ONC HEALTH IT CERTIFICATION PROGRAM

Program Policy Resource #18–02:

Disclosure of Material Information

(Last updated: October 5, 2018)

Table of Contents

I. INTRODUCTION

A. Background and Purpose

This resource will assist ONC-Authorized Certification Bodies (ONC-ACBs) with their surveillance and assessment of health IT developers' product disclosures required by 45 CFR 170.523(k)(1) (the **Mandatory Disclosure Requirement**). Under ONC's 2015 Edition Certification Rule[1] (2015 Edition final rule), a health IT developer must conspicuously disclose in plain language—on its website and in all marketing materials, communications statements, and other assertions related to its certified health IT—a detailed description of all known material information concerning limitations and additional types of costs that a person may encounter or incur to successfully implement or use certified health IT capabilities (collectively, "**mandatory disclosure information**").

The Mandatory Disclosure Requirement is important to customers and users of certified health IT and to the overall effectiveness of the ONC Health IT Certification Program. The mandatory disclosure information assists customers and users to better understand the capabilities, limitations, and trade-offs of certified health IT products, allowing them to more effectively compare and select health IT solutions that meet their needs. Without this information, customers and users are less likely to be able to select appropriate technologies and are more likely to encounter unanticipated costs, limitations, and problems when attempting to implement and use certified health IT in their production environments.

B. Scope

This resource provides ONC-ACBs with information and practical tips on how to assess whether a developer has complied with the Mandatory Disclosure Requirement. It does not address other transparency and disclosure requirements or additional disclosure requirements related to the documentation of application programming interfaces (*see* 45 CFR 170.315(g)(7)(ii), (8)(ii), and (9)(ii)).

This resource should be reviewed in conjunction with other applicable resources and regulations, including but not limited to the following documents, which contain detailed information and additional analysis concerning many of the requirements discussed herein—

- Program Policy Resource #18–03: Surveillance Resource (**Surveillance Resource**)
- Program Policy Resource #18–01: Post-certification Assessment of Program Requirements Resource (**Post-certification Assessment Resource**)
- 2015 Edition final rule (80 FR 62601)
  - ↳ *Section IV.D.1 — "In-the-Field" Surveillance and Maintenance of Certification*
  - ↳ *Section IV.D.2 — Transparency and Disclosure Requirements*
- ONC Health IT Certification Program: Enhanced Oversight and Accountability final rule, 81 FR 72404 (Oct 19, 2016) (**EOA final rule**)

[1] 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications final rule, 80 FR 62601 (Oct 16, 2015).

↳ *Section II.A.1.a(1) — Requirements of the Program*

C. Applicability of Mandatory Disclosure Requirement

Beginning with the 2014 Edition and subsequent editions of certification criteria, all certified health IT is subject to, and all developers must comply with, the Mandatory Disclosure Requirement. The only exception is health IT self-developers, who are not required to make the mandatory disclosures (45 CFR 170.523(k)(1)(v)).

D. Relationship to Other Program Requirements

The Mandatory Disclosure Requirement is closely related to and should be evaluated alongside other requirements of the Program, including certification criteria that establish the capabilities and outcomes that a certified health IT product must support in the field. Importantly, a certified product does not conform to the requirements of its certification if it is subject to limitations or additional types of costs that are likely to substantially interfere with the successful implementation or use of the product's certified capabilities.[2] Therefore, separate from and in addition to determining whether a given limitation or additional type of cost must be disclosed, an ONC-ACB must consider, more fundamentally, whether the limitation or additional type of cost is permissible, in light of its potential impact on the implementation or use of any certified capabilities.

As discussed in Part IV below, if in the course of administering the Mandatory Disclosure Requirement an ONC-ACB encounters a limitation or additional type of cost that substantially interferes with the implementation and/or use of the certified capabilities, the ONC-ACB must require the developer to take appropriate corrective actions to remediate such limitation or additional type of cost, in addition to curing any defective disclosures, if applicable.

E. Terminology

To make this resource more accessible, plain language terms are used as a short-hand for certain regulatory concepts. The use of these terms is strictly for convenience and does not create any new requirements or alter the interpretation of existing requirements under the Program. When encountering any of these terms, the reader should substitute the definitions in Table 1 below.

Table 1: Terms Used in this Resource

Term	Definition
compliance	With respect to a requirement of the Program, conformity with such requirement.
Comprehensive Disclosure Statement	The complete and up-to-date version of the mandatory disclosure information (as defined below) that a developer makes available on a publicly accessible website.
developer	A person or entity that submits health IT for certification under the Program and/or is responsible for maintaining a certification issued to health IT under the Program.
mandatory disclosure information	The information about limitations and additional types of costs that a developer is required to disclose under the Mandatory Disclosure Requirement (as defined below).

[2] For further discussion of substantial interferences with the implementation or use of certified capabilities refer to the Post-certification Assessment Resource, Part III.E.2, as well as provisions of the 2015 Edition final rule (80 FR 62711).

Term	Definition
Mandatory Disclosure Requirement	The requirement under 45 CFR 170.523(k)(1) that developers make mandatory disclosures about their certified products.
non-conformity	The failure of certified health IT or of a certified health IT developer to conform to a requirement of the Program.
product	A Complete EHR, Health IT Module, or other health IT that has been issued a certification or has been submitted for certification under the Program (as the context requires).
Program	The ONC Health IT Certification Program.
required capability or **certified capability**	A capability or other aspect of health IT that is required by one or more certification criteria to which the technology is certified, typically comprising one or more required outcomes (as defined below).
required outcome	Any characteristic that a product must possess or any outcome it must enable to support a required capability (as defined below).
technology	A "product" (as defined above).

II. EVALUATING COMPLIANCE: MANNER OF DISCLOSURE

A. Have Disclosures Been Made in all Required Forms?

Requirement:

A Health IT developer must include its mandatory disclosure information on its website and in all marketing materials, communications statements, and other assertions related to the Complete EHR or Health IT Module's certification (45 CFR 170.523(k)(1)).

The 2015 Edition final rule identifies a broad range of "communications" that are subject to the Mandatory Disclosure Requirement and must include the mandatory disclosure information. The types of communications include:

- website marketing and sales materials that promote or advertise certified health IT products;
- traditional (i.e., non-website based) marketing materials that promote or advertise certified health IT products;
- communications statements that promote or describe the benefits, capabilities, features, or functionality of certified health IT; and
- other assertions (however made) related to a health IT product's certification.

Evaluation Tip: ONC-ACBs should not, when evaluating a developer's conformity with the Mandatory Disclosure Requirement, be overly concerned about the form in which a communication is made. Rather, an ONC-ACB should focus on identifying instances in which a developer promotes the benefits, capabilities, features or functionality of their certified health IT product, and should satisfy itself that, in each instance, the developer has included the mandatory disclosure information.

1. Comprehensive Disclosure Statement

For the convenience of prospective and existing customers and users, a health IT developer must publish on a publicly accessible website a comprehensive and up-to-date version of the mandatory disclosure information for each of the developer's certified health IT products (**Comprehensive Disclosure Statement**) (80 FR 62724). The URL for this website will be identified on each certified health IT product's entry in the CHPL (80 FR 62724).

Where a health IT developer has multiple health IT products it has a few options available to it so long as the end result is that a member of the public can access each product's comprehensive disclosure statement (e.g., a hyperlink of each product or various approaches to provide a single listing that provides "chapters" for each product or individually navigable listings). It will be this landing page that will be identified on each CHPL entry for the health IT developer's products.

> Evaluation Tip: A health IT developer that does not market its products online via the Internet, or that does not operate a company website, is still required to make its Comprehensive Disclosure Statement available online via a website or an online accessible resource. This is to ensure that ONC can link to the disclosure statement from the CHPL, and that health IT customers and users can rely on the CHPL as a single authoritative source of developer disclosures.

2. Website Marketing and Sales Materials

A health IT developer's website is typically the best source of information about a developer's health IT products and services. Because of this, developers are required to publish the mandatory disclosure information on all parts of the developer's website that describe or promote the benefits, capabilities, and functionality of a developer's certified health IT products or services.[3] This may mean that a developer will need to include the mandatory disclosure information on multiple pages within the developer's website, including the information wherever there are representations about certified products and capabilities.

> Evaluation Tip: Because developers may attempt to restrict access to certain marketing and sales materials—for example, by testing the bona fides of prospective customers by requiring that they furnish basic information about themselves and/or sign a non-disclosure agreement—ONC-ACBs should consider requesting that developers provide copies of all marketing and promotional materials as part of surveillance activities.

3. Other Marketing, Sales, and Communications Materials

A health IT developer must ensure that it also includes the mandatory disclosure information in all non-website-based marketing and sales materials, communications, and assertions that relate to a Complete EHR or Health IT Module's certification (80 FR 62724). Marketing materials, communications statements, and other assertions include, for example:

- A press release about the launch of a new certified Complete EHR or Health IT Module.
- Printed marketing materials, such as brochures.
- Advertisements in any media (print, online, radio, etc.).

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[3] *See* 80 FR 62724. The mandatory disclosure information must be included and updated on the developer's website (and in all other relevant "communications") regardless of whether explicit reference is made to the product's certification or certified status. A health IT developer cannot circumvent the Mandatory Disclosure Requirement by omitting any discussion of a product's certification or any reference to a product's certified capabilities.

- Product demonstrations.

4. Satisfying the Mandatory Disclosure Requirement by an Abbreviated Disclaimer

Requiring a comprehensive disclosure in all marketing materials (online or otherwise), communication statements, and assertions may be burdensome and counterproductive to ONC's goal of ensuring that customers and users become aware of the mandatory disclosure information in a manner that is meaningful and likely to inform. As such, developers can choose not to include *all* mandatory disclosure information in marketing materials, communications statements, and assertions about a certified health IT product, so long as they provide a disclaimer about the existence of limitations and additional types of costs and inform readers/viewers/listeners as to where they can find information about those limitations and additional costs (**abbreviated disclaimer**). This would typically involve the developer identifying the location of, and where practicable, linking to the developer's Comprehensive Disclosure Statement. *See* 80 FR 62724.

The nature of the abbreviated disclaimer used by a developer will depend upon the medium used for the communication. For example:

- A webpage or direct marketing email must include, at minimum, a hyperlink to the Comprehensive Disclosure Statement.
- Printed materials must clearly identify the existence of limitations and additional types of costs, and specify the URL where the Comprehensive Disclosure Statement can be accessed.
- For any electronic media (TV, radio and Internet), the developer must identify (and for non-visual media, describe) the existence of limitations and additional types of costs and communicate where the Comprehensive Disclosure Statement is located on their website with enough specificity to allow the statement to be located without special effort. If the URL is simple and short, it may be appropriate for the developer to provide that URL.

In practice then, developers may need to make two separate disclosures in order to meet the Mandatory Disclosure Requirement. First, the developer will make a disclosure via the Comprehensive Disclaimer Statement that it publishes on its website. Second, the developer will make an abbreviated disclaimer whenever the developer's website, marketing materials, communication statements, or assertions make any representations about certified products and capabilities. Of course, a developer may elect to present their full Comprehensive Disclosure Statement whenever it makes representations about certified products and capabilities, which, as a matter of form, would conform to the requirements of 45 CFR 170.523(k)(1).

> Evaluation Tip: ONC-ACBs may identify instances where a developer provides no mandatory disclosure information in their marketing materials, communication statements or assertions. While it is possible that there are no limitations or additional types of costs applicable to the health IT developer's product(s) that need to be disclosed, ONC-ACBs should always cross-check the developer's representations (or lack of representations) with the developer's Comprehensive Disclosure Statement to satisfy itself that the developer has not made an omission. An ONC-ACB may also need to make inquiries with the developer if it appears that the developer has failed to include the mandatory disclosure information.

B. Is a Disclosure Sufficiently Conspicuous?

Requirement:

A Health IT developer's mandatory disclosure information must be communicated conspicuously (45 CFR 170.523(k)(1)).

A health IT developer's Comprehensive Disclosure Statement and mandatory disclosure information must be located in a place, and presented in a manner, that is accessible and obvious to viewers and contextually relevant to the certified capability (or certified capabilities) to which the disclosure pertains (80 FR 62724). That is, the disclosure must be designed to inform and presented in a way that ensures that a person will not learn about the features and functionality of a health IT's capabilities without also learning about the material limitations and additional types of costs he may encounter to successfully implement and use the capabilities.

Evaluation Tip: If the mandatory disclosure information will not be seen/heard, the disclosure is not effective and will not satisfy 45 CFR 170.523(k)(1).

Evaluation Tip: In evaluating the conspicuousness of a developer's disclosure, ONC-ACBs should consider the overall net impression of, for example, the marketing materials or communications statements at issue. This means that an ONC-ACB should be focused on the claims that a current or prospective user will take from the developer's materials or statements.

1. Placement and Presentation

a. Comprehensive Disclosure Statement

A health IT developer's Comprehensive Disclosure Statement should be presented in a manner designed to inform a reader of its content and significance (80 FR 62724). It would be unacceptable, for example, for a health IT developer to include their Comprehensive Disclosure Statement at the end of a PDF document that provided no clear cues to a reader that the information was contained in the document.

Evaluation Tip: A health IT developer does not satisfy the Mandatory Disclosure Requirement if its Comprehensive Disclosure Statement is published on a part of the developer's website that a typical customer would be unlikely to visit or that is not an obvious place to include important information about the costs and capabilities of a product. For example, it is not acceptable to publish this information on a webpage described as containing information about "government regulations" or "compliance." In such cases, the developer would have to separately disclose the information in a more obvious place, such as on a webpage entitled "Costs and Limitations" that is referenced/linked to/from other parts of the developer's website that contain marketing materials relating to the certified product.

b. Mandatory Disclosure Information Included In Website and Other Marketing Materials, Communication Statements, and Assertions

For website-based marketing and sales materials, developers should include the mandatory disclosure information (whether in total or by using an abbreviated disclaimer) on each webpage that describes or promotes the product or service to which the disclosure pertains. This should be done regardless of whether the product's certification or certified capabilities are expressly referenced on those pages (80 FR

62724).[4] The same principles apply to non-web-based communications. In the context of print materials, a developer must avoid burying the disclosure/abbreviated disclaimer in "fine print."

ONC expects that most developers will try to satisfy the conspicuous requirement by using an abbreviated disclaimer. An abbreviated disclaimer will meet the conspicuousness requirement if all of the following conditions are met:

- The abbreviated disclaimer is placed near relevant information and is obvious (80 FR 62724). This would typically mean that the abbreviated disclaimer is placed within or adjacent to other information that describes the developer's certified product. For example, if a developer's website described a product's quality reporting capabilities, but the developer will impose charges on the customer if the customer wishes to interface with specialized registries, the developer should identify that limitation and additional type of cost (or provide an appropriate abbreviated disclaimer) as close as possible in proximity to the statement(s) that describe the quality reporting capability.
- The developer uses consistent disclaimer approaches on their website and in their materials—readers should not be left in any doubt as to the existence of the linked disclosure.
- The disclosure that the developer is linking is conspicuously presented on the click-through. This means that the page or screen that a hyperlink leads to should present the information to the customer quickly and a customer should not need to take extra steps to get to the disclosure or be required to first read extraneous materials.

The 2015 Edition final rule does not prescribe a form or words that developers must use when relying on an abbreviated disclaimer to satisfy their requirements under 45 CFR 170.523(k)(1). However, the disclosure or abbreviated disclaimer (including any hyperlink) should be designed to plainly inform a reader (or viewer or listener) of the nature and importance of the information in question. This means, for example, that hyperlinks should be clearly labeled in a way that immediately alerts a reader to the existence of limitations or types of costs and to the need to carefully examine the content of the disclosure. This can be accomplished in a variety of ways and developers have flexibility in how they communicate to their existing and prospective customers. For example, an acceptable disclosure might be communicated via a hyperlink located adjacent to a description of a health IT product's capabilities in the following terms: "**Costs and Limitations Apply**" or "**Understanding the Costs and Limitations of [Product X]**." In contrast, for the abbreviated disclaimer, hyperlink labels such as "Disclosure Information," "Meaningful Use Price Transparency," and "Regulatory Compliance Information" are neither obvious nor contextually relevant, and as such do not meet the requirements of 45 CFR 170.523(k)(1).

> Evaluation Tip: If a health IT developer presents their disclosure (or abbreviated disclaimer) in a way that departs significantly from the developer's approach to communicating the benefits, advantages, features, and capabilities of a health IT product, an ONC-ACB should be on high alert when evaluating the developer's compliance with 45 CFR 170.523(k)(1). By contrast, developers that treat their

[4] The mandatory disclosure information must be included and updated on the developer's website (and in all other relevant "communications") regardless of whether explicit reference is made to the product's certification or certified status. A health IT developer cannot circumvent the Mandatory Disclosure Requirement by omitting any discussion of a product's certification or any reference to a product's certified capabilities. 80 FR 62724.

mandatory disclosure information as an intrinsic part of the developer's product marketing activities will typically conform to the requirements.

Evaluation Tip: When evaluating the conspicuousness of an abbreviated disclaimer used in media that relies on audio or moving images, an ONC-ACB should consider whether the abbreviated disclaimer is made at a volume and in a cadence that customers can hear and understand, and that visual disclosures are displayed for a sufficient duration.

2. Accessibility

A health IT developer's Comprehensive Disclosure Statement should be accessible to all website visitors (80 FR 62724) and should not be hosted behind a 'pay-wall' or other website user registration mechanism.

III. EVALUATING COMPLIANCE: SUBSTANCE OF DISCLOSURE

A. "Additional Types of Costs" and "Limitations"

Developers are required to disclose, in plain language, a detailed description of all known material information concerning:

- **additional types of costs** that a user may be required to pay to implement or use the Complete EHR or Health IT Module's capabilities, whether to meet meaningful use objectives and measures or to achieve any other use within the scope of the health IT's certification (45 CFR 170.523(k)(1)(iii)(A)); and
- **limitations** that a user may encounter in the course of implementing and using the Complete EHR or Health IT Module's capabilities, whether to meet meaningful use objectives and measures or to achieve any other use within the scope of the health IT's certification (45 CFR 170.523(k)(1)(iii)(B)).

That is, developers must disclose all limitations and additional types of costs that could interfere with the ability to implement or use health IT in a manner consistent with its scope of certification.

Evaluation Tip: Unlike the earlier disclosure requirements included in the 2014 Edition final rule,[5] the Mandatory Disclosure Requirement is *not* limited to the use of certified capabilities to demonstrate meaningful use objectives or measures. Developers must disclose material information about all limitations and additional types of costs that a provider may experience or incur to successfully implement or use health IT for any purpose reasonably within the scope of its certified capabilities.

1. Additional Types of Costs

Developers typically charge a base cost for their software and services. This cost, whether it be an annual license fee, monthly service charge, or revenue sharing arrangement, is usually clearly communicated by developers and is well understood by customers. Customers use this base cost arrangement to compare the prices offered by competing developers and formulate a budget for their health IT acquisition.

[5] Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, 77 FR 54163 (Sept. 4, 2012) ("2014 Edition final rule").

Many developers impose additional types of costs over and above the base costs that a user may be required to pay to implement, maintain, upgrade, use, or otherwise enable and support, the capabilities to which the health IT is certified. Alternatively, some developers require their customers to pay additional costs (such as licensing fees) to third parties in order to implement a product's certified capabilities. Historically, these costs have been opaque and many health IT users have been surprised to learn of their existence when attempting to implement and use the capabilities to which their health IT is certified. It is these additional types of costs that must be disclosed by developers as part of their mandatory disclosure information.

Examples of additional types of costs include but are not limited to:

- Fees or costs for "relied upon software" that the certificate includes.
- A yearly "subscription fee" or other costs for the use of a certified capability, such as the ability to exchange transitions of care summaries.
- A "transaction fee" or other costs for sending or receiving standardized data.
- A "connection fee" or other costs to connect to a third party's data exchange network or health information exchange.
- A fee or other cost for establishing or maintaining interfaces or connections with external data sources (e.g., specialty registries).
- A fee or other cost for exporting or converting data.
- A fee or other cost to integrate the certified health IT (or related data) with other technologies or services or to provide access to documentation, APIs, or other materials that may be useful for accomplishing such integration.

A health IT developer should disclose an additional type of cost irrespective of whether the cost is imposed on the customer directly or on a third party that provides services to (or for the benefit of) the customer. This is because any costs imposed on a third party service provider or vendor could ordinarily be passed through to the customer, or could nonetheless be a factor in a customer's ability to implement or use health IT in a manner consistent with its certification.

2. Limitations

The 2015 Edition final rule identifies, by way of example, two types of limitations that could interfere with a user's ability to implement or use health IT in a manner consistent with its certification:

- Limitations, whether by contract or otherwise, on the use of any capability to which technology is certified for any purpose within the scope of the technology's certification; or in connection with any data generated in the course of using any capability to which health IT is certified. 45 CFR 523(k)(1)(iv)(B). Examples of this type of limitation include:
  - ↳ A developer will not exchange electronic health information with an organization outside of the developer's trust network or with whom the developer does not have a trust agreement.
  - ↳ A developer will not facilitate connectivity with certain technologies or developers.
  - ↳ A developer requires third party vendors to agree to terms, other than a reasonable non-disclosure agreement, before the third party vendor's product can be integrated or used with the developer's certified health IT (e.g., a non-compete agreement or an agreement to surrender rights to intellectual property created or to share revenue from services provided in connection with the certified health IT).

- ↳ A developer restricts or imposes conditions (other than a reasonable non-disclosure agreement) on the employees or business associates of the customer who can access information or materials (such as documentation, APIs, data dictionaries) that may be useful for integrating the certified health IT (or related data) with other technologies or services.
- ↳ A developer's policy or practice of imposing testing and certification requirements as a precondition of exchanging data with certain types of persons or entities, such as health information exchange organizations or specialty registries.
- ↳ A developer requires customers to procure updated versions of "relied upon software."

- Limitations, including but not limited to technical or practical limitations of technology or its capabilities, that could prevent or impair the successful implementation, configuration, customization, maintenance, support, or use of any capabilities to which technology is certified; or that could prevent or limit the use, exchange, or portability of any data generated in the course of using any capability to which technology is certified. 45 CFR 523(k)(1)(iv)(B). Examples of this type of limitation include:
  - ↳ A product can only export a fixed number of records, support a fixed number of API requests, or exchange a fixed number of Direct messages in a given 24 hour period.
  - ↳ A developer requires five business days to retrieve and furnish archived Direct messages.
  - ↳ A product may not be updated or may not be able to support updated versions of code sets, clinical quality measures, clinical content, or other relevant information.
  - ↳ A product can only support the viewing or the submission of certain types of clinical quality measures or related data, or can only submit such data to certain types of registries, reporting methods, or receiving systems.
  - ↳ A product only supports specific versions of "relied upon software" (e.g., Windows 10 or later).

B. Determining Whether a Disclosure is Complete

Requirement:

A Health IT developer must disclose all material mandatory disclosure information that the developer knows about or should know about under the circumstances (45 CFR 170.523(k)(1)(iii); 80 FR 62722).

To be complete, a developer's mandatory disclosure information must include all material information about limitations and additional types of costs that the developer knows about or should know about in the circumstances (80 FR 62722).

Evaluation Tip: An evaluation of the completeness of a developer's mandatory disclosure information requires a sophisticated understanding of the certified health IT product about which a disclosure relates. As such, ONC-ACBs will ordinarily need to make the following inquiries when evaluating the completeness of a disclosure:

- Does the disclosure itself raise questions or "flags" regarding limitations that may not have been disclosed?
- Does the information that the developer makes available publicly, or makes available to current or prospective users, about its certified health IT products, raise any questions or "flags" regarding limitations that may not have been disclosed?

- Does the ONC-ACB's knowledge of the developer or the product (such as from past certification and surveillance activities) suggest that any limitations have been omitted?

1. Is the Information 'Material'?

Information about limitations and additional types of costs is "material" if the failure to disclose it could substantially interfere with the ability of a current or prospective user to implement certified health IT in a manner consistent with its certification (80 FR 62722).

This means that information will be "material" if:

- a reasonable health IT customer needs the information to effectively understand and estimate the kinds of costs and implementation issues they may face in the event that they purchase or license the certified health IT; or
- the absence of the information might influence a reasonable prospective customer's decision whether to purchase or license the certified health IT.

However, information will not be material if it is of such minor importance or value (e.g., a trivial cost) that a reasonable prospective customer would have ignored it if it were disclosed.

It is not necessary to establish that the disclosure would have changed the customer's decision to acquire the certified health IT. Rather, it is enough that the disclosure, if made, would have informed the customer's considerations as to whether to acquire the certified health IT. Put another way, whether the omitted information raises types of costs or limitations that are of a quality that a reasonable customer would have an interest in knowing them.

The "materiality" of a type of cost or limitation might differ between customers. For example, the failure to disclose a one-time $900 license fee as an additional cost may be material for a small health care provider, but would not be material in the context of a $500 million EHR procurement by a large regional health care system. However, developers must assume that their Comprehensive Disclosure Statement will be read by all current and prospective customers and so must include types of costs and limitations that would be material for any size or type of organization that might acquire the developer's certified health IT.

Some limitations and types of costs will arise in connection with every implementation or use of a certified health IT product, and are thus material. Additionally, however, developers must, through their mandatory disclosure information, proactively identify material limitations and additional types of costs that a reasonable customer or user *may* experience/pay in order to successfully implement or use health IT for any purpose reasonably within the scope of its certified capabilities (45 CFR 170.523(k)(1); 80 FR 62722). This reflects a developer's standing as an expert on the developer's own products and services and recognizes that developers possess sophisticated technical and market knowledge related to the implementation and use of their technology. In short, developers should use their accumulated knowledge and experience in the implementation and use of their certified health IT to better inform customer decision-making.

ONC has identified certain kinds of limitations and additional types of costs that will always be material and thus, if known, must be disclosed. Material information includes, but is not limited to:

- Additional types of costs or fees (whether fixed, recurring, transaction-based, or otherwise) imposed by a developer (or any third-party or relied upon software from whom the developer obtains any technology, products, or services in connection with its certified health IT) to purchase, license, implement, maintain, upgrade, use, or otherwise enable and support the use of capabilities to which health IT is certified; or in

connection with any data generated in the course of using any capability to which health IT is certified. 45 CFR 523(k)(1)(iv)(A).

- Material limitations, whether by contract or otherwise, on the use of any capability to which technology is certified for any purpose within the scope of the technology's certification; or in connection with any data generated in the course of using any capability to which health IT is certified. 45 CFR 523(k)(1)(iv)(B).
- Material limitations, including but not limited to technical or practical limitations of technology or its capabilities, that could prevent or impair the successful implementation, configuration, customization, maintenance, support, or use of any capabilities to which technology is certified; or that could prevent or limit the use, exchange, or portability of any data generated in the course of using any capability to which technology is certified. 45 CFR 523(k)(1)(iv)(C).

2. Is the Information 'Known'?

Developers have accumulated significant experience in developing and providing health IT solutions to their customers and should be familiar with the limitations and types of costs that most users encounter when implementing and using the developer's certified health IT. However, developers cannot be expected to disclose information of which they are not and could not reasonably be aware. Nor are developers expected to account for every conceivable cost or implementation hurdle that a customer may encounter in order to successfully implement and use the capabilities of a developer's certified health IT (80 FR 62722). Indeed, in recognition of the fact that third party technologies and services, together with local implementation factors, may impair a developer's visibility of certain material limitations and types of costs, a developer's disclosure obligations are limited to only material information about which the developer knows or should know under the circumstances (80 FR 62722).

In assessing the knowledge of a health IT developer, it is reasonable to assume that a health IT developer (80 FR 62721):

- is an expert on the developer's own products and services;
- knows about all costs that the developer itself imposes or that are imposed by a third party from whom the developer obtains any technology, products, or services in connection with its certified health IT;
- possesses sophisticated technical and market knowledge related to the implementation and use of the developer's health certified IT products in a variety of settings in which their products are used;
- has a sophisticated understanding of any "relied upon software" included in the developer's product certification, to the extent that the "relied upon software" is relied upon for the purpose of implementing or using the vendor's product; and
- has made diligent inquiries and exercised reasonable care to inform itself about all potential limitations and additional types of costs that a user might experience in the course of implementing or using the capabilities of the developer's certified health IT to achieve any use within the scope of its certification.

ONC expects that it will be rare for a health IT developer, having made diligent inquiries and exercised reasonable care, to have no knowledge of the existence of a material limitation or the types of costs that may impact the implementation or use of the developer's product within the scope of its certification. This is because developers, in providing products that adhere to certification requirements, are necessarily alert to the practical, technical, and financial barriers that may impede the use of capabilities to which the health IT is certified, and to the

additional types costs that may need to be incurred to support the use of capabilities to which health IT is certified.

To illustrate this, we note that a health IT developer could not be expected to be aware of the existence of a novel type of cost to be imposed by a third party with whom the developer has no contractual relationship, if the developer has not been made aware of the cost and is unable to ascertain or predict the existence of the cost for itself. In contrast, a developer would be expected to be aware of material limitations of a practical or technical nature caused by a third party from whom the developer purchases, licenses, or obtains any technology, products, or services in connection with its certified health IT (notwithstanding the existence or not of a contractual relationship).

A determination about the sufficiency of a developer's disclosure will be made on the basis of the specific facts and circumstances of a disclosure and may require an ONC-ACB to make inquiries about what the developer should have known and what information should have been available to it at the time the disclosure was made and at the time the disclosure was seen or heard by an existing or prospective customer.

A health IT developer's Mandatory Disclosure Obligation is an ongoing obligation. As such, when evaluating the sufficiency of a developer's mandatory disclosure information, an ONC-ACB should not limit its analysis to the sufficiency of mandatory disclosure information at the time that the disclosure was prepared by the developer. Rather, because developers are under an obligation to ensure that the mandatory disclosure information was and remains accurate and up-to-date at all times (*see* 80 FR 62724).

Evaluation Tip: In reaching a conclusion that a health IT developer has violated 45 CFR 523(k)(1), an ONC-ACB does not need to consider whether the developer has engaged in deception, or whether it has sought to mislead existing or prospective customers about the capabilities or costs associated with its certified health IT. Rather, 45 CFR 523(k)(1) is violated whenever a developer fails to disclose the mandatory disclosure information that it knows about, or should know about, in the circumstances.

C. Does the Disclosure Have Required Particularity?

Requirement:

A health IT developer's mandatory disclosure information must provide a detailed description of all known material information 45 CFR 170.523(k)(1)(iii).

In addition to being "complete"—in the sense that each and every type of cost and material limitation are identified—a developer's mandatory disclosure information must be provided with sufficient particularity (80 FR 62722).

A disclosure will only have the requisite particularity if it contains sufficient information and detail from which a reasonable person under the circumstances would, without special effort, be able to reasonably identify the material limitations or types of costs (80 FR 62722). This means that a bare disclosure that does nothing more than identify the existence of a material limitation or types of costs will not usually be sufficient to meet the requirements of 45 CFR 523(k)(1). Rather, a health IT developer must describe with particularity the nature, magnitude, and extent of any identified limitations or types of costs so that potential customers have all the information they need to make informed acquisition and implementation decisions (80 FR 62722).

For each material limitation and the type of cost identified in a developer's mandatory disclosure information, the developer must provide sufficient detail for an average customer to reasonably comprehend—without special effort (*see* 80 FR 62722). For instance, the developer should consider including:

- the nature of the limitation or type of cost;
- when and how the material limitation or type of cost apply;
- the factors (e.g., user, geographical, volume, usage etc.) that impact the limitation or type of cost;
- the impact that the limitation may have on the health IT's capabilities;
- the consequence to the health IT's certified capabilities if the customer does not accept and pay the 'additional types of costs' which the developer identifies; and
- the implications that any material limitation or type of cost might have for the customer's practice and needs.

Only when this level of particularity is provided will a prospective customer be placed in a position to properly understand the true cost they may have to pay, and the limitations that they may have to overcome, to implement and use the product. Moreover, without this level of detail, a customer cannot properly compare the product with similar products that are offered in the market, and loses the opportunity to choose a different product that better meets their needs.

For example, it would be insufficient for a developer to disclose that "additional software licensing costs may be payable" without informing prospective customers about:

- the capability to which the software licensing costs related;
- the basis on which those costs would be imposed (e.g., one-time fee, enterprise license, per-seat license, etc.);
- any factors that might impact those costs, including but not limited to geographical considerations, volume, and usage; and
- any material limitations that may impact the implementation or use of the health IT's capabilities for any purpose within the scope of the health IT's certification, in the event that the customer did not acquire the additional software licenses.

1. Developers must only particularize to the extent known

The requirement that a developer describe in detail its mandatory disclosure information is contingent upon the assumption that the developer knows, or ought to know, about the type of cost or limitation. That is, a developer is only required to provide so much detail as it knows, or should know, in the circumstances (80 FR 62722). This recognizes, for example, that in respect to additional types of costs:

- certified health IT often functions in combination with third party technologies, relied upon software, and services whose specific costs and limitations may be difficult for a health IT developer to precisely predict or ascertain;
- local implementation factors and other individual circumstances may vary substantially among customers and impact the cost and complexity of implementing certified health IT; and
- the costs of upgrading health IT to meet new regulatory requirements or compliance timelines, which are subject to change, may make some particular types of additional costs especially difficult to forecast.

However, simply because a developer does not know each and every detail about a limitation or additional type of cost does not excuse the developer from including the limitation or additional type of cost in their mandatory disclosure information. Rather, a developer is required to disclose the information with as much precision as possible in the circumstances (80 FR 62723). The disclosure should be detailed enough to:

- put the customer on notice about the existence of the limitation or additional type of cost;
- inform the customer that the developer's knowledge about the limitation or additional type of cost is not complete; and
- facilitate the customer's making their own inquiries with the relevant third party and/or give the customer an opportunity to seek out the advice of a technical advisor.

2. Disclosing limitations arising from non-certified capabilities

Because certified technical capabilities may be bundled with non-certified capabilities, a developer's disclosure must include, if relevant, an explanation of any limitations that such other non-certified capabilities may have on the use or implementation of the certified capabilities (80 FR 62723).

3. Disclosure of confidential information

Developers are understandably sensitive about disclosing their prices or cost structures or unnecessarily disclosing information that they deem confidential. The 2015 Edition final rule established safeguards to ensure that developers have substantial flexibility in choosing how they describe the particular limitations and additional types of costs associated with their certified health IT products. For example, rather than disclosing detailed price information, developers may identify and describe the nature of the costs and the factors that will influence the amount of the cost that the customer may incur. 80 FR 62723.

Importantly, these safeguards are preventative and do not provide a substantive basis for a developer to refuse to comply with the Mandatory Disclosure Requirement. As such, a developer cannot cure a deficient disclosure or avoid a non-conformity finding by asserting that the disclosure of known material limitations or types of costs would require it to disclose proprietary or confidential information. 80 FR 62724.

D. Is Disclosure in Plain Language?

Requirement:

A Health IT developer's mandatory disclosure information must be in plain language (45 CFR 170.523(k)(1)(iii)).

For a disclosure to be effective, a reader/viewer/listener must be able to understand it. Health IT acquisition decisions are often made by customers with limited technical IT and regulatory knowledge, such as a clinician or practice manager. As such, developers must ensure that mandatory disclosure information is designed to be understood—without special effort—by an average customer with minimal technical knowledge or familiarity with certification requirements. This means that disclosures should be as simple and straightforward as possible.

Evaluation Tip: ONC-ACBs should consider whether the developer has used language that is no less plain, and no more technical, than the approach taken by the developer in its general sales and marketing material? If the language is more complex/overly technical, the disclosure is likely to be non-compliant.

IV. CORRECTIVE ACTION

A. General

It is the developer's responsibility to propose corrective action in response to an ONC-ACBs finding of non-conformity. ONC-ACBs are not required to identify the appropriate remedy(ies), nor are ONC-ACBs required to facilitate the dissemination of a remedy(ies) proposed by the developer. Instead, the ONC-ACB would work with the developer to devise a reasonable resolution. An ONC-ACB's role is to make a determination regarding whether a developer's proposed corrective action would remove the likelihood of substantial interference with the certified capability. If the proposed corrective action would remove the likelihood of substantial interference with the certified capability, the ONC-ACB would accept the developer's corrective action plan. However, if such corrective action fails to correct the non-conformity, further corrective action or other possible remedies, including termination of a certificate, would also be within the purview of the ONC-ACB and/or ONC as appropriate.

B. Correcting Disclosure Violations

If an ONC-ACB determines that a developer has failed to disclose required information, or to disclose such information in a form and manner that complies with the Mandatory Disclosure Requirement, the ONC-ACB must find a non-conformity to 45 CFR 170.523(k)(1) and ensure that the developer takes all necessary corrective actions in accordance with 45 CFR 170.556(d).

To correct a disclosure violation (and restore a product's conformity to 45 CFR 170.523(k)(1)), a developer must cure all deficiencies in its mandatory disclosure information so that future customers and users are fully informed of the material limitation(s) or additional types of costs before acquiring the developer's certified technology (*see* 45 CFR 170.556(d)). Therefore, the ONC-ACB needs to ensure that the developer's proposed corrective action plan requires the developer to take all necessary actions to cure the deficient aspects of its mandatory disclosure information. ONC would expect, at a minimum, the corrective action plan to include requirements that the developer:

- Update its comprehensive public disclosure statement and other public-facing disclosures to include the mandatory disclosure information that the developer failed to disclose.
- Prospectively update all other marketing materials, communications, and assertions about the certified health IT to include the mandatory disclosure information. Readily updateable materials/communication modes (e.g., webpage) would be expected to be updated simultaneously with the implementation of the corrective action plan. All others, especially physical materials (e.g., flyer) would need to be updated consistent with the corrective action plan at the next available opportunity.
- Ensure that all of the developer's disclosures comply with the requirements governing the manner of disclosures (*see* Part II) and the substance of disclosures (*see* Part III).

The goal of the actions described above is to correct the disclosure violation and restore the product's conformity to 45 CFR 170.523(k)(1).

C. Correcting Limitations and Types of Costs

In Section IV.B above, we describe the actions we expect developers to take to correct non-disclosure violations. In this section we discuss situations in which a limitation or type of cost is of a kind that — even once disclosed — may require corrective actions under the Program because it is likely to substantially impair the use of the certified health IT (80 FR 62711). In these instances, the developer must: (1) disclose the material limitation or additional type of cost (as described in Section IV.B); and (2) remedy the underlying material limitation or additional type of cost (80 FR 62711). When an underlying material limitation or additional type of cost exists, the developer may need to take additional corrective actions to ensure that the limitation or additional type of cost at issue does

not substantially impair the use of the developer's certified health IT. Examples of these additional corrective actions are described below.

A limitation or additional type of cost constitutes a non-conformity if it substantially interferes with the successful implementation or use of any certified capability (80 FR 62711). Such interference may arise in two ways:[6]

- The limitation or additional type of cost substantially interferes with some customers' ability to successfully implement or use certified capabilities; or
- The nature of the limitation or additional type of cost is such that the developer's failure to disclose it results in unanticipated implementation or other challenges that substantially interfere with some customer's ability to successfully implement or use certified capabilities.

If an ONC-ACB finds that a limitation or additional type of cost has substantially interfered with any customer's successful implementation or use of a certified capability, it must find a non-conformity to the relevant certification criterion (80 FR 62711). The developer must remedy the limitation or additional type of cost for all customers whose implementation or use of the certified capability has been, or may be, substantially impaired.

The developer's proposed corrective action plan regarding an additional type of cost must require the developer to remedy the situation (*see* 45 CFR 170.556(d)). Some actions the developer may consider including in the corrective action plan, based on the specific non-conformity at issue, include:

- not imposing the fee, charge, or cost prospectively;
- cancelling and voiding any invoiced fees, charges, or costs still outstanding; and
- refunding or otherwise compensating customers for fees, changes, or costs that they have paid.

The developer's proposed corrective action plan regarding a material limitation must require the developer to remedy non-technical limitations for impacted customers and, where feasible, technical limitations, and to otherwise take all actions necessary to restore the full use of the certified capabilities (*see* 45 CFR 170.556(d)). Some actions the developer may consider including in the corrective action plan, based on the specific non-conformity at issue, include:

- removing non-technical limitations in their entirety, for example by—
    - ↳ in the case of a contractual restriction, amending contracts to remove the restriction;
    - ↳ in the case of an affirmative policy or practice, repudiating and ceasing to engage in the policy or practice;
- removing technical limitations, where feasible, such as by redesigning and/or patching the certified capability so that it is no longer subject to the limitation; and
- where removing a technical limitation is not feasible, providing to the customer an appropriate accommodation that restores their ability to access and use the certified capabilities in a manner that is:
    - ↳ consistent with the intended purpose and objectives of the certification criteria to which the product is certified;
    - ↳ free from further limitations; and
    - ↳ accurate, reliable, and successful[7].

[6] For further discussion of interferences with the implementation or use of certified capabilities—including limitations and additional types of costs—refer to the Post-certification Assessment Resource, Part III.E.2, and the provisions of the 2015 Edition final rule cited therein.

[7] If corrective action fails to correct the non-conformity, further corrective action or other possible remedies, including termination of a certificate, would also be within the purview of the ONC-ACB and/or ONC as appropriate.