



**ISO/IEC 17065
EHR Certification Guide**

Drummond Group LLC

EHR Certification Guide

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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 a new version of the 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), 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, Drummond 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. Drummond’s accredited EHR Certification Body has certified more than 2,000 Health IT products. Products certified by Drummond 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 and for other programs.

This guide covers information related to Drummond’s EHR certification services. For more information on Drummond’s testing services, please see the EHR Testing Guide on the Drummond website.

Drummond Group Decision Guide to 2015 Edition Testing and Certification. Please note that the complexity of certification choices significantly increased with 2015 Edition. Drummond’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 via email at EHR@drummondgroup.com.

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

In the ONC’s Health IT program, clients can test and certify with an ONC-approved testing lab/certification body of their choosing. For instance, if a client’s product was certified by an ACB (Authorized Certification Body) during previous editions of the program, that client can use any other ATL or ACB it chooses for further testing and/or certification.



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How to Apply and Schedule Certification For 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 developer wants to test and certify with Drummond, registration on the Drummond website is easily done. The details for testing with Drummond are outlined in the [EHR Testing Guide](#). Once the developer completes the testing evaluation, they will be asked to register with a simple form to start the certification process. The Drummond Certification Body will help ensure that all documentation is submitted to prepare for certification.

Certification ONLY: (for applicants that tested with another ATL and want to certify only with Drummond)

Step One.

Register [here](#).

Please remember to include the correct product name with version and release number (if applicable) on the application form. This information will be used to identify the product.

Step Two.

Confirmation. The client will receive a confirmation email from Drummond with instructions to fill out and return several documents, including: Master Services Agreement, Statement of Work, Gap Certification Inheritance Form, Mandatory Disclosures form, Transparency Attestation form and Product Name Form. The Drummond certification body will request an ATL-approved Final Test Report from the ATL that conducted the evaluation. Please note that to enter a product for review by the Drummond Certification Body, the client must submit all documents listed above and make payment as outlined below.

Step Three.

Payment. A deposit must be received before the test or certification review will occur, and the balance of fees must be paid before a certification can be issued.



Section Three: Certification Procedure

Nondiscriminatory statement Drummond’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. Access to the certification process shall not be conditional upon the size of the client or membership of any association or group, nor shall certification be conditional upon the number of certifications already issued. There shall not be undue financial or other conditions. 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 Drummond is an ANSI-accredited Authorized Certification Body. The Drummond 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. Drummond’s Certification Body is supported financially by the fees of its customers. For a list of fees, please email 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 all approval requirements of the ONC for facilitating this program

Certification applicants and clients are expected to:

- Provide Drummond with complete and accurate information about all attestation



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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 has been completed successfully, required documents have been received by Drummond, and fees paid in full, the certification process typically takes 10 business days and includes:

- Application for Certification
- Application Analysis
- Review/Decision of your testing evaluation and certification documentation
- Issuance of Certificate of Compliance and related materials
- CHPL report submittal to ONC

CERTIFICATION DECISION OPTIONS:

Granting. The Drummond Certification Body will review and approve/reject the test results. To receive a Certificate of EHR Compliance from Drummond:

- * client must successfully complete the registered EHR testing
- * all required registration documents must be sent into the Drummond certification body
- * testing must be reviewed and approved by Drummond Certification Technical Review Team
- * final payment from the developer must be received by Drummond

Upon certification:

- the now-certified product/client will receive a Congratulations Email with 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



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that may be used on the vendor's website home page, internal product description pages, press releases or other marketing materials

- Drummond will notify ONC of the product's certification status
- The client may email the Certification Body Manager for inquiries regarding certification
- Final Test Report will be posted in accordance with ONC requirements

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. To initiate modification services, fill out a [registration form](#) on the Drummond website.
2. Select the appropriate service option boxes under the edition for which the product is certified.
3. Submit the form. If information that is not covered on the registration form needs to be reviewed by our team, please send an email to EHR@drummondgroup.com and a conference call will be arranged.

Upon receipt of the information, Drummond will determine whether the updates and/or modifications 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. If an attestation review results in additional testing, this testing will incur a fee. In such cases where testing is not required, only certification fees will apply.



Certified Products Reseller Policy Clients that have certified a product with Drummond may resell that product by submitting a letter jointly signed by the original manufacturer and the reseller that confirms the relationship, and through which both agree to maintain the ONC-ACB certification rules, and that changes are not allowed to be made by the reseller.

Steps to initiate this service.

1. Fill out a [registration form](#) on the Drummond website
2. Select the appropriate RESELLER service option.
3. Submit the form. A confirmation email will be sent outlining next steps.

Questions related to this service may be directed to EHR@drummondgroup.com.

Confidentiality Drummond has a policy that protects the information shared during 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.

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.



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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 Drummond 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 Drummond an approved Drummond 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, Drummond 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. The Technical Review Team reviews and audits product changes regularly, per the signed Master Services Agreement.

Fees for Re-testing: Contact client services via 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 active 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 product’s certification:



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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 certified product’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 when implementing and using the certified product’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. 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 (Drummond) to software solutions that have been certified by the Drummond’s ONC-ACB. The marketing guidelines for the ONC seal and the Drummond seal are provided to the customer by Drummond upon certification. **Links to the marketing guidelines:** [Drummond Health IT Certificate and Marks Usage Requirements Criteria and Terms of Use for the ONC Certified Health IT Certification and Design Mark](#)



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Certificate of Compliance Clients that have certified software solutions are given a Certificate of Compliance and may use the certificate and seal in print ads, company communications, sales materials and related promotional items targeted to 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, Drummond 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 efforts of Drummond's ACB are closely monitored by the ONC and ANSI to ensure that products are maintaining their certification. The time and effort for surveillance has significantly increased in the latest Final Rule. Surveillance ensures confidence that products certified by Drummond Group continue to comply with the criteria to which they were certified. Each client signs a Drummond Master Services Agreement that includes a surveillance section requiring a variety of items.

Refer to the [Drummond Surveillance Plan](#) for the current year for instructions on how surveillance will be applied and maintained, including in-the-field surveillance.

Complaints to Suppliers Drummond 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 Drummond. We require that the client provide these complaints to us via email upon receiving Drummond'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.



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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 Drummond contact. If discussed with Drummond 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/health-it-services-and-testing>).

END OF DOCUMENT