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**Office of the National Coordinator
for Health Information Technology**
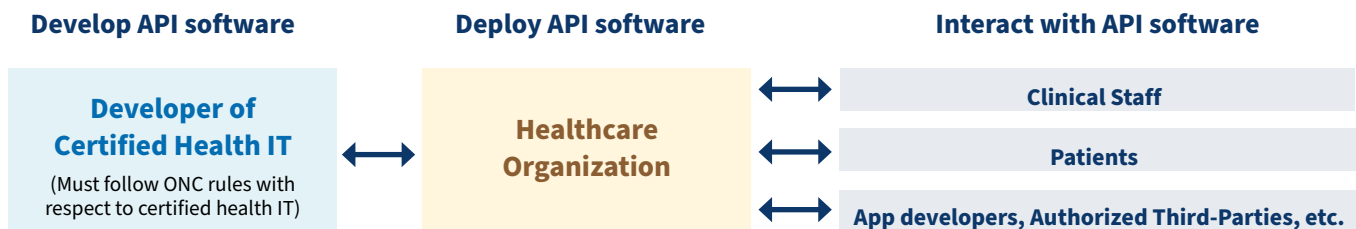
The API Condition of Certification

As part of the 21st Century Cures Act (Cures Act), Congress established seven conditions of certification. One of those conditions of certification, including its maintenance of certification requirements, focuses on application programming interfaces (APIs). In the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (85 FR 25642), ONC adopted several requirements for the API Condition of Certification (API Condition) at 45 CFR 170.404, including ongoing responsibilities for developers of certified health IT to whom the API Condition applies. The Health Data, Technology and Interoperability (HTI-1) Final Rule updates these requirements for maintaining certification for API developers.

The API Condition only applies to health IT developer practices associated with certified API technology. Certified API technology means the capabilities of Health IT Modules that are certified to any of the API-focused certification criteria adopted in 45 CFR 170.315(g)(7) through (10). The references to certified health IT developers in this Explained! document should be understood to mean health IT developers of certified API technology, which are referred to as "Certified API Developers" in the context of the API Condition.

This Explained! document is primarily for healthcare organizations, clinical staff, patients, app developers, and third-party services. It provides a simplified overview of the API Condition's requirements to help health IT users and app developers understand what they mean and how they apply to developers of certified health IT. In order to fully understand this Explained! document, a reader should also review the applicable regulation at 45 CFR 170.404.

Develop API software	**Deploy API software**	**Interact with API software**
Developer of Certified Health IT (Must follow ONC rules with respect to certified health IT) ⟷	**Healthcare Organization** ⟷	**Clinical Staff**
	⟷	**Patients**
	⟷	**App developers, Authorized Third-Parties, etc.**

The rule says... that the API Condition applies to health IT developers with technology certified to any of the four adopted API certification criteria in 45 CFR 170.315(g)(7) through (g)(10) (collectively referred to as "certified API technology").

This means... the API Condition began to apply to developers of certified API technology as of April 5, 2021 and will continue to apply them, including for the new HL7® FHIR®-based APIs that are specified in the certification criterion adopted at 45 CFR 170.315(g)(10).

This also means... that the API Condition only applies to the API functionality and practices associated with these specific certification criteria and not, for example, to a non-certified, proprietary API.

Office of the National Coordinator for Health Information Technology

Transparency Conditions

The rule says... that complete business and technical documentation must be published via a publicly accessible hyperlink that anyone can access.

This means... that you should be able to find disclosures regarding business and technical information about certified API technology from any certified health IT developer to whom the API Condition applies.

The rule says... that certified health IT developers must publish all terms and conditions for their certified API technology.

This means... as of April 5, 2021, certified health IT developers to whom the API Condition applies must be transparent about their business and technical practices regarding certified health IT, such as fees, app registration processes, and what steps are needed to deploy apps in production environments that use the certified API. Click here to read this provision in detail.

The rule says... that any and all fees charged for the use of certified API technology must be described in detailed, plain language.

This means... as of April 5, 2021, you should be able to find a full disclosure of the fees that would apply to the use of certified API technology, including but not limited to: the persons or classes of persons to whom the fee applies; the circumstances in which the fee applies; and the fee amount. For example, once a developer of certified API technology has certified its health IT to the new FHIR-based criterion adopted at 45 CFR 170.315(g)(10), these fee transparency requirements would apply to both the single patient API interactions as well multi-patient API interactions ("bulk"). Click here to read this provision in detail.

Fees Conditions

The rule says... that certified health IT developers are only permitted to charge certain fees related to certified API technology according to specific requirements. And, in some cases, are prohibited altogether from charging certain types of fees.

This means... that developers of certified API technology are prohibited from charging certain types of fees. For the fees a developer of certified API technology is permitted to charge, it must always keep certain factors in mind. For example, that the fees are based on objective and verifiable criteria that are uniformly applied to all similarly situated parties. Click here to read more about permitted fee requirements and here to read more about prohibited fees.

The rule says... that certified health IT developers are permitted to charge fees to recover the costs reasonably incurred by a developer to develop, deploy, and upgrade certified API technology.

This means... that it is ok for a developer of certified API technology to charge its customers (i.e., healthcare organizations) fees related to getting certified API technology up, running, and ready to use as well as for upgrades. The fee(s) charged may also include fees that result in a reasonable profit margin (click here to read more, including how permitted fees align with the Fees Exception to information blocking under the regulations).

The rule says... that certified health IT developers are permitted to charge fees related to the use of certified API technology but that these fees must be limited to the recovery of incremental costs reasonably incurred by the developer when it hosts certified API technology on behalf of its customer.

This means... that it is ok for a developer of certified API technology to charge its customers (i.e., healthcare organizations) these types of fees if the developer hosts the certified API technology for the customer. In this case, a reasonable profit margin as part of this fee type is not permitted.

$ Fees Conditions (Cont.)

The rule says... that certified health IT developers are permitted to charge fees for value-added services related to certified API technology so long as such services are not necessary to efficiently and effectively develop and deploy production-ready software that interacts with certified API technology.

This means... that it is ok for developers of certified API technology to charge an API user (e.g., third-party software developer) this type of fee (including a reasonable profit margin as permitted by the information blocking regulations Fees Exception) when the services it offers associated certified API technology go above and beyond what is needed to develop and deploy product-ready software that interacts with certified API technology.

This also means... that certain fees associated with value-added services related to certified API technology are not allowed. For instance, if a developer of certified API technology requires third-party software developers to use a test environment or sandbox in order to prove their application's "production-readiness" for use with certified API technology, then any fees associated with that kind of test environment would be prohibited. However, if the purpose of the testing environment "was to provide specific testing above-and-beyond production-readiness for use with certified API technology, then fees could be charged for such testing as part of the value-added services permitted fee."

The rule says... that developers of certified API technology must keep for inspection detailed records of any fees charged with respect to certified API technology, the methodology(ies) used to calculate such fees, and the specific costs to which such fees are attributed.

This means... that in the event of a possible violation of the API Condition, ONC will be able to review a developer of certified API technology's records and adherence to the API Condition.

Openness and Pro-competitiveness Conditions

The rule says… that certified health IT developers must give their customers the independent ability to permit a person or entity that creates or uses software applications that interact with the certified API technology to interact with their certified API technology.

This means… that a certified API developer's customer (i.e., healthcare organization) can engage with whomever they want regarding the use of their certified API technology without needing to first seek their developer's permission.

In other words, when it comes to certified API technology, a healthcare organization is 100% in control of determining the business partners to whom they wish to grant access to their certified API technology as well as which third party apps it wants to use *within* its enterprise with certified API technology.

This includes, for example, the use of homegrown applications and services for internal clinical uses, as well as contracted services/business partners to whom the healthcare organization may want to grant access to its certified API technology.

The rule says… that certified health IT developers need to follow certain non-discriminatory practices with respect to certified API technology.

This means… that developers of certified API technology have to follow specific requirements when it comes to the terms they set and services they offer, such as not factoring in whether a competitive relationship exists or would be created when offering differing terms or services.

The rule says… that certified health IT developers need to follow certain practices when it comes to the rights that must be granted with respect to certified API technology.

This means… that developers of certified API technology are required to grant their customers (and users) all rights that may be necessary to: access and use the certified API technology in a production environment; develop products and services that interact with the certified API technology; and market, offer, and distribute products and services associated with the certified API technology. Click here to read more about access and use rights that must be granted as well as practices on which health IT developers are prohibited from conditioning the receipt of these rights, such as agreeing to not compete with the health IT developer.

Openness and Pro-competitiveness Conditions (Cont.)

The rule says... that certified health IT developers must provide all support and other services reasonably necessary to enable the effective development, deployment, and use of certified API technology.

This means... that developers of certified API technology are responsible for ensuring, as reasonably necessary, the certified API technology they provide works and continues to work. In particular, a developer is required to make reasonable efforts to maintain the certified API technology's compatibility and avoid disrupting its use in production environments.

This also means... that in most cases, prior to making changes to its certified API technology or to the terms and conditions that apply to it, developers of certified API technology must provide notice and a reasonable opportunity for customers (and others, like certain app developers and third-party services) to update their applications to preserve compatibility with certified API technology and to comply with applicable terms and conditions.

Maintenance of Certification Requirements

The rule says... that for API technology certified to the FHIR-based API certification criterion, health IT developers must meet certain timing milestones with respect to registering applications created by users (e.g., the developer's customers, the customer's business partners, third-party applications).

This means... that developers of certified API technology are permitted to institute a process to verify the authenticity of API users so long as such process is objective and the same for all users and completed within ten business days of receipt of a user's request to register their software application.

This also means... that a developer of certified API technology must register and enable all applications for production use within five business days of completing its verification of a user's authenticity.

This also means... presuming an app developer completes all applicable authenticity verification and app registration requirements, that such app developer should expect a maximum of 15 business days before an app developed for certified API technology will be available for production.

⚙️✓ Maintenance of Certification Requirements (Cont.)

The rule says... that for API technology certified to the <u>FHIR-based API certification criterion</u>, health IT developers must publish the "service base URLs" (commonly referred to as "FHIR endpoints") and related organization details that can be used by patients to access their electronic health information. This must be done free of charge and in a machine-readable FHIR Bundle format regardless of whether the certified API technology is centrally managed by the developer or locally deployed by its customer by December 31, 2024.

This means... that, with respect to Health IT Modules certified to 45 CFR 170.315(g)(10), the URL and related organization details necessary for patients to access their electronic health information – at a minimum constituting the data in the US Core Data for Interoperability (USCDI) – will be publicly discoverable at no cost.

This also means... that while the API Condition does not explicitly require, for example, the open publication of the FHIR endpoints a healthcare organization uses for its own purposes (such as by clinical apps and business partners), those endpoints cannot always be restricted as not making them available in certain instances could constitute information blocking.

The rule says... that any certified health IT developer who has certified API technology previously certified to the certification criterion adopted at 45 CFR 170.315(g)(8) must provide all of its customers with such certified API technology deployed with certified API technology upgraded to the <u>FHIR-based API certification criterion</u> (45 CFR 170.315(g)(10)) by no later than December 31, 2022.

This means... that health IT developers' existing customers with previously certified API technology received a notification regarding the availability of new certified API technology before December 31, 2022. The API Condition required these developers to replace their previously certified API technology with an industry-standard, FHIR-based API. Keep in mind that per the Fee Conditions described above, certain practices associated with this upgrade are permitted as well as prohibited.

This also means... The API Condition applies to API interactions involving a single patient as well as API interactions involving multiple patients ("bulk") that are part of the new FHIR-based APIs. It is important to note that this new certified API technology is for more than just supporting patient access. The technology enabled by these FHIR-based APIs is also for clinical uses by health professionals, for "business-to-business" transactions, and by health care organizations when it comes to the bulk capabilities.

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