athenahealth

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Submitted electronically to www.regulations.gov; RIN 0955-AA01

Re: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Notice of Proposed Rulemaking

Dear Dr. Rucker,

Thank you for the opportunity to provide athenahealth's perspective on the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program proposed rule ("proposed rule").

Over the past twenty-one years, athenahealth has built a network of over 160,000 clinicians in both the ambulatory and acute settings. We provide electronic health record ("EHR"), practice management, care coordination, patient engagement, data analytics, revenue cycle management, and related services to physician practices and hospitals. More than 116,000 of our clinicians utilize our single instance, continuously updated, cloud-based platform. Since announcing a combination with Virence Health in early 2019, we also support on-premise software solutions. In both hosting paradigms, athenahealth seeks out and establishes connections with partners across the care continuum, enabling our clinicians to improve the quality of care they deliver. As the #1 rated KLAS Most Interoperable EHR in 2017, we integrate with more than 1,800 insurance payers, 12,000 labs and imaging centers, and 95% of pharmacies in the U.S.

The ONC proposed rule is the logical progression of more than a decade's worth of frustration from providers, health systems, policymakers, and EHR vendors at the pace of interoperability progress. We believe the industry is committed to a health ecosystem where information exchange is the norm, not the exception. As we look forward, we must also recognize that the health industry is undeniably better connected today than it was yesterday – and certainly than it was ten years ago. ONC should complement, rather than usurp, this progress. In our experience, meaningful information exchange occurs in response to market demands when two or more entities solve for a business use case. As ONC and CMS continue to promote interoperation, it is critical that the agencies support these use cases by removing any unnecessary requirements for physicians and their technology partners.

We applaud ONC for appropriately promoting these objectives in several provisions throughout the proposed rule. First, ONC astutely recognizes the need for actors to recoup the costs and earn a "reasonable" profit associated with sharing electronic health information. Building and maintaining integrations that bring value to the end user require a significant developer resource commitment. Without the ability to earn a reasonable profit for these interoperation investments, actors in a market economy would be incentivized to prioritize the development of other products and simply meet the minimum requirements for interoperability. We have seen the impact of "low bar" requirements play out through the first iterations of the Meaningful Use program and commend ONC for recognizing that a functioning market is a pre-requisite for meaningful information exchange. By permitting a "reasonable" (not fixed) profit margin, ONC

strengthens the business use case for innovative and impactful information-sharing. Second, we praise ONC's approach to investigating information-blocking allegations. We believe that uniform enforcement would have created a de facto safe harbor and lowered the regulatory bar to a point of functional insignificance. ONC's decision to weigh the unique facts of each allegation and the resources of each actor will help ensure targeted, proportional enforcement with the appropriate context for a reasonable assessment. Third, athenahealth commends ONC for proposing logical updates to the 2015 Edition Certification criteria, rather than overhauling the program or establishing a new edition of certification. Iterative changes allow the industry to adapt to new market forces, and maintain stability, whereas sweeping overhauls have a cooling effect on organic innovation and growth. ONC should continue to seek to maximize the impact of these certification changes and pursue all opportunities to simplify existing criteria.

In addition, ONC perceptively identified three of the most pervasive forms of information-blocking in the proposed rule. In our experience, failed requests to integrate with other systems are often attributed to excessive and discriminatory costs, "box outs,"[1] and restrictive technical and contractual terms. By simply identifying the appropriate categories in the proposed rule, ONC will make significant progress deterring these practices.

Finally, we applaud the proposed rule's general structure regarding information-blocking exceptions. After Congress enacted a sweeping prohibition against information-blocking behavior, it was incumbent upon ONC to carve out precise and unexploitable categories of acceptable behavior that impedes information flow. athenahealth praises ONC for thoughtfully identifying seven allowable behaviors or "exceptions" where an actor might judiciously choose not to share electronic health information. This categorization and the conditions under each exception allow companies to engage in the healthcare ecosystem with confidence and flexibility. This kind of environment is essential for our industry to achieve meaningful, widespread interoperation.

While we praise ONC's desire to promote market-based innovation and business use cases for interoperability, we are convinced that there are three critical changes that ONC must adopt in a final rule to ensure it effectively accomplishes these goals.

1. ONC Must Add a Permitted Fee for API Usage Costs to Properly Account for Platform Technology Market Participants

ONC's rationale for fee restrictions placed on API Technology Suppliers in the proposed rule does not appropriately account for platform models, where the technology company brings value to consumers by reducing the onsite technical resources required to run a fully connected EHR system.

The proposed rule is understandably written specifically to address on-premise software models, where provider organizations purchase software and maintain their own technical management onsite. We recognize that the majority of the industry operates on this model and there are tangible benefits for health systems to choose locally-installed health IT solutions. For example, most on-premise software allows an added degree of customization and control for healthcare organizations and providers. We also know that innovative companies will continue to operate in the healthcare market, leveraging the advantages of cloud-based platforms to build

[1] "Box out" refers to healthcare network action of limiting the health IT choice of a provider under the false pretense that the only way to share clinical information is using a single vendor across an entire affiliate network.

networks from which we can glean important information, similar to those used in personal finance, banking, and travel.

The "platform" model extends beyond software hosted in the cloud. A platform company leverages full network data visibility to allow third-party companies to innovate on top of, or alongside, a primary product offering. For example, a health system can seamlessly integrate with tools from multiple vendors operating on the same continuously updated, cloud-based foundation. An underlying principle of any platform technology company's mission is that the facilitated interactions between external developers and end users add value for all participants. Today, athenahealth offers *both* locally-installed managed software, as well as a cloud-based platform. Leveraging both models of software solutions that span the spectrum of industry offerings, we are positioned to address the challenges of widespread interoperability and the practical impact of ONC's proposed rule. It is from this perspective that we find the proposed rule does not appropriately account for the business models of platform technology companies.

Platform companies operate as an "API Technology Supplier" *and* also carry out many technical functions of a typical "API Data Provider," as defined in the proposed rule. For example, a cloud-hosted vendor such as athenahealth builds and maintains the API integrations between API Data Providers (our health system and physician clients) and trusted third-party applications on behalf of provider clients in the production environment. This type of technical management and work is typically reserved for the technical staff of API Data Providers in most locally-installed software models according to ONC's defined roles of regulated actors. The platform model drives down costs and allows integrations to occur at scale by virtue of the single instance, cloud-hosted model. The rule states:

> We propose that any fees that an API Technology Supplier charges for developing, deploying, or upgrading API technology must be charged solely to the API Data Provider(s) for whom the capabilities are deployed. We propose this limitation because we believe that these costs should be negotiated between the API Technology Supplier that supplies the capabilities and the API Data Provider (i.e., health care provider) that implements them in its production environment. In our view, it is inappropriate to pass these costs on to API Users as doing so would impose considerable costs on the API Data Provider's current or potential partners, such as those offering third-party applications and services, as well as the end-users of API technology and would amount to the kind of "special effort" that the Cures Act's API Condition of Certification seeks to prevent.[2]

In fact, it is our experience that existing business arrangements between API Technology Suppliers and API Users, primarily app and other technology developers, directly promote and facilitate the meaningful exchange of health information "without special effort on behalf of the user,"[3] as Congress intended in the 21st Century Cures Act.

We propose that ONC adopt an additional permitted fee for API usage costs between the API Technology Supplier and API User. A permitted fee for API usage costs creates a mutually beneficial relationship between API Technology Suppliers and API Users to support their shared physician clients. API Users gain secure access to potential clients and valuable data to build

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[2]21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 84 Fed. Reg. 42 (March 4, 2019). *Federal Register: The Daily Journal of the United States.* Web. April 2019.
[3]42 U.S.C. § 300jj

their applications, while API Technology Suppliers are incentivized to innovate and build integrations that increase physician capability and, ultimately, performance. Meanwhile, API Data Providers, specifically independent physicians and small health systems, benefit from streamlined, seamless workflows without the "special effort" of shouldering the technical integration. Today, athenahealth brings this value to its physician clients by integrating more than 230 approved applications into our platform and partnering directly with app developers. Health data flows abundantly under this symbiotic arrangement.

Given that the rule's information-blocking provisions would still govern fees associated with API arrangements, the risk for discriminatory application and exploitation of usage-based fees has been sufficiently addressed. This proposed limitation of permitted fees is not necessary to protect against fee exploitation between API Technology Suppliers and API Users.

Further, the prohibition of an API usage fee between API Technology Suppliers and API Data Providers will inadvertently disadvantage API Data Providers by forcing them to purchase additional IT resources to fully realize the benefits of EHR systems. If API Technology Suppliers and API Users are not permitted to respond to market incentives and engage in a business relationship, the additional cost incurred by API Technology Suppliers will eventually – and unfortunately – be passed onto providers. ONC should ensure that all parties have the flexibility to respond to market forces and reduce the financial and administrative burden on providers already operating on razor-thin margins.

Furthermore, we believe that, without a permitted fee between API Technology Suppliers and API Users that accounts for usage-based costs, innovation will occur at a slower rate than ONC intended by this proposed rule. The healthcare ecosystem is constantly evolving, with new types of entities working with each other in ways that present new, value-driven opportunities. In fact, information exchange is often needed between many different parties, all of whom benefit from access to the information. For example, a third-party app developer may build a patient-facing app designed to ensure that patients are seen by their primary care physicians shortly after being discharged from the hospital. For this app to function, it must access chart data from the hospital (to indicate the patient was discharged) and scheduling data from the primary care physician (to find open times in their calendar). A payer may decide to directly bear the full cost of providing the application to its patients, to reduce costly readmissions. Ultimately, the provider and patient each benefit, as does the app developer, but the payer has the most financial upside and, thus, is most willing to directly bear the cost. The proposed rule does not currently account for payment in this example by the payer. We believe it is important to permit the payment for costs related to such exchange for the potential new entrants into the healthcare ecosystem.

Ultimately, we believe that the usage-based fee prohibition between API Technology Suppliers and API Users would interfere with the market forces that drive down costs and restrict platform companies from creating innovative solutions for information exchange. In order to foster an interoperable healthcare ecosystem for both platform technology companies and on-premise software, ONC should adopt this additional permitted fee for API usage costs in its final rule.

2. <u>ONC Must Protect Against the Abuse of Patient Access Provisions</u>

A patient's choice to play an active role in his or her care delivery must remain a core principle of the final rule. athenahealth has long believed that patients should be positioned at the center of care, empowered and enabled to access and direct their own health data alongside their care team. Regarding patient access, the rule states:

> In the context of this proposed permitted fee's scope and the proposed general prohibition on fees, we seek to make clear that API Technology Suppliers would be prohibited from charging (or including in their contracts and agreements with API Data Providers) any usage-based fees for API uses that are associated with the access, exchange, and use of EHI by patients or their applications, technologies, or services. This would include, among other things, API calls or other transactions initiated by or on behalf of a patient, including third parties (e.g., an application or any other technology or service) authorized by the patient or their representative to request data on their behalf.[4]

We believe that the proposed rule intends to enable such direct access for patients and the individuals closely managing care on their behalf (family member, trusted friend, care manager, etc.), but does *not* intend to grant unlimited access to patients' health information without charge for any third party performing services "on behalf of the patient." As drafted, the proposed rule could be interpreted to allow for several layers of third parties accessing data free of charge if there is ultimately a patient in the chain of custody, regardless of the attenuation or whether the purpose for the data collection was to benefit the patient. Further, use of "on behalf of a patient" may operate as a veil for less altruistic secondary uses (i.e. targeted advertisements or selling of data to third parties). Without limitation on who can request information on behalf of a patient, there is a high level of risk for abuse by third parties that may result in patient harm.

Throughout the rule, ONC recognizes that meaningful integrations require resource costs and that allowing technology companies to recover costs and earn a profit ultimately fuels future innovation. Even a small degree of uncertainty relating to free access "on behalf of the patient" is ripe for abuse by third parties claiming to access information "on behalf of a patient."

As more patients engage in their healthcare data management and utilize personal health record (PHR) applications, ONC should be clear and consistent regarding the cost-exempt category of "transactions initiated by or on behalf of the patient." Accordingly, ONC should clarify use cases for exchange without charge "on behalf of the patient" to ensure that regulated actors do not abuse this provision and that it is only applicable when a patient or a patient designated representative is requesting their information. For example, an overly broad interpretation of use cases "on behalf of the patient" could unintentionally result in every sector of the care continuum requesting information without charge "on behalf of the patient." Such an arrangement would prevent technology companies from recouping reasonable costs, misapply patients' rightful ability to access their data while compromising privacy, and ultimately cut against objectives of the proposed rule.

Further, without additional clarification that information must be requested by the patient (or on their behalf), API Technology Suppliers are faced with a futile exercise when performing any level of diligence regarding whether the information is being appropriately requested. API Technology Suppliers owe obligations of privacy and security to their clients (providers and hospital systems) and are required to ensure that safeguards are employed to protect the privacy of such clients' patients. Once information is provided to an end user, it is impossible for the API Technology Supplier to identify or control how the information is used and whether it was used by or on behalf of the patient, regardless of contractual provisions.

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[4] 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 84 Fed. Reg. 42 (March 4, 2019). *Federal Register: The Daily Journal of the United States.* Web. April 2019.

By protecting patients and technology companies alike from such exploitative interpretation, ONC will promote a market for information exchange that fuels future innovation, greater patient access, and improved healthcare outcomes.

3. ONC Must Continue to Streamline and Focus on Outcomes to Improve the Electronic Health Record Certification Program

athenahealth commends ONC for proposing logical updates that build on the first version of 2015 Edition Certification for Electronic Health Record Technology (CEHRT), rather than proposing a net-new certification program. While we believe these provisions are broadly beneficial to the health IT industry, their success ultimately lies with an effective implementation for the entire industry. The updates are a significant technological lift for all certified EHR vendors. For context, we estimate that past iterations of certification have required at least one-third of athenahealth's developer resources in a given year. A significant portion of this time is devoted to repetitive testing and proving baseline functionality.

The proposed rule evidences ONC's laudable desire to streamline and simplify certification criteria for health IT. Changing 30 current 2015 Edition test procedures to attestation-only, along with six-month attestation periods will lessen health IT developers' burdens and costs while maintaining a high standard for compliance. We agree with ONC that testing is inefficient and expensive for the entire industry and urge the agency to move even more testing requirements to attestation-only or testing managed entirely by private, third-party entities. ONC should specifically examine moving baseline, industry mature functionality, such as e-prescribing, to attestation-based testing. The time and financial savings achieved by both health IT developers and ONC would improve resource allocation towards the building of high-quality, seamlessly interoperable functionality and in-the-field compliance.

ONC's current implementation timeline for updates to 2015 Edition Certification in the proposed rule is aggressive. We recommend an extension in the final rule to allow vendors the flexibility to appropriately address ONC-mandated updates and physician end-user requests, as well as long-term strategic innovation. As currently proposed, vendors will be forced to make short-term development resource decisions slanted towards certification-related updates. These decisions will come at the expense of market research and physician requests to improve various parts of each EHR system. In order to balance the importance of physician end-user-driven development and ONC updates to CEHRT, we ask that the final rule adopt a 30-month, rather than 24-month, implementation timeframe for 2015 Edition Certification criteria updates.

It is important that ONC not deviate from the timeframe it establishes in the final rule. Regulatory inconsistency and delayed implementations cause the industry uncertainty, reduce resource efficacy, and can suspend important development efforts. Unforeseen "eleventh hour" delays in certification enforcement also complicate other HHS programs that depend on the use of 2015 Certified EHR software. To best allow vendors to meet the technology needs of physicians, introduce innovative new functionality, and meet updated certification criteria, ONC should establish – and adhere to – a longer 30-month implementation timeline in the final rule.

In addition to these suggestions, we provide the following specific comments.

Specific comments

§ 170.315(b)(10) Electronic health information export
Included in 2015 Edition Base EHR Definition? *Yes*
Electronic health information export. (i) Single patient electronic health information export. (A) Enable a user to timely create an export file(s) with all of a single patient's electronic health information the health IT produces and electronically manages on that patient. (B) A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate. (C) Limit the ability of users who can create such export file(s) in at least one of these two ways: (1) To a specific set of identified users. (2) As a system administrative function. (D) The export file(s) created must be electronic and in a computable format. (E) The export file(s) format, including its structure and syntax, must be included with the exported file(s). (ii) Database export. Create an export of all the electronic health information the health IT produces and electronically manages. (A) The export created must be electronic and in a computable format. (B) The export's format, including its structure and syntax must be included with the export. (iii) Documentation. The export format(s) used to support single patient electronic health information export as specified in paragraph (b)(10)(i) of this section and database export as specified in paragraph (b)(10)(ii) of this section must be made available via a publicly accessible hyperlink.
Preamble FR Citation: 84 FR 7446-49 **Specific questions in preamble?** *Yes*
Regulatory Impact Analysis: Please see 84 FR 7568-70 for estimates related to this proposal.
Public Comment Field: ONC must move the industry towards bulk data export via API. As stated in our general remarks, athenahealth supports the premise that patients and providers should have access to individual health data to coordinate care and improve outcomes. We also believe that providers should be able to easily switch EHRs by utilizing seamless data export. For both use cases, we agree with ONC that with time, APIs – and not raw database exports – are the appropriate solution. However, the data export provisions in the proposed rule will move the industry further away from achieving this long-term goal of standards-based API exports. While on-premise software companies store all patient data in a single server onsite, it is standard practice for fully cloud-based technology companies to utilize *multiple* storage mechanisms to optimize physician and patient experiences. This storage model enables more seamless

exchange of discrete data across systems, but it is not conducive to a single, bulk database export as ONC envisions.

To meet ONC's requirement for a broad interpretation of "electronic health information," a platform company would need to devote dozens of developer years to account for the difference in data schema. ONC states that "the health IT developer would not need to make public their proprietary data model," in order to fully comply with ONC's proposal. In practice, compliance would indeed compel API Technology Suppliers to fully expose the proprietary schema to the public. This inadvertently and negatively impacts industry competition and market forces. Ultimately, this provision would force platform companies to change their internal architecture to achieve the short-term goal of a full data export, further distancing the industry from standards-based API exchange of full chart data upon switching EHRs. To enable a more direct path to this stated long-term goal, we propose that ONC allow an export of the required data set through a defined set of FHIR APIs as an option for compliance with the data export provision.

ONC can accomplish the end goal of a comprehensive data export - in an interoperable format readily leveraged by all market participants - by building on the USCDI clinical data set to include specified billing and administrative data. For areas not yet covered by the FHIR standards process but clearly of export value, ONC could enumerate specific required data types without requiring a format. This would require high-value data export from a provider's existing system while allowing technology vendors the necessary flexibility as standards evolve and expand. We suggest specifically including images of additional patient documents not covered by FHIR, a ledger of financial transactions, and 837/835 files exchanged with payers in these requirements.

By providing this alternative and focusing on the intended outcomes, as opposed to the means to achieve the outcome, ONC would allow vendors to more efficiently export data without translating between complex vendor schemas. Further, ONC should clarify the scope of data which should be exported. Sharing *all* "electronic health information," as defined in the proposed rule, would result in an overwhelming and burdensome amount of data for patients and providers to untangle. Additionally, the inclusion of *all* "electronic health information" would inadvertently tax an integrated technology vendor and incentivize the fragmentation of products to limit the scope of requirements for a given technology offering. In order to improve receiving parties' ability to utilize exported data and prevent this maligned incentive, ONC should specify a particular data set, using the USCDI clinical data set as a foundation, for export purposes.

Request for Information on the Development of Similar Independent Program Processes

Recognition of the FDA Software Pre-Certification Program for purposes of certification of health IT to 2015 Edition criteria may eventually be determined to be infeasible or insufficient to meet our goals of reducing burden and promoting innovation. With this in mind, we request comment on whether ONC should establish new regulatory processes tailored towards recognizing the unique characteristics of health IT (e.g., electronic health record (EHR) software) by looking first at the health IT developer, rather than primarily at the health IT presented for certification, as is currently done under the Program. We also welcome more specific comments on the health IT developer criteria for such an approach and what the Conditions and/or Maintenance of Certification requirements should be to support such an approach within the framework of the proposed Conditions and Maintenance of Certification requirements discussed in section VII of this proposed rule.

Preamble FR Citation: 84 FR 7439 **Specific questions in preamble?** *No*

Regulatory Impact Analysis: Not applicable

Public Comment Field:

We believe that the EHR certification program is ripe for reform, and we enthusiastically welcome the changes ONC proposed in this particular request for information. While the first edition of certification was designed to align health IT with Meaningful Use provider requirements, the industry has changed drastically since then – so much, in fact, that this particular quality program has been completely replaced. From that time, ONC's EHR certification program has strayed far from its original purpose and now dictates the development of specific technology features. As athenahealth allocates a myriad of resources to meeting these functionality requirements, we experience the opportunity cost of fulfilling end-user requests and investing in long-term strategic innovation. This prescriptive approach limits our ability to flexibly respond to market forces and meet the evolving needs of physicians, particularly as the industry transitions to a value-based care payment model. We believe that a certification program that evaluates the health IT developer, rather than specific functionality, will move the industry substantially forward. ONC should assess companies' consistent engagement in high-quality software design, testing, and maintenance, and allow them to efficiently prioritize the tools that meet end users' needs. Under this paradigm, the market forces that drive innovation would also contribute to successful certification, rather than force companies to choose between innovation and certification. We are supportive of this effort and look forward to engaging with the National Coordinator to make this a reality.

§ 170.205(b) Electronic prescribing

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(1) Standard. National Council for Prescription Drug Programs (NCPDP), Script Standard Implementation Guide, Version 2017071 (incorporated by reference in § 170.299).

Preamble FR Citation: 84 FR 7444 **Specific questions in preamble?** *No*

Regulatory Impact Analysis: Not applicable

Public Comment Field:

As specific EHR certification test plans are crafted, we urge ONC to set appropriate timelines to ensure that implementation is done properly and that providers fully and appropriately adopt the changes. Consistent with our general remarks, we ask that ONC delay the NCPDP standard implementation to be in line with the rest of the updates to 2015 Edition Certification.

Additionally, vendors should be empowered to work with their physician clients to determine what information should be brought forth to the user interface. ONC should focus on the desired outcome and allow vendors to work with their end-user physicians to determine the preferred approach.

§ 170.523 Principles of proper conduct for ONC-ACBs (Authorized Certification Bodies)

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(a) Accreditation. Maintain its accreditation in good standing to ISO/IEC 17065 (incorporated by reference in § 170.599).

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(f) Reporting. * * *

(2) [Reserved]

(g) Records retention.

(1) Retain all records related to the certification of Complete EHRs and Health IT Modules to an edition of certification criteria beginning with the codification of an edition of certification criteria in the Code of Federal Regulations through a minimum of 3 years from the effective date that removes the applicable edition from the Code of Federal Regulations; and

(2) Make the records available to HHS upon request during the retention period described in paragraph (g)(1) of this section;

(h) Testing. Only certify Health IT Modules that have been:

(1) Tested, using test tools and test procedures approved by the National Coordinator, by an:

(i) ONC-ATL;

(ii) ONC-ATL, NVLAP-accredited testing laboratory under the ONC Health IT Certification Program, and/or an ONC-ATCB for the purposes of performing gap certification; or

(2) Evaluated by it for compliance with a conformance method approved by the National Coordinator.

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(k) Disclosures. * * *

(1) All adaptations of certified Health IT Modules;

(2) All updates made to certified Health IT Modules affecting the capabilities in certification criteria to which the "safety-enhanced design" criteria apply;

(3) All updates made to certified Health IT Modules in compliance with § 170.405(b)(3) and (4); and;

(4) All voluntary standards updates successfully made to certified Health IT Modules per § 170.405(b)(5).

§ 170.523 Principles of proper conduct for ONC-ACBs (Authorized Certification Bodies)

(p) Real world testing.

(1) Review and confirm that applicable health IT developers submit real world testing plans in accordance with § 170.405(b)(1).

(2) Review and confirm that applicable health IT developers submit real world testing results in accordance with § 170.405(b)(2).

(3) Submit real world testing plans by December 15 of each calendar year and results by April 1 of each calendar year to ONC for public availability.

(q) Attestations. Review and submit health IT developer Conditions and Maintenance of Certification attestations made in accordance with § 170.406 to ONC for public availability.

(r) Test results from ONC-ATLs. Accept test results from any ONC-ATL that is:

(1) In good standing under the ONC Health IT Certification Program, and

(2) Compliant with its ISO 17025 accreditation requirements.

(s) Information for direct review. Report to ONC, no later than a week after becoming aware of, any information that could inform whether ONC should exercise direct review under § 170.580(a).

(t) Standards Voluntary Advancement Process Module Updates Notices. Ensure health IT developers opting to take advantage of the Standards Version Advancement Process flexibility per § 170.405(b)(5) provide timely advance written notice to the ONC-ACB and all affected customers.

(1) Maintain a record of the date of issuance and the content of developers' § 170.405(b)(5) notices; and

(2) Timely post content of each § 170.405(b)(5) notice received publicly on the CHPL attributed to the certified Health IT Module(s) to which it applies.

Preamble FR Citation: 84 FR 7456-57 Specific questions in preamble? *Yes*

Regulatory Impact Analysis: Please see 84 FR 7559 and 84 FR 7582-84 for estimates related to this proposal.

Public Comment Field:

Consistent with our general remarks regarding platform technology, we urge ONC to design testing and future processes to be more conducive to cloud technology. Companies often innovate in small, iterative steps. These frequent, incremental upgrades impact the entire production environment, and the testing environments ONC utilizes create many avoidable inefficiencies.

§ 170.405 Real world testing

(a) Condition of Certification. A health IT developer with Health IT Modules to be certified to any one or more 2015 Edition certification criteria in § 170.315(b), (c)(1) through (3), (e)(1), (f), (g)(7) through (11), and (h) must successfully test the real world use of those Health IT Module(s) for interoperability (as defined in 42 U.S.C.300jj(9) and § 170.102) in the type of setting in which such Health IT Module(s) would be/is marketed.

(b) Maintenance of Certification.

(1) Real world testing plan submission. A health IT developer must submit an annual real world testing plan to its ONC-ACB via a publicly accessible hyperlink no later than December 15 of each calendar year for each of its certified 2015 Edition Health IT Modules that include certification criteria referenced in paragraph (a) of this section.

(i) The plan must be approved by a health IT developer authorized representative capable of binding the health IT developer for execution of the plan and include the representative's contact information.

(ii) The plan must include all health IT certified to the 2015 Edition through August 31st of the preceding year.

(ii) The plan must address the following for each of the certification criteria identified in paragraph (a) of this section that are included in the Health IT Module's scope of certification:

(A) The testing method(s)/methodology(ies) that will be used to demonstrate real world interoperability and conformance to the certification criteria's requirements, including scenario- and use case-focused testing;

(B) The care setting(s) that will be tested for real world interoperability and an explanation for the health IT developer's choice of care setting(s) to test;

(C) The timeline and plans for any voluntary updates to standards and implementation specifications that the National Coordinator has approved through the Standards Version Advancement Process.

(D) A schedule of key real world testing milestones;

(E) A description of the expected outcomes of real world testing;

(F) At least one measurement/metric associated with the real world testing; and

(G) A justification for the health IT developer's real world testing approach.

(2) Real world testing results reporting. A health IT developer must submit real world testing results to its ONC-ACB via a publicly accessible hyperlink no later than January 31 each calendar year for each of its certified 2015 Edition Health IT Modules that include certification criteria referenced in paragraph (a) of this section. The real world testing results must report the following for each of the certification criteria identified in paragraph (a)of this section that are included in the Health IT Module's scope of certification:

(i) The method(s) that was used to demonstrate real world interoperability;

(ii) The care setting(s) that was tested for real world interoperability;

(iii) The voluntary updates to standards and implementation specifications that the National Coordinator has approved through the Standards Version Advancement Process.

§ 170.405 Real world testing

(iv) A list of the key milestones met during real world testing;

(v) The outcomes of real world testing including a description of any challenges encountered during real world testing; and

(vi) At least one measurement/metric associated with the real world testing.

(3) USCDI Updates for C-CDA. A health IT developer with health IT certified to § 170.315(b)(1), (e)(1), (g)(6), (f)(5), and/or (g)(9) prior to the effective date of this final rule must:

(i) Update their certified health IT to be compliant with the revised versions of these criteria adopted in this final rule; and

(ii) Provide its customers of the previously certified health IT with certified health IT that meets paragraph (b)(3)(i) of this section within 24 months of the effective date of this final rule.

(4) C-CDA Companion Guide Updates. A health IT developer with health IT certified to § 170.315(b)(1), (b)(2), (b)(9), (e)(1), (g)(6), and/or (g)(9) prior to the effective date of this final rule must:

(i) Update their certified health IT to be compliant with the revised versions of these criteria adopted in this final rule; and

(ii) Provide its customers of the previously certified health IT with certified health IT that meets paragraph (b)(4)(i) of this section within 24 months of the effective date of this final rule.

(5) Voluntary standards and implementation specifications updates. A health IT developer subject to paragraph (a) of this section that voluntary updates its certified health IT to a new version of an adopted standard that is approved by the National Coordinator through the Standards Version Advancement Process must:

(i) Provide advance notice to all affected customers and its ONC-ACB –

(A) Expressing its intent to update the software to the more advanced version of the standard approved by the National Coordinator;

(B) The developer's expectations for how the update will affect interoperability of the affected Health IT Module as it is used in the real world;

(C) Whether the developer intends to continue to support the certificate for the existing certified Health IT Module version for some period of time and how long or if the existing certified Health IT Module version will be deprecated; and

(ii) Successfully demonstrate conformance with approved more recent versions of the standard(s) or implementation specification(s) included in applicable 2015 Edition certification criterion specified in paragraph (a) of this section.

Preamble FR Citation: 84 FR 7495-97 **Specific questions in preamble?** *Yes*

Regulatory Impact Analysis: Please see 84 FR 7578-82 for estimates related to this proposal.

Public Comment Field:

athenahealth remains supportive of ONC moving towards more attestation-based and real-world testing to improve efficacy and compliance.

§ 170.315(b)(12) Data segmentation for privacy – send
Included in 2015 Edition Base EHR Definition? *No*
Data segmentation for privacy – send. Enable a user to create a summary record formatted in accordance with the standard adopted in § 170.205(a)(4) and (a)(4)(i) that is tagged as restricted at the document, section, and entry (data element) level and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1).
Preamble FR Citation: 84 FR 7452 **Specific questions in preamble?** *Yes*
Regulatory Impact Analysis: Please see 84 FR 7575-77 for estimates related to this proposal.
Public Comment Field: We ask ONC for additional clarity regarding whether the Data Segmentation for Privacy "send" provision will become mandatory for 2015 Edition Certification or if it will remain a voluntary criterion. Our suggestion is that each mature health IT company should have the flexibility to continue to ensure patient privacy in a way that best suits that individual system's infrastructure.

§ 170.315(b)(13) Data segmentation for privacy – receive
Included in 2015 Edition Base EHR Definition? *No*
Data segmentation for privacy – receive. Enable a user to: (i) Receive a summary record that is formatted in accordance with the standard adopted in § 170.205(a)(4) and (a)(4)(i) that is tagged as restricted at the document, section, and entry (data element) level and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1); and (ii) Preserve privacy markings to ensure fidelity to the tagging based on consent and with respect to sharing and re-disclosure restrictions.
Preamble FR Citation: 84 FR 7452 **Specific questions in preamble?** *Yes*
Regulatory Impact Analysis: Please see 84 FR 7575-77 for estimates related to this proposal.
Public Comment Field: We ask ONC for additional clarity regarding whether the Data Segmentation for Privacy "receive" provision will become mandatory for 2015 Edition Certification or if it will remain a voluntary criterion. Our suggestion is that each mature health IT company should have the flexibility to continue to ensure patient privacy in a way that best suits that individual system's infrastructure.

We look forward to engaging with your office on this important proposed rule. Please do not hesitate to reach out directly by phone at (617) 402-8516, or by email at gcarey@athenahealth.com.

Sincerely,

Greg Carey
Director, Government & Regulatory Affairs
athenahealth, Inc.