API Conditions of Certification (and more!)

Steve Posnack, Executive Director, Office of Technology, ONC
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• Please submit comments through the formal process outlined in the Federal Register.
  https://www.healthIT.gov/NPRM
  

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• ONC cannot address any comment suggestion or statement made by anyone attending the presentation or consider any such comment or suggestion in the rule writing process.
Two Statutory Sections Implemented Together
45 CFR Part 170.4xx and Part 171.2xx

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<th>Conditions of Certification</th>
<th>Information Blocking Exceptions</th>
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<td>• 170.401 Information blocking</td>
<td>• 171.201 Preventing harm</td>
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<td>• 170.402 Assurances</td>
<td>• 171.202 Promoting the privacy of electronic health information</td>
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<td>• 170.403 Communications</td>
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<td>• <strong>170.404 APIs (without special effort)</strong></td>
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<td>• 170.406 Attestations</td>
<td>• 171.206 Licensing of interoperability elements on reasonable and non-discriminatory terms</td>
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<td>• 170.40x EHR Reporting Program</td>
<td>• 171.207 Maintaining and improving health IT performance</td>
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</table>
• API = Application Programming Interface

• FHIR® = Fast Healthcare Interoperability Resources (an HL7® standard)

• USCDI = United States Core Data for Interoperability

• ARCH = API Resource Collection in Health

• CoC = Conditions of Certification
The Really Big Picture
Scope and Applicability: Certified-API Proposals

- Applies to certified health IT developers, health information exchanges, health information networks, & health care providers
- Electronic health information is expected to be accessible, exchangeable, & useable unless an “interference” is required by law or covered by an exception(s)
- An action(s) covered by an exception(s) would not be subject to penalties or disincentives

- Applies only to health IT developers with “certified APIs”
- Three specific conditions:
  ▪ Transparency Conditions
  ▪ Permitted Fees Conditions
  ▪ Openness and Pro-Competitive Conditions
- Maintenance of Certification Requirements

- New 2015 Edition “Cures Criterion”
  ▪ Secure, standards-based API (170.315(g)(10)) – “read-only” focus
  ▪ HL7® FHIR® as base standard
  ▪ SMART App Launch Framework + OAuth 2 + OpenID Connect 1.0
  ▪ Support for provider and patient-access use cases
Who?

**API Technology Supplier:** Health IT developer of certified API technology (45 CFR 170.315(g)(7)-(11))

**API Data Provider:** Health care organization that deploys the API technology

**API User:** Persons and entities that use or create software applications that interact with API technology

What?

Applies to all API-focused certification criteria (170.315(g)(7) through proposed (g)(10) and (11))

*(Practically speaking “FHIR Servers”)*

How?

The API Condition of Certification applies only to health IT developers and health IT that is certified to any of the API-focused certification criteria
Securing API Access 101
With a focus on 3rd Party Apps & Patient Access

Key points
1. Today, health information is made accessible to web applications over the internet via web servers.
2. What “tethered-portals” and 3rd party apps do programatically to securely connect to HTTPS-based web servers is very similar.
3. The same information security steps used by the Health Insurance Portability and Accountability Act (HIPAA) Covered Entities for tethered-portals can be/are being used for 3rd party apps.

<table>
<thead>
<tr>
<th>Security Step</th>
<th>&quot;Tethered-Portal&quot;</th>
<th>How?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The Only App (typically web application)</td>
<td>3rd Party App Many Possible Apps (programmatic access)</td>
</tr>
<tr>
<td>App Registration</td>
<td>Not Applicable (1-to-1 connection between portal and web server)</td>
<td>Each app must be registered and receives a unique Client ID and Client Secret*</td>
</tr>
<tr>
<td>Secure Connection</td>
<td>HTTPS with TLS (<a href="https://portal.drXYZ.com">https://portal.drXYZ.com</a>) A patient’s visual experience is directly with the portal based on server responses</td>
<td>HTTPS with TLS (<a href="https://fhir.drXYZ.com">https://fhir.drXYZ.com</a>) App connects to the FHIR Server and the patient’s visual experience is handled by app</td>
</tr>
<tr>
<td>User Authentication</td>
<td>Patient directly enters the credentials issued by Dr. XYZ into their portal</td>
<td>App is redirected for patient authentication Patient enters credentials issued by Dr. XYZ App <em>never</em> sees/gets access to patient credentials</td>
</tr>
<tr>
<td>App Authorization</td>
<td>All actions are trusted completely by web server (all data accessible to patient via portal)</td>
<td>Dr. XYZ’s FHIR Server does not need to “trust” the App. Access to data is authorized by the patient After patient authorization, app gets time-limited “access token”</td>
</tr>
</tbody>
</table>
Go here: [https://www.hhs.gov/hipaa/for-professionals/faq/index.html](https://www.hhs.gov/hipaa/for-professionals/faq/index.html)

Check out these FAQs (#2060, #2061, #2039):

- **#2060**: Do individuals have the right under HIPAA to have copies of their PHI transferred or transmitted to them in the manner they request, even if the requested mode of transfer or transmission is unsecure?
  
  [https://www.hhs.gov/hipaa/for-professionals/faq/2060/do-individuals-have-the-right-under-hipaa-to-have/index.html](https://www.hhs.gov/hipaa/for-professionals/faq/2060/do-individuals-have-the-right-under-hipaa-to-have/index.html)

- **#2061**: Is a covered entity responsible if it complies with an individual’s access request to receive PHI in an unsecure manner (e.g., unencrypted e-mail) and the information is intercepted while in transit?
  
  [https://www.hhs.gov/hipaa/for-professionals/faq/2061/is-a-covered-entity-responsible-if-it-complies/index.html](https://www.hhs.gov/hipaa/for-professionals/faq/2061/is-a-covered-entity-responsible-if-it-complies/index.html)

- **#2039** What is the liability of a covered entity in responding to an individual’s access request to send the individual’s PHI to a third party?
  
  
  o “Further, the covered entity is not liable for what happens to the PHI once the designated third party receives the information as directed by the individual in the access request.”
### Required Capability(ies)
- App Registration
- Secure Connection
- 1st time Authentication & App Authorization + (get refresh token)
- Data Response (query)
- Search
- Subsequent Authentication & App Authorization + (new refresh token)
- Documentation

### Applicable Standard(s)
- None;
  Dynamic Registration permitted
- SMART Application Launch Framework IG
- OpenID Connect + SMART Application Launch Framework IG
- FHIR (Release 2) + ARCH + Argonaut Data Query IG Profiles
- Argonaut Data Query IG Server
- SMART Application Launch Framework IG
- None;
  Must be made publicly accessible

### Additional Context
- Associated API CoC
- Must support patient- and clinical-access
- Must support access to a single patient’s data & multiple patients data
- Must support “Standalone Launch” and “EHR Launch”
- Refresh tokens with a lifetime of at least 3 months
- Associated API CoC

**New API Certification Criteria 170.315(g)(10) to Replace (g)(8) Standards-based API for Patient and Population Services**
Of the hospitals and Merit-based Incentive Payment System (MIPS) eligible clinicians that use certified products, we found that almost:

- 87% of hospitals
- 69% of MIPS eligible clinicians

are served by health IT developers with product(s) certified to any FHIR version.

### The US Core Data For Interoperability (USCDI v1)

<table>
<thead>
<tr>
<th>Assessment and Plan of Treatment</th>
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<tbody>
<tr>
<td>Care Team Members</td>
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<tr>
<td>Clinical Notes</td>
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<tr>
<td>- Consultation Note</td>
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<tr>
<td>- Discharge Summary Note</td>
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<tr>
<td>- History &amp; Physical</td>
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<tr>
<td>- Imaging Narrative</td>
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<tr>
<td>- Laboratory Report Narrative</td>
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<tr>
<td>- Pathology Report Narrative</td>
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<td>- Procedure Note</td>
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<td>- Progress Note</td>
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<th>Medications</th>
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<tr>
<td>- Medications</td>
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<td>- Medication Allergies</td>
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<th>Problems</th>
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<tr>
<td>Procedures</td>
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<tr>
<td>- Author</td>
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<tr>
<td>- Author Time Stamp</td>
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<td>- Author Organization</td>
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<table>
<thead>
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<th>Patient Demographics</th>
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<tbody>
<tr>
<td>- First Name</td>
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<tr>
<td>- Last Name</td>
</tr>
<tr>
<td>- Previous Name</td>
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<tr>
<td>- Middle Name (incl. middle initial)</td>
</tr>
<tr>
<td>- Suffix</td>
</tr>
<tr>
<td>- Birth Sex</td>
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<tr>
<td>- Date of Birth</td>
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<tr>
<td>- Race</td>
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<tr>
<td>- Ethnicity</td>
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<tr>
<td>- Preferred Language</td>
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<tr>
<td>- Address</td>
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<tr>
<td>- Phone Number</td>
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<thead>
<tr>
<th>Vital Signs</th>
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<tr>
<td>- Diastolic BP</td>
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<tr>
<td>- Systolic BP</td>
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<tr>
<td>- Body height</td>
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<tr>
<td>- Body weight</td>
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<tr>
<td>- Heart Rate</td>
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<tr>
<td>- Body temperature</td>
</tr>
<tr>
<td>- Pulse oximetry</td>
</tr>
<tr>
<td>- Inhaled oxygen concentration</td>
</tr>
<tr>
<td>- BMI percentile per age and sex for youth 2-20</td>
</tr>
<tr>
<td>- Weights for age per length and sex</td>
</tr>
<tr>
<td>- Occipital-frontal circumference for children &gt;3 years old</td>
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<tr>
<th>Immunizations</th>
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<td>Goals</td>
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<td>- Patient Goals</td>
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<thead>
<tr>
<th>Vital Signs</th>
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<td>Laboratory</td>
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<tr>
<td>- Tests</td>
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<tr>
<td>- Values/Results</td>
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</tbody>
</table>

| Unique Device Identifier(s) for a Patient’s Implantable Device(s) |
Applicable FHIR Resources were selected to support USCDI Data Classes and Data Elements
What is the API Resource Collection in Health (ARCH)?

The ARCH
15 Specific FHIR Resources
Aligned to support the USCDI
Referenced in new 170.315(g)(10) certification criterion
API Conditions and Maintenance of Certification
High-level Overview

Cures Act Condition
An API Technology Supplier must publish APIs and must allow health information from such technology to be accessed, exchanged, and used without special effort through the use of APIs or successor technology or standards, as provided for under applicable law, including providing access to all data elements of a patient’s electronic health record to the extent permissible under applicable privacy laws.

Transparency
• Publicly accessible documentation
  ▪ Terms and conditions
  ▪ Fees and structure
  ▪ App developer verification process

Permitted Fees
• Only specific types of fees are permitted
  ▪ Must have objective and verifiable criteria
  ▪ Three categories of permitted fees
  ▪ Must keep detailed records for fees

Openness and Pro-competitive
• Must grant API Data Providers sole authority
  ▪ Terms must be non-discriminatory
  ▪ All necessary “rights” must be provided
  ▪ Must maintain service and support levels

Maintenance of Certification
• An API Technology Supplier must register and enable apps for production use within one business day of completing its verification of an app developer’s authenticity
• An API Technology Supplier must support the publication of Service Base URLs (i.e., FHIR API endpoints) for all of its customers and make such information publicly available (in a computable format) at no charge
• An API Technology Supplier with API technology previously certified to § 170.315(g)(8) must provide all API Data Providers with a (g)(10)-certified API within 24 months of a final rule’s effective date
The API Conditions of Certification

Transparency Conditions

The business and technical documentation published by an API Technology Supplier must be complete. All documentation must be published via a publicly accessible hyperlink that allows any person to directly access the information without any preconditions or additional steps.

Material Information

The API Technology Supplier must publish all terms and conditions for its API technology, including any fees, restrictions, limitations, obligations, registration process requirements, or other similar requirements that would be needed to:

1. Develop software applications to interact with the API technology;
2. Distribute, deploy, and enable the use of software applications in production environments that use the API technology;
3. Use software applications, including to access, exchange, and use electronic health information by means of the API technology;
4. Use any electronic health information obtained by means of the API technology; and
5. Register software applications.

Any and all fees charged by an API Technology Supplier for the use of its API technology must be described in detailed, plain language. The description of the fees must include all material information, including but not limited to:

1. The persons or classes of persons to whom the fee applies;
2. The circumstances in which the fee applies; and
3. The amount of the fee, which for variable fees must include the specific variable(s) and methodology(ies) that will be used to calculate the fee.

An API Technology Supplier is permitted to institute a process to verify the authenticity of application developers so long as such process is objective and the same for all application developers and completed within 5 business days of receipt of an application developer’s request to register their software application for use with the API Technology Supplier’s API technology.
The API Conditions of Certification & Information Blocking
Permitted Fees
The API Conditions of Certification & Information Blocking Permitted Fees

API User

API Tech Supplier

API Data Provider

Information Blocking

API Conditions of Certification

Permitted Fee #1: Development, Deployment, & Upgrade

Permitted Fee #2: API Usage Costs

Permitted Fee #3: Value Added Services

Information Blocking
The API Conditions of Certification & Information Blocking Permitted Fees

Scenario 1

API Tech Supplier  →  API Data Provider  →  API User

- Information Blocking
- API Conditions of Certification
- Permitted Fee #1: Development, Deployment, & Upgrade
- Permitted Fee #2: API Usage Costs

Scenario 2

API Tech Supplier  →  API User

- Information Blocking
- API Conditions of Certification
- Permitted Fee #3: Value Added Services
### The API Conditions of Certification

#### Permitted Fees: General Conditions

All fees related to API technology not otherwise permitted are prohibited from being imposed by an API Technology Supplier.

<table>
<thead>
<tr>
<th>Permitted Fees: General Conditions</th>
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<tbody>
<tr>
<td>Ensure that fees are based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests.</td>
</tr>
<tr>
<td>Ensure that fees imposed on API Data Providers are reasonably related to the API Technology Supplier’s costs of supplying and, if applicable, supporting API technology to, or at the request of, the API Data Provider to whom the fee is charged.</td>
</tr>
<tr>
<td>Ensure that the costs of supplying and, if applicable, supporting the API technology upon which the fee is based are reasonably allocated among all customers to whom the API technology is supplied, or for whom the API technology is supported.</td>
</tr>
<tr>
<td>Ensure that fees are not based in any part on whether the requestor or other person is a competitor, potential competitor, or will be using the API technology in a way that facilitates competition with the API Technology Supplier.</td>
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</table>
Scenario #1, Permitted Fee #1
Development, Deployment, and Upgrade Fees

• An API Technology Supplier is permitted to charge fees to an API Data Provider to recover the costs reasonably incurred by the API Technology Supplier to develop, deploy, and upgrade API technology for the API Data Provider.

• An API Technology Supplier is **NOT** permitted to establish “relationship” fees between itself and an API User just because of the API User’s connectivity to or mutual business relationship with the API Technology Supplier’s customer (i.e., the API Data Provider).
An API Technology Supplier is permitted to charge fees to an API Data Provider to recover the incremental costs reasonably incurred by the API Technology Supplier to support the use of API technology deployed by or on behalf of the API Data Provider.

An API Technology Supplier is only permitted to charge the API Data Provider. If an API User exceeds service established levels, the API Data Provider would be responsible for paying the extra charges.

If an API Data Provider administers the API on its own (i.e., assumes full responsibility), then API Technology Supplier would not be permitted to charge usage fees.

The costs recovered under “usage-based” fees would only be able to reflect “post-deployment” costs.

No particular fee amount, threshold, or methodology is proposed. It is up to the API Technology Supplier to determine consistent with the “general conditions” and information blocking.
This permitted fee **DOES NOT** include:

- Any costs incurred by the API Technology Supplier to support uses of the API technology that facilitate a patient’s ability to access, exchange, or use their electronic health information.
- Costs associated with intangible assets (including depreciation or loss of value), except the actual development or acquisition costs of such assets.
- Opportunity costs, except for the reasonable forward-looking cost of capital.

(reiterated) An API Technology Supplier is **NOT** permitted to establish “relationship” fees between itself and an API User just because of the API User’s connectivity to or mutual business relationship with the API Technology Supplier’s customer (i.e., the API Data Provider).
Scenario #2, Permitted Fee #3
Value Added Services Fees

- An API Technology Supplier is permitted to charge fees to an API User for value-added services supplied in connection with software that can interact with the API technology, provided that such services are not necessary to efficiently and effectively develop and deploy such software (i.e., production-ready software).

- Permits API Technology Suppliers to offer market differentiating services that could make it attractive for API Users to develop software applications that can interact with the API technology.

- Examples: advanced training, premium development tools and distribution channels, enhanced compatibility/integration testing assessments, co-branded integration, co-marketing arrangements, promoted placement in “app store.”

- API Technology Suppliers would be able to administer their own “app stores” provided that they do not violate this condition of certification and information blocking policies.
  - For example, if a software developer’s app were required to go through a paid listing process as a precondition to be able to be deployed (and generally accessible) to the API Technology Supplier’s health care provider customers to use, this would not be a permitted fee under this Condition of Certification, would constitute special effort, and could raise information blocking concerns.
The API Conditions of Certification
Openness and Pro-Competitive Conditions (1)

An API Technology Supplier must grant an API Data Provider the sole authority and autonomy to permit API Users to interact with the API technology deployed by the API Data Provider.

Non-Discriminatory Terms

An API Technology Supplier must provide API technology to API Data Providers on terms that are no less favorable than it provides to itself and its own customers, suppliers, partners, and other persons with whom it has a business relationship.

The terms on which an API Technology Supplier provides API technology must be based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests.

An API Technology Supplier must not offer different terms or service on the basis of:
1) Whether the API User with whom an API Data Provider has a relationship is a competitor, potential competitor, or will be using electronic health information obtained via the API technology in a way that facilitates competition with the API Technology Supplier.
2) The revenue or other value the API User with whom an API Data Provider has a relationship may derive from access, exchange, or use of electronic health information obtained by means of API technology.
An API Technology Supplier must have and, upon request, must grant to API Data Providers and their API Users all rights that may be reasonably necessary to access and use API technology in a production environment, including:

1) For the purposes of developing products or services that are designed to be interoperable with the API Technology Supplier’s health information technology or with health information technology under the API Technology Supplier’s control;

2) Any marketing, offering, and distribution of interoperable products and services to potential customers and users that would be needed for the API technology to be used in a production environment; and

3) Enabling the use of the interoperable products or services in production environments, including accessing and enabling the exchange and use of electronic health information.

An API Technology Supplier must not condition any of the rights described on the requirement that the recipient of the rights do, or agree to do, any of the following:

1) Pay a fee to license such rights, including but not limited to a license fee, royalty, or revenue-sharing arrangement.
2) Not compete with the API Technology Supplier in any product, service, or market.
3) Deal exclusively with the API Technology Supplier in any product, service, or market.
4) Obtain additional licenses, products, or services that are not related to or can be unbundled from the API technology.
5) License, grant, assign, or transfer any intellectual property to the API Technology Supplier.
6) Meet additional developer or product certification requirements.
7) Provide the API Technology Supplier or its technology with reciprocal access to application data.
An API Technology Supplier must provide all support and other services reasonably necessary to enable the effective development, deployment, and use of API technology by API Data Providers and their API Users in production environments.

An API Technology Supplier must make reasonable efforts to maintain the compatibility of its API technology and to otherwise avoid disrupting the use of API technology in production environments.

Except as exigent circumstances require, prior to making changes or updates to its API technology or to the terms and conditions thereof, an API Technology Supplier must provide notice and a reasonable opportunity for its API Data Provider customers and registered application developers to update their applications to preserve compatibility with API technology and to comply with applicable terms and conditions.

Service and Support Obligations
Don’t Miss
Requests for Comment

• Four options proposed for FHIR Standard(s) adoption
  o Option 1: Just FHIR Release 2 (proposed)
  o Option 2: FHIR Release 2 and Release 3 (as either one for certification option)
  o Option 3: FHIR Release 2 and Release 4 (as either one for certification option)
  o Option 4: Just FHIR Release 4

• For the DocumentReference and Provenance resources, which are currently present in the base FHIR standard, we request comments on the minimum “search” parameters that would need to be supported

• On any additional specific “permitted fees” not addressed above that API Technology Suppliers should be able to recover in order to assure a reasonable return on investment. Furthermore, we request comment on whether it would be prudent to adopt specific, or more granular, cost methodologies for the calculation of the permitted fees.

• On a reasonable upper bound for Refresh Token period of use

• On whether we should require support for OAuth 2.0 Dynamic Client Registration Protocol
Thank you and please comment! https://www.healthIT.gov/NPRM

Upcoming Webinars

• 3/19 -- Information Blocking and the Notice of Proposed Rulemaking
• 3/28 -- ONC 21st Century Cures Act Notice of Proposed Rulemaking Overview and Q&A