Mandatory Disclosure Statement

This document explains the mandatory disclosure statement required for product certification in the ONC Health IT Certification Program. The health IT developer must provide the disclosure language they will use for their product-version. The Drummond Group LLC ONC-ACB **must** have this information prior to issuing a certification. For additional information on disclosure requirements, visit Drummond's Surveillance Webpage. Per ONC regulations, the hyperlink to the disclosure statement on your company's website will be made publicly available on the CHPL.

This document includes the following sections:

Document Created by:
DRUMMOND GROUP LLC
www.drummondgroup.com

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Overview of ONC Regulation

This section is an overview of the Mandatory Disclosure Statement requirements. Developers are now required to post both a mandatory disclosure statement of costs/fees and material limitations as well as specific product information regarding their certification on their website. The hyperlink that includes both of these components must be provided to Drummond Group to post on the CHPL. For a complete explanation of the disclosure requirements, refer to the ONC 2015 Edition Final Rule found here: https://www.gpo.gov/fdsys/pkg/FR-2015-10-16/pdf/2015-25597.pdf

Disclosure Statement
Regulation § 170.523(k)(1)(iii) states that a health IT developer must conspicuously include, in plain language, the following on its website and in all marketing materials, communications statements and other assertions related to the Complete EHR (2014 Edition) or EHR Module's certification (2014 or 2015 Edition):

> *(A) Any 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.*
>
> *(B) Limitations that a user may encounter in the course of implementing and using the Complete EHR of 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.*

The costs or fees disclosed may be imposed by the developer or third party to purchase, license, implement, maintain, upgrade, use, or otherwise enable and support the use of capabilities to which health IT is certified. These may be one-time or recurring costs, or both. Drummond must ensure that EHR technology developers disclose, with particularity, the types of additional costs, but does not require that the actual dollar amounts of such costs be disclosed.

Limitations are, by contract or otherwise, limits on the use of any capability to which technology is certified for any purpose within the scope of the technology's certification. These limitations include, but are 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 the technology is certified. Limitations that could prevent or limit the use, exchange, or portability of any data generated in the course of using a certified capability must also be disclosed.

Product Information
Regulation § 170.523(k)(1)(i)-(ii) requires that developers post the following information on their website for all active CHPL listings. This information can be found on the product's Certificate of Compliance issued by Drummond Group upon successfully achieving certification.

- Developer organization name
- Date the product was certified
- Product name and version
- Unique certification number
- Certification criteria to which the product has been certified
- CQMs to which the product has been certified

- Any additional software the certified product relied upon to demonstrate its compliance with certification criteria
- ONC Disclaimer: "This [Complete EHR or Health IT Module] is [2014/2015] Edition compliant and has been certified by an ONC-ACB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services."

For additional information, please see Drummond's Surveillance FAQs.

Important Considerations!
Please keep the following important details in mind as you create your Mandatory Disclosure:

- The purpose of the Mandatory Disclosure is to inform. Therefore, it must include a description of the capability and costs/limitations in **plain language**. Plain language means a description that is no more technical than how it would be explained in your marketing materials.
- The requisite plain language also applies to the **title of this information on your website** and in marketing materials/communications. Any title header or document name for posting you mandatory disclosure statement must be labeled using the terminology "Costs and Limitations." Do NOT reference it as a Mandatory Disclosure Statement or Price Transparency Statement. ONC has indicated that these titles would NOT meet the definition of plain language.
- You are required to post your mandatory disclosure statement of costs and fees and required product information **conspicuously on your website** as well as in all marketing materials and communication statements related to your certified technology. This information should be easily accessible and clearly visible in a logical location on your website. While this information is not required to be on your homepage, it should be **no more than a few clicks away and placed on a page to which a provider would logically navigate for this type of product information**. For example, posting it in a news story section or within contract terms would NOT be considered compliant. As a rule of thumb, if an individual who is not familiar with your website is unable to locate your statement of costs and limitations within one minute, the location may not meet the requirement to be conspicuously available.
- Please note that these costs, fees and limitations are regarding **anything within the scope of your certified functionality**, not only costs or limitations in meeting the Meaningful Use measures. Therefore, be mindful in how you reference Meaningful Use in your statement.
- If there are no limitations or additional costs related to a particular certified capability, that information must be **clearly and explicitly stated**.
- The required product language must be posted for **ALL active CHPL listings**. If the product has been sunset and is no longer in use, request that the product be withdrawn from the CHPL. If the listing remains active on the CHPL, it must comply with Mandatory Disclosure requirements.

Additional Information

Requirements for Self-Developers

Health IT self-developers are excluded from the requirement to post a mandatory disclosure statement of costs/fees and material limitations (170.523(k)(1)(iii)). However, please note that self-developers are still required to post the product information listed above in § 170.523(k)(1)(i)-(ii) on their website.

Self-developers must submit a letter to Drummond Group that indicates that their certified technology will not be marketed or made commercially available for sale to health care providers. This letter must also include the hyperlink to the product information listed in (k)(1)(i)-(ii). For further instructions, please reference the Disclosure Letter Instructions to include the necessary language for all attestations

Changes to the Disclosure Language

An organization may change their disclosure language at any time to reflect new business policies or decisions. The new language must be sent to DG in the form of the disclosure letter described in this document. There are no additional costs for updating disclosure language.

Non-compliance Consequences

Per the Final Rule, the ONC-ACB is responsible for ensuring compliance and determining appropriate consequences if EHR technology developers fail to disclose the information specified in § 170.523(k)(1), including inaccurate or missing disclosure information. Organizations will be regularly surveyed to confirm they are properly reporting their disclosures in conjunction with their certification status. Randomized surveillance activities will include validation that the information in the developer's disclosure is conspicuously posted and compliant with all requirements.

Organizations failing to conspicuously include the required disclosure details on their web site and in all marketing materials, communications statements, and other assertions related to the certified technology, or who do not provide an acceptable disclosure letter to Drummond Group within the requested timeframe may receive corrective action and/or have their product's certification suspended.

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Questions for Creating Disclosure Language

The specifics of the disclosures language are left to each certifying organization, but the following rules and guidelines for ensuring transparency compliance are used by DG ONC-ACB (key words from RFC 2119).

The attributed service, functionality or software MUST be referenced in "human readable" text and not solely in reference to the ONC criteria. For example, "online portal service" rather than "170.314.e.1". However, the ONC criteria MAY be included for clarity. A description of the function should also be included in plain language. The inclusion of dollar values is neither required nor restricted.

Use these questions to help you think through potential costs or limitations of your certified product when writing your disclosure statement. However, these questions are to serve as a tool and are NOT intended to be all-inclusive or utilized in this format on your website.

ADDITIONAL COSTS/FEES:	
What costs/fees may a user incur to implement or use the certified software?	Implementation, data transformation and data cleanup if required
Are these costs/fees fixed, one-time, recurring, ongoing, monthly, transaction based, annual, etc.?	Implementation and data cleanup cost is one-time cost unless the product version from which we receive data changes significantly. The data transformation cost is per program year and is dependent on number of measures that have significantly changed from previous program year.
What additional software must be purchased that is not included in the initial purchase of this software?	None
What kinds of services, functionality, or software are attributed to this cost?	Implementation, data transformation and data cleanup
Are there factors that impact additional types of costs, including but not limited to geographical considerations, volume and usage, costs associated with necessary interfaces or other licenses or technology, and costs associated with exchange partner technology and characteristics, among other relevant factors?	None

CONTRACTUAL LIMITATIONS:	
Does a provider have to sign a contract when purchasing your product? Does the contract impose limitations that could	Provider has to sign a contract with us or our business partners to use our product.

limit the implementation or use of certified capabilities or the data generated by these capabilities?	
Are there business policies or practices that may cause limitations in the implementation or use of certified capabilities?	None
Is it necessary for the user to engage with a third party?	Product does not require providers to engage with third party.
If necessary to engage with a third party, to your knowledge, is there an agreement that providers must enter into with this third party?	Not Applicable, as Product does not require use of third party softwares.
If there are third parties involved, are there any limitations on who they choose for this service?	If Providers choose to involve a third party, Persivia does not impose any limitations on who the providers can chose for service.

TECHNICAL OR PRACTICAL LIMITATIONS:	
Are there any product limitations that could prevent or impair the implementation, configuration, maintenance, support or use of a certified capability?	There are no such limitations regarding implementation, configuration, maintenance and support of our product.
Are there any limitations of workstations or licenses where the software is deployed, volume of transactions or usage, or associated bandwidth limitations?	None
Are there any limitations that a user may encounter regarding the exchange or portability of any data generated when using the capability?	None
Are there limitations with non-certified capabilities that may interfere with the use or implementation of any certified capabilities?	None

ITEMS THAT DO NOT NEED TO BE INCLUDED:

- Do not include additional software or services that an EP, EH or CAH MAY elect to obtain but that are not within the scope of the Health IT's certification and do not impact certified features. For example, a separate PMS software to enable billing but is not related to nor does it impact any use within the scope of the health IT's certification.

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Examples of Mandatory Disclosures

Some examples of potential attributed costs and limitations that may be part of your statement are given below. The format of the disclosure is determined by your organization (paragraphs, table, spreadsheet, etc.), but should be organized logically and separately address additional costs/fees, contractual limitations and technical or practical limitations.

Example #1

As your primary examples, see the "ONC Sample: Mandatory Disclosure" here. This example closely aligns with the Drummond template provided on the last page of this guide.

Example #2

EHR technology is certified to the 314.e.1 "view, download, and transmit to a 3rd party" certification criterion. However, EP must pay an "ongoing" monthly service fee to the EHR technology developer for it to host/administer this capability in order for the EP to meet the correlated MU objective and measure, the existence of this potential "ongoing" cost would need to be disclosed by the EHR technology developer.

Example of Disclosure Language: *This certified product-version may require ongoing monthly costs to support online patient portal service (170.314.e.1). Patient portal service allows patients to view their health information online as well as download and transmit a summary of their healthcare information to a third party electronically. The ongoing monthly cost is a flat rate per provider facility.*

Example #3

An EHR Module is certified to the immunization registry transmission (170.314.f.2), public health electronic lab reporting certification (170.314.f.4) and transmission to cancer registries (170.314.f.6) criteria. However, for the purposes of achieving MU, an EP, EH or CAH may be expected to pay a separate "one-time" fee for customizing the transmission interface development and configuration necessary for a state reporting agency.
In addition, the EHR technology developer charges a "one-time" fee to integrate its certified EHR technology with a hospital's other certified EHR Modules or a health information exchange organization.

Example of Disclosure Language: *This certified product-version may require one-time and monthly costs to establish interfaces for reporting to immunization registries, reporting cancer registries, and sending data to public health agencies (170.314.f.2, 170.314.f.4, 170.314.f.6). The one-time cost is charged at the facility level per interface. The monthly costs are based on the volume of messages sent to the registry in blocks of 1000 messages.*

Example #4

EHR technology is certified to 170.315(b)(6) for data export to create a set of export summaries in real time base on a relative time and date. Though the user can create a set of export summaries in real time based on relative time and date, this type of mass export is only allowed every 24 hours to reduce performance stress on the system.

Example of Disclosure Language: *This certified product-version is certified to data export criteria 170.315(B)(6) and can generate a set of export summaries in real time. However, the ability to utilize the mass export functionality for data export is only allowed once every 24 hours to ensure optimal system performance.*

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Required Document Templates

Prior to issuing a certification, Drummond Group LLC (DG) must receive a disclosure letter dated and signed by an authorized representative who has the legal authority to represent the company in such matters on formal company letter head. T

Disclosure Letter Instructions

Use the Mandatory Disclosure Letter Template below. The letter must include the following:

1. The name of your organization and the product name and version seeking certification.
2. An attachment of the exact disclosure language you will use for this certified product version. Use the Costs and Limitations of Certified Health IT table attached to the Mandatory Disclosure Letter Template below. Please follow the rules and guidelines for this language described in this document. If this language is an update to a previously submitted disclosure letter, please note this and the approximate date on which this new disclosure information will be in effect and displayed on your marketing materials.
3. The exact URL where your disclosure language is displayed on your website or will be displayed upon successfully achieving certification.
4. If a self-developer of EHR technology claiming exclusion from mandatory disclosure requirements, submit this attestation that you are an EHR technology self-developer and your EHR technology will not be marketed or made commercially available for sale to health care providers. You do not need to include an attachment of costs and limitations. However, Product information listed in § 170.523(k)(1)(i)-(ii) must be included on your website and the hyperlink to this information included in the letter. The below language from #4-6 must also be included in this letter.

EVERY LETTER MUST INCLUDE A URL AND LANGUAGE FROM 5-7:

5. Your agreement to notify DG of any and all future changes to your disclosure language.
6. Your understanding and agreement that the ONC Health IT Certification Program Final Rule statement gives DG, as an ONC-ACB, the sole responsibility for ensuring compliance and determining appropriate consequences if EHR technology developers fail to disclose accurate information.
7. Your understanding and agreement that you will provide to DG copies of or be given access to any and all websites, marketing materials, communication statements, and other assertions made by your organization regarding the ONC certification status of your product in a reasonable time to ensure the disclosure information is being accurately disclosed.

Document must be signed, scanned and uploaded using the Online Mandatory Disclosure Form. The DG EHR Certification Body requires this disclosure document before granting a certification on a product-version.

ATTN: Drummond Group, LLC
13359 North Hwy. 183
Suite B 406-238
Austin, TX 78750

March 21, 2018
Persivia Inc.
CQM Services 3.0
Meaningful Use Solution 3.0

To Drummond Group:

The Mandatory Disclosure statement of costs and limitations for our certified product(s) is attached to this letter and will be posted along with the required product information on our website here:

http://persivia.com/solutions/mips-macra

> ***Note:** Your URL must include both the attached mandatory disclosure information and all bullets referenced in the Product Information section of this document.

We agree to notify Drummond Group of any and all future changes to our transparency and disclosures language for this certified product-version.

We understand and agree that the ONC Health IT Certification Program Final Rule statement gives Drummond Group, as an ONC-ACB, the sole responsibility for ensuring compliance and determining appropriate consequences if EHR technology developers fail to divulge accurate transparency and disclosures information.

We understand and agree that we will provide to Drummond Group copies of or give access to any and all websites, marketing materials, communication statements, and other assertions made by your organization regarding the ONC certification status of this product in a reasonable time to ensure the transparency and disclosures information is being accurately disclosed.

Sincerely,

Fauzia Khan MD, FCAP
Chief Medical Officer & Chief Operating Officer
Persivia
fauzia.khan@persivia.com
900 Chelmsford Street, Tower 3, 7th Floor, Lowell, MA 01851

978-856-4502 (Direct) | 508-612-3872 (Mobile) | 978-856-4599 (fax)

Costs and Limitations of Certified Health IT

Capability	Description of Capability	Costs or Fees *Types of costs or fees that a user may be required to pay to purchase, license, implement, maintain, upgrade, use, or otherwise enable and support the use of the implementation or use of the capability -OR- in connection with the data generated in the course using the capability*	Contractual Limitations *Limitations of a contractual nature (including developer policies and other business practices) that a user may encounter in the implementation or use of the capability -OR- in the connection with the data generated in the course of using the capability*	Technical or Practical Limitations *Limitations of a technical or practical nature that a user may encounter that could prevent or impair the successful implementation, configuration, maintenance, support or use of the capability -OR- prevent or limit the use, exchange or portability of any data generated in the course of using the capability*
The certified products - CQM Services 3.0 and Meaningful Use Solution 3.0 will have capability to have user login and check their CQM measure performance that they selected to report to CMS. It will also generate required output file for CMS. Associated Certification Criteria: • C.1 – Clinical Quality Measures – Record & Export • C.2- Clinical Quality Measures – import and calculate • C.3 – Reserved for Clinical Quality Measures – report • D.1 – Authentication, Access Control, Authorization • D.2 – Auditable Events and Tamper Resistant • D.3 – Audit Report(s) • D.5 – Automatic Access Time-Out • G.4 – Quality Management System • G.5 – Accessibility – Centered Design	The certified products - CQM Services 3.0 and Meaningful Use Solution 3.0 will have capability to have user login – User able to login to the Persivia quality portal to check the performance of measures. Once user signoff on their reports Persivia will generate QRDA files to submit to CMS.	The certified products – CQM Services 3.0 and Meaningful Use Solution 3.0, may require additional costs/fees for Implementation, data transformation and data cleanup. Implementation and data cleanup cost is a one-time fee unless the product version from which Persivia receives data changes significantly. The data transformation cost is per program year and is dependent on number of measures that have significantly changed from the previous program year. No additional software must be purchased that is not included in the initial purchase of the Persivia products. Persivia products use Software as a Service (SAAS) based solution. Our pricing is based on the number of users and number of measures.	The certified products - CQM Services 3.0 and Meaningful Use Solution 3.0, require clients to sign a contract either with Persivia or with Persivia business partners, in order to use the products. Typically, the contract term is three years, but Persivia provides flexibility of 1 year or 5 year contracts. Under certain circumstances, clients may be allowed to opt out of the contract. Such conditions are stipulated under the contract. Persivia products do not require clients to engage with third parties.	The certified products – CQM Services 3.0 and Meaningful Use Solution 3.0, have no technical or practical limitations.