Application Programming Interface (API) Task Force Recommendations

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Table of Contents

I. Overview

INTRODUCTION

Application Programming Interface (API) refers to technology that allows one software program to access the services provided by another software program. In its 2015 Edition of Health IT Certification Criteria (2015 CHIT), the Office of the National Coordinator for Health Information Technology (ONC) established three new criteria at §170.316(g)(7), (g)(8) and (g)(9) that requires certified health IT to demonstrate the ability provide a patient-facing app access to the Common Clinical Data Set via an API.

§170.316(g)(7) - Application Access, Patient Selection

§170.316(g)(8) - Application Access, Data Category Request

§170.316(g)(9) - Application Access, All Data Request

To be certified for API criteria, three privacy and security criterion must also be met:

§170.315(d)(1) "authentication, access control and authorization;"

§170.315(d)(9) "trusted connection;" and

§170.315(d)(10) "auditing actions on health information" or §170.315(d)(2) "auditable events and tamper resistance"

In parallel, CMS included two objectives in Stage 3 of the Medicare and Medicaid Electronic Health Record Incentive Program (MU3) that reference the use of APIs:

- Objective 5: Patient Electronic Access to Health Information
- Objective 6: Coordination of Care Through Patient Engagement

These MU3 objectives specify basic actions that a patient (or patient-authorized representative) should be able to take in respect to the patient's health information:

- View, Download, and Transmit (VDT) to a third party.
- Access through an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient-authorized representatives) access to their health information, within 24 hours of its availability to the provider.

SCOPE

The API Task Force was created in response to concerns expressed to ONC about privacy compliance and security of APIs. The Task Force was charged with the following scope:

- Identify perceived security concerns and real security risks that are barriers to the widespread adoption of open APIs in healthcare.
    - For risks identified as real, identify those that are not already planned to be addressed in the Interoperability Roadmap (for example, identify proofing and authentication are not unique to APIs);
- Identify perceived privacy concerns and real privacy risks that are barriers to the widespread adoption of open APIs in healthcare.
    - For risks identified as real, identify those that are not already planned to be addressed in the Interoperability Roadmap (for example, harmonizing state law and misunderstanding of HIPAA);
- Identify priority recommendations for ONC that will help enable consumers to leverage API technology to access patient data, while ensuring the appropriate level of privacy and security protection.

MOTIVATION FOR LIMITED SCOPE

Ultimately, the Task Force focused on needs specific to MU3 requirements and 2015 CHIT. Specifically, our recommendations focus on *read-only access to a single patient's record for disclosure to an app selected by that patient, and used to access all or some data elements defined in the Common Clinical Data Set*.

Other "out of scope" issues include:

- Terms of Use
- Licensing Requirements
- Policy Formation
- Fee Structures
- Certifying Authorities
- Formulation of Standards
- Electronic documentation of consents required by law or policy
- Issues unique to writing new data into the EHR
- Issues unique to annotating data in the EHR

The aggregate ecosystem of consumer-facing apps includes apps that interact with health care data in ways that are beyond this scope. We expect developers to innovate and provide enhanced functionality through API technology.

II. Task Force Approach

The Task Force held virtual hearings on January 26 and 28, 2016. Panelists were represented from across both non-healthcare and healthcare industries. The Task Force reviewed written testimonies and public comments, and conducted analysis to summarize common themes. (Additional information regarding the hearings can be located in the Appendix.)

GENERAL SUPPORT FOR APIs

Like any technology, APIs allow new capabilities and opportunities, and, like any other new technology, these opportunities come with some risks. There are fears that APIs may open new security vulnerabilities, with apps accessing patient records "for evil", and without receiving proper patient authorization. There are also fears that APIs could provide a possible "fire hose" of data, as opposed to the "one sip at a time" access that a web site or email interface may provide.

In testimony, we heard almost universally that, when APIs are appropriately managed, the opportunities outweigh the risks. We heard from companies currently offering APIs that properly managed APIs provide better security properties than ad-hoc interfaces or proprietary integration technologies.

While access to health data via APIs does require additional considerations and regulatory compliance needs, we believe existing standards, infrastructure and identity-proofing processes are adequate to support patient-directed access via APIs today.

Recommendations

1. We recommend that ONC address other API use cases in the future when the work can be informed by the lessons learned from experience with the initial use case. For example, future use cases include:
    - Patient-directed APIs with Write and Update access to EHRs, including the incorporation of patient-generated health data from a non-clinical setting. Such APIs might underpin future certification requirements.
    - Patient-directed APIs that access multiple patients (for example, aggregation of populations of patients).
2. ONC should continue its pursuit of an API strategy as one important mechanism for enabling patient choice and promoting a more efficient healthcare marketplace.
    - This Task Force did not identify any “show-stopping” barriers that would prevent the deployment of APIs within the timelines for ONC 2015 CHIT and MU3. Nevertheless, we urge ONC to respond to our recommendations in a timely fashion, especially where we have requested clarification and guidance.

OVERSIGHT AND ENFORCEMENT OF APIs

Background

Depending on its functions and intended use, an app may need to comply with several federal laws, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Federal Trade Commission Act (FTC Act) and the FTC’s Health

Breach Notification Rule (as directed by the American Recovery and Reinvestment Act of 2009). The Task Force agrees this is a complicated framework, and it is not always intuitive as to which law applies at any given time. It is difficult for providers and developers to fully embrace API technology when there is uncertainty as to their respective rights, obligations and liabilities.

Many of the discussions within the Task Force centered around the notion that the patient-directed app of our purview supports the patient's HIPAA right to access his/her own PHI from a Covered Entity, as required under HIPAA § 164.502. This could be characterized in several ways: 1) the individual requesting access to their information, 2) an entity designated by the individual to receive a copy of PHI (as part of the individual exercising his/her right to access PHI), or 3) the medium on which the individual requests that PHI be provided or transmitted (as part of the individual exercising his/her right to obtain a copy of PHI). Alternatively, the patient-directed app may also be characterized as a third party formally authorized by the individual to receive PHI, or a tool for engaging the individual in treatment. Each of these scenarios creates challenges when attempting to determine oversight of an app's behavior - and there is not one clear solution.

Until authoritative guidance is available, we predict providers will align compliance practices to support the patient-directed app as closely as possible with their existing paper or EHR-based practices, likely with a very conservative approach, to mitigate the risk of unauthorized disclosures of PHI and thus avoid possible sanctions and penalties. Continued ambiguity in compliance requirements may result in providers adding unnecessary complexity and burden to their practices, which ultimately may chill support for and overall adoption of patient-directed data exchange.

Findings

FTC Oversight

Recognizing that health app developers are often confused about which legal requirements apply to them, FTC launched an online tool[1] to help health app developers determine which federal laws may apply to their mobile apps called "The Mobile Health Apps Interactive Tool". The tool is interactive, leading the developer through a series of ten short questions about the app's functions. Based on the developer's answers, the tool indicates whether the developer may need to follow any of the laws when creating or administering the app. Once a developer determines which law(s) apply, the tool provides hyperlinks to access each agency's guidance.

Unfair or deceptive acts

As outlined in recent testimony to the U.S. House Committee on Oversight[2],

> The FTC's primary authority is Section 5 of the FTC Act, which prohibits unfair or deceptive acts or practices in or affecting commerce. If a company makes materially misleading statements or omissions about a matter, including privacy or data security, and such statements or omissions are likely to mislead reasonable consumers, they can be deceptive in violation of Section 5. Further, if a company's practices cause or are likely to cause substantial injury to consumers that

[1] The tool can be accessed here: https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool

[2] https://oversight.house.gov/wp-content/uploads/2016/03/2016-03-22-Rich-Testimony-FTC.pdf

is neither reasonably avoidable by consumers nor outweighed by countervailing benefits to consumers or to competition, those practices can be unfair and violate Section 5.

The FTC's Section 5 authority extends to both HIPAA and non-HIPAA covered entities, though generally this authority does not reach non-profit entities. The FTC Act is currently the primary federal statute applicable to the privacy and security practices of businesses that collect individually identifiable health information where those entities are not covered by HIPAA.

Reasonable and appropriate data security practices

The FTC has also used its Section 5 authority to bring enforcement actions against companies that fail to maintain reasonable and appropriate data security practices regarding consumer data, including health data.

Breach notifications

Pursuant to Section 13407 of the HITECH Act, the FTC's Health Breach Notification Rule[3] applies to vendors of personal health records and their third party service providers. Under the FTC Rule, companies that have had a security breach must: 1) notify everyone whose information was breached; 2) in many cases, notify the media; and 3) notify the FTC. FTC's Rule applies only to health information that is not secured through technologies specified by the Department of Health and Human Services. Also, the Rule does not apply to entities regulated under HIPAA. (In case of a security breach, entities covered by HIPAA must comply with the HHS breach notification rule.)[4]

FDA Oversight

Through guidance[5], FDA is focusing its oversight on mobile medical apps that present a greater risk to patients if they do not work as intended - specifically, apps that:

- Are intended to be used as an accessory to a regulated medical device; or
- Transform a mobile platform into a regulated medical device.

FDA intends to exercise its enforcement discretion for the majority of mobile apps, which pose minimal risk to consumers.

The FDA published guidance for effective cybersecurity management, which outlines recommendations that manufacturers should consider in order to protect patient information that may be stored on medical devices or transferred between wireless systems. The agency defines cybersecurity as "the process of preventing unauthorized access, modification, misuse or denial of use, or the authorized use of information that is stored, accessed or transferred from a medical device to an external recipient."

[3] https://www.ftc.gov/tips-advice/business-center/guidance/health-breach-notification-rule

[4] 45 CFR §§ 164.400-414

[5] http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf

On January 26, 2016, FDA issued the draft guidance "Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices." This draft guidance specifies APIs as elements to consider in the design of the device's electronic data interface as well as with exchange of data to and from medical devices.

HIPAA Oversight

The HIPAA Rules apply only to Covered Entities and their Business Associates (Regulated Entities). When a Regulated Entity discloses PHI to a non-Regulated Entity, the HIPAA Rules do not govern the non-Regulated Entity's use or disclosure of the PHI. A Regulated Entity may choose to limit a non-Regulated Entity's use or disclosure of the PHI as a condition of releasing it, but those limitations would not be enforceable under HIPAA. Similarly, where an individual chooses to exercise his or her HIPAA rights to share health information with a non-Regulated Entity, the HIPAA Privacy Rule no longer provides the individual's privacy rights. The individual may have privacy rights based in contract, state privacy laws, or other relevant federal law.

HIPAA only governs the use and disclosure of PHI by Regulated Entities (Covered Entities and their Business Associates); PHI used or disclosed by a non-Regulated Entity is outside the scope of HIPAA.

An app developer is a business associate if it is creating, receiving, maintaining or transmitting protected health information on behalf of a covered health care provider. So, an app developer that is providing services to a provider that involves PHI is a business associate of the provider.

Navigating this process is complex and the Task Force supports the concept of a simple solution; however, we disagree with the notion that every app that connects to the patient-designated API should be required to be regulated under HIPAA (i.e., must be a business associate to the covered entity/provider).

The Office for Civil Rights (OCR) produced specific guidance including a set of scenarios describing when health apps require a BAA[6]. Based on OCR's presentation of these scenarios, the Task Force recognized a number of circumstances where no BAA is required. Relationships among healthcare organizations and health IT developers can be complex, and it is often difficult to map real-life circumstances into the OCR's prescribed scenarios.

OCR has also launched a platform for mobile health developers and others interested in the intersection of health information technology and HIPAA privacy and security protections. The website, monitored by OCR, http://hipaaqsportal.hhs.gov/, provides education and guidance, and allows users to submit questions or offer comments.

Recommendations

1. ONC should coordinate with the relevant agencies and Congressional committees of jurisdiction where legislation and rulemaking are needed to give agencies the ability to effectively implement rules and regulations that ensure privacy and security of all health data.

[6] http://hipaaqsportal.hhs.gov/

2. ONC should analyze the feasibility of a single, simple, comprehensive oversight framework mechanism that would address the needs of the patient-directed API ecosystem (for all health data shared with all organization types using any technology).

- We recognize implementation of such a framework may require Congressional action; however, using its role as advisor for all things health IT, ONC should seek to harmonize conflicting, redundant and confusing laws that govern access to health information.
- ONC should coordinate with the relevant agencies a single location for all API actors (EHR API developers, app developers, providers and patients) to access in order to become educated and to ask questions about the oversight and enforcement mechanisms specific to patient-directed health apps, as well as their specific rights, obligations and duties.
- Patients should have one place to access in order to log complaints regarding an app's behavior.
    - For example, the patient should not have to navigate the complex oversight environment to know whether his/her complaint is a HIPAA complaint or an FTC complaint.
- App developers should have one place to access in order to log complaints that could launch investigations regarding a provider or an EHR API developer's behavior regarding information blocking.
- Penalties for "bad actors" should be clearly communicated, as well as the source of law and enforcing agencies.

3. We recommend that ONC coordinate with the relevant agencies to publish guidance as quickly as possible for EHR API developers, app developers, providers and patients, as to whether, from a HIPAA perspective, sharing data with a patient-directed application should be considered as: an individual's access; or access by a third party; or as a tool for engaging in treatment (or a combination thereof), so the respective actors could anticipate how to meet HIPAA-specific requirements.

- We note there may be a need for further distinction based on the nature of the app and its function, in a manner that affords the patient both the greatest flexibility and the highest protections.

4. ONC should work with the relevant agencies to provide guidance to providers as to the patient-specific warnings and notices that can and should be made available via the provider's portal prior to the app approval/authorization process.

III. Generic Use Case

We frame our discussion of API issues specific to our scope and charge through the use of a generic use case, described below.

> App Developer builds an app that can benefit from patient data accessed via an API-based connection to EHR data (Topic 1). App Developer registers App with Hospital or its EHR (Topic 2). Patient becomes aware of App (Topic 3), reviews App's data use and privacy policies (Topic 4) and decides to connect App to her EHR data at Hospital. Patient signs into Hospital's portal, which displays an authorization screen. Patient agrees to share (Topic 5) some or all of her EHR data for some duration of time with App (Topic 6), and Hospital records this decision (Topic 7). Hospital's portal sends Patient back to App, and App gets a unique, time- and scope-limited access token for Patient (Topic 8). App can use the token to access Patient's authorized EHR data for some duration of time in keeping with Patient's approval.

We organize this document to correspond accordingly to topics raised in the use case:

> Topic 1: Types of Apps and the Organizations That Provides Them
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> Topic 2: App Registration
>
> Topic 3: Endorsement/Certification of Apps
>
> Topic 4: Communication of the App's Privacy Policies and Practices
>
> Topic 5: Patient Authorization Framework
>
> Topic 6: Limitations and Safeguards on Sharing
>
> Topic 7: Auditing and Accounting for Disclosures
>
> Topic 8: Identity Proofing, User Authorization, App Authorization

Terms used are defined in the Appendix Glossary.

VARIANTS ON USE CASE

Apps can be developed by various parties (e.g., provider organizations, insurers, patients, consumer technology companies, researchers, or criminals), and may or may not be "cloud" based. A few examples of apps include:

> **Personally-Controlled Health Record-** For example, Microsoft HealthVault. A site that is managed exclusively by a patient, storing information on the patient's behalf and making it easily available to the patient. (Note the Task Force's limited scope to focus on Read Only Access.)

Personal health app- For example, a tool to manage diabetes. This app could be discovered and selected by the patient, or recommended by a provider. (Note the Task Force's limited scope to focus on Read Only Access.)

Patient-authored app- For example, a homemade tool to improve care coordination or plot lab results.

Rogue app- For example, an app specifically designed from the ground up to steal data from a patient for financial gain. Or a "good" app that has been hacked.

TOPIC 1: TYPES OF APPS AND ORGANIZATIONS WHO PROVIDE THEM

Background

Within the framework of 2015 CHIT and MU3, patient data must be "available for the patient (or patient-authorized representative) to access using **any application of their choice that is configured to meet the technical specifications of the API** in the provider's CEHRT".[7]

Findings

During our testimony, we heard from panelists across the industry who described various health apps that will likely participate in the ecosystem. We heard about existing and potential apps developed by consumers themselves, or their friends and families (DIY movement); consumer companies; healthcare providers; insurers; clinical professional societies; HIT vendors; employers; medical device manufacturers; consumer device manufacturers; data aggregators; research organizations; health data platform companies; governments; and others.

The CHIT and MU3 regulations do not differentiate based on who has written an app, or the app's purpose or credibility. The key determinants of whether an app may be used for access appear to be **technical compatibility** and **patient choice**.

Recommendations

1.a ONC should coordinate with the relevant agencies and explicitly state in formal guidance that the type of app, and the kind of organization that developed it, are not considerations with respect to patient access. The only relevant concerns should be technical compatibility (i.e. app works with the API technical specifications) and patient choice.

[7] https://www.federalregister.gov/articles/2015/10/16/2015-25595/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-3-and-modifications

TOPIC 2: APP REGISTRATION

Background

The term "registration" designates some up-front technical process by which a client application is "introduced" to an API, and certain details are recorded within the API provider's system. (We use the term "API Provider" to refer to the entity that makes the API available to the patient's designated app. This could be the patient's healthcare provider organization and/or the EHR API developer working on behalf of that organization.) For example, registration might convey: app name; app URLs; name and contact information for the app developer; or other entities responsible for hosting the app.[8]

In some user-mediated authorization frameworks, like OAuth 2.0, registration is a technical necessity. The registration process establishes the identifiers that an app will need when it asks for a patient's approval to access data. Although registration may be a technical necessity, it need not present a policy barrier. Web APIs often allow quick, frictionless registration of apps through two common patterns:

1. *Self-Service Registration Portal.* In this pattern, the API provider hosts a web site where developers can register a new client application by filling out a web form, perhaps providing some assurances or confirming details about their app. Generally, registration is "automatic" in the sense that it requires no manual off-line review of evidence associated with the developer and imposes no artificial waiting period. However, it may require the app developer to manually complete a Web-based form. Note that the mere act of registering the app does not share data with the app. Data won't flow until a post-registration step called "app approval", where the API provider verifies the patient's identity and records the patient's decision to share. So registration itself is a low-risk activity: patient information is not released during this step.

2. *Dynamic Registration Protocol.* In this pattern, the API provider hosts a fully automated API for adding a new client application to a provider organization. For example, the OAuth Dynamic Client Registration Protocol[9] fills this role. This process can be entirely automated, with no manual form-filling and no waiting period. Note again that the mere act of registering the app does not share data with the app; data won't flow until a patient's decision to share. So registration itself is a lower-risk activity.

[8] Note that some apps are deployed as a single, centralized service (e.g., HealthVault, Microsoft's personal health record platform), while others can be deployed multiple times, by different organizations and users (e.g., Indivo, an open-source personal health record). Apps can even be designed to have a separate "deployment" for every user. Registration is generally a "once-per-deployment" event, although it can be desirable for an API provider to know that a set of registrations all refer to different deployments of "the same app".

[9] https://tools.ietf.org/html/rfc7592

An API provider can follow these patterns separately, or together. For example, an API provider can offer self-service registration *and* dynamic registration, which may be a particularly convenient way to suit diverse API developer needs.

In the 2015 Edition Health IT Certification Criteria (2015 Edition), ONC stated[10], "our intention is to encourage dynamic registration and strongly believe that registration should not be used as a means to block information sharing via APIs". But ultimately, ONC removed the strict requirement for dynamic registration, stating "from the comments received it was clear that our intention was not understood. Further, open source standards for dynamic registration are still under active development, there is currently no consensus-based standard to apply".

Findings

ONC's intention was to ensure that app registration procedures and policies did not limit a patient's ability to choose health apps. When ONC rejected the criterion of dynamic client registration, they apparently did not consider requiring self-service registration portals as an alternative.

When the final 2015 Edition was published, ONC expressed concern that standards were still under active development; but in fact a finalized release of the OAuth 2.0 Dynamic Client Registration Protocol[11] was published by the IETF in July 2015 as the standards-track RFC 7591.

Confusingly, ONC appears to suggest that the 2015 certification criteria should suffice to allow application access without any registration process:

> *"a Health IT Module certified to this criterion [must] be capable of ensuring that: valid user credentials such as a username and password are presented … ; the provider can authorize the user ...; the application connects through a trusted connection... These certification requirements* ***should be sufficient to allow access without requiring further application pre-registration****." (emphasis added)*

Recommendations

2.a ONC should clarify that its goal is to ensure that when app registration is required, it does not impose an unreasonable barrier to patient choice.

2.b ONC should ensure that in scenarios where registration is a technical requirement, the registration process is frictionless and does not impose unreasonable delays. For example, the registration process is not intended to be a point where apps undergo rigorous testing, clearinghouse approval, on-site inspection, or other "high bars" of control.

2.c ONC should further clarify that self-service registration portals and dynamic registration protocols are two complementary ways to ensure frictionless app registration. In subsequent

[10] https://www.federalregister.gov/articles/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base#p-1071

[11] https://tools.ietf.org/html/rfc7591

rules, ONC should require both of these modes of app registration, since they address different developer needs, and it is easy to build a self-service registration portal on top of a dynamic registration protocol.

2.d ONC should clarify its claim that existing certification criteria are "sufficient to allow access without requiring further application pre-registration," since this statement is out of line with real-world authorization protocols (e.g., OAuth 2) where registration is sometimes a technical requirement.

2.e ONC should coordinate with the appropriate oversight agencies to ensure that API providers do not charge a fee for the app registration process, when registration is required. We note that HIPAA in general allows CEs to apply reasonable charges for a patient's access to data -- but such charges should not be applied to the registration process, before any data are flowing. ONC and OCR should clarify that "reasonable" charges in this context are vanishingly low, even to the point where levying the fee might cost more than the fee itself.

2.f ONC should coordinate with the appropriate oversight agencies to specify how app developers should report any "data blocking" issues that occur within a provider's app registration process.

TOPIC 3: ENDORSEMENT/CERTIFICATION OF APPS

Background

In a diverse health app ecosystem, some apps will be "more trustworthy" than others. Trustworthiness is a broad concept with many facets including:

- clinical (e.g., "does the app make safe recommendations?")
- privacy (e.g., "does the app propose to share my data in unexpected ways?")
- security (e.g., "are the app's servers well-guarded against attackers?")
- value (e.g., "is the app worth the money it costs?")
- stability (e.g., "will the app be around and well-supported in 18 months?")
- reputation (e.g., "what is known about the app's authors and their motivation?")

Patients will face an increasing number of choices in the marketplace; it is important to ensure the availability of tools and services that allow discovery of the best and most trustworthy apps.

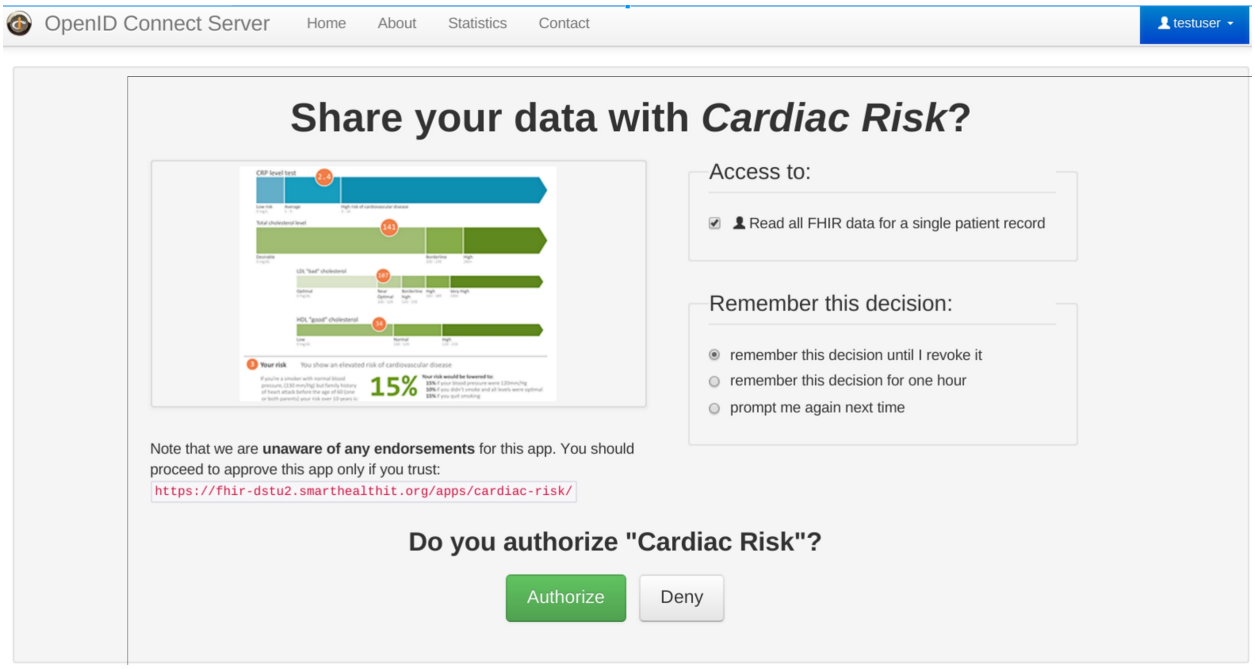
Findings

We heard from a number of healthcare providers who shared concerns about allowing unknown patient-designated apps to connect to their APIs. These concerns included a worry that patient-designated apps might work against the patient's interest (e.g., leaking data), or that patient-designated

apps might attempt to compromise the security of the provider's system. In general, we heard that providers would feel more comfortable in an environment where connections were restricted to well-vetted apps, through a process where apps obtained "certification" or a "seal of approval" or "endorsement". At the same time, we heard from patients and consumer representatives who expressed the concern that the expectation of app certification would unduly restrict consumer choice. We heard from consumer advocates that such restrictions would violate the patient's right to access.

The Task Force discussed the pros and cons of a consumer protection benefits of an app certification process; however, ultimately, we favor a secondary market in app endorsements. In such a market, various kinds of organizations (EHR vendors; security experts; consumer advocacy groups; clinical professional societies; provider organizations[12]) can "endorse" a given app through a distributed, publicly visible process, without centralized regulatory oversight. For example, an endorsement might take the form of openly published, cryptographically signed statement listing verified attributes of the endorsed app. Then, a consumer's evaluation of a given app could take such endorsements into account. This kind of infrastructure enables third-party app discovery services where consumers can filter apps based on criteria they consider most important (e.g., "only show me apps that Consumer Reports recommends", or "only show me apps that that promise not to share my personal data with advertisers, according to an analysis of their privacy policy conducted by the National Associate for Trusted Exchange"). This approach to endorsements avoids the pitfalls of defining a centralized certification process; and it avoids the difficulty of standardizing privacy policies; but still allows the consumer-facing discoverability benefits.

Below is a mockup of an example authorization workflow, indicating how such third-party endorsements could be communicated to the patient.



[12] A provider's "endorsement" of an app should not, by itself, indicate a business associate agreement between the app developer and provider.

Recommendations

3.a ONC should not require centralized certification or testing of apps. Instead, ONC should encourage a secondary market in app endorsements.

- ONC should ensure that provider organizations must not use endorsements (or the lack of endorsements) as a reason to block the registration of an app, or to block a patient's ability to share data with an app.
- Provider organizations, however, should have the ability to present some of an app's endorsements to the patient at the time of app approval. For example, a provider could display endorsements from trusted sources (or conversely, if the app has none, the provider may display a warning and request extra patient confirmation).

3.b ONC should coordinate with the relevant federal agencies that are also holders of patient data (Department of Defense, Veterans Health Administration, Centers for Medicare and Medicaid Services) to encourage the publication of federal app endorsement criteria, by which their patient populations would benefit.

- For example, the DoD may create a list of criteria by which apps that access the EHR data of active military would meet to indicate the app's trustworthiness.

3.c ONC should encourage a secondary market by which patients are able to share their experiences about an app.

TOPIC 4: COMMUNICATION OF THE APP'S PRIVACY POLICIES

Background

Risks associated with disclosures of protected health information (PHI) using well-known mechanisms are fairly well understood and mitigated in today's healthcare environment. We heard from providers concerned that patient-directed API technology may introduce risk owing to variables beyond the provider's control (e.g., when disclosed information is subsequently used or accessed inappropriately).

As entities regulated by HIPAA, providers are familiar with the HIPAA Notice of Privacy Practices for Protected Health Information and have oriented their compliance practices accordingly. The portals by which patients may access APIs are provided by HIPAA-regulated entities, yet it is expected a patient's data may be disclosed to an app that is not regulated under HIPAA.

While HIPAA is a starting point for the disclosure, once the disclosure is made to a non-HIPAA regulated entity, it is not clear to patients and many providers which laws prevail and how privacy issues must be identified and enforced, or who is responsible for what actions (provider, API developer, app developer) when a patient's privacy rights are violated. Providers are concerned they will miss making the necessary updates to their risk and compliance processes to account for these new communication tools and may be held liable or penalized for an unexpected outcome that may or may not be within their control.

Findings

The Task Force heard from commenters who were concerned the typical patient is not savvy enough to understand the information presented enough to navigate the complex privacy landscape.

The Task Force recognizes the patient must have a fundamental level of "privacy literacy" in order to make an informed decision about whether an app is allowed to access their health data, which requires patients to be aware of the app's privacy practices for the access, collection, use and disclosure of their health information.

The Task Force also recognizes that many elements contribute toward whether a patient can be considered "aware" of the app's privacy practices. For example, the usability and readability of the privacy notices may be complicated by small font size or a language inappropriate for the actual consumer (English, Spanish, etc.), or the user may have needs specific to one or more disabilities. Further, patients may click "I Accept" yet not actually read the provisions.

There are several existing Model Privacy Notices we can draw on for reference.

- ONC Voluntary PHR Model Privacy Notice (currently under revision)
- OCR HIPAA Model Notices of Privacy Practices http://www.hhs.gov/ocr/privacy/hipaa/modelnotices.html

There are several existing best practices for transparent communications to consumers:

- FDA Nutrition Facts Label and the Schumer Box for credit card disclosures

There are several practices and industry guidelines we can draw on for reference.

- Future of Privacy Forum Best Practices for Mobile App Developers https://www.cdt.org/files/pdfs/Best-Practices-Mobile-App-Developers.pdf

- HealthKit's requirement for an app to have a privacy policy (refers to OCR & ONC MPNs) and accessed at https://developer.apple.com/library/ios/documentation/HealthKit/Reference/HealthKit_Framework/

- Google (accessed at https://developers.google.com/terms/#your-api-clients) - sections of interest:

    - Section 3d. User Privacy and API Clients: You will comply with all applicable privacy laws and regulations including those applying to PII. You will provide and adhere to a privacy policy for your API Client that clearly and accurately describes to users of your API Client what user information you collect and how you use and share such information (including for advertising) with Google and third parties.

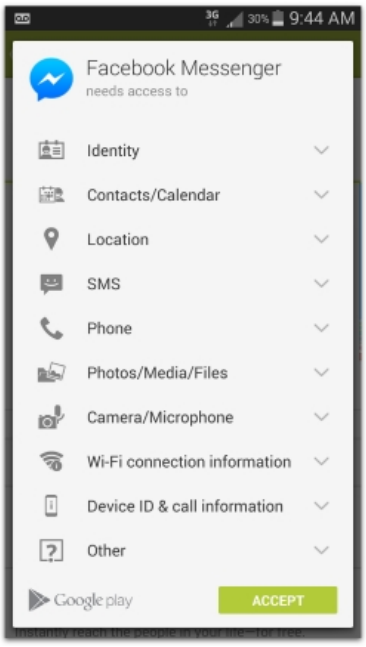
- Apple - Developers must provide clear and complete information to users regarding collection, use and disclosure of user or device data. (Section 3.3.10 of the iOS Developer Program License Agreement) Apps should have all included URLs fully functional when you submit it for review,

such as support and privacy policy URLs. (Section 3.12 of the App Store Review Guidelines) Apps cannot transmit data about a user without obtaining the user's prior permission and providing the user with access to information about how and where the data will be used. (Section 17.1 of the App Store Review Guidelines)

- Android - "If users provide you with, or your app accesses or uses user names, passwords, or other log-in or personal information, you must make users aware that this information will be available to your app, and you must provide legally adequate privacy notice and protection for those users." (Section 4.3 of the Android Market Developer Distribution Agreement) "It is important to respect user privacy if certain parameters, such as demographics or location, are passed to ad networks for targeting purposes. Let your users know and give them a chance to opt out of these features."

- Facebook - "You will have a privacy policy that tells users what user data you are going to use and how you will use, display, share, or transfer that data and you will include your privacy policy URL in the Developer Application." (Section II(3) of Facebook Platform Policies)

- Short form notices use a limited number of characters that highlight the key data practices disclosed in the full privacy policy.



  - Screen capture of Facebook Messenger App short form notice. Note that here, the decision is "all-or-nothing", and that a user must make the decision ahead of time. More recent Android releases allow the user to make fine-grained decisions, and allow the user to delay some decision-making until after an app has been installed (e.g., access to contacts might be requested only when the user attempts to look up a friend).

There are several existing applicable laws and regulations that address transparent communications to consumers regarding privacy and security practices:

- FTC
    - From Jan. 2016, the FTC's 2015 Privacy and Security Update sheds light on the FTC's authority over privacy and security matters and examples of actions they've taken in recent years:

        "The FTC uses a variety of tools to protect consumers' privacy and personal information. The FTC's principal tool is to bring enforcement actions to stop law violations and require companies to take affirmative steps to remediate the unlawful behavior. This includes, when appropriate, implementation of comprehensive privacy and security programs, biennial assessments by independent experts, monetary redress to consumers, disgorgement of ill-gotten gains, deletion of illegally obtained consumer information, and provision of robust notice and choice mechanisms to consumers. If a company violates an FTC order, the FTC can seek civil monetary penalties for the violations. The FTC can also obtain civil monetary penalties for violations of certain privacy statutes and rules, including the Children's Online Privacy Protection Act, the Fair Credit Reporting Act, and the Telemarketing Sales Rule. To date, the Commission has brought hundreds of privacy and data security cases protecting billions of consumers.

    - The FTC's other tools include conducting studies and issuing reports, hosting public workshops, developing educational materials for consumers and businesses, testifying before the U.S. Congress and commenting on legislative and regulatory proposals that affect consumer privacy, and working with international partners on global privacy and accountability issues." (https://www.ftc.gov/reports/privacy-data-security-update-2015)

    - Of particular note is the list of actions they've taken against orgs. such as TRUSTe (a certification body) and PaymentsMD (a health billing portal) that are related to some of the API Task Force's discussions.
      https://www.ftc.gov/reports/privacy-data-security-update-2015#enforcement

    - Some of the rules listed, including the health breach notification rule, also seem relevant for enforcement authority. (https://www.ftc.gov/reports/privacy-data-security-update-2015#rules)
    - The FTC also keeps a large list of press releases for privacy related actions that may help to give an idea of its reach (https://www.ftc.gov/news-events/media-resources/protecting-consumer-privacy/enforcing-privacy-promises)

    - The FTC published a guide titled "Marketing Your Mobile App: Get It Right From the Start" to guide app developers on what truth-in-advertising and privacy principles apply to their products. (https://www.ftc.gov/tips-advice/business-center/guidance/marketing-your-mobile-app-get-it-right-start)

- Other non-privacy enforcement actions of the FTC:

  "The Federal Trade Commission (FTC) protects consumers from unfair or deceptive acts or practices as well as false or misleading claims. Where mHealth is concerned, it has focused on the claims companies have made about the effectiveness of their devices or apps. The FTC also has jurisdiction over health data breaches when the entities involved are not HIPAA-covered entities. The FTC has already been active, taking enforcement action against several mobile health app marketers that have not met the requirements of the FTC. The FTC collaborates closely with both the FDA and FCC on areas where there is jurisdictional overlap." (http://cchpca.org/mhealth-laws-and-regulations)

- HIPAA
  - National privacy standards for the protection of individually identifiable health information for certain regulated entities.
  - HHS enforces the HIPAA privacy, security and breach notification regulations using a variety of tools, including outreach to consumers, guidance to covered entities, complaint investigations, covered entity and business associate audits, breach notification requirement for entities with protected health information and compliance reviews. A wealth of information is available at http://www.hhs.gov/hipaa.

- Children's Online Privacy Protection Act of 1998 (COPPA)
  - Sets forth rules governing the online collection of information from children under 13 years of age, including restrictions on marketing to those under 13 years of age.

Recommendations

4.a We recommend that ONC coordinates with the relevant agencies to pursue a concept of "privacy literacy," similar to what is known as "health literacy." This would include defining the basics of privacy literacy, and outlining strategies and techniques for the government either to action directly - or through providers and app developers - to improve privacy literacy at the community and organizational level.

- Privacy literacy is the degree to which individuals have the capacity to obtain, process, and understand basic privacy information needed to make appropriate decisions regarding the sharing of personal information, including health data.

4.b We recommend that ONC supports a Model Privacy Notice for app developers.

- The MPN should clearly define who is responsible for what (individual, app developer, provider, API developer), including example indemnification clauses where applicable.
- The MPN should provide standard definitions and terms.

- To facilitate easy review and a user-friendly experience, a short-form privacy notice may be valuable, with a link to access the full notice or more detailed information. ONC should provide guidance in its MPN for the minimum data set required for short form notices.
- The MPN should allow for the download - or other electronic "save" - of the privacy notice (or otherwise saved electronically).
- The MPN should ensure a "just in time" communication when the patient accesses the app.
- Users must be informed when the app's practices change
- Privacy policies must be easily accessible in the app for later review
- Where the patient has choice and control, the app should provide meaningful controls such as opt-outs.
- Contact information regarding how a patient can contact the app developer if there are problems are concerns.

4.c We recommend that ONC should encourage an app developer voluntary "Code of Conduct" that outlines best practices regarding how and what an app should communicate to consumers regarding its privacy and security policies.

4.d We recommend that ONC collaborate with FTC to provide ongoing support to app developers to ensure the app's privacy practices align with the app's marketing practices according to Section 5 of the FTC Act, which prohibits unfair or deceptive acts or practices, including deceptive statements and unfair practices involving the use or protection of consumers' personal information.

4.e We recommend that ONC evaluates methods by which a consumer is able to compare the privacy policies of two or more apps.

4.f We encourage ONC to pursue enforceability of "click through" agreements specific to health information.

4.g We encourage the private market to develop standards specific to the usability of consumer apps, and until such time, app developers should be encouraged to consult Web Content Accessibility Guidelines (WCAG AA) for a wide range of recommendations to make apps more usable to more types of users.

4.h We encourage the development of private-market endorsements to indicate those apps that strive to make content accessible to a wider range of people with disabilities, including blindness and low vision, deafness and hearing loss, learning disabilities, cognitive limitations, limited movement, speech disabilities, photosensitivity and combinations of these.

TOPIC 5: PATIENT AUTHORIZATION FRAMEWORK

Background

We hold the fundamental assumption that the *APIs by which patient-directed apps gain access to patient data are "logically" administered by providers who are Covered Entities under HIPAA* (that is, even if the Covered Entity does not run and maintain the hardware and software stack, this functionality is provided *on behalf of* the covered entity, by a Business Associate).

As noted in Regulatory Oversight and Enforcement of APIs, information may be shared through a patient directed app for many purposes, such as to fulfill an individual's access request or as treatment communication between a patient and a clinician. It could also be the means selected by the patient for the provider to make a patient-authorized disclosure to a third party.

We recognize, however, that providers will have existing HIPAA practices (implemented as a Covered Entity or via a Business Associate) specific to patient consent, patient authorization to disclose to third parties, and access to the individual's own record. Each of these pathways indicates terms specific to what essentially represents the patient's go-ahead for the app to receive his/her data (referred to as consent, authorization, approval, or request for access), and has downstream effects, such as requirements for notification of breach and accounting of disclosures. Throughout this document, we try to use the correct term in its correct context. Generally, we refer to this process as the patient's "authorization."

- We note that the term "authorization" as used in this section is *not* the term used when referencing the technical protocol that allows users to approve an application to act on their behalf (e.g., OAuth) as referenced in Topic 8: Identity Proofing, User Authorization and App Authorization.

- The need for the provider to document the patient's authorization is a critical component which we further discuss in Topic 7: Auditing and Accounting for Disclosures.

There are some challenges in applying certain HIPAA processes to the patient-directed API. For example, under HIPAA, individuals may request access to their PHI and a Covered Entity is required to provide such access if the PHI is maintained in a designated record set and no grounds for denial exist (providers may deny a patient's request to access his/her own PHI in whole or in part; HIPAA § 164.524 stipulates grounds and requirements for denial of access). Under current HIPAA regulations, providers have no later than 30 days to respond to an individual's request to access his/her information. Recognizing the "on the fly" nature of patient-directed apps, it is not feasible to assume a site administrator can manually mitigate patient requests for access to their individual information within this framework. Additionally, the HIPAA designated record set contains a broader set of data than what EHRs implement to support the CCDS; for example, the HIPAA designated record set also contains data related to enrollment and payment.

Recommendations

5.a We recommend that until clear guidance is available, providers should proceed in defining practices for API disclosures in a manner that focuses on ensuring the patient is in possession of all essential information in order to give his/her valid, informed go-ahead for the provider to enable the patient-directed app access to the patient's data.

- While we expect this is no different than what a patient is already asked to agree to for use of the portal for View, Download and Transmit functions, this ensures the authorization represents the patient's control to direct the disclosure (or use the app to make the request).

5.b We recommend that ONC coordinate with the relevant agencies a model authorization form with reusable/reference-able language, that contains the following information:

- The name of the patient whose records will be shared
    - The relationship of the authorizer to the patient (e.g., guardian, parent)
        - We note the legal challenges inherent in releasing information to and on behalf of minors. We do not provide comment on this topic and recommend ONC coordinate appropriate guidance.
- The name of the app requesting information
- A description of the information that identifies the information in a specific and meaningful manner, such as listing the data categories the app is requesting access to (scope of permissions)
    - While we recognize the need to provide more granularity in access permissions as capabilities evolve, we note ONC should be clear in its guidance that there is no expectation to support granular permissions beyond data categories for the 2015 CHIT Edition API requirements. For example, Grant "Access to My Meds," not "Access to My Diabetes Meds."
- A statement as to whether the app can or cannot change information currently in the EHR. (Note that the Task Force scope is read only access.)
- Duration (expiration date)
- Whether the app is authorized to access the EHR asynchronously (when the consumer is not present)
- A representation of the individual's intent to complete the authorization (such as "Sign" "OK" "Complete" button)
    - Note the Task Force is not commenting on best practices for e-signature; however, this information should be readily obtainable from a web interface (clicking on buttons or typing) and should not require offline processes (such as a faxed signature) or special software.
- "Save as" or "Email a copy to" Option: The patient must be provided a mechanism to email or otherwise electronically save the authorization for his/her own records.

- Access to the policies regarding the API developer and the provider's obligations to disable access to an app (such as through the provider's obligations to respond to threats under the HIPAA Security Rule), as well as the patient's ability to be made aware of the reasons for which an app is disabled (and any related appeal process).
    - We recommend additional guidance to determine whether there are grounds and specific requirements to support the provider to deny the patient's request to authorize a patient-directed app, such as those specified in 164.524.

5.c As we expect patients will be managing access to their data across multiple EHR APIs from multiple provider portals, use of a model authorization form will help patients be aware of and navigate inconsistencies. We recommend that ONC encourage a standardized mechanism by which a patient can compare authorization requirements for two or more providers.

5.d We recommend that ONC continue advancing work in support of standardized machine computable consent.

- At the same time, we emphasize that a lack of granular, computable consent standards should not be viewed as a barrier to exchanging data through APIs. Generally, standardized machine computable consent may be helpful for the "to what" aspects of the disclosure. Supporting the request of the API through a standardized, computable process could facilitate the response matching the request as accurately and completely as possible, and consistently across multiple systems.

- In the Interoperability Roadmap, ONC referred to computable privacy as "the technical representation and communication of permission to share and use identifiable health information, including when law and applicable organizational policies enable information to be shared without need to first seek an individual's permission. Once implemented effectively, using technology for privacy compliance saves time and resources, and can build trust and confidence in the system overall." Standards for computable privacy will go a long way to address automating the complex legal, regulatory and policy landscape for patient-directed exchange of health information via apps.

5.e We recommend that ONC coordinate with the relevant agencies to publish guidance to providers on best practices for patient-directed API authorizations. We recommend the provider include the following statements, which are typical of HIPAA authorizations, to notify the individual of the following:

5.f The individual has the right to revoke the app authorization, and provide a description of the process to do so.

5.g The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on the authorization.

5.h The potential for information disclosed pursuant to the authorization to be subject to re-disclosure by the recipient and no longer protected by HIPAA.

- We recommend that, where feasible, the provider should be required to disclose its relationship to the app and indicate whether the app is covered by HIPAA.

5.h A statement directed at the patient to the effect of, "Please ensure you refer to the app's terms of service and notice of privacy practices for further details." (See Topic 4: Communication of the App's Privacy Policies.)

TOPIC 6: LIMITATIONS AND SAFEGUARDS ON SHARING

Background

Three parties must come together to enable the flow of data into a patient-selected app: the patient, the API provider, and the application. All three parties must agree before data can be shared between systems. Questions about the circumstances in which each party can impose limitations on access to data include:

1. *API Provider.* Under what circumstances can the API provider limit access to patient data? For example, can an API provider prevent certain applications from registering, or disable access to apps that have already been approved by a patient?

2. *Patient*. When a patient decides to share data with an application, what limitations can the patient impose on this decision? Any limitations (e.g., of duration, or scope of access) must be "supported" by the API provider in a technical sense, in order to have an actual effect. In this model, the patient and API provider together define a policy for access, and the API provider implements that policy with respect to a given application.

Findings

We heard from consumer health technology firms and healthcare providers who host APIs today. In general, many API providers impose restrictions at app registration, limiting registration to apps that fall under the API Provider's terms of use guidelines. API providers sometimes dictate the terms by which a third party app may use data from the API, for instance to prevent the downstream sale of data to third-parties, or to prevent use in advertising. API Providers also impose limitations on rate of access and security-related details, such as requiring encrypted connections and the expiration/refreshing of access tokens.

API certification can provide a level of assurance and stability that certain standards and requirements are being met - both for the interfaces that are being supported and for the security and permissioning capabilities.

Secondly, a registration service which lists all of the running instances of these APIs would allow for a central point of control, registration, version management and verification of running status.

We believe that there will be an evolving set of services around patient record locator services that will enable a patient or a provider to find the sources of data and links and/or coordinates to access the APIs for that information.

We heard from patients who would like to share their data with apps and services on a long-term, ongoing basis, with minimum friction. We also heard about use cases for limited sharing, such as an app that helps a patient search for better medication prices: such an app would not necessarily be expected to require access to a patient's entire data set (e.g., lab tests, immunizations, problem list).

> *Note*: ONC's 2015 certification program requires that an API provider offer access at the "data category" level (e.g., lab results, or immunizations), but there is not currently a requirement that patient be allowed to define a sharing policy at the category level. In other words, the 2015 certification criteria allow an API where a patient's only choice is to share "all or nothing" with an app; and it would be entirely up to the app to decide which categories of data to access, after receiving blanket approval.

We heard testimony that authorization standards have mechanisms for capturing such limitations as an explicit set of permissions at app approval time (e.g., OAuth 2.0 has a "scopes" mechanism for this purpose).

Recommendations

6.a ONC should clarify that while API Providers may impose security-related restrictions on app access (e.g., rate-limiting, encryption, and expiration of access tokens), it is inappropriate for API providers to set limitations on what a patient-authorized app can do with data downstream.

- Given the nature of patient access rights, the provider is not in a legal position to prevent the registration of apps that would aggregate or share data, for example (though the provider might certainly decide to warn the patient, or endeavor to educate and explain these issue to the patient, as part of the provider-hosted app-approval workflow).

6.b ONC should clarify that API providers are not obligated to protect patients by identifying "suspicious" apps. API providers may suspend API access to an app that has breached the API provider's terms of service, or appears to have been compromised, or if the app poses a threat to the provider's own system. The Task Force recognizes that there are thresholds of risk, and patients should be able to override some app suspensions if owed to a lower-risk (except in the case where an app poses threat to the provider's own system or violates allowable terms of service). ONC and the relevant agencies should provide clear guidance as to the obligations of API providers when mitigating risk of a suspicious app.

6.c ONC should coordinate with the relevant agencies the threshold of proof by which an app may be disabled in order to avoid considerations of Information Blocking.

6.d ONC should update the HIT certification requirements to ensure that API providers enable patients to share data with certain (coarse-grained, for now) limits, rather than "all or nothing". Under the updated requirements, patients should be able to view a provider-generated list of

apps that currently have access to their records; revoke access at any time; and to make sharing decisions that restrict the scope of access.

6.e ONC should require that CHIT enable patients to share data with apps at the category level.

- While we believe in the value of fine-grained permissions, we also recognize that implementing many narrowly-scoped access control policies would require a costly and difficult re-design of existing systems. Therefore in the near-term we propose a pragmatic approach that ties back to the capabilities described in the 2015 CEHRT Certification Criteria: since CEHRT must already enable access through separate API calls at the data category level (e.g., medications, vital signs, or lab results), ONC should ensure that patients can approve access at this same level.

- ONC should update its "data category request" requirements to clarify that the first six elements of the MU Common Clinical Data Set (patient name, sex, date of birth, race, ethnicity, preferred language)[13] can be grouped into a single "demographics" category and exposed all together, rather than requiring six separate API calls for these data elements.

TOPIC 7: AUDITING AND ACCOUNTING FOR DISCLOSURES

Background

Multiple parties participate in the API ecosystem - the patient, the provider (Covered Entity), the app developer, and the EHR API developer - and each of these parties plays an important role in bringing to light unauthorized accesses to personal health information (PHI). Further, there are several existing oversight mechanisms that contribute to overall auditing and accounting for disclosures practices. Effective auditing is a crucial tool to detect system intrusion attempts, to track disclosures of PHI, to provide forensic evidence during investigations of a security incident, and to ensure policies are being followed.

Patient: Providing individuals with an accounting of disclosures fosters transparency and patient trust. When patients review these accountings, they inherently assist providers to ascertain weakness in privacy and security practices by identifying possible unauthorized disclosures and detecting possible breaches. HIPAA provides individuals with the right to view an accounting of disclosures made by a Covered Entity; however, this does not include disclosures made to the individual, to a third party specified by the individual, or to any entity for treatment, payment or healthcare operations purposes.

Provider: Must meet the requirements of various sources specific to auditing needs and accounting for disclosures. (For example, HIPAA, HITECH, Meaningful Use, Joint Commission (JCAHO), and so on.)

EHR API Developer: Responsible for enabling both the auditing of the disclosure and auditing the authorization of disclosure—i.e. the event where the patient authorizes the disclosure of

[13] https://www.healthit.gov/sites/default/files/2015Ed_CCG_CCDS.pdf

his/her PHI to the app. The EHR API developer must comply with the ONC CHIT audit related criterion.

App Developer: Responsible for auditing what is done with the data by the application, including any further disclosures. Realistically, the app developer is the only one that has enough context to provide a meaningful record of what happened after the initial disclosure made by the API. Apps are not certified, so there are no requirements for apps comparable to the ONC CHIT audit related criterion. There are various sources of guidance available for app developers specific to privacy and security.

Findings

We analyzed whether patient-designated, read-only APIs introduce risks that we would not expect to be addressed in existing audit and accounting for disclosures practices under ONC CHIT and HIPAA.

CHIT Auditing Requirements

We assessed the 2015 CHIT certification rule and relevant companion guides to understand audit requirements intended to address Read access to PHI from third-party apps via API: § 170.315(d)(10) ''auditing actions on health information'' or § 170.315(d)(2) ''auditable events and tamper resistance.'' The CHIT must track actions pertaining to electronic health information in accordance with sections 7.2 through 7.4, 7.6, and 7.7 of the ASTM E2147-01 standard, and the actions and information should be captured in a manner that supports the forensic reconstruction of the sequence of changes to a patient's chart.

- 7.2 Date and Time of Event - The exact date and time of the access event and the exit event.
- 7.3 Patient Identification - Unique identification of the patient to distinguish the patient and his/her health information from all others.
- 7.4 User Identification - Unique identification of the user of the health information system.
- 7.6 Type of Action (additions, deletions, changes, queries, print, copy)—Specifies inquiry, any changes made (with pointer to original data state), and a delete specification (with a pointer to deleted information).
- 7.7 Identification of the Patient Data that is Accessed - Granularity should be specific enough to clearly determine if data designated by federal or state law as requiring special confidentiality protection has been accessed. Specific category of data content, such as demographics, pharmacy data, test results, and transcribed notes type, should be identified. For example, the ability of the audit log to record that the user accessed a patient's medication list would be sufficient; it is not necessary for the audit log to record the specific medication.

We are satisfied that the above Certified Health IT (CHIT) auditing requirements address the needs of Read access by a consumer-direct app to the EHR API.

We note there are potential challenges inherent in auditing app accesses to the API, such as a high frequency of occurrences flooding the audit with so much noise it is difficult upon review to discern what actually happened based. To this end, we anticipate practices and services will evolve to address these challenges and are not compelled to comment.

HIPAA - Accounting of Disclosures

Patients have the right to receive an accounting of their PHI under § 164.528 (Accounting of disclosures of protected health information). Specifically, an individual has a right to receive an accounting of disclosures of protected health information made by a covered entity in the six years prior to the date on which the accounting is requested, except for disclosures to individuals of protected health information about them.

There is no individual right under HIPAA to receive an accounting of disclosures made to an app at the direction of the individual. If an individual requests a Covered Entity to release his/her PHI to an app, that is the equivalent of releasing PHI to the individual directly and, as such, no accounting of disclosures is required. An individual also does not have a right to an accounting of disclosures made by a Covered Entity pursuant to an individual's authorization.

There is no individual right under HIPAA to receive an accounting of disclosures made to an app by a Covered Entity (or by a Business Associate at the direction of a Covered Entity) for treatment, payment, or operations purposes. In the limited circumstance in which an accounting might be required (i.e., disclosures for public health purposes), note that the obligation to account for disclosures falls on the Covered Entity, not the Business Associate, even if the Business Associate made the disclosure.

App developers not acting as Business Associates are not regulated by HIPAA. An app developer that is not acting as a Business Associate and thus not regulated by HIPAA does not have to comply with HIPAA and would not have to provide an accounting of any disclosures TO OR FROM the app. However, this activity may be governed by terms of use that an individual may agree to when using the app.

Although providers must have audit controls that record and examine activity involving PHI (§ 164.502(a)(1), there is no general right granted to the individual to request these audit records.

The supporting CHIT requirements for Accounting of Disclosures are as follows:

- § 170.315(d)(11) - Accounting of Disclosures - Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(d).
- § 170.210(d) - The date, time, patient identification, user identification, and a description of the disclosure must be recorded for disclosures for treatment, payment, and health care operations, as these terms are defined at 45 CFR 164.501.
- Note: There is no requirement to make the Accounting of Disclosures available via the portal.

While an app developer may or may not be subject to HIPAA audit requirements, it is not only important for CHIT to audit access to the API, but apps should have some level of audit as well to enable consumers better control and review of their data use and sharing.

Recommendations

7.a We recommend that ONC expand certification criteria to require CHIT to make API access audit logs available to patients through an Accounting of Disclosures via the portal.

- Show patients a list of all active app authorizations in the portal

- Include the ability for the patient to revoke any app authorization
- Show patients a list of which apps have accessed their data via the API (including relevant details)
    - Working with the appropriate authorities, ONC should provide guidance to the EHR API developer regarding the information that should be logged to detail the disclosure by the API to the app, in terms of the "of what" information relevant to both the Accounting of Disclosures and the audit that may be used to meet requirements of the HIPAA Security Rule.
    - We recommend that ONC review the Task Force's recommendations for patient authorization requirements in Topic 5: Patient Authorization to ensure CHIT audit capabilities sufficiently support an artifact that represents such patient authorization.
- The patient should be informed of the process which he/she needs to follow in order to flag any of the displayed disclosures as potentially inappropriate, which then could trigger an investigation by the provider.
    - The patient flagging process should be supported electronically through the portal and not require any manual processes (such as faxing a signed complaint).

7.b We recommend ONC coordinate with the relevant HHS agencies to publish patient-facing guidance that explains to patients what their rights are when the app developer is not covered under HIPAA as a Business Associate (and therefore not required to provide an accounting of disclosures).

7.c While apps are not covered under ONC's certification program for health IT and we are not suggesting that they should be, we do recommend ONC should provide guidance regarding voluntary best practices of audit capture and accountings for disclosures to developers offering apps that are intended to interact with CHIT.

7.d We recommend ONC coordinate with the appropriate authorities, including states, to provide an easy-to-use educational resource that details for all API ecosystem actors (patients, providers, app developers and EHR API developers) the rules and responsibilities specific to breach notifications across all enforcement mechanisms (e.g., HIPAA, FTC).

TOPIC 8: IDENTITY PROOFING, USER AUTHENTICATION, AND APP AUTHENTICATION

Background

When healthcare data flows from a HIPAA-covered entity into a patient-selected app, there are several points where identity assurances can be used. A typical sequence of steps might include Registration, App Approval, and Data Access. Registration occurs up-front, before a user requests information access.

Registration is conducted by the App Developer, and involves that API Provider potentially reviewing and ultimately granting or denying the App's registration request. This step does not provide access for any specific patient – it's an up-front setup step that allows patients to subsequently request access.

App Approval occurs when a specific patient communicates to the API Provider that she wants to authorize the app in question to access her clinical data. This step requires that the patient be identity-proofed and authenticated before she can communicate the authorization decision to her API provider. This step, where a user grants approval to an app, is recorded in the API Provider's audit logs as outlined in Topic 7: Auditing and Accounting for Disclosures.

Finally, each time an app access patient data through the API, these requests are also logged for audit purposes.

Note these steps (Registration, Approval and Access) could be performed in rapid sequence, or they could occur over a period of time ranging from minutes to days to months or even years. In no case should these steps be used as a barrier to access – they should be frictionless and simple for the end user to complete.

Specifically:

- *Registration Time.* The API Provider may need assurance about the identity of the application developer. Registration of apps with API Providers is covered in Topic 2: App Registration.
- *App Approval Time.* The API Provider needs assurance of the patient's (or authorized representative's) identity in order to enable a data-sharing decision. The API Provider and patient may need assurance of the app's authenticity (e.g., "the app that I'm using is the one hosted at https://my-app.com") to make an informed decision.
- *Data Access Time*. The API Provider may need assurance of the app's authenticity in order to permit access.

In this topic, we focus on how patient identity is established.

Findings

We heard testimony from health care provider organizations indicating that procedures have been developed and widely deployed to enable patients to access their own data online today that have been in operation for a long time (up to a decade in some cases) and deployed to millions of consumers[14]. These procedures have spread across the healthcare delivery system as incentivized by MU2 patient access objectives, and they involve different combinations of in-person proofing (e.g., during an office visit, the patient gets a one-time "registration code" to sign up for portal access), postal mail-based proofing (e.g., portal sign-up instructions are sent to the patient via the US Postal Service), or online identity proofing (e.g., patients complete an automated identity proofing process relying on knowledge based responses to consumer specific content derived from financial records). While these practices are

[14] Specifically, HIPAA § 164.312(d) and § 164.514 (h)

diverse, they are not unique to APIs, and existing solutions have enabled patients to access their data through online portals in the MU2 era.

We heard testimony from API providers in the consumer space where app registration is offered on a self-service basis (e.g., registering an app with Google via https://developers.google.com). In such cases, the API provider verifies some attribute about the app developer (e.g., e-mail address and the app's URL), and requires the app developer to agree to terms of service. At approval time and data access time, a combination of the app's domain and (in some cases) app credentials is used to verify the identity of the app.

Recommendations

8.a ONC should provide guidance that the patient identity proofing and authentication requirements in an API ecosystem are not different from the requirements for MU2-era patient portal sign-in and View, Download, Transmit.

- Specifically, a provider organization must have an appropriate level of assurance of a patient's identity, and must authenticate the patient through an appropriate mechanism. The same sign-up and login process that is used for portal access can and should be used to bootstrap API access.

- At the same time, ONC should continue working with other federal stakeholders including the National Strategy for Trusted Identities in Cyberspace to better define a national approach for identity management.

8.b ONC should recommend that APIs should be secured via standardized mechanisms (such as OAuth) that allow patients and/or their authorized representatives to use existing provider portal account credentials during the app approval process.

8.c ONC should indicate that API Providers must not impose patient identify-proofing or authentication barriers for API access that go beyond what's required for “View, Download, Transmit” access. APIs give the opportunity to provide simple and seamless access to patient information.

8.d ONC should collaborate with the appropriate agencies to provide clear and distinct API developer and API appropriate usage privacy and security standards in order to encourage API development and adoption.

8.e ONC should clarify that for registering patient-authored apps (or any app authored by an individual to benefit only that individual or the individual’s close relationships, such as family members), existing patient identity proofing and authentication is sufficient: in other words, any patient who is able to sign into the portal of an API provider should be able to register any app that they chose with that API provider. For other apps, ONC should clarify that identity proofing of developers must be non-onerous and automatable (e.g., e-mail address or domain verification would be reasonable; a review of tax records or inspection of facilities would not).

8.f ONC should further clarify that in situations where greater assurance is desired, app endorsements can achieve this assurance in a non-blocking, low-friction way without preventing registration of non-endorsed apps.

8.g ONC should recommend that at approval and data access time, authenticating apps via standards-based mechanisms like OAuth 2.0 client authentication should be acceptable, and that providers must ensure that app approval and data access can occur without active involvement from the API Provider or app developer.

- In other words, the only person who should have to take action to approve an app's access to patient data is the patient (or representative).

8.h ONC should establish that an API provider's portal-based identity proofing and patient authentication procedures (i.e. the capabilities they use to enable access to patient portals) are deemed sufficient for granting an app access to the API.

- Any process that presents a substantially greater burden to the patient for API access approval should be considered Information Blocking.

IV. Appendix

A. Virtual Hearing Information

Background

- Virtual hearings for the Joint API Privacy and Security Task Force were held on January 26th and 28th, 2016
- Panelist representation spanned across both non-healthcare and healthcare industries
- Written testimonies and public comments were collected
- Common themes across the two days of testimony and discussion were analyzed and summarized

Virtual Hearing Panelists

Hearing January 26th		Hearing January 28th		
Panel 1 - Consumer Tech 1	**Panel 2 - Consumer Tech 2**	**Panel 3 - Healthcare Delivery**	**Panel 4 - Health IT Vendors**	**Panel 5 - Consumer Advocates**
David Wollman, PhD- NIST	Alisoun Moore-LexisNexis	Stanley Huff, MD-Intermountain	John Moehrke- GE Healthcare	Adrian Gropper, MD- Patient Privacy Rights (PPR)
Stephan Somogyi-Google	Evan Cooke, PhD-US Digital Service	Paul Matthews-Oregon Community Health Information Network (OCHIN)	Ted LeSueur-McKesson	Mark Savage-National Partnership for Women & Families (NPWF)
David Ting-Imprivata	David Berlind-Programmable Web	Sean Kelly, MD- Imprivata	Chris Bradley-Mana Health	Steven Keating-Patient Advocate/ Consumer
Greg Brail- Apigee	Marc Chanliau-Oracle	Tim McKay, PhD- Kaiser Permanente	James Lloyd-Redox Engine	
Eve Maler-ForgeRock	Shue-Jane Thompson, PhD-IBM	Brian Lucas-Aetna		
	Gray Brooks-GSA			

Key Items for Consideration

- Privacy and security issues for adoption of open-APIs
- Read-only APIs
- Based on 2015 Health IT Certification Criteria
- APIs in the context of consumer-facing applications

- View, Download, Transmit (VDT)
- Patient Access
- Single patient access to their Common Clinical Data Set

Out of Scope Issues

- Terms of Use
- Licensing Requirements
- Policy Formulation
- Fee Structures
- Certifying Authorities
- Formulation of Standards
- Electronic documentation of consents required by law or policy
- Issues unique to write-APIs

Key Themes from Hearings

1. General Support for API Adoption
2. Standards
3. Identity-proofing and Access Management
4. Consumer Education and Resources
5. Granularity/Permissions
6. Consent
7. Security Best Practices
8. Certification, "Good Housekeeping Seal"
9. Policy and Cultural Factors to Promote Security
10. API-Specific Factors to Promote Security
11. Read-Only Access API
12. Business & Legal Issues (Out of Scope)
13. Patient Access Rights
14. Data Ownership
15. Liability

1. General Support for API Adoption

When proactively managed and secured, the efficacy of APIs greatly outweighs the risks associated with deploying them.

- APIs are not uniquely insecure or vulnerable; they provide a well-documented, secure method to share and access data with security, privacy and flexibility.
- Panelists overall agreed that APIs are effective and widely used for securely and openly sharing data.
- APIs that are well-designed and secure provide an additional layer of authentication and authorization for accessing data.
- APIs should be easy to use for developer(s) and safe for owners of the information exposed; hundreds of tools and resources are available to build APIs.
- Many of the organizations who testified, including Intermountain, use APIs for apps that are available both internally and to third parties.

- Consumer/patient advocates testified that access to data and APIs should be open to patients; liability of any resulting data breaches rests with patient.
- Panelists agreed that APIs were the right vehicle to facilitate data flow.
- Providers, organizations, and consumer/patient advocates argued that access to information outweighed the risks to privacy and security - many of which could be mitigated by technology.

2. Standards

There was consensus among panelists that having industry-standard APIs would be beneficial to the developer community. They would promote innovation and provide access to patient data from multiple provider systems and from various types of consumer devices.

- Fast Health Interoperability Resources (FHIR) and Blue Button were repeatedly provided as best-case examples.
- Strong overall support for industry standards to facilitate interoperability, address privacy and security concerns, and reduce cost.
- Open Bank Project API UK, provided as an example by panelists, enables bridging of different data sources with fewer vulnerabilities.
- Mana Health identified the lack of true standards as a barrier. They emphasized that the value of standards would be enhanced by ensuring they addressed issues including the lack of common identifiers, practices, and authorizations.
- Consumer/patient advocates, including Patient Privacy Rights (PPR), indicated that a unified public API with the appropriate security controls including encryption (with underlying technologies such as FHIR, Health Relationship Trust (HEART), and OAuth 2.0) would close potential security gaps and is the best solution for patients and the industry.

3. Identity-proofing and Access Management

Panelists discussed the challenges of verifying and authenticating identity, user accounts and linkage problem - although these are not new or unique to the healthcare industry.

- E-prescribing technology solutions and mechanisms were provided as a successful example of patient matching, authentication, and authorization.
- Panelists emphasized that APIs do indeed incorporate the necessary verification of identity, authentication and authorization restrictions.
- Additionally, the establishment of common identifiers was mentioned as a solution that would aid and encourage widespread adoption.
- Providers should work with patients to recommend effective apps to meet their needs.
- Ultimately, the decision on which apps to use must rest with the patients and consumers.
- PPR argued that the use of the same interface for patients and providers mitigates patient matching issues.
- PPR also stated that User Managed Access (UMA) and HEART works for general clinical access.
- UMA and HEART were stated to be scalable to the appropriate and varying levels of needs of security and privacy of consumers.

4. Consumer Education and Resources

ONC, OCR and CMS should collaborate to educate consumers and providers on APIs, their respective rights, and how to protect their personal data.

- Application developers must clearly communicate privacy policy/Terms of Service to consumers.
- Concerns were also noted on the limited resources available to educate providers and staff at smaller practices compared to the large organizations with more resources (OCHIN).

5. Granularity/Permissions

Permissions (scope) using APIs provides the granularity to go beyond opt-in/opt-out.

- APIs can permit varying levels of permission and data-scope based on role, data needs, etc.
- The ability to select data granularly provides security controls which can be modified and adapted.
  - Panelists discussed granularity in the levels of permission and the associated implications.
  - Aetna suggested that developing standards (to normalize) will aid developers.
- APIs are extremely precise and provide the opportunity to dictate the appropriate levels of access to specific types of data for an explicit need.
- API management and security protocols ensure only correct users get through.
  - OAuth, OpenID and UMA
  - APIs can technically control rates/quantity of an app's access to deflect malicious attacks

Additional testimony on the use of OAuth, OpenID and UMA:

- *NIST*: OAuth allows management of the conveyance of rights to data for a specific individual or account – no PII is exchanged (Green Button).
  - Scope negotiation is a big part of Green Button
  - Prior to authorization when a customer logs in, customers are guided through a process to determine the availability of customer data the third party may access. [1]
- 2015 Cert Rule states that applications should not be required to pre-register (or be approved in advance) before being allowed to access the API. [2]
- *ForgeRock*: OAuth is coarse-grained, does not put the patient at center and is limited in consent and authentication. OpenID and UMA are more granular and ready for use as the communication tools.
- *Imprivata*: UMA is critically important to securing access to data.
- *Apigee*: OAuth is flexible, effective and includes 'scope'.
  - Scope mechanism is an effective way to communicate to developers where end-users can be authenticated using a web browser, token, or other authentication mechanisms.
- *US Digital Service*: APIs are used within systems for network protocols, security mechanisms, authentications, authorizations, request/response methods and serialization formats.

6. Consent

- Panelists recognized that when an app is used to seek an individual's data, and the app is not used by the individual themselves, the data custodian/API host will want to confirm that the data can be released.
  - Characterized this as a consent issue, but "consent" is not required for all data releases.
- 2015 Edition Rule permits apps to be registered, which can document the required consent.
- Can apps used directly by individuals be presumed to be consenting to access their own data? The OCR access rule seems to indicate as much.

7. Certification, "Good Housekeeping Seal"

- Many panelists commented on the need to verify that apps accessing APIs are reliable and secure.
  - Many panelists discussed a "good housekeeping seal" from a potential third party certifier.
  - Others advocated for publicly available technical documentation for API use to test and affirm technical security.
- EHR Incentive Program Stage 3 states that providers are expected to provide patients with detailed instructions on how to authenticate their access, and leverage available applications to access their data through the API.[3]

- Others wanted to be able to strictly vet/internally certify the apps that interacted with their systems.
  - 2015 Cert Rule states that applications should not be required to pre-register (or be approved in advance) with the provider or their Health IT Module developer before being allowed to access the API. [4]
- Others wanted the apps to have open and transparent terms of use along with disclosures on what the apps did with data collected.

8. Security Best Practices

APIs are not inherently more vulnerable to security risks and should be treated using best practices including all technical controls, policies, procedures, an "engineering culture", and adapting to the constant evolution of threats and newest security standards.

- Technical controls are necessary, but not sufficient to building a secure system (Google).
- Well-known best practices for security hygiene not unique to APIs include:
  - Use of encryption
  - Authorization/authentication/identity verification mechanisms
  - Data access management controls, role-based, and attribute-based access
  - Code review
  - Testing
  - Monitoring and audit logs
  - Integrity controls
  - Rate-limiting mechanisms
  - Scanning for incoming attack vectors (e.g., SQL Injection)

9. Policy and Cultural Factors to Promote Security

- Fraud prevention partnerships between public and private sectors are formed to share information on vulnerabilities.
- GE testified that internal policies are more important than technology with respect to authentication, consent and accountability.
- Development of internal policy is out of scope.
- Technology exists to support good policies, but the policies have to come first followed by the aim for security best practices.
- Organizational buy-in, culture and workflow considerations should also be taken into account as it is difficult to change.
- Fostering this kind of 'engineering culture' requires a tremendous amount of organizational bias.
- APIs that are backed by an engaged developer community have an increased likelihood to be leveraged by a developer.

10. API-Specific Factors to Promote Security

Well-designed APIs are clear with specifications and documentation of security controls and differentials that need to be acquired before they are built and used (Apigee).

- These can also be offered with a 'web-portal' for potential developers to learn and interact with the offering team.
- However, a secure ecosystem and infrastructure is necessary, no matter how clever the engineering, for those who wish to exploit a system.
- Organizations need to stay on top of current best practices.

11. Read-Only Access API

There are additional challenges when an API allows data to be written to the system it is connected. ONC's 2015 Edition API requirement is for a read-only API.

Comments about APIs that may have data written to them, while out of scope, include:

- Accuracy, matching, provenance and reliability of patient generated health data (PGHD) that is written to a record through an API (Imprivata).
- Security of the arriving data asserted that all data coming from the outside should be considered unsecure unless tested (Google).
- Imprivata discussed the challenge in assuring the integrity of PGHD and the need to assert the integrity of that block of data from the moment the patient is uploaded to verify identity by some means.

12. Business & Legal Issues (Out of Scope)

Privacy and security regulations may be a barrier to market progress for fears of legal liability, criminal charges to 'white hat' activity, and uncertainty of standards meeting compliance policy.

- Complex contracting including issues of intellectual property protection and indemnification (ForgeRock, LexisNexis).
- It is difficult to take advantage of 'white-hat' hacking in healthcare due to regulation of the underlying data (Google, Programmable Web, and ForgeRock).
  - In the healthcare industry, 'white hats' will not risk legal liability as they do in other sectors.
  - Testimony was asserted that 'hackathons' provide valuable information (IBM).

13. Patient Access Rights

- Consumers are really looking for APIs as a way to gain access to their health information that may be held in multiple provider and payer systems today.
  - OCR is releasing new guidance on the right of consumers to access their health information and records.
- Consumer panelists uniformly wanted to access their own health information even if it was through insecure methods.
  - Consumers would rather have their data than risk their care providers NOT providing access to the information.
  - Consumers want to send their information where they want, even if it is to a less secure environment.
  - A task force member stated a patient was exercising their rights, not giving them away by sending their data outside their provider's system. Consumers need to be educated on their rights and the risks. Patients have right to use their data as they wish.
- HIPAA highlights a patient's right to access their health information.
- Many providers have 'closed' systems and patient portals that limit access to data.
- Open frameworks, improved interoperability, and access to data was supported and advocated for by groups including Imprivata, Aetna, Redox Engine as well as by Consumer/Patient Advocates.

14. Data Ownership

There was much discussion on who owns patient data. NIST testified that for energy usage data (green button), NIST was able to engineer access despite early concerns about "ownership".

- Need clarification from OCR on patient's right to access and whether data ownership is a question the task force needs to address to make recommendations to ONC.

15. Liability

- OCR Access guidance, as of 1/7/16, states that when a consumer directs that a copy of their data be transmitted to a third party of their choosing, the discloser is not responsible for security failures at the destination.
- ONC/OCR Fact Sheets, published 2/4/16, state that when two providers are sharing, if the disclosing provider sends the data in a manner compliant with the HIPAA Security Rule, the disclosing provider is not responsible for security failures at the destination.
- It remains to understand any other liability issues that remain to be solved that derive from privacy or security.

Top Challenges

- Business drivers for enabling open API access
- Need for trust across the ecosystem
- Enabling patient driven trust decisions
- Transparent Terms of Use
- Disparities in resources, means, and information between larger organizations and smaller provider practices
- Cultural and workflow issues
- Fear of legal liability

Key Drivers for Success

- Industry collaboration to develop standards-based open APIs
- Fostering a cultural shift to encourage development and innovation
- Financial incentives
- Shifts in costs with move to value-based care and delivery of services
- Shift from low tech to higher tech including more prevalent consumer driven technologies

[1]http://osgug.ucaiug.org/sgsystems/OpenADE/Shared%20Documents/Testing%20and%20Certification/GreenButtonTestPlan/referenceMaterial/GreenButtonAuthorization.docx

[2]https://www.federalregister.gov/articles/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base#h-10

[3]https://www.federalregister.gov/articles/2015/10/16/2015-25595/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-3-and-modifications

[4]https://www.federalregister.gov/articles/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base#h-102

B. Technical Actors, Roles, Responsibilities and Operations

Technical Actor	Role	Operation	Rights/Responsibilties	HIPAA
Patient	**Data Requestor**	Request Accounting of Disclosure	No Right For Disclosures To Self	HIPAA Regulated
		Identify Unauthorized Access	No Right For Disclosures To Self	HIPAA Regulated
Provider (CE)	**Data Provider**	Provide Accounting of Disclosure	Meet legal requirements: HIPAA, HITECH, Meaningful Use, Joint Commission, FIPPS, etc.	HIPAA Regulated
		Maintain Audit Records	Meet legal requirements: HIPAA, HITECH, Meaningful Use, Joint Commission, FIPPS, etc.	HIPAA Regulated
		Breach Notification	Meet legal requirements: HIPAA, HITECH, Meaningful Use, Joint Commission, FIPPS, etc.	HIPAA Regulated
EHR System	**Data Custodian**	Generate Audit Records	Meet legal requirements: HIPAA, HITECH, Meaningful Use, Joint Commission, FIPPS, Etc.	HIPAA Regulated
		Maintain or Forward Audit Records	Meet legal requirements: HIPAA, HITECH, Meaningful Use, Joint Commission, FIPPS, Etc.	HIPAA Regulated
		Identify Breach	Meet legal requirements: HIPAA, HITECH, Meaningful Use, The Joint Commission, FIPPS, Etc.	HIPAA Regulated
EHR API Developer	**Not a CE or BA**	Provide Read API Functionality	Meet FTC Requirements	Not Regulated by HIPAA
		Provide Read API Functionality	Meet responsibilities as described in business contract	Not Regulated by HIPAA
EHR API Developer	**CE or BA**	Provide Read API Functionality	Meet responsibilities as described in business contract	HIPAA Regulated

Technical Actor	Role	Operation	Rights/Responsibilties	HIPAA
EHR API Developer	**CE or BA**	Generate Audit Records	Meet legal requirements: HIPAA, HITECH, Meaningful Use, Joint Commission, FIPPS, etc.	HIPAA Regulated
		Maintain Or Forward Audit Records	Meet legal requirements: HIPAA, HITECH, Meaningful Use, Joint Commission, FIPPS, etc.	HIPAA Regulated
		Identity Breach	Meet legal requirements: HIPAA, HITECH, Meaningful Use, Joint Commission, FIPPS, etc.	HIPAA Regulated
App Developer	**Not a CE or BA**	Provide Read Operation	Meet FTC Requirements	Not Regulated by HIPAA
App Developer	**CE or BA**	Provide Read Operation	Meet FTC Requirements	HIPAA Regulated
		Generate Audit Records	Meet legal requirements: HIPAA, HITECH, Meaningful Use, Joint Commission, FIPPS, etc.	HIPAA Regulated
		Identify Breach	Meet Legal Requirements: HIPAA, HITECH, Meaningful Use, Joint Commission, FIPPS, etc.	HIPAA Regulated
API Provider	**Not a CE or BA**	Distributor of the API used by apps to access healthcare data	Meet FTC Requirements	Not Regulated by HIPAA
API Provider	**CE or BA**	Distributor of the API used by apps to access healthcare data as service to CE	Meet FTC Requirements	HIPAA Regulated
		Generate Audit Records	Meet HIPAA Requirements	HIPAA Regulated

C. Glossary of Terms

1. **Access** – The ability and means to communicate with or otherwise interact with a system, to use system resources to handle information, to gain knowledge of the information the system contains, or to control system components and functions. NICCS

2. **Application** – Software program that performs a specific function directly for a user and can be executed without access to system control, monitoring, or administrative privileges. NICCS

3. **Application Programming Interface (API)** – A software application function that can be invoked or controlled through interactions with other software applications. APIs allow the user experience to be seamless between two or more software applications since the APIs are working behind the actual user interface. The API specifies how software components should interact and APIs are used when programming graphical user interface (GUI) components. They are published and accessible in a way that makes them easy for interested developers to find and use without a program host system intervention, and for which there are no fees or other intellectual property restrictions that limit their availability to any competent and interested programmer. Interoperability Roadmap Supplementary Materials – Appendix F; Glossary

4. **Assurance** – The grounds for confidence that the set of intended security controls in an information system are effective in their application. NIST

5. **Attack** – An attempt to gain unauthorized access to system services, resources, or information, or an attempt to compromise system integrity. NICCS

6. **Audit trail** - A chronological record that reconstructs and examines the sequence of activities surrounding or leading to a specific operation, procedure, or event in a security relevant transaction from inception to final result. NICCS

7. **Authentication** – Verifying the identity of a user, process, or device, often as a prerequisite to allowing access to resources in an information system. NIST

8. **Authorization** – Represents the amount or type of information a person or system is allowed to access. For example, the absence of any authorization means a person or system may not access any information. Authorization to access all information means a person or system may access 100% of the information in the system. Interoperability Roadmap Supplementary Materials – Appendix F; Glossary

9. **Authorization Code** – An authorization grant, obtained by using an authorization server as an intermediary between the client and resource owner, which provides the ability to authenticate a client, as well as the transmission of the access token directly to the client without passing it through the resource owner's user-agent and potentially exposing it to others, including the resource owner. OAuth 2.0 Authorization Framework /Introduction to OAuth 2.0 Presentation

10. **Authorization Server** – The server issuing access tokens to the client after successfully authenticating the resource owner and obtaining authorization. OAuth 2.0 Authorization Framework/ Introduction to OAuth 2.0 Presentation

11. **Back Channel** – Uses direct HTTP connections between components, the browser is not involved. OAuth 2.0 Authorization Framework/ Introduction to OAuth 2.0 Presentation

12. **Blacklist** – A list of entities that are blocked or denied privileges or access. NICCS

13. **Blockchain Technology** – A specific type of distributed database (or ledger) that stores transactions with a number of cryptographic features in a string of digital "blocks", with each block referencing the prior one, effectively eliminating the possibility of fraudulent transactions and making it virtually impossible to retroactively alter any single block of the chain. Business Insider

14. **Bootstrap** – A free and open-source collection of tools for creating websites and web applications. Wikipedia

15. **Business Associate** – A person or entity that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, a Covered Entity. A member of the covered entity's workforce is not a business associate. A covered health care provider, health plan, or health care clearinghouse can be a business associate of another covered entity. HIPAA

16. **Business Associate Agreement (BAA)** – A contract between a HIPAA covered entity and its business associate or a business associate and its subcontractor that must contain the elements specified at 45 CFR § 164.504(e). For example, among other requirements, the contract must:

    - Describe the permitted and required uses of protected health information by the business associate;
    - Provide that business associate will not use or further disclose the protected health information other than as permitted or required by the contract or as required by law; and
    - Require the business associate to use appropriate safeguards to prevent a use or disclosure of the protected health information other than as provided for by the contract. Interoperability Roadmap Supplementary Materials – Appendix F; Glossary

17. **Certification** – A comprehensive assessment of the management, operational and technical security controls in an information system, made in support of security accreditation, to determine the extent to which the controls are implemented correctly, operating as intended, and producing the desired outcome with respect to meeting the security requirements for the system. NIST

18. **Certified EHR Technology (CEHRT)** – Gives assurance to purchasers and other users that an EHR system or module offers the necessary technological capability, functionality, and security to help them meet the Meaningful Use Incentive Program criteria. Certification also helps providers and patients be confident that the electronic health IT products and systems they use are secure, can maintain data confidentially, and can work with other systems to share information. CMS.gov

19. **Client** – An application making protected resource requests on behalf of the resource owner and with its authorization. The term "client" does not imply any particular implementation characteristics (e.g., whether the application executes on a server, a desktop, or other devices) OAuth 2.0 Authorization Framework/ Introduction to OAuth 2.0 Presentation

20. **Common Clinical Data Set (CCDS)** – Listed in § 170.102, the Common Clinical Data Set was previously called the Common MU Data Set and was revised in the Final Rule for 2015 Certification. 45 CFR Part 170 - Final Rule, 2015 Edition Certification Companion Guide

21. **Confidentiality** – Ensuring that information is accessible only to those authorized to have access to PHI.

22. **Consent** – Agreement to an action based on knowledge of what the action involves and its likely consequences. http://medical-dictionary.thefreedictionary.com/consent / Interoperability Roadmap Supplementary Materials – Appendix F; Glossary

23. **Consumer Facing Applications** – Include hardware, software or technology with user interfaces (UI) or applications that directly interact with customers. Techopedia

24. **Covered Entity (CE)** – (1) A health plan; (2) A health care clearinghouse; or (3) A health care provider, who transmits any health information in electronic form in connection with a transaction covered by 45 CFR 160.103. HIPAA

25. **Credential** – Attestations of qualification, competence, or authority that support a claim of identity or assertion of an attribute and usually are intended to be used more than once. 1) NIST 2) Healthcare Design Magazine

26. **Credential Service Provider (CSP)** – A trusted entity that issues or registers Subscriber tokens and issues electronic credentials to Subscribers. The CSP may encompass Registration Authorities (RAs) and Verifiers that it operates. A CSP may be an independent third party, or may issue credentials for its own use. NIST

27. **Credentialing** – The process used to establish the qualifications of professionals, organizational members, or organizations and to assess their background and legitimacy to meet predetermined and standardized criteria. Individuals, organizations, processes, services, or products may be credentialed. Healthcare Design Magazine

28. **Data Aggregation** – The process of gathering and combining data from different sources, so that the combined data reveals new information which may be more sensitive than the individual data elements themselves. CNSSI

29. **Data Breach** – The unauthorized movement or disclosure of sensitive information to a party, usually outside the organization, that is not authorized to have or see the information. NICCS

30. **Delegated Authority** – The ability to delegate rights or authority to another to act in a specific capacity on behalf of the grantor of the right. HealthIT.gov

31. **Denial of Service** – An attempt to make a machine or network resource unavailable to its intended users, such as to temporarily or indefinitely interrupt or suspend services of a host connected to the Internet. Wikipedia

32. **Designated Record Set (DRS)** – A group of records maintained by or for a covered entity that is the medical and billing records about individuals; enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; information used in whole or in part by or for the HIPAA covered entity to make decisions about individuals. Harvard

33. **Emergency Access (Break Glass)** – Granting of user rights and authorizations to permit access to protected health information and applications following a declaration of emergency conditions. Emergency access is characterized by broad system access out of the ordinary. Security systems enforce "Emergency" policies in effect, including special user permissions for broad access and specific patient consent directives regarding preferences in an emergency situation (code blue, chemical/biological/nuclear incidents, natural disaster, etc.). HL7- VA Emergency Access

34. **Encryption** – The process of encoding messages or information in such a way that only authorized parties can read it. Wikipedia

35. **Fast Healthcare Interoperability Resources (FHIR, pronounced "Fire")** – Defines a set of "Resources" that represent granular clinical concepts. The resources can be managed in isolation, or aggregated into complex documents. Technically, FHIR is designed for the web; the resources are based on simple XML or JSON structures, with an http-based RESTful protocol where each resource has predictable URL. Where possible, open internet standards are used for data representation. Interoperability Roadmap Supplementary Materials – Appendix F; Glossary

36. **Front Channel** – Uses HTTP redirects through the web browser, no direct connections OAuth 2.0 Authorization Framework/ Introduction to OAuth 2.0 Presentation

37. **Greylist** – A list or register of unknown entities, providing temporarily degraded service to unknown email clients as an anti-abuse mechanism, which might be trusted on first use but could be subject to extensive auditing and logging as well as special rules on when to move to the white or black lists IETF

38. **Health Insurance Portability and Accountability Act (HIPAA)** – HIPAA is the acronym of the Health Insurance Portability and Accountability Act of 1996. The Office for Civil Rights (OCR) enforces the HIPAA Privacy Rule, which protects the privacy of individually identifiable health information; the HIPAA Security Rule, which sets national standards for the security of electronic protected health information; the HIPAA Breach Notification Rule, which requires covered entities and business associates to provide notification following a breach of unsecured protected health information; and the confidentiality provisions of the Patient Safety Rule, which protect identifiable information being used to analyze patient safety events and improve patient safety. Interoperability Roadmap Supplementary Materials – Appendix F; Glossary

39. **Identity and Access Management** – The methods and processes used to manage subjects and their authentication and authorizations to access specific objects. NICCS

40. **Identity Proofing** – The process of collecting and verifying information about a person for the purpose of proving that a person who has requested an account, a credential, or other special privilege is indeed who he or she claims to be, and establishing a reliable relationship that can be trusted electronically between the individual and said credential for purposes of electronic authentication. HealthIT.gov

41. **Information Blocking** – Occurs when persons or entities knowingly and unreasonably interfere with the exchange or use of electronic health information. HealthIT.gov

42. **Integrity** – The property whereby information, an information system, or a component of a system has not been modified or destroyed in an unauthorized manner. A state in which information has

remained unaltered from the point it was produced by a source, during transmission, storage, and eventual receipt by the destination. NICCS

43. **Interoperability Roadmap** – the vision from ONC which describes their 10 year plan for how interoperability is necessary for a "learning health system" in which health information flows seamlessly and is available to the right people, at the right place, at the right time. Interoperability Roadmap Final Version 1.0

44. **Key** – The numerical value used to control cryptographic operations, such as decryption, encryption, signature generation, or signature verification. NICCS

45. **Level of Assurance (LOA)** – Authentication focuses on verifying a person's identity based on the reliability of a credential offered. LOA refers to how much confidence a relying party has that the credential presented is in the possession of the person whose identity is being asserted. Interoperability Roadmap Supplementary Materials – Appendix F; Glossary

46. **National Institute of Standards and Technology (NIST)** – Founded in 1901, NIST is a non-regulatory federal agency within the U.S. Department of Commerce. NIST's mission is to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards and technology in ways that enhance economic security and improve our quality of life. Interoperability Roadmap Supplementary Materials – Appendix F; Glossary

47. **OAuth** – An open standard for authorization, commonly used as a way for Internet users to log into third party websites using their Microsoft, Google, Facebook or Twitter accounts without exposing their password. Wikipedia

48. **OAuth 2.0** – An authorization framework that enables applications to obtain limited access to user accounts on an HTTP service. It works by delegating user authentication to the service that hosts the user account and authorizing third-party applications to access the user account. OAuth 2.0 provides authorization flows for web and desktop applications and mobile devices. Interoperability Roadmap Supplementary Materials – Appendix F; Glossary

49. **Office for Civil Rights (OCR)** – The Office for Civil Rights enforces the HIPAA Privacy Rule, which protects the privacy of individually identifiable health information; the HIPAA Security Rule, which sets national standards for the security of electronic protected health information; the HIPAA Breach Notification Rule, which requires covered entities and business associates to provide notification following a breach of unsecured protected health information; and the confidentiality provisions of the Patient Safety Rule, which protect identifiable information being used to analyze patient safety events and improve patient safety. Interoperability Roadmap Supplementary Materials – Appendix F; Glossary

50. **Office of the Assistant Secretary for Preparedness and Response (ASPR)** – The Office of the Assistant Secretary for Preparedness and Response was created under the "Pandemic and All Hazards Preparedness Act" in the wake of Hurricane Katrina to lead the nation in preventing, preparing for and responding to the adverse health effects of public health emergencies and disasters. ASPR focuses on preparedness planning and response, building federal emergency medical operational capabilities, countermeasures research, advance development and procurement, and providing grants to hospitals and health care systems in public health

emergencies and medical disasters. Interoperability Roadmap Supplementary Materials – Appendix F; Glossary

51. **Office of the National Coordinator (ONC)** - ONC is organizationally located within the Office of the Secretary for the U.S. Department of Health and Human Services (HHS). ONC is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information. The position of National Coordinator was created in 2004, through an Executive Order, and legislatively mandated in the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009. HealthIT.gov

52. **Outside(r) Threat** – A person or group of persons external to an organization who are not authorized to access its assets and pose a potential risk to the organization and its assets. NICCS

53. **Password** – String of characters (letters, numbers, and other symbols) used to authenticate an identity or to verify access authorization. NICCS

54. **Patient-Authored App** – An app that is developed by a patient/consumer for his or her own use.

55. **Patient-Authorized Representatives** – Generally speaking, a patient representative may legally be one of the following: 1) Conservator/guardian of an adult; 2) Attorney-in-Fact – a person authorized to make healthcare decisions under a patients Advanced Healthcare Directive; 3) Parent or guardian of a minor patient (unless minor is entitled to consent); 4) Beneficiary or personal representative of a deceased patient. (May be someone outside these legal terms when a patient gives another person their login credentials to a portal or mobile app.)

56. **Patient Right to Access** – HIPAA requires the sharing of health information with the patient when the patient requests access to or a copy of his or her PHI. Consequently, patients have greater rights with respect to the sharing of their health information than other health care providers. The specific provision providing patients with the right to access or obtain a copy of his or her PHI allows patients to receive this information "in the form or format requested by the individual, if it is readily producible in such form or format…" HealthIT.gov

57. **Penetration Testing (Pen test)** – Security testing in which evaluators mimic real-world attacks in an attempt to identify ways to circumvent the security features of an application, system, or network. Penetration testing often involves issuing real attacks on real systems and data, using the same tools and techniques used by actual attackers. Most penetration tests involve looking for combinations of vulnerabilities on a single system or multiple systems that can be used to gain more access than could be achieved through a single vulnerability. NIST

58. **Personal Health App** – Health apps are application programs that offer health-related services for smartphones and tablet PCs. Examples might include an app to manage a chronic condition.

59. **Personally-Controlled Health Record** – a site that is managed exclusively by a patient, storing information on the patient's behalf and making it easily available, such as through a website or mobile app.

60. **Privacy** – The relationship between collection and dissemination of data, technology, the public expectation of privacy, and the legal and political issues surrounding them. Privacy concerns exist wherever personally identifiable information or other sensitive information is collected, stored,

used, and finally destroyed or deleted – in digital form or otherwise. Improper or non-existent disclosure control can be the root cause for privacy issues. Wikipedia

61. **Privilege Escalation** – The act of exploiting a bug, design flaw or configuration oversight in an operating system or software application to gain elevated access to resources that are normally protected from an application or user. The result is that an application with more privileges than intended by the application developer or system administrator can perform unauthorized actions. Wikipedia

62. **Protected Health Information (PHI)** – Protected health information is information, including demographic information, which relates to: (A) the individual's past, present, or future physical or mental health or condition; (B) the provision of health care to the individual; or (C) the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual. Protected health information includes many common identifiers (e.g., name, address, birth date, Social Security Number) when they can be associated with the health information listed above. HIPAA

63. **Protected Resource** – Access-restricted set of information. OAuth 2.0 Authorization Framework/ Introduction to OAuth 2.0 Presentation

64. **RESTful API** – A method of allowing communication between a Web-based client and server that employs representational state transfer (REST) constraints. A RESTful API is an application programming interface (API) that uses HTTP requests to GET, PUT, POST and DELETE data. RESTful APIs break down a transaction to create a series of small modules, each of which addresses a particular underlying part of the transaction. Interoperability Roadmap Supplementary Materials – Appendix F; Glossary

65. **Registration** – The process through which a party applies to become a subscriber of a Credentials Service Provider (CSP) and a Registration Authority validates the identity of that party on behalf of the CSP. NICCS

66. **Resource Owner** - An entity capable of granting access to a protected resource. When the resource owner is a person, it is referred to as an end-user. OAuth 2.0 Authorization Framework/ Introduction to OAuth 2.0 Presentation

67. **Risk** – A measure of the extent to which an entity is threatened by a potential circumstance or event, and typically a function of: (i) the adverse impacts that would arise if the circumstance or event occurs; and (ii) the likelihood of occurrence. Information system-related security risks are those risks that arise from the loss of confidentiality, integrity, or availability of information or information systems and consider the adverse impacts to organizational operations (including mission, functions, image, or reputation), organizational assets, individuals, other organizations, and the Nation. NIST

68. **Risk Assessment** –The appraisal of the risks facing an entity, asset, system, or network, organizational operations, individuals, geographic area, other organizations, or society, and includes determining the extent to which adverse circumstances or events could result in harmful consequences. NICCS

69. **Risk Mitigation** – The application of one or more measures to reduce the likelihood of an unwanted occurrence and/or lessen its consequences. NICCS

70. **Risk Tolerance** – The level of risk an entity is willing to assume in order to achieve a potential desired result. NIST

71. **Rogue App** – Any number of applications/software that may act maliciously or threaten the security of information - examples may include: malware, ransomware, scareware, "trickware", botnet engines, spyware, smitfraud, etc. An app that has been hacked may also be considered. Webopedia

72. **Sandboxing** - A restricted, controlled execution environment that prevents potentially malicious software, such as mobile code, from accessing any system resources except those for which the software is authorized. NIST

73. **Safeguards** – Protective measures prescribed to meet the security requirements (i.e., confidentiality, integrity, and availability) specified for an information system. Safeguards may include security features, management constraints, personnel security, and security of physical structures, areas, and devices. Synonymous with security controls and countermeasures. NIST

74. **Security** – The practice of defending information from unauthorized access, use, disclosure, disruption, modification, perusal, inspection, recording or destruction. Wikipedia

75. **Standard** – Common and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods and related management systems practices. Interoperability Roadmap Supplementary Materials – Appendix F; Glossary

76. **Standards Development Organization (SDO)** – SDOs are member-based organizations whose members set the priorities for which standards will be developed and refined. Each SDO has a very refined process for developing, balloting, piloting, finalizing and maintaining standards within its domain. Interoperability Roadmap Supplementary Materials – Appendix F; Glossary

77. **Third Party Application** – Third party software refers to software programs developed by companies other than the operating system developer. It may also refer to third party plug-ins, which are developed by other companies besides the original application developer. PC.net

78. **Vulnerability** – A characteristic or specific weakness that renders an organization or asset (such as information or an information system) open to exploitation by a given threat or susceptible to a given hazard. NICCS

79. **Threat** – A circumstance or event that has or indicates the potential to exploit vulnerabilities and to adversely impact (create adverse consequences for) organizational operations, organizational assets (including information and information systems), individuals, other organizations, or society. NICCS

80. **Token** – The token is used in addition to or in place of a password to prove that the customer is who they claim to be. The token acts like an electronic key to access something. Wikipedia

81. **View/Download/Transmit (VDT)** – One of the Stage 2 Meaningful Use Core Measures under the CMS EHR Incentive Programs is to, "provide patients the ability to view online, download and transmit their health information within four business days of the information being available to the eligible professional." Interoperability Roadmap Supplementary Materials – Appendix F; Glossary

82. **Whitelist** – A list/register of entities that are being provided a particular privilege, service, mobility, access or recognition. Entities on the list will be accepted, approved and/or recognized. NICCS