exception. ONC had originally discussed limiting the scope of a TEFCA exception to those practices required by the Common Agreement or necessary to implement Common Agreement requirements. In other words, the original concept of a TEFCA exception would only provide TEFCA Actors certainty that it would not be information blocking if they signed and implemented the requirements of the Common Agreement. The proposed TEFCA exception, if finalized, will insulate TEFCA Actors for practices that occur outside of TEFCA and are not required or necessary to implement the Common Agreement.

Clarification and Expansion of the Infeasibility Exception

It is not information blocking if an actor does not fulfill an EHI request due to the infeasibility of the request, provided certain conditions are met. Under the current IBR rule, the three primary infeasibility conditions of the Infeasibility Exception (45 CFR 171.204) are—(1) uncontrollable events; (2) data segmentation; and (3) infeasibility under the circumstances. ONC seeks to clarify and expand the Infeasibility Exception by creating two new types of infeasibility—"third party seeking modification of use" and "manner exception exhausted"—and clarifying when an actor might qualify for infeasibility due to "uncontrollable events." All of these infeasibility conditions currently require (and will continue to require) that the actor notify the requestor of the infeasibility in writing, including why the request is infeasible, within ten business days of receipt of the EHI request.[10] An actor bears the burden of proving that the actor satisfies all applicable requirements and conditions of the Infeasibility Exception at all relevant times.[11]

Uncontrollable Events Condition.

An uncontrollable event condition refers to a "natural or human-made disaster, public health emergency, public safety incident, war, terrorist attack, civil insurrection, strike or other labor unrest, telecommunication or internet service interruption, or act of military, civil or regulatory authority."[12] The Infeasibility Exception currently excuses interferences that are "due to" such uncontrollable events. ONC proposes to modify this infeasibility condition by replacing the words "due to" with "because of" to clarify that there must be a causal connection between the uncontrollable event and the interference with the access, exchange or use of EHI. For example, the declaration of a public health emergency (PHE) does not in itself qualify an actor for the exception. Rather, the actor bears the burden of proving that the PHE caused the interference with the access, exchange or use of EHI in addition to meeting the other requirements of the Infeasibility Exception.

Third Party Seeking Modification of Use.

ONC also proposes to add a new infeasibility condition that will allow actors to deny any EHI requests that would involve the use of EHI in order to modify it, including but not limited to the deletion function. For example, if a patient requests to use a third-party application's API to delete or modify EHI in a provider's system—such as changing the patient's vital signs or deleting content from a clinical note, the provider actor could deny the request as infeasible.

This exception is ***not*** available to an actor that is a business associate of a health care provider—such as a health IT developer of certified health IT—that receives such a request from the provider. This means that if a health care provider requests that its EHR vendor write data from its practice management software vendor—such as updated patient demographic data—or from its CDS software vendor—the EHR vendor cannot use this exception to refuse the request made by business associates of the same provider customer. ONC explains, however, that an actor may be able to leverage another exception, such as "infeasibility under the circumstances," to deny such a request. For example, if the CDS software vendor's modification use request is incompatible with the EHR technology, the EHR vendor may look to the new proposed "manner exhausted exception" (described below) or "infeasibility under the circumstances."

The touted benefits of this new infeasibility condition are that it:

- Is not subject to the same onerous documentation requirements as "infeasibility under the circumstances" (45 CFR 171.204(a)(3));
- Does not require an investment of time and resources to work through the Manner Exception and/or new "manner exception exhausted" infeasibility condition; and
- Does not require justification under the Security Exception (45 CFR 171.203).

Interestingly, however, this exception is limited in two potentially significant and consequential ways that might ultimately undermine its intended purpose. First, it is limited to the "use" of EHI to "modify" the EHI. In the IBR context, "use" means the "ability for electronic health information, once accessed or exchanged, to be understood and acted upon."[13] ONC explain in the preamble to the 2020 Final Rule that acting upon EHI includes the "ability to read, write, modify, manipulate, or apply the information . . . ."[14] Although "modify" is not defined in the IBR, it is commonly understood to mean "to change."[15] This exception thus arguably would not apply to requests to "exchange" EHI—that is, "the ability for electronic health information to be transmitted between and among different technologies, systems,

platforms, or networks"[16]— to add to (but not to change) the EHI accessible in the actor's system. That could be a critical distinction for actors who are concerned not only with the feasibility of "using" EHI to modify it in their systems but adding new EHI to their systems through "exchange" from third parties.

Second, this exception cannot be used by business associates of health care providers. This carve out from the exception makes good sense given that, under the HIPAA Security Rule, it would be a HIPAA violation for a business associate to prevent a covered entity from using its own EHI to modify it.[17] Indeed, one of the intended purposes of the IBR is to stop vendors from prohibiting their customers from using other technologies to access, exchange and use their own EHI. However, this carve out is not broad enough to cover customers of actors who are not HIPAA covered entities—such as health care providers that do not electronically bill health plans—or customers who are not health care providers, but who might be maintaining EHI in systems licensed by an actor. For example, a developer actor that maintains EHI on behalf of a HIN/HIE could use this exception to deny a HIN/HIE's request to use a third-party technology to modify the EHI maintained by the HIN/HIE. Such a result would be counter to, and undermine the intent of, the IBR.

ONC seeks comments on the following:

- Should this infeasibility condition be of limited duration? That is, should it expire after a certain period similar to the content component of the Content and Manner Exception, in which actors could use it to limit the EHI returned to only the EHI represented by the USCDI v1 data elements?
- Should ONC propose, in the future, that this condition be eliminated if/when health IT can support third-party modification use of EHI by any party with a legal right to do so with no option to assert an Infeasibility Exception?

Manner Exception Exhausted.

ONC further proposes to add a new "manner exception exhausted" infeasibility condition that could be used by actors who are unsuccessful in qualifying for the revised "Manner Exception." With this exception, ONC seeks to recognize that there may be legitimate practical changes beyond an actor's control—such as technological capabilities or other costs/burdens—that may limit its ability to comply with the EHI request. This new infeasibility condition has 3 requirements which must be met at all relevant times:

- The actor could not reach agreement with the requestor to fulfill the EHI request in the manner it was requested under the Manner Exception (*see* 45 CFR 171.301(a)) ***or*** was technically unable to fulfill a request for EHI in the manner requested;
- The actor offered ***all of the alternative manners*** in accordance with the Manner Exception (*see* 45 CFR 171.301(b))[18] for the EHI requested but could not reach agreement with the requestor; ***and***
- The actor does not ***currently provide*** the ***same*** access, exchange or use for the EHI requested to a ***substantial number*** of individuals or entities that are ***similarly situated*** to the requestor.

The purpose of the third requirement is to ensure that complying with the EHI request would, in fact, impose a substantial burden on the actor and be plainly unreasonable, while allowing actors to deny EHI requests from requestors for non-standard, non-scalable solutions that are unsupported by the actor (and after the actor has offered to provide the access, exchange or use in an alternative, standards-based manner). ONC hopes that with this infeasibility condition

actors will reasonably allocate resources to standards-based manners for accessing, exchanging and using EHI without misusing it to stifle innovation and competition. Hence why ONC requires that actors seeking to use this infeasibility condition not provide the same requested manner to a "substantial number" of individuals or entities "similarly situated" to the requestor.

ONC purposefully does not propose to define or quantify "substantial" because what might be substantial to a national EHR vendor will be different when compared to a community HIE, for example. Nevertheless, ONC seeks comment on whether it should propose in the alternative a specific number to quantify "substantial number"—such as more than 1 or between 1 and 10. ONC also solicits comment on whether it should clarify the meaning of "similarly situated," such as clarifying that if an actor provides EHI access to health care providers in a certain form (*i.e.*, manner), that same form of access should be made available to individuals baring other potential considerations, such as privacy and security.

The "manner exception exhausted" infeasibility condition's benefits to actors include:

- It can be used without having to meet the contemporaneous documentation and factors analysis required by "infeasibility under the circumstances;"
- Actors need not assess whether they could theoretically or technically meet a requestor's particularized demands, so long as the requirements of this condition are met; and
- Actors may consider whether fulfilling the EHI request in the manner requested would require substantial technical or financial resources, including significant opportunity costs.

However, this new condition may operate to entrench existing standards to the detriment of novel and new approaches that would advance the goals of interoperability, innovation and competition. To mitigate this risk, ONC has proposed the second requirement, which requires an actor to offer ***all of the alternative manners*** set forth in the proposed Manner Exception. ONC seeks comment on whether it should propose, in the alternative, that an actor offer a certain number of alternative manners, such as:

- Offering at least two or at least three alternative manners;
- Offering to fulfill the request in two manners that use standardized content and transport standards; or
- Offering at least one manner that uses standardized content and transport standards and an alternative machine-readable format.

Finally, it is unclear why the first requirement restates technical inability as the reason for the infeasibility under the Manner Exception when the Manner Exception itself (45 CFR 171.301)—even as revised—provides that an actor must fulfill the EHI request in the manner requested, "unless ***the actor is technically unable to fulfill the request*** or cannot reach agreeable terms with the requestor to fulfill the request in the manner requested."[19] ONC does not explain how this alternative requirement in the "manner exception exhausted" condition is materially different from or expands the options for meeting the first requirement.

IBR Requests for Information

In the NPRM, the ONC is also soliciting information from the public on the following three topics: (1) additional exclusions from the "offer health IT" definition; (2) an additional TEFCA exception; and (3) data segmentation and use/patient access.

With respect to the additional exclusions from the "offer health IT" definition, ONC seeks comment on whether:

- There are other beneficial arrangements that ONC should specifically exclude because they are beneficial to patients or providers, but the possibility of IBR applicability is causing them to occur less often;
- The exclusions from "offer health IT" are potentially insulating individuals or entities with shoddy practices or nefarious intent from accountability; and
- Steps that can be taken to further encourage the lawful donation or other subsidized provision of certified health IT to health care providers who struggle to afford such technology.

ONC also seeks comment on what, if any, specific practices required of TEFCA Actors under TEFCA pose potential IBR concerns.

Lastly, ONC recognizes that data segmentation is an integral capability for enabling the access, exchange, and use of EHI in compliance with sensitive data laws and individual privacy preferences. ONC also recognizes that there is significant variability in health IT products' capabilities to segment data based on user and purpose. ONC seeks comment on:

- Steps ONC could take to improve data segmentation efforts, such as through functional or standards-based certification requirements;
- The capabilities of existing health IT to segment data and apply data sharing preferences;
- How greater consistency in provider documentation practices could enhance the feasibility of technical segmentation solutions; and
- What barriers to technical feasibility are presented by local, state and federal laws.

Interested in Learning More?

You can learn more about the IBR and the NPRM on the ONC's website at https://www.healthit.gov/topic/information-blocking. You can also register for ONC information sessions and access fact sheets about the NPRM at https://healthIT.gov/proposedrule. If you'd like to learn more about TEFCA please read *What You Need to Know about TEFCA: The Common Agreement* or visit the RCE's TEFCA Resource webpage.

About the Author

Melissa (Mel) A. Soliz, a partner with Coppersmith Brockelman, is highly sought out for her deep expertise on data privacy and interoperability issues ranging from HIPAA and 42 CFR Part 2 compliance to the ONC Information Blocking Rule, TEFCA (the Trusted Exchange Framework and Common Agreement) and CMS interoperability mandates. Her

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By the way, you know the Coppersmith Briefs are not legal advice, right? Right!
Check with your attorney for legal advice applicable to your situation.

Endnotes

[1] 45 CFR 171.102 "Health IT developer of certified health IT."
[2] Steven Posnack, *Pssst…Information blocking practices, your days are numbered…Pass it on.*, HEALTH IT BUZZ BLOG (Dec. 16, 2020).
[3] 88 FR 23746, 23915 (Apr. 18. 2023).
[4] Specifically, the ONC explains that the key differentiating factors would be: (1) "The individual or entity furnishing the administrative or operational management consulting services acts as the agent of the provider or otherwise stands in the shoes of the provider in dealings with the health IT developer(s) or commercial vendor(s) from which the health IT the client health care providers ultimately use is obtained."; (2) "The administrative or operational management consulting services must be a package or bundle of services provided by the same individual or entity and under the same contract or other binding instrument, and the package or bundle of services must include a comprehensive array of business administration functions, operations management functions, or a combination of these functions, that would otherwise fall on the clinician practice's or other health care provider's partners, owner(s), or in-house staff."; (3) "[T]he bundle of business administrative and operational management consulting services must include multiple items and services that are not health information technology"; and (4) "[N]on-health IT services must represent more than half of each of the following: [(a)] the person hours per year the consultant bills or otherwise applies to the services bundle (including cost allocations consistent with Generally Accepted Accounting Principles), and [(b)] the total cost to the client for, or billing from, the consultant per year (including pass-through costs for the health IT items and services)." 88 FR at 23863.
[5] *See* at 88 FR at 23864.
[6] ONC proposes to define "provide" as "the action or actions taken by a health IT developer of certified Health IT Modules to make the certified health IT available to its customers." 88 FR at 23905.
[7] 88 FR at 23905.
[8] *See* 45 CFR 171.300.
[9] 45 CFR 171.301 (emphasis added).
[10] *See* 45 CFR 171.204(b).
[11] *See* 45 CFR 171.200.
[12] 45 CFR 171.204(a)(1).
[13] 45 CFR 171.102 "Use."
[14] 85 FR 25642, 25806 (May 1, 2020).
[15] "Modify." Merriam-Webster's Unabridged Dictionary, Merriam-Webster, https://unabridged.merriam-webster.com/unabridged/modify. Accessed 28 Apr. 2023.
[16] 45 CFR 171.102 "Exchange."
[17] *See* OCR, FAQ #2074.
[18] These alternative manners are as follows (and in this order of priority) under the NPRM: "(i) Using technology certified to standard(s) adopted in part 170 that is specified by the requestor. (ii) Using content and transport standards specified by the requestor and published by:(A) The Federal Government; or (B) A standards developing organization accredited by the American National Standards Institute. (iii) Using an alternative machine-readable format, including the means to interpret the electronic health information, agreed upon with the requestor." 88 FR at 23916. These alternative manners must also meet the requirements of the Fees and Licensing Exceptions with respect to any fees charged or license of interoperability elements in relation to fulfilling the EHI request. *Id.*
[19] 88 FR at 23916.