

Drummond Group LLC

EHR Certification Guide

August 15, 2017

Scope of Document

This Drummond Group Certification Guide consists of four sections. Section One provides an overview of the Drummond Health IT Certification Program. Section Two addresses scheduling certification activities and application steps, including instructions on obtaining pricing information. Section Three is an explanation of the accredited certification procedure for EHRs and Health IT systems. Section Four covers how certification is maintained, including requirements on certification inheritance to new version of EHR, surveillance of the EHR, complaints and mandatory disclosures.

Section One. Overview of the Drummond Group, LLC EHR Certification Program

ONC Authorized Certification Body: Drummond Group LLC

[Drummond Group, LLC](#) (DG), approved for 2014 Edition and 2015 Edition, has been accredited by the U.S. Department of Health and Human Services and [American National Standards Institute \(ANSI\)](#) as a certification body for the Office of the National Coordinator (ONC) Health Information Technology (Health IT) Certification Program. Also, DG has been accredited by the [National Voluntary Laboratory Accreditation Program \(NVLAP, NVLAP Lab Code: 200979-0\)](#) of the [National Institute of Standards and Technology \(NIST\)](#) to test electronic health record (EHR) technology under the auspices of the [ONC Health IT](#). DG's accredited EHR Certification Body has certified more than 500 2014 Edition EHR products. Products certified by DG can be used by eligible providers and hospitals as part of their criteria for qualifying for Center for Medicare and Medicaid Services (CMS) incentive payments.

This guide covers information related to DG's EHR certification services.
For more information on DG's testing services, please see the [EHR Testing Guide](#).

Drummond Group Decision Guide to 2015 Edition Testing and Certification. Please note that the complexity of certification choices significantly increased with 2015 Edition. DG's "Decision Guide to 2015 Edition" can reduce the complexity of the decision-making process on certifying to the new criteria. To receive a copy of this guide, which includes pricing, please contact Client Services by sending email to EHR@drummondgroup.com. A similar document for 2014 Edition certification is also available by request.

Section Two. Scheduling Certification, Steps to Apply, and Pricing

DG's accredited EHR ONC-ACB has certified almost 2,000 2014 Edition and 2015 Edition EHR products. Products certified by DG can be used by eligible providers and hospitals as part of their criteria for qualifying for Centers for Medicare and Medicaid Services (CMS) incentive payments.

In the ONC's Health IT program, clients can move their testing and certifications to another ONC-approved testing lab/certification body. For instance, if a client's product was certified by an ACB (Authorized Certification Body) during previous editions of the program, that client can now move its testing and/or certification to any other ATL and ACB of its choosing, as well as move current certified product listings to another ACB.

How to Apply and Schedule Certification

With all the choices, if a client needs help with questions along the way, please send an email to EHR@drummondgroup.com or call 512-826-2938.

For Testing and Certification: If a client wants to test with DG, they can easily register on this [form](#). The details for testing with DG are outlined in the [EHR Testing Guide](#). Once the client completes its testing evaluation, they will be asked to register with a simple form to start the certification process. Our Client Engagement Manager will help with this process, ensuring all documentation is submitted to prepare for certification.

Certification ONLY:

(for clients that tested with another ATL and want to certify only with DG)

Step One.

Register [here](#).

Please remember to include the correct product name with version and release number on the application form. This information will be used in the certification process.

Step Two.

Confirmation. The client will receive a confirmation email from DG including: the Master Services Agreement, Pre-Certification Survey, Gap Certification Inheritance Form, Mandatory Disclosures form, Transparency Attestation form, Product Name Form and a request for an ATL-approved Final Test Report, if the client is requesting Certification only. Please note that to enter a product for review by the DG Certification Body, the client must submit a completed Master Services Agreement and make arrangements for payment as outlined below.

Master Services Agreement DG will provide the client the DG Master Services Agreement for EHR Certification. The client must provide a signature on our Master Services Agreement and return the form via email to LisaS@drummondgroup.com. Questions? Email: LisaS@drummondgroup.com

Product Name Form. Client must complete this form with client name and product name as it should be listed on our website as well as on the CHPL listing. It is imperative that this information is listed correctly; therefore, we require a signature from a member of the client's senior management. This form must be received prior to client's product(s) being submitted for review by the certification body.

Transparency Attestation. Clients need to submit this attestation whether certifying 2014 Edition or 2015 Edition. In this attestation, the client hereby attests, either in the affirmative or in the negative, that it will provide in a timely manner, in plain writing, and in a manner calculated to inform, any part (including all) of the information required to

be disclosed under 45 CFR § 170.523(k)(1) under the following circumstances:

- **To all persons who request such information.**
- **To all persons who request or receive a quotation**, estimate, description of services, or other assertion or information from [*Developer Name*] in connection with any certified health IT or any capabilities thereof.
- **To all customers prior to providing or entering into any agreement** to provide any certified health IT or related product or service (including subsequent updates, add-ons, or additional products or services during the course of an on-going agreement).

The DG ONC-ACB must have this information prior to issuing a certification. For more information on Transparency, see Section Four: Maintaining Your Product Certification.

Mandatory Disclosures. Clients must submit their required disclosure language regarding any additional costs or fees that an EP, EH, or CAH would pay to implement or use the Complete EHR's or EHR Health IT Module's capabilities in order to attempt to meet meaningful use objectives and measures within the scope of the Health IT's certification. Developers must also include any material practical, technical or contractual limitations. Click [here](#) for more details.

Gap Certification Inheritance Form. If client tested and certified its product under the earlier certification criteria, some of the client's criteria may be eligible for Gap Certification. Please review the form and fill out accordingly. If client has further questions, please contact DG at 512-826-2938.

Step Three.

Payment. Payment must be received before the test or certification activity, and the balance must be paid before a certification can be issued.

Pricing

Please contact Client Services for pricing list.

Send email to EHR@drummondgroup.com or phone 512-826-2938.

Section Three. Certification Procedure

Nondiscriminatory statement

DG's Certification Body does not discriminate in its policies or procedures nor in the administration of them. The Certification Body makes its service accessible to all applicants whose activities fall within its scope of operations. No procedure shall be used by the Certification Body to block access by applicants, other than those allowed for in the ISO/IEC 17065 standard.

Roles and Responsibilities

DG is an ANSI-accredited Authorized Certification Body (ONC-ACB). The DG Certification Body is structured for impartiality, efficiency and objectivity in all matters pertaining to certification criteria as adopted by the Secretary at 45 CFR 170 subpart C, with a specific designation separating the Certification Body from all testing activities. This Certification Body (CB) is regularly evaluated and audited on its ability to assure impartiality and objectivity in its practices, decision-making and authority in all matters related to certification through its implemented quality system. DG's Certification Body is supported financially by the fees of its customers. For a list of fees, please send email to EHR@drummondgroup.com.

Clients and applicants have certain rights and responsibilities. Clients and applicants can expect the Certification Body to:

- Maintain the requirements of ISO/IEC 17065
- Be impartial and fair in their certification decisions;
- Maintain confidentiality in their work;
- Provide ongoing surveillance of certified products per ONC requirements
- Be thorough in their review of the documents presented for certification;
- Follow the certification criteria adopted by the ONC;
- Uphold the ONC's Principles of Proper Conduct;
- And uphold any and all approval requirements of the ONC for facilitating this program.

Certification applicants and clients are expected to:

- Provide DG with complete and accurate information about all attestations, declarations, representations, warranties, descriptions and other information provided or used in connection with the product to be certified;
- Successfully complete the registered EHR testing, if certification is granted
- Pay required fees;
- After granting of certification, follow all rules regarding maintenance of certification as described in 45 CFR Part 170. (Details on maintaining your certification are received with your certification materials.)

Certification Process

After testing (or evaluation) has been completed, the certification process, which typically takes

10-15 days, includes:

- Application for Certification
- Application Analysis
- Review/Decision of your Evaluation/Certification documentation
- Product Certification completion
- CHPL report submittal to ONC

CERTIFICATION DECISION OPTIONS:

Granting. The DG Certification Body will review and approve/reject the test results. In order to receive a Certificate of EHR Compliance from DG:

- * client must successfully complete the registered EHR testing
- * all required registration documents must be sent in to the DG certification body
- * testing must be reviewed and approved by DG Certification Review/Decision Maker.
- * final payment from the developer must be received by DG

Upon certification:

- the now-certified product/client will receive a Congratulations Email with attached documentation to help the client maintain its product certification,
- the now-certified product/client will receive a Certificate of Compliance, which can be utilized in marketing their certification,
- the now-certified product/client will receive an ONC and Drummond Certified™ seal that may be used on the vendor's website home page, internal product description pages, press releases or other marketing materials
- DG will notify ONC of the product's certification status.
- A representative of DG's Certification Body will schedule an optional phone call and review the responsibilities of certification with the primary contact on the registration form and answer any questions.
- Final Test Report will be posted in accordance with ONC requirements

Please allow up to 10 business days [business days are measured from date of approval by the certification body] for the product to be listed on the ONC and DG websites.

Rejection. A product may have some modules rejected yet still receive certification for the modules that pass.

Maintaining, Reducing or Extending the Scope of Certified Products.

A previously certified EHR module may be updated in ways that affect capabilities both related and unrelated to the certification criteria adopted by the Secretary without its certification becoming invalid.

If changes are made to a certified product, the client will be required to do the following:

1. Click on this [link](#).
2. Select appropriate “updates” box under the edition to which the product is certified.
3. Complete the form.

Please note: If additional information besides text needs to be reviewed by our team, please send an email to EHR@drummondgroup.com and we will set up a conference call to discuss.

Upon receipt of the information, DG will determine whether the updates and/or modifications are such that the new version would adversely affect previously certified capabilities and therefore need to be retested and recertified, or whether to grant certified status to the new version derived from the previously certified EHR product. Please note that additional attestation reviews do have a fee. If the attestation results in additional testing, the testing will be done for an additional fee. In such cases where testing is required, the attestation fee will be waived and replaced by the normal testing and certification fee.

Certified Products Reseller Policy

Clients that have certified a product with DG are allowed to resell that product through resellers by submitting a letter jointly signed by the original manufacturer and the reseller that confirms the relationship, that both agree to maintain the ONC-ACB certification rules, and that changes are not allowed by the reseller.

1. Click on this [link](#).
2. Select the appropriate form “RESELLER.
3. Complete the form.

This would initiate a response from Client Services to assist you.

If you have specific questions on this, please send email to EHR@drummondgroup.com.

Confidentiality

DG has a policy that protects the information shared during the course of testing and certification activities. Confidentiality, security and loss prevention of all data collected during testing and certification is maintained through a variety of security precautions, including secure limited password access and secure backup of data.

Section Four. Maintaining Product Certification

Updates on Criteria and Regulations within HHS/ONC Certification Program

If certified on the 2014 Edition or 2015 Edition criteria, Client agrees and acknowledges that the Certificate of EHR Compliance for 2014 Edition or 2015 Edition is valid until ONC updates the certification criteria or makes other changes to the program requirements or regulations. At the end of this period or when ONC updates its requirements, the client must certify on the next ONC-approved certification criteria or make other required updates or client will no longer be able to satisfy the definition of certified EHR technology, because the Secretary of the U.S. Department of Health and Human Services (HHS) has changed the certification requirements.

If certified on the 2014 Edition or 2015 Edition criteria, client agrees and acknowledges that the requirements for maintaining Certificate of EHR Compliance for 2014 Edition or 2015 Edition are conditional upon any new rules or regulations ONC may introduce in federal regulations or guidance. This includes, but is not limited to, requirements on surveillance, disclosures or attestations. Client agrees and acknowledges that they must stay within compliance of any new rules or regulations ONC may introduce in federal regulations or guidance or risk certification being suspended or withdrawn.

Per the rules set forth by the HHS Secretary, client further agrees to furnish periodic attestations signed by an authorized senior executive regarding the status of the certified product and to be subject to unannounced product audits and reviews that may be conducted at the discretion of DG or as directed by ONC.

Rules for Modifying Certified Products

Client agrees and acknowledges that a previously certified module may be updated for routine maintenance or to include new features that affect capabilities both related and unrelated to the certification criteria adopted by the HHS Secretary without its certification becoming invalid. If major or minor changes are made to the Drummond Certified EHR product, the client must submit to DG an approved DG attestation document indicating the changes that were made, the reasons for those changes, and a statement from the client's development team as to whether these changes do or do not affect the client's previous certification, and other such information and supporting documentation that would be necessary to properly assess the potential effects the new version would have on previously certified capabilities. **Routine software maintenance changes do not require attestation unless the maintenance changes potentially affect the certified criteria.** Upon receipt of the attestation, DG will determine whether the updates and/or modifications are such that the new version would adversely affect previously certified capabilities and therefore need to be retested and recertified, or whether to grant certified status to the new version derived from the previously certified product.

Attestation. As product changes are attested, the Review/Decision Maker has the ability to review and audit test those being reviewed per the signed Master Services Agreement.

Fees for Re-testing:

Please contact Client Services for pricing list.

Send email to EHR@drummondgroup.com or phone 512-826-2938.

Certification Disclaimer, Mandatory Disclosures, and Certified Product Information

For certification under 2014 Edition or 2015 Edition, client agrees that during its certification period it must conspicuously include the following text on its website and in all marketing materials, communications statements, and other assertions related to the Complete EHR or EHR Module's certification:

1. The correct identifying information for certified products, as found on the Certificate of Compliance:
 - Developer name
 - Date the product was certified
 - Product version
 - Unique certification number
 - Certification criterion or 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
2. 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."
3. Costs and Limitations: Any additional types of costs or fees 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. Also, any practical, technical or contractual 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.

*A certification that is issued to an integrated bundle of EHR Modules shall be treated the same as a certification issued to a Complete EHR (2014 Edition only) except that it must

also indicate each EHR Module that comprises the bundle;

*A certification issued to a Complete EHR (2014 Edition only) or EHR Module based on applicable certification criteria adopted by the Secretary at subpart C of this part must be separate and distinct from any other certification(s) based on other criteria or requirements.

* It is permitted to reference a website hyperlink on marketing material that points to the required disclaimer information rather than printing the disclaimer language on every marketing literature verbatim.

Certification Marketing Guidelines

Certification Seal

Certification seals are provided by ONC and Drummond Group (DG) to software solutions that have been certified by the DG's ONC-ACB Certified program for Health IT.

The marketing guidelines for the ONC seal and the DG seal are provided to the customer by DG upon certification.

Links to the marketing guidelines:

[DG Certificate of Compliance and Marks Guidelines](#)

[Criteria and Terms of Use for the ONC Certified Health IT Certification and Design Mark](#)

Certificate of Compliance

Clients that have certified software solutions are given a Certificate of EHR Compliance and may use the certificate and seal in print ads, company communications, sales materials and related promotional items targeted to reach customers. It displays to potential partners, customers and competitors that a client's solutions are compliant with the certification criteria and have been listed on the Office of the National Coordinator (ONC) Certified Health IT Product Listing (CHPL), which ensures that it is eligible for CMS incentives.

Please note that public display of the Drummond Certified EHR seal, DG Logo or Certificate of Compliance does not replace ONC-required marketing language detailed in the Certification Adherence section above.

Surveillance

In the Office of the National Coordinator Health IT Certification Program, the surveillance effort of DG's ACB is closely monitored by the ONC and ANSI to ensure that products are maintaining their certification over time. The time and effort for surveillance has significantly increased in the latest Final Rule. Surveillance ensures confidence that Drummond Certified™ products continue to comply with the criteria to which they were certified. Each client signs a DG Master Services Agreement that includes a surveillance section that requires a variety of items related to surveillance activities.

Refer to the Drummond Surveillance Plan for this current year for instructions on how surveillance will be applied and maintained, including in-the-field surveillance (<https://www.drummondgroup.com/surveillance>).

Complaints to Suppliers

DG requires that the client keep a record of all complaints made known to it that relate to the client's compliance with the criteria set forth by the HHS Secretary and the resulting certification by DG. We require that the client provide these complaints to us via email upon receiving DG's request. This information is important to us and to ONC. All complaints will become part of our due diligence for continued process improvement to ensure the overall confidence in the ONC-ACB Program.

All appeals and complaints about the Certification Body, EHR Test Lab or a Drummond Certified product should be submitted to EHRcomplaints@drummondgroup.com or discussed with your DG contact. If discussed with DG contact, we ask that you also outline the nature and severity of the problem in an email and send to EHRcomplaints@drummondgroup.com.

Complaints can result in findings of non-compliance of certification. Refer to the Drummond Surveillance Plan for this current year for instructions on procedures for handling, resolving and reporting non-compliances (<https://www.drummondgroup.com/surveillance>).

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