



The Office of the National Coordinator for
Health Information Technology



Health IT Product Information and Disclosures Under the 2015 Edition Final Rule

Joint Health IT Policy and Standards Committee
Certified Technology Comparison Task Force
Virtual Hearing

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New Product Information Available Under the 2015 Edition Final Rule

- New Open Data CHPL Elements
- Corrective Action Information
- Mandatory Product Disclosures
- Transparency Pledge

- The Open Data CHPL (Spring 2016) will contain an expanded set of information about certified products.
- Examples:
 - Standards the developer used for quality management, safety-enhanced design, and accessibility.
 - Additional software relied upon to meet certification.
 - API documentation and terms of use.*
 - **Corrective action information.**
 - **Mandatory product disclosures.***

* Information provided by a hyperlink to developer's website.

- Health IT products and their developers will be surveilled **in the field** to verify that capabilities work as expected and that developers are meeting requirements.
- If a product fails surveillance, the following information is posted to the Open Data CHPL within **one week**:
 - The specific capabilities or requirements that were found to be deficient.
 - The ONC-ACB's summary of the deficiencies.
 - The developer's explanation of the deficiencies (if provided).
 - The date the deficiencies were verified.
 - Corrective action timeline (dates started, due, and completed)
 - A description of the resolution of the deficiencies.

- Developers disclosure requirements have been significantly expanded.
- Developers must include disclosures on their websites and in marketing materials.
- Developers must disclose all known material **limitations** and **types of costs** that a user may have to pay to use certified health IT capabilities **for any purpose within the scope of certification.**
- Disclosures must be in **plain language.**
- Disclosures must include the **nature, magnitude, and extent** of the limitations or types of costs.
- Disclosures must be detailed enough that a reasonable customer could — **without special effort** — identify and reasonably understand:
 - The specific limitations he may encounter.
 - The potential costs he may incur.
 - The nature, magnitude, and extent of such limitations and types of costs.

Mandatory Product Disclosures (cont.)

Example:

- A product is certified to the 2014 Edition transitions of care (ToC) capability.
- The developer charges a yearly “subscription fee” to use ToC.
- The developer bundles the ToC capability with its own HISP.
- The developer is not a member of any trust network but negotiates some one-off trust agreements with third-party HISPs.
- The developer charges a “transaction fee” for each ToC summary sent or received via a third-party HISP.

(See 80 FR 62723.)

Mandatory Product Disclosures (cont.)

The developer must disclose in plain language and with particularity:

- That the developer charges an **annual subscription fee** for ToC, including:
 - The factors used to determine the amount of the subscription fee (e.g., number of licenses, volume of transactions or usage).
- The **developer's HISP policy**, including:
 - That users will be unable to exchange ToC summaries with users of unsupported HISPs.
 - Which third-party HISPs the developer supports.
 - Whether the developer is willing to negotiate trust agreements with additional HISPs (and the process and associated types of costs for the customer (e.g., factors such as geographical variation or variability in HISP technologies and trust policies that impact the amount a customer would have to pay)).
 - Any HISPs with whom the developer will not permit exchange or which the developer knows will not agree to a trust agreement with the developer (e.g., because the developer is not a member of a particular trust network).
 - How the developer's limited network of supported HISPs and lack of participation in trust networks could impact a customer's ability to exchange ToC summaries within the customer's referral area.
- The **transaction fee** for sending/receiving ToC summaries to third-party HISPs, including:
 - That it charges a fee for every ToC summary sent/received.
 - Factors on which the transaction fee is based (e.g., volume, geography, exchange partner technology).
 - Additional information to assist the customer in realistically understanding his costs.
- The **potential impact** of these fees and limitations on a customer's implementation and use of ToC.

- Developers have the opportunity to voluntarily pledge to proactively providing information about their products in more meaningful ways:
 - **Targeted** — Based on customer or requestor's specific circumstances and needs.
 - **Proactive** — At a time and in a manner most likely to be useful.
 - **Responsive** — Responds to specific questions and in format requested (if applicable).
 - **Open** — To anyone who asks.
- Organizations that represent health IT purchasers can request information from developers to help them evaluate and compare products.
- **Use Case: Comparative Data on Products:**
 - **Professional association sends a structured questionnaire to developers who have taken the Pledge in order to obtain comparative information about specific costs, services, and capabilities that are most relevant and important to the association's members.**
- ONC will publish a list of all certified health IT developers who have — and have not — taken the pledge.