ONC HEALTH IT PRODUCT TEST AND CERTIFICATION SERVICES
SERVICE TERMS

These Service Terms shall govern the ONC Health IT Product Test and Certification Services performed by UL Contracting Party ("we", "our" or "us" as the context requires and as identified in the Quotation or Project Confirmation) and set out the responsibilities and obligations of the UL Contracting Party and the Client ("you" or "your" as the context requires). These Service Terms and the terms of the Global Service Agreement ("GSA") are incorporated by reference into and are an integral part of each Service Agreement entered into by the Parties for ONC Health IT Product Test and Certification Services. The capitalized terms in these Service Terms which are not defined herein shall have the same meaning as in the GSA.

1. Scope of Services.

1.1 **Testing**. UL Contracting Party will perform necessary ONC Health IT Product testing of the Client's products ("EHR Product") in accordance with the applicable Certification Criteria for the ONC Health IT Certification Program. Details of the testing will be set out in individual Quotations.

1.2 **Certification.** Upon receipt of an EHR Product test report, the Certification Body, as defined below, will review the EHR Product test report for determination of compliance with the applicable Certification Criteria for the ONC Health IT Certification Program. Details of the certification will be set out in individual Quotations.

2. Definitions.

2.1. "2014 Edition Certification" means the testing to the final set of standards, implementation specifications and Certification Criteria released in the 2014 Edition certification criteria final rule (77 FR 54163, September 4, 2012), as may be amended from time to time.

2.2. "2015 Edition Certification" means the testing to the final set of standards, implementation specifications and Certification Criteria released in the 2015 Edition certification criteria final rule (80 FR 62601, October 16, 2015), as may be amended from time to time.

2.3. "Adaptations" means "a software application designed to run on a different medium that includes the full and exact same capabilities included in the Complete EHR or certified Health IT Module, including EHR Modules." (2015 Edition Certification Criteria Final Rule).

2.4. "Annual Surveillance Fee" means the annual fees billed to the Client for the surveillance activities, by the UL Contracting Party, that are required to be performed in maintaining the Certification.

2.5. "Application" means the completed Certification Application Form submitted by Client to have its EHR Product evaluated by UL Contracting Party for compliance with the applicable Certification Criteria.

2.6. "ATL" means Accredited Testing Laboratory accredited by the National Voluntary Laboratory Accreditation Program (NVLAP).

2.7. "ATL/ACB Transfer Agreement" means the agreement entered by and between the UL Contracting Party and the Third Party ACB or ATL that allows a Third Party ACB or ATL to use the test results from UL Contracting Party, and vice versa, in accordance with the requirements and limitations of ISO/IEC 17065:2012.

2.8. "Certificate" means the Certificate of Compliance document describing the scope of certification provided to Client by the UL Contracting Party Certification Body.

2.9. **"Certification"** or **"Certified"** means the status achieved by the EHR Product after UL Contracting party has (a) reviewed test results for the EHR Product against the applicable Certification Criteria (b) determined that Certification is appropriate; (c) notified Client of such determination; and (d) issued Certificate(s).

2.10. **"Certification Body"** is a group of UL Contracting Party personnel independent from the Test Body.

2.11. **"Certification Criteria"** means the certification criteria adopted in 45 CFR Part 170 for testing and certification of Complete EHRs and Health IT Modules.

2.12. **"Certification Process"** means the certification process followed by UL Contracting Party to evaluate for the Certification and maintaining of Certification of Client's EHR Product.

2.13. **"Complete EHR"** has the meaning set forth at 45 CFR § 170.102, as the same may be amended from time to time.

2.14. **"EHR"** means electronic health record(s).

2.15. **"EHR Product"** means a Health IT Module or Complete EHR as set forth under the Product Information section of the Client completed Application or the ONC CHPL, as applicable.

2.16. **"Health IT Module"** has the meaning set forth at 45 CFR § 170.102, as the same may be amended from time to time.

2.17. **"HHS"** means the U.S. Department of Health and Human Services.

2.18. **"Inherited Certified Status" means either:**

(a) the extension of Certification to a newer version of the Certified EHR Product, for which changes made to the newer version have not adversely affected any previously certified capabilities; or

(b) any change to Certification, including but not limited to (i) name of the ONC Authorized Certification Body (ONC-ACB), and/or (ii) changes to the Certified EHR Product which changes have not adversely affected any previously certified capabilities.

2.19. **"National Coordinator"** or **"ONC"** means the Office of the National Coordinator for Health Information Technology, HHS.

2.20. **"Non-conformity"** means a finding by the Certification Body that the Certified EHR Product or the Client does not conform to the requirements of certification.

2.21. **"ONC-ACB"** means an ONC-Authorized Certification Body accredited by the American National Standards Institute (ANSI).

2.22. **"ONC Certified Health Information Technology Product Listing (CHPL)"** means the ONC website list of all certified EHR Products.

2.23. **"ONC Health IT Certification Program"** means the certification program established by ONC to ensure health IT conforms to the standards and certification criteria adopted at 45 CFR 170.

2.24. **"Reseller"** means the purchaser of the EHR Product for reselling to the general public and once Certification has been received; at that point the Reseller becomes the vendor designate for the private-label product.

2.25. **"Retest"** means a retest of any test steps for which Client's EHR Product was found to be noncompliant during the Test Process.

2.26. **"Test Body"** is a group of UL Contracting Party personnel independent from the Certification Body.

2.27. **"Test Process"** means the test process followed by UL Contracting Party to test Client's EHR Product for compliance with all applicable Certification Criteria.

3. **Price and Applicable Fees**. The Quotation will establish the price for UL Contracting Party's Services. The Quotation will depend upon the type of product, test requirements, and

certification criteria. The Quotation is subject to change at the UL Contracting Party's discretion, upon reasonable notice to Client, depending upon the requirements of the specific project.

4. Client Responsibilities.

4.1. Test Requirements.

(a) **Documentation**. Client shall promptly submit any supporting materials requested by UL Contracting Party. All submitted materials shall be considered Your Information in accordance with the GSA.

(b) **Test Environment**. Client shall fully set-up the required test environment prior to the scheduled testing of Client's EHR Product.

(c) **Single Point of Contact**. Client shall designate a single point of contact, and make available each day of the Test Process such single point of contact as well as other Client personnel necessary to execute the test steps and demonstrate Client's EHR Product effectively to UL Contracting Party. Client's single point of contact must also be readily available to review elements contained in any other testing method, and to answer questions and attend meetings as requested by UL Contracting Party. Client will promptly notify UL Contracting Party in the event of a change in Client's single point of contact.

4.2. Certification Requirements. Client shall comply with the certification requirements, including implementing those certification requirements changes communicated by the Certification Body, and notify the Certification Body immediately of any modification made or planned that may affect its conformity with the certification requirements.

(a) **New Versions**. Client shall comply with the maintenance of Certificate requirements set forth by the Certification Body and/or the ONC, as updated from time to time. Client shall not claim Certification of any other HER Product version(s) other than the EHR Product version(s) certified, if any updates or modifications are made after Certification is granted without following the Inherited Certified Status procedure established by ONC at 170.545(d) and 170.550(k)

(b) **Customer Complaints**. Client shall take appropriate action with respect to complaints and any deficiencies found relevant to the Certified EHR Product(s) that affect compliance with the Certification Criteria. The Client shall also keep a record of any and all customer complaints relating to compliance with the Certification Criteria, made known to Client, concerning their Certified EHR Product(s) and make those records available to the Certification Body upon request, compliant with ISO/IEC 17065:2012. Records shall include the date of the complaint, identification of the complainant, a description of the complaint, resolution, and corrective action taken, if any. Failure to participate, as requested by the Certification Body, may result in withdrawal or suspension of Certification.

(c) **Transparency and Disclosures.** Client shall support any and all transparency requirements concerning their Certified EHR Product(s) as set forth in 45 CFR § 170.523(k)(1) and 45 CFR § 170.523(k)(2), as the same may be amended from time to time. Failure to comply may result in withdrawal or suspension of Certification.

(d) **Test Result Transparency.** Client shall support any and all test result transparency requirements concerning their Certified EHR Product(s) as set

forth in 45 CFR § 170.523, as the same may be amended from time to time. Failure to comply may result in withdrawal or suspension of Certification.

(e) **Surveillance Activities**. Client shall support any and all Surveillance activities concerning their Certified EHR Product(s), as set forth in ISO/IEC 17065:2012, 45 CFR § 170.523, and 45 CFR § 170.556, as the same may be amended from time to time. These activities include, but are not limited to, investigation of complaints, examination of documentation, performance of testing (in a test environment and/or in the field), and the participation of observers. Client shall provide a complete list of users of the Certified EHR Product(s) upon request by the Certification Body. An annual surveillance plan compliant with ONC's annual surveillance guidance is available upon request. An Annual Surveillance Fee shall be paid by Client for such Surveillance Activities. The amount of the Annual Surveillance Fee will be determined by the number of certification criteria for each certified product, and as stated in the Annual Fee Notice published by the UL Contracting Party and/or in the applicable Quotation. The Annual Surveillance Fee shall be charged in advance, thirty (30) days before the anniversary of the initial certification and shall be paid by the Client per the terms provided on the invoice. Where the Annual Surveillance Fee does not cover an entire year, the Annual Surveillance Fee shall be calculated on a pro rata basis.

Failure to participate, as requested by the Certification Body, may result in withdrawal or suspension of Certification.

(f) **Use and Marketing of Certification**.

(1) Per 45 CFR § 170.523(k)(1), where Client's Certified EHR Product has received Certification, Client shall conspicuously include the required information on its website and in all marketing materials, communications statements, and any other assertions related to the Certification of the Complete EHR and/or Health IT Module(s).

(2) Where Client's EHR Product has received Certification by the Certification Body, Client shall not use its Certification in such a manner as to bring the Certification Body into disrepute and shall not make any statement regarding its EHR Product Certification which the Certification Body may consider misleading or unauthorized

(3) Where Client's Certified EHR Product has received suspension, withdrawal, or termination of its Certification, Client shall immediately discontinue its use of all advertising matter that contains any reference thereto and return the Certificate.

(g) **Copies of Certificate**. If Client provides copies of the Certificate to others, the Certificate shall be reproduced only in its original entirety.

(h) **Reporting of Adaptations and Updates**. Per 45 CFR §170.523(m), if Client creates any Adaptations, Client shall report such adaptations to UL Contracting Party on a quarterly basis. If no such Adaptations were made, an attestation of no adaptation is still required on a quarterly basis.

In addition, if Client makes any modifications affecting the capabilities in certification criteria to which the "safety-enhanced design" criteria apply, Client shall report these changes to UL Contracting Party on a quarterly basis. If no such modifications were made, an attestation of no changes is still required on a quarterly basis.

(i) **New Requirements.** If ONC releases new requirements that require compliance related to Certified EHR Products, the Certification Body will provide notice to Client. The notice will include the specific actions and

timeframe required for completion. Failure to comply with the new requirements may result in withdrawal or suspension of Certification.

(j) **Corrective Action, Suspension, Withdrawal, and Termination**.

Should the Certification Body identify any non-conformity of the Certified EHR Product to the Certification Criteria or the Service Agreement, the Certification Body shall issue a non-conformity to Client and require corrective action. Information about the corrective action process is provided in the annual surveillance plan, available upon request.

Non-conformities related to Certification Criteria in 45 CFR 170.314 (2014 Edition) or 170.315 (2015 Edition) shall incur fees invoiced to the Client. The invoice(s) shall cover investigation of the confirmed non-conformity and verification of implementation of the corrective action.

In any case, should the Certification Body identify any non-conformity of the Certified EHR Product to the Certification Criteria or the Service Agreement, the Certification Body shall have the authority to suspend the Certification of the EHR Product. During such suspension, Client shall be required to refrain from using or marketing such reference in accordance with the Service Agreement.

The Certification Body shall provide written notification to Client listing any and all non-conformant findings of the Certified Product and Client shall have a specified timeframe from the notification date to resolve the issue(s) causing suspension. If the issue(s) cannot be resolved to the satisfaction of the Certification Body, Certification shall be withdrawn. This may subject the Client to ONC's Certification Ban as defined in 45 CFR 170.581. Upon withdrawal of the Certification, Client shall be required to refrain from using or marketing any claims of Certification in accordance with the Service Agreement.

Client shall, at any time, have the right to request termination of Certification. Upon termination, Client shall be required to refrain from using or marketing any claims of Certification in accordance with the Service Agreement.

5. **Use of ONC Certified HIT Mark.** The Office of the National Coordinator (ONC) Certified HIT Mark is intended for use in association with Complete EHRs and Health IT Modules that have been certified by the UL Contracting Party under the ONC Health IT Certification Program. The Client may use the Mark under the following terms and conditions
   - **5.1.** The ONC Certified HIT Mark is a certification mark of ONC, which retains exclusive rights to control its use.
   - **5.2.** The ONC Certified HIT Mark may only be used as permitted in the "Criteria and Terms of Use for the ONC Certified HIT Certification and Design Mark", as updated from time to time. This "Criteria and Terms of Use for the ONC Certified HIT Certification and Design Mark" document is available at: https://www.healthit.gov/sites/default/files/hit_certificationterms_of_use_final.pdf
   - **5.3.** Permission for use of the ONC Certified HIT Mark may be revoked at the discretion of the UL Contracting Party and ONC at any time.
   - **5.4.** Permission to use the ONC Certified HIT Mark in no way constitutes or implies product endorsement by UL Contracting Party or by ONC.
   - **5.5.** Use of the ONC Certified HIT Mark as specified above may begin upon receipt of the Certificate(s).

6. **Appeals and Complaints.** Client shall, at any time, have the right to make an appeal (disagreement with a Certification Body decision) or complaint. A UL Contracting Party representative shall be appointed to investigate any reported appeals or complaints and

provide a formal response. That individual shall not have been a part of the original certification review or decision.

7. Confidential Information.

7.1. Confidential Information. "Confidential Information" shall include the following:

(a) EHR Product documentation and technical information provided to UL Contracting Party by Client under the Service Agreement(s);

(b) Product operation, display screens, controls, workflows and any other features and capabilities made visible to any UL Contracting Party employee during the course of any Test Process or Retest;

(c) Item-by-item compliance results for Client's EHR Product developed during the course of any Test Process or Retest; and

(d) Any other nonpublic information that is disclosed by one Party (the "Disclosing Party") to the other (the "Receiving Party"), whether before or after execution of the Service Agreement(s), provided that such information is designated in writing as "Confidential" or "Proprietary".

7.2. Notwithstanding any attempted designation to the contrary, Confidential Information shall not include:

(a) Client's company name, EHR Product name and version, and contact information for Client's representatives;

(b) Item-by-item compliance results, when de-identified as to Client and aggregated statistically with corresponding compliance results from other vendors;

(c) Information required to be provided by UL Contracting Party to the National Coordinator, under 45 CFR Part 170, Subpart E. This may include, but is not limited to, usability testing results, transparency and disclosure information, and surveillance results;

(d) Information made visible to the ONC or its authorized agent(s) during their observation of testing or certification conducted by UL Contracting Party in its capacity as an ATL or ONC-ACB, provided that UL Contracting will remain subject to its confidentiality obligations set forth at 7.1 above;

(e) Information that is, or subsequently becomes, generally available to the public through no act or fault of the Receiving Party;

(f) Information that was in the possession of the Receiving Party, without being subject to confidentiality restrictions, prior to its disclosure;

(g) Information that was lawfully acquired by the Receiving Party from a third party not under an obligation of confidentiality to the Disclosing Party;

(h) Information that was independently developed by the Receiving Party without using the other Party's Confidential Information; or

(i) Information that would be Confidential Information but with the Disclosing Party's prior written consent to the Receiving Party that such information may be disclosed, in accordance with the terms of such consent.

7.3. Required Disclosure. It will not be a violation of this Agreement to disclose any information required to be disclosed by law or legal process; provided, however, that with the exception of Sections 7.2(c) and 7.2(d) above (which shall not require prior notification), prior to making any legally compelled disclosure, the Receiving Party shall (a) promptly notify the Disclosing Party of the disclosure request, and (b) at the request of the Disclosing Party, provide reasonable assistance in any effort by the Disclosing Party to prevent or limit such disclosure.

7.4. Disclosure and Use Restrictions. Except as otherwise provided in the Service Agreement(s), the Receiving Party shall:

(a) Keep in confidence all Confidential Information, using at least the same degree of care in safeguarding the Disclosing Party's Confidential Information as it uses in protecting its own confidential information, subject to a minimum standard of reasonable diligence and protection;
(b) Use and disclose Confidential Information only in the course of performing its obligations under this Agreement;
(c) Disclose Confidential Information within its organization only to those employees, agents or subcontractors who have both (i) a need to know such information for the purpose of the Receiving Party's performance under this Agreement, and (ii) a legal duty to protect such information comparable to the obligations of the Receiving Party hereunder; and
(d) Upon termination of the Service Agreement(s) or upon Disclosing Party's request, promptly return or destroy, at its own cost, all Confidential Information of the Disclosing Party, and shall certify in writing compliance with this subsection, with the exception of Confidential Information required to be retained under UL Contracting Party's Record Storage and Retention Policy as an ATL and ONC-ACB.

7.5. Injunctive Relief. Each Party recognizes and acknowledges that any use or disclosure of the other Party's Confidential Information in a manner that is inconsistent with the provisions of the Service Agreement(s) may cause irreparable harm to such other Party for which damages may be an inadequate remedy. Each Party therefore agrees that in any request to a court of competent jurisdiction by the other Party for injunctive or equitable relief seeking to restrain the use or disclosure of such Party's Confidential Information; it will not maintain that such remedy is inappropriate under the circumstances.

8. Term and Termination.

8.1. Term. The Service Agreement(s) shall commence on its effective date and continue until terminated pursuant to this Section 8.

8.2. Termination by Convenience. Either Party may terminate the Service Agreement(s) at any time by providing written notice to the other Party of its intent to terminate. If Client terminates the Service Agreement(s), Client is entitled to reimbursement in full for all Services provided and any other sums due pursuant to the applicable Service Agreement(s) up to the effective date of termination, including any other direct costs and expenses incurred by Client in connection with the termination.

8.3. Termination for Cause. UL Contracting Party may terminate a Service Agreement by providing written notice to Client, if in UL Contracting Party's sole discretion, it determines that the Vendor breached the terms of this Agreement.

8.4. Effects of Termination. Automatic termination of the Service Agreement(s) occurs in the event of termination of the Certification pursuant to Section 9. Upon termination: (i) the Service Agreement(s) shall automatically terminate; (ii) the Client shall refrain from using or marketing any claims of Certification; (iii) Client shall discontinue use of the Certificate on its website, in all marketing materials that contains any reference to the Certificate and Certification, any communication statements, and any other assertions related to the Certification; and (iv) Client shall discontinue use of the ONC Certified Health IT Mark. UL Contracting Party will update the Certification on the ONC CHPL to show that the Certificate has been terminated by the Client and remove the Certificate from the UL website.

9. Transition of Services.

9.1. Termination of Certification. Client acknowledges that UL Contracting Party may transition from providing the services, and terminate the Certification and applicable Service Agreement(s) at any time during the term of the Service Agreement(s) upon notice to Client. In consideration of UL Contracting Party's right to transition from and no longer provide the services, Client may, at any time, terminate Certification and the applicable Service Agreement(s) by providing written notice to UL Contracting Party of its request or intent to terminate.

9.2. Transfer of Certification and/or test data to a third party ONC-ACB. Upon termination by UL Contracting Party pursuant to Section 8.2, UL Contracting Party will make commercially reasonable efforts to assist Client in its transition of UL Contracting Party test data and/or Certification to a third party ONC-ACB, who has entered into an ATL/ACB Transfer Agreement with UL Contracting Party.

9.2.1. If Client elects to transfer Certification to a third party ONC-ACB, it will enter into a separate agreement with the third party ONC-ACB.

9.2.2. Client agrees that: (i) UL Contracting Party is not providing any opinions or findings regarding whether Client will be issued a certification; (ii) that UL Contracting Party cannot guarantee acceptance of UL Contracting Party test data or Certification by the third-party ONC-ACB; and (iii) UL Contracting Party shall not be liable or responsible in any manner whatsoever for the test data or Certification following transfer to third party ONC-ACB.

10. Use of Names and Marks. The Services shall not result in UL Contracting Party issuing product safety certification or any authorization to use the Marks. Except as otherwise expressly authorized by UL Contracting Party, Client shall not use UL Contracting Party's, or any other UL Company's, name, abbreviation, symbols, Marks or any other form of reference which may be interpreted to refer to UL Contracting Party or any other UL Company on any goods or their containers or packaging, or in connection with any oral or written advertising, promotions, or otherwise.