



**Certification Commission
for Healthcare
Information Technology**

233 N. Michigan Avenue, Suite 2150
Chicago, Illinois 60601-5800
Tel 312.233.1582 Fax 312.896.1466
www.cchit.org

Certification Handbook

Ambulatory EHR Products 2006

Version 1.2
May 1, 2006

- 1.0 CCHIT Background 3
- 2.0 Certification Program Overview..... 3
- 3.0 Certification Program Terms and Conditions 4
 - 3.1 Certification Agreement..... 4
 - 3.2 Pricing and Payment Schedule 4
 - 3.3 Term of Certification – Product Version Applicability..... 5
 - 3.4 Certification of New Versions..... 5
- 4.0 Products Eligible for Certification..... 6
 - 4.1 Comprehensive EHR Product..... 6
 - 4.2 Practice Specialties and Specialized Markets 6
 - 4.3 Pre-Market Conditional Certification 6
 - 4.4 Internally-Developed, Non-Marketed EHR Systems 7
- 5.0 The Certification Process 7
 - 5.1 Application Process 9
 - 5.1.1 Completing the Application 9
 - 5.1.2 Review Application 9
 - 5.1.3 Submission of Signed Certification Agreement and Application Fee..... 9
 - 5.1.4 Submitting Self-Attestation Materials 9
 - 5.1.5 Desktop Review 10
 - 5.1.6 Scheduling Inspection Dates..... 10
 - 5.2 Inspection Process 11
 - 5.2.1 Functionality Inspection..... 11
 - 5.2.2 Time Allotment for Functionality Inspection 12
 - 5.2.3 Security Inspection 12
 - 5.2.4 Time Allotment for Security Inspection 12
 - 5.2.5 Review Self-Attestation Materials 13
 - 5.2.6 Retesting with a New Jury..... 13
 - 5.2.7 Appeal for Commission Review 13
 - 5.3 Certification Outcomes..... 14
 - 5.3.1 Products Achieving Certification 14
 - 5.3.2 Products Failing to Achieve Certification 14
 - 5.3.3 Certification Descriptions and Disclaimers..... 14
 - 5.4 Juror Qualifications, Selection and Assignment..... 14
 - 5.5 Buyer Complaint Process 15
- 6.0 Marketing Guidelines 15

1.0 CCHIT Background

The Certification Commission for Healthcare Information Technology's (CCHITSM) mission is to accelerate the adoption of healthcare information technology throughout the US by creating a credible mechanism for the certification of healthcare IT (HIT) products. Certification was listed by Dr. David Brailer as a key action in delivering the goals of the Office of the National Coordinator (ONC) as outlined in the 2004 Strategic Framework for advancing HIT adoption.

CCHIT was founded in 2004 with sponsorship from three industry associations in HIT:

- The American Health Information Management Association (AHIMA),
- The Healthcare Information and Management Systems Society (HIMSS) and
- The National Alliance for Healthcare Information Technology (the Alliance).

Additional funding support came in 2005 from the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), the American College of Physicians (ACP), the California HealthCare Foundation (CHCF), Hospital Corporation of America, McKesson, Sutter Health, United Health Foundation, and WellPoint Health Networks, Inc. In September 2005, CCHIT was awarded a \$7.5 million, three year contract by the Department of Health and Human Services (HHS) to develop certification criteria and an inspection process for Electronic Health Records (EHRs) and the infrastructure components through which they interoperate. HHS clearly stated the expectation that CCHIT take steps to evolve into a self-sustaining organization with increased independence by the termination of the contract.

With the release of this Handbook, CCHIT is preparing for the commercial launch of the first stage of its work—Certification of Ambulatory EHR products. Physicians, physician groups, payers and purchasers will all benefit from having information in the marketplace assuring them of the basic capabilities of Certified EHR offerings. Based on certification criteria and an inspection process that was publicly vetted and validated, with multi-stakeholder input, CCHIT believes this information will facilitate EHR adoption.

Finally, it is important to note that the development of CCHIT's rigorous, transparent and reliable inspection process was made possible by the efforts of dedicated volunteers working alongside our capable staff. Our Board of Commissioners and Workgroup volunteers have contributed thousands of hours of senior level clinical, healthcare IT and security expertise. We extend our gratitude and thanks to CCHIT staff and volunteers for making this endeavor possible.

2.0 Certification Program Overview

CCHIT's initial scope of work is the certification of Ambulatory EHR products, and that is the domain covered by this Handbook. CCHIT will assess the applicant's Ambulatory EHR product for conformance with its current criteria for Functionality, Interoperability, and Security¹. These criteria were developed based upon available, widely-accepted industry standards. Test scripts were developed to simulate realistic clinical use scenarios, with each step in the script mapped against one or more of the criteria. The CCHIT inspection process uses a combination of documentation review/self-attestation, jury-observed demonstration, and jury-observed technical testing, in a sequence guided by the test scripts, to confirm compliance of an applicant's EHR product with the certification criteria.

Applicants are able to access and familiarize themselves with the criteria, testing scenarios and test scripts on the CCHIT web site. Applicants are urged to prepare for their inspection date by

¹ Note that due to limited availability of interoperability standards, there are no testable criteria for interoperability at this point. Interoperability criteria will appear later in 2006 and in 2007.

reviewing and practicing their demonstration of the test scripts. One finding from CCHIT's pilot process was that applicants who had prepared and practiced the test scripts completed the inspection process more quickly and required less repeat testing to demonstrate that their product met the criteria.

If an applicant's product meets all the criteria, it will become "CCHIT CertifiedSM". For criteria which are not met on the initial round of inspection, there are multiple opportunities for retesting, as well as an appeal process, described in Section 5.0.

When the inspection process is complete, CCHIT issues a Certification Document as well as the CCHIT Certified Ambulatory EHR Seal for the specific criteria year and product version reviewed. CCHIT also provides instructions on using the Seal in promotions via its marketing and advertising guidelines.

CCHIT's certification process maintains the highest standards for credibility, reliability and transparency. All criteria, test scripts and inspection methods are developed and maintained by CCHIT Workgroups, publicly vetted by multiple stakeholders, and approved by its Board of Commissioners (see Section 6.0).

Applicants who participate in CCHIT's rigorous inspection process and receive Certification are distinguished in the industry among other vendors who are not certified. CCHIT's work includes active outreach to physicians, physician groups, payers, purchasers and other interested parties to communicate the benefits of selecting a CCHIT Certified product.

3.0 Certification Program Terms and Conditions

3.1 Certification Agreement

As part of the application process, applicants are required to review and sign two (2) copies of the CCHIT Certification Agreement. The Agreement includes the following points:

- The applicant desires to have its product inspected by CCHIT for the purpose of obtaining certification
- The applicant agrees to comply with CCHIT's published policies and process for application and inspection (see Section 5.0) as well as its marketing and advertising guidelines for use of the Certification Seal (see Section 6.0).
- The applicant irrevocably waives any right to pursue litigation in respect to the matter of the certification process and result for its product. CCHIT shall not be liable for any damages.
- CCHIT agrees to inspect the product in accordance with its published policies and process, in a timely and professional manner, and certify the product if it is found in compliance with all current criteria for that product domain, or notify the applicant as to the specific deficiencies if it is not found in compliance.
- CCHIT agrees to allow retesting and appeals in accordance with its published policies and process. The applicant agrees to abide by the CCHIT's published policies and process regarding retesting and appeals (see Section 5.0).
- CCHIT irrevocably waives any right to pursue litigation in respect to the matter of the certification process and result for the applicant's product.
- The agreement confers on CCHIT only the limited right to use the product for testing purposes. CCHIT agrees to hold all of the applicant's trade secrets in confidence.

3.2 Pricing and Payment Schedule

Please see the Certification Agreement for the complete Fee Schedule and Description of Fees.

CCHIT wishes to create a fee structure that makes certification affordable and avoids having cost become a barrier to success for healthcare IT companies both large and small, while ensuring that CCHIT can continue as a sustainable entity after Federal developmental funding ends.

In addition, CCHIT believes the industry benefits most when products evolve in step with CCHIT's roadmap. To that end, CCHIT wishes to encourage retesting of products against the new certification criteria issued each year,

CCHIT believes the best means to achieve these goals is by combining a fixed Certification Fee for conducting the application and inspection process and a Certification Maintenance Fee applied to each Certified Vendor who chooses not to apply for recertification against updated criteria in subsequent years.

To protect against cost overruns, CCHIT invokes optional Service Charges for Incomplete Applications, Test Cancellations and Additional Testing for applicants requiring multiple rounds of testing to demonstrate compliance.

3.3 Term of Certification – Product Version Applicability

Term. The term for Ambulatory EHR Certification, as it relates to a specific product version, will be three (3) years from the applicable Batch Announcement Date on which CCHIT includes the applicant in its list of Certified Vendors.

Substantial Equivalence. When an applicant releases a newer version of the applicant's EHR product, before marketing such version as CCHIT Certified, the applicant must file with CCHIT, using the form available on the CCHIT web site, a Statement of Substantial Equivalence. Upon receiving the applicant's Statement of Substantial Equivalence, CCHIT will add such newer version number to CCHIT's list of Certified version(s) of that applicant's EHR product on the CCHIT web site. Unless otherwise requested by the applicant, the earlier Certified version number(s) will remain on the list as well. If the applicant is found to have misrepresented the newer version of the applicant's EHR product in its Statement of Substantial Equivalence (including, without limitation, as evidenced by a complaint from a purchaser of EHR products submitted to CCHIT through its customer complaint intake process), the applicant may be subject to penalties up to and including withdrawal of the applicant's Certification and/or being disallowed from applying for Certification for a period of up to one (1) year from the date of CCHIT's decision concerning such misrepresentation.

3.4 Certification of New Versions.

When the applicant releases a newer version of the applicant's EHR product that represents a significant redesign or re-architecting of the applicant's EHR product, the applicant should not make a Statement of Substantial Equivalence, and should instead apply for Certification of such newer version.

- If the Certification Criteria used in the inspection process for the earlier, Certified version of the applicant's EHR product are still current, the applicant shall pay fifty percent (50%) of the application fee for inspection of the newer version of the applicant's EHR product, and, if Certification is achieved, the three (3) year initial Certification term or the current renewal term, as applicable, will be reset to begin on the date of re-inspection of such newer version. The inspection process for such newer version will encompass only those areas of the applicant's EHR product that have changed as compared to the earlier, Certified version.
- If CCHIT has updated or modified the applicable Certification Criteria since Certification of the earlier version of the applicant's EHR product, the applicant shall pay the full amount of the application fee for a full inspection of the newer version of the applicant's EHR product, and, if Certification is achieved, a new three (3) year Certification term will

begin on the Batch Announcement Date of such newer version. The inspection process for such newer version will use the updated or modified Certification Criteria, and will encompass all areas of such newer version. Unless otherwise requested by the applicant, the earlier Certified version number(s) will remain on the list of Certified EHR products as well, until the end of the applicable Certification term(s) for those version(s).

4.0 Products Eligible for Certification

4.1 Comprehensive EHR Product

CCHIT has developed its criteria for 2006 to cover comprehensive EHR products targeted to ambulatory healthcare settings. To qualify for Certification, the product must be comprehensive (i.e., meeting all CCHIT criteria), be identified with a specific product name, version/release level, and date, be in production use at one or more live sites, and be available for sale in the US marketplace.

If an applicant's EHR product meets only a subset of the CCHIT Certification Criteria, that application for Certification may be combined with applications for Certification for other products or systems that, collectively, are comprehensive. The applicant must act as the prime vendor for such a combination, and as such shall submit the applications and pay applicable application fees. If the combination achieves Certification, the combination will receive a single listing on the CCHIT web site. At the applicant's option, the combination may be listed under the applicant's name (e.g., "Vendor A EHR System") or in a single combination listing (e.g., "Vendor A/Vendor O EHR Solution").

4.2 Practice Specialties and Specialized Markets

CCHIT recognizes the existence of practice specialties and vendors focusing on specialized markets within the broad spectrum of ambulatory care. We acknowledge that our first year criteria are broad-based and not necessarily appropriate for some specialty situations. CCHIT will include a disclaimer to this effect on its website in association with the listing of certified EHR products. CCHIT will examine the possibility of addressing certification for specialty-oriented products during 2006-2007.

4.3 Pre-Market Conditional Certification

For full Certification, the CCHIT criteria require that a product be in production use at one or more live sites. CCHIT will verify this status (see Section 5.0).

If an applicant's EHR product is ready for the marketplace, but not yet in production use, the applicant may so indicate on its application for Certification, and pay the full amount of the then-current application fee. In such event, the inspection process will proceed without verification of production use at a live site, and, if Certification is achieved, the applicant's EHR product will be granted Pre-Market Conditional Certification until it is implemented at its first live site. During the period the applicant's EHR product has the status of Pre-Market Conditional Certification, the applicant may reveal such status to its prospective customers but may not use the CCHIT Certification Seal in its generally distributed marketing and advertising materials in a way that implies that the applicant's EHR product is fully Certified. Promptly after applicant's EHR product is in production at a live site, the applicant shall supply CCHIT with contact information for such live site, and, upon CCHIT's verification of production use at such live site, the status of the applicant's EHR product will be converted to full Certification, with all marketing and advertising privileges and obligations as set forth in the Marketing Guidelines (see Section 6.0). There is no additional fee for such conversion to full Certification status.

4.4 Internally-Developed, Non-Marketed EHR Systems

CCHIT is aware that some organizations have developed their own EHR systems internally. Although we have not worked out details, CCHIT will assess the demand for a modified certification process that could permit these organizations to qualify for incentives or regulatory exemptions reserved for users of certified EHR products. If demand exists, we will develop an applicable process and fee structure.²

5.0 The Certification Process

For a step-by-step flowchart of the certification process, please refer to Figure 1 on the next page. Each of the areas and steps in this flowchart will be described in greater detail in this Section 5.0 of the Handbook.

² Please see Amendment to Certification Agreement opening certification to organizations with internally-developed EHRs as of November 1, 2006.

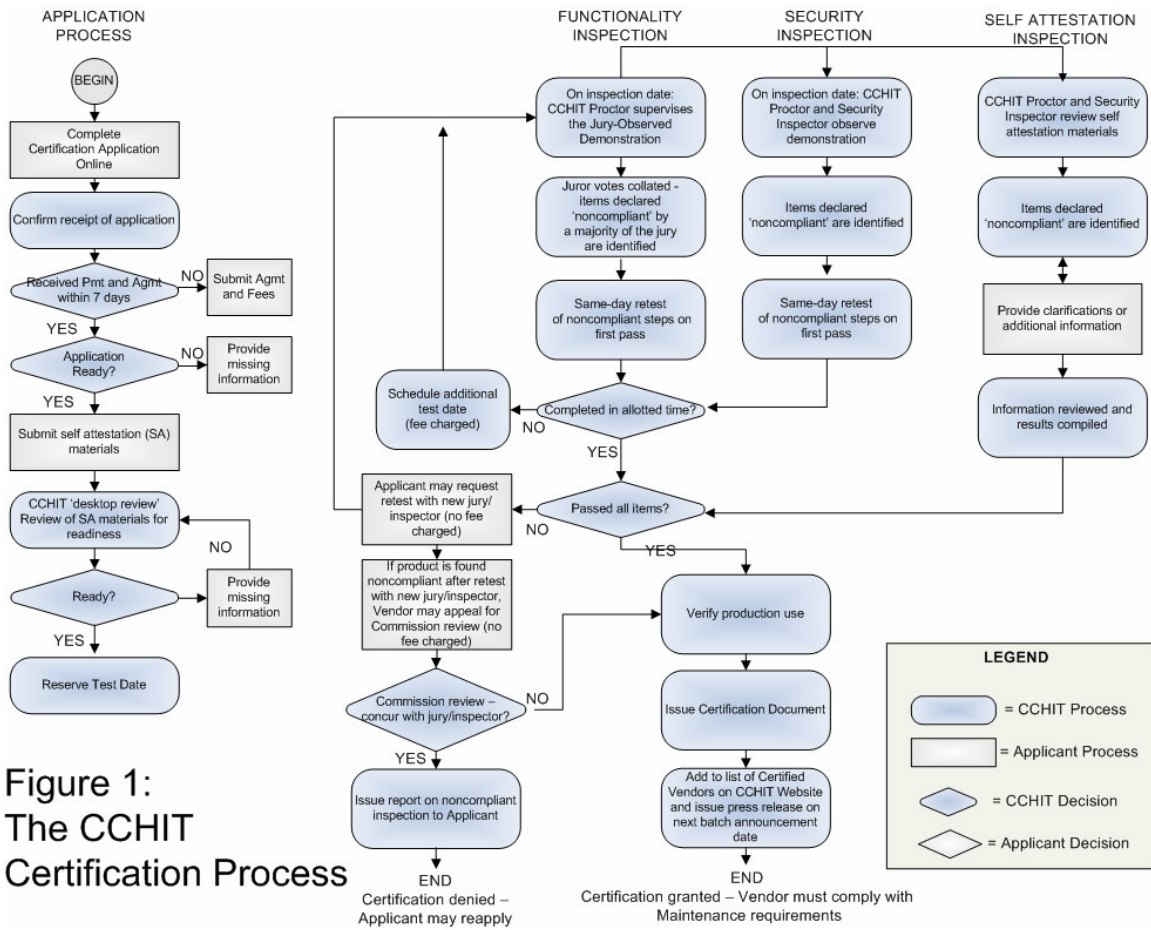


Figure 1:
The CCHIT
Certification Process

5.1 Application Process

Before applying, the applicant should carefully review the current CCHIT Certification Criteria, test scripts and inspection process as posted on the web site for the applicant' product. Application fees are nonrefundable, so the applicant should ensure that, in the applicant's opinion, the product satisfies all CCHIT criteria, and applicant personnel can successfully demonstrate that fact during the inspection process.

By initiating the application process, the applicant is bound by the terms and conditions of the CCHIT Certification Program as described in this Handbook.

5.1.1 Completing the Application

The applicant begins by registering at CCHIT's web site and completing an on-line application. The application requires basic company information such as the business name, address, and point of contact. The forms also require specific information on the product to be certified, such as the product name, version/release number, and other necessary product information.

The applicant shall make available personnel and facilities requested by CCHIT to verify the accuracy of information provided in the application.

The applicant must also provide contact information for one installed live site for purposes of verifying that the version is in full production use. By providing the contact information the applicant grants CCHIT permission to contact the site. (For a product that is not yet in production use, please see the section on "Pre-Production Conditional Certification" (See Section 4.3).)

5.1.2 Review Application

CCHIT will confirm receipt of the Certification application and will review the application for completeness. The applicant shall make available personnel and facilities requested by CCHIT to verify the accuracy of information provided in the Certification application. CCHIT will notify the applicant if the product does not qualify for Certification, such as non-EHR products, etc.

5.1.3 Submission of Signed Certification Agreement and Application Fee

The applicant must submit two (2) signed copies of the CCHIT Certification Agreement, downloadable from the CCHIT web site. The Agreement must be executed by an executive of the applicant organization who is authorized to execute binding contracts, and must be accompanied by a check for the full amount of the application fee and the first-year Certification maintenance fee.

5.1.4 Submitting Self-Attestation Materials

The applicant will be required to submit materials supporting those elements designated in the CCHIT self-attestation test script. Additional information regarding the self-attestation requirements and materials are provided on the CCHIT web site. Self-attestation materials must undergo and pass a desktop review (as described below) before an inspection date will be confirmed.

CCHIT shall retain this information as long as is necessary to maintain the Certification of that product. This information will be held in confidence and kept secure. CCHIT shall return these materials if the product is found to be non-compliant during the inspection process or when the Certification term ends.

CCHIT prefers to receive self-attestation materials in electronic form, but will also accept materials in printed form, as well as information provided through an on-line help system. Materials may be submitted as follows:

- 1) E-mail materials and/or notify CCHIT Certification Coordinator about interest in providing access to materials in electronic form to certify@cchit.org;
- 2) Send printed materials or CD-ROM with instructions via courier to:
CCHIT
233 N Michigan Ave, Suite 2150
Chicago, IL 60601

The information should be clearly marked as Self-Attestation Materials and include the applicant's name.

The applicant must submit the self-attestation materials no later than ten (10) calendar days after submitting the Certification application. CCHIT will not confirm inspection dates until the self-attestation materials are received and pass the desktop review process outlined below.

5.1.5 Desktop Review

Once the applicant submits the Certification application, the full payment, two (2) executed copies of the Certification Agreement and the self-attestation materials, CCHIT staff will conduct a "desktop review" of the application materials by:

- reviewing the self-attestation materials to assess their completeness or readiness for the inspection process,
- informing the applicant of any clarifications or information needed in the self attestation materials in order to begin the inspection,
- notifying the applicant upon successful completion of the desktop review.

If the applicant is unable to resolve all deficiencies in the application and related self-attestation materials to CCHIT's satisfaction, CCHIT may reject the application as incomplete. In this case, CCHIT will retain 15% of the application fee as a nonrefundable service charge. The applicant may reapply in the future by resubmitting its application and the full application fee and first-year Certification maintenance fee.

CCHIT will confirm the applicant's inspection date after the applicant successfully passes the desktop review process.

5.1.6 Scheduling Inspection Dates

When the applicant has received notice that the application has been accepted and passed desktop review, the applicant will be notified of available inspection dates. The applicant must reserve a single date for the Functionality Inspection, and another for the Security Inspection or request that the inspections occur on the same day.

Comment: The inspections may be conducted separately since they must be witnessed by personnel with different skill sets. In the future, when new versions of the Certification Criteria are released, an Interoperability Inspection will also be conducted, either as part of one of the other inspections or separately.

Inspection dates will be confirmed on a first-come-first-serve basis.

5.2 Inspection Process

While CCHIT continues the development of Certification Criteria in the areas of Functionality, Interoperability, and Security, Certification will initially only test the Functionality and Security criteria. With the advent of harmonized standards, to be delivered by the Health Information Technology Standards Panel (HITSP), testable Interoperability criteria will be added later.

CCHIT's inspection process is a rigorous, structured review of the product using three methods:

- Inspection of Self-Attestation Materials
- Jury-Observed Demonstration of clinical functionality
- Jury-Observed Demonstration of security functionality

These methods will be discussed in greater detail within the appropriate part of the Handbook.

CCHIT's test scripts are used to guide the sequence of the inspections, demonstrations and technical tests included in the inspection process to confirm compliance of the applicant's EHR product with the applicable Certification Criteria. The test scripts also provide guidance to the applicant for the inspection process. They are available on the CCHIT web site to enable the applicant to familiarize itself with them in preparation for the inspection process. CCHIT recommends that each applicant prepare for the inspection process by conducting practice runs with its own personnel in order to reduce the testing time required during the inspection process and thereby avoid the additional internal costs of prolonged testing, as well as fees for any additional blocks of testing time that otherwise might be required.

5.2.1 Functionality Inspection

CCHIT has developed an extensive set of Functionality criteria, and has determined that the most practical and reliable method of ensuring compliance with these criteria is via a Jury-Observed Demonstration. The inspection team consists of a CCHIT staff proctor and a jury made up of three clinical experts, at least one of whom must be a practicing physician. The inspection team witnesses a live demonstration of the product, following Test Scenarios 1, 2, and 3, containing a closely defined series of test steps. In addition, the CCHIT staff proctor will review self-attestation materials related to the Functionality criteria. (See Section 5.2.4 for more details.)

During the demonstration, the applicant has an operational version of the product to be inspected running at the applicant's own facility, operated by applicant personnel, while the Functionality Inspection team witnesses the demonstration via web conferencing technology and a simultaneous audio teleconference circuit. The CCHIT staff proctor and each of the jurors are at different locations, as is the applicant.

The CCHIT staff proctor will monitor the progress of the demonstration and ensure that each step in the applicable test scripts is completed by the applicant and observed by each of the jurors. Each juror will record on a worksheet his or her individual determination of compliance/non-compliance for each step. Any juror may ask the applicant to repeat any step if that juror did not adequately observe it.

It is the policy of CCHIT for jurors not to confer or discuss their votes during this phase of the Functionality Inspection. Each juror is required to note his or her reason for each vote for non-compliance for any step. CCHIT will retain all juror worksheets as part of the official record of the inspection process.

Collation of Votes — After completing a first pass through the test scripts, the applicant will have a rest period during which the CCHIT staff proctor and the jurors separately will reconvene on an audio teleconference to collate the votes. CCHIT uses a simple majority voting rule; therefore, a

step will be marked Non-compliant on First Pass only if two (2) or more of the jurors marked it as “non-compliant.” The CCHIT staff proctor is responsible for this collation process. The result of this process will be a list of test steps, if any, that were Non-compliant on First Pass, as well as the reasons for failure noted by the jurors.

Same Day Retest—If any steps were Non-compliant on First Pass, the applicant will be rejoined to the conference for a Same Day Retest of those steps. The CCHIT staff proctor will inform the applicant of the steps designated as Non-compliant on First Pass and the reasons listed by the jurors, and will request the applicant to repeat the non-compliant steps. The applicant may include adjacent steps in this demonstration if the applicant feels they are necessary to adequately demonstrate the non-compliant steps. During the Same Day Retest, the jurors will record on their worksheets any changes they wish to make in their votes.

Completion of Functionality Inspection—After completion of the retest, the CCHIT staff proctor will inform the applicant that its portion of the Functionality Inspection has been completed. Once the applicant has exited the conference, the CCHIT staff proctor will collate the jurors’ votes for the retested steps, using the same majority voting rule described in above, and then will end the Functionality Inspection conference.

5.2.2 Time Allotment for Functionality Inspection

The applicant and CCHIT will reserve a full, eight (8) hour day for the Functionality Inspection. If the applicant has not completed the first pass through the Test Scripts and any required Same Day Retest within this time allotment, the applicant may schedule additional testing time for a fee of \$1,000 per hour.

5.2.3 Security Inspection

The inspection team for Security criteria consists of the CCHIT staff proctor and a Security inspector.

In Test Scenario 4, the inspection team will observe a demonstration of Security capabilities of the applicant’s EHR product in the same remote demonstration environment described for the Functionality Inspection. However, the Security test scripts may require the applicant personnel to have access to the system beyond that of the normal user interface, e.g., administrative access to files, logs, etc. Since there is no need for collation of votes, the inspection team can request an immediate retest for non-compliant steps. In addition, the CCHIT staff proctor and Security inspector will review the self-attestation materials to assess conformance with Security criteria tested through self-attestation. (See Section 5.2.4 for more details.)

5.2.4 Time Allotment for Security Inspection

A half day, four (4) hours, will be reserved for the Security Inspection using Test Scenario 4, based on initial results suggesting that the test can be completed, on the average, in two (2) hours. If an applicant has not completed the first pass and a retest of any failed steps within four (4) hours, additional testing time can be scheduled in three (3) hour blocks at a fee of \$3,000 per block. To avoid this charge as well as internal costs of prolonged testing, applicants are advised to prepare for the test by conducting practice runs with their own personnel before the actual CCHIT inspection.

5.2.5 Review Self-Attestation Materials

For Test Scenario 5, CCHIT has determined that the most practical and reliable method of assessing compliance for certain criteria is through self-attestation and review of related product information.

For these items, the applicant attests that the product supports the identified Security or Functionality requirements and that any related information or documentation provided for that step reflects the actual capabilities of the product. The applicant submits these materials to CCHIT for inspection. The inspection is conducted without a web or audio conference session.

The CCHIT staff proctor and the Security inspector will review and verify that the materials supplied by the applicant prove compliance with the Certification Criteria, and that the applicant has signed an attestation as to the accuracy of the supporting materials.

CCHIT staff and the Security inspector will communicate with the designated applicant point of contact at intervals to resolve questions and request additional materials as needed. For items judged incomplete or non-compliant, the inspection team may request additional information or clarification. This works much like the retest process described in Section 5.2.7 below. The applicant will have an opportunity to provide additional information or clarification to demonstrate conformance with the test steps. Test steps found to be non-compliant” may also be appealed as described in Section 5.2.8 below.

5.2.6 Retesting with a New Jury

CCHIT will combine the results from the Functionality Inspection and the Security Inspection and inform the applicant which, if any, test script steps were judged as Non-compliant on First Pass and could not be resolved during the Same Day Retest (including during any additional testing time scheduled by the applicant pursuant to Sections 5.2.2 and 5.2.4). If the applicant believes, in good faith, that the inspection process results do not accurately reflect the compliance of the applicant’s EHR product with the Certification Criteria, the applicant may request a New Jury Retest. The New Jury Retest will test only the non-compliant items and will be recorded.

If the applicant’s EHR product is found non-compliant by the New Jury Retest, the applicant may file an Appeal for Commission Review.

If the New Jury Retest is completed within three (3) hours, there will be no additional fee for the New Jury Retest. Additional time required over three (3) hours for the New Jury Retest will be charged at \$1,000 per hour.

5.2.7 Appeal for Commission Review

As discussed above, if the applicant’s EHR product is found non-compliant after a New Jury Retest, then, if the applicant believes, in good faith, that the results do not accurately reflect the compliance of the applicant’s EHR product with the Certification Criteria, the applicant may submit an Appeal for Commission Review pursuant to the Appeal and Compliance Policy. CCHIT’s complete Appeal and Compliance Policy is included in Exhibit A of the Certification Agreement.

5.3 Certification Outcomes

After completion of the inspection process and of any New Jury Retests and Appeals for Commission Review, CCHIT will reach its decision regarding Certification of the applicant's EHR product and will notify the applicant's designated point of contact via email within five (5) days of its decision.

5.3.1 Products Achieving Certification

If the applicant's EHR product has successfully achieved Certification, CCHIT will issue to the applicant a Certification Document and the Seal. On CCHIT's next scheduled Batch Announcement Date, CCHIT will add the applicant to the list of Certified Vendors on the CCHIT web site and issue a press release regarding the Certification of the applicant's EHR product. In addition, CCHIT will post information specific to the applicant and the Certified product on the CCHIT web site, including the version of CCHIT's Certification Criteria used during the inspection process, the Batch Announcement Date and information about applicant's EHR product (such as name, version and applicant contact information). The applicant shall not make public announcements regarding Certification of the applicant's EHR product until the applicable Batch Announcement Date, if any. The applicant may prepare sales and marketing materials carrying the Seal at any time after achieving Certification, but may not distribute such materials until the applicable Batch Announcement Date. All such materials must comply with requirements of the Marketing Guidelines (see Section 6.0).

CCHIT, in accordance with its communication plan, will be actively engaged in efforts to communicate the benefits of investing in CCHIT certified products to the provider community through multiple communication channels.

5.3.2 Products Failing to Achieve Certification

If the applicant's EHR product is found non-compliant with the Certification Criteria, CCHIT will issue a confidential report to the applicant regarding the test items that led to such result. The applicant may reapply for Certification as soon as it has modified the applicant's EHR product or improved its preparation for the inspection process, by resubmitting in full the application fee and the first-year Certification maintenance fee. CCHIT shall not make any public report on the non-compliance of the applicant's EHR product with CCHIT's Certification Criteria.

5.3.3 Certification Descriptions and Disclaimers

On its web site, CCHIT will post disclaimers that caution potential purchasers of products about the limits of CCHIT's Certification. Among these is that our criteria at this point can only represent broad, basic capabilities, and that these may prove insufficient for some practice specialties, or may be inappropriate or excessive for others; that our criteria do not assess product usability; and other facts.

5.4 Juror Qualifications, Selection and Assignment

The jury panel for Functionality testing consists of three clinical experts, at least one of whom must be a practicing physician. The juror for Security testing is an IT Security expert. The jurors will be selected as follows:

- Position Descriptions will be posted on the CCHIT web site describing the qualifications, background and experience of prospective jurors.
- Organizations may nominate and sponsor individuals, filling out and submitting an on-line juror application.

- Individuals may apply without organizational sponsorship by filling out and submitting an on-line juror application.
- CCHIT staff will review and assess the juror applicants' qualifications and experience. This includes screening and rejecting any potential jurors on the basis of inadequate qualifications, background and experience, conflict of interest, or actual, potential or perceived bias.
- CCHIT staff take their recommendations for jurors to a subcommittee of the Commission for approval.

CCHIT jurors will be paid a nominal amount and must execute a contract with CCHIT covering Conflict of Interest and Confidentiality. Jurors must also complete an orientation and may be required to observe at least one inspection as a non-voting auditor before serving as a voting juror. Juror orientation will address the Certification Criteria, the Test Scenarios/steps, the CCHIT inspection process, and methods by which CCHIT works to avoid juror bias. From the Pilot Test, CCHIT has learned that juror reliability increases with experience. We will therefore endeavor to recruit and retain a core of experienced jurors who serve on multiple inspection sessions over the course of the year.

Once fully qualified, CCHIT will assign jurors from the jury pool to Functionality and Security Inspection dates based on their availability.

Juror performance will be monitored by CCHIT for consistency, reliability, and lack of bias (method to be determined in more detail with assistance from NIST) and remedial efforts will be undertaken by CCHIT as needed.

5.5 Buyer Complaint Process

CCHIT will maintain a complaint intake process on its web site in the event a buyer of a CCHIT Certified product has a grievance. CCHIT will process the complaints as follows:

- Keep a record of all complaints,
- Begin a staff investigation that includes consulting with the buyer and the vendor,
- Notify the vendor of the product of the results of that investigation,
- Refer complaints with staff documentation and vendor comments to the Commission's Appeal and Compliance Committee to recommend a course of action
- Document all actions taken based on the Committee's recommendations.

If a vendor has been found to have made substantial misrepresentations in their attestations to CCHIT, the vendor could be subject to penalties up to and including having Certification suspended and being disallowed from reapplying for Certification for a period of one (1) year.

6.0 Marketing Guidelines

These Marketing Guidelines are part of CCHIT's Certification Program. The terms and conditions for CCHIT Certification may be revised by CCHIT in its sole discretion. Without the prior written consent of CCHIT, each of the vendors participating in the Certification Program is prohibited from publicly disclosing any of the results of its participation, including, but not limited to, any written or oral comments made about the vendor or its EHR product by CCHIT or its jurors.

CCHIT's Certification Program assures the healthcare industry and healthcare consumers that EHRs with CCHIT Certification can be expected to deliver the following benefits:

- Increase the transparency of the EHR marketplace and reduce risk for physicians and hospitals that select, purchase, and implement HIT.

- Redirect HIT investment toward EHRs that have the necessary functionality to improve the quality, safety, and efficiency of care.
- Protect the privacy of health information by requiring adequate security standards within EHR products and network infrastructure.
- Ensure the interoperability of EHRs through standards-based compatibility with the emerging national health information network (NHIN) architecture.
- Encourage healthcare purchasers and payers to offer incentives to physicians and other providers to adopt EHRs.

Taken together, these benefits have the potential to accelerate the widespread adoption of robust, interoperable EHRs.

To achieve these goals, vendors can use their Certification status as a visible part of their marketing and advertising materials.

All marketing promotion that refers to CCHIT Certification must be clear and factual. Compliance with these guidelines ensures a level playing field in the competitive HIT marketplace and protects the integrity of CCHIT's Certification Program.

Certification

References to the terms "marketing and/or advertising materials," "advertising" or "promotional materials" in these Guidelines include all publicly consumable external communications and material to be published in or disseminated through the following:

Print: newspapers, magazines, professional journals, newsletters, direct mails, directories, product collateral, product packaging, product labeling, product documentation

Electronic: web content, e-newsletters, on-line advertising, blogs, downloadable material, Flash animations, web seminars or presentations, e-mail promotions, search optimization, CDs, photography, video or film

Broadcast: radio, television, web

Advertising specialties and premiums: bags, t-shirts, mugs, commemoratives, etc.

Vendors should read and examine these Marketing Guidelines prior to producing any promotional material that refers to CCHIT or CCHIT's Certification Program.

Policy Note: Certified vendors are required to submit to CCHIT, for its prior review and written approval, all press releases mentioning CCHIT, CCHIT's Certification Program or products with CCHIT Certification. Vendors are not required to submit other promotional materials to CCHIT for approval. Vendors will be held accountable for any violations of this policy and these Marketing Guidelines. Any failure to secure CCHIT's prior written approval for press releases and any variance from pre-approved statements and uses of Certification Seals in a vendor's marketing, advertising or business materials, its public interviews, or its publicly observed behaviors shall be considered a violation of this policy and grounds for revocation of the vendor's Certification status. This policy extends to any statements made

by vendors that are in any way false and misleading, as determined by CCHIT in its sole discretion.

Contact CCHIT's Communication Director at (503) 703-0813 for additional information or clarification about these Guidelines.

Only vendors that have received a Certification Document and Seal from CCHIT indicating they have successfully met all Certification Criteria or their substantial equivalents within an identified program category and have completed the appropriate agreements to earn CCHIT Certification can market or advertise products as CCHIT Certified.

If Certification is suspended or withdrawn for any reason, all materials referring to Certification must be immediately removed from distribution, and a vendor must discontinue any use of references to Certification.

Reference to CCHIT Certified Status:

In reference to its status as CCHIT Certified, a vendor must clearly indicate:

- The name of the vendor
- The version of the EHR product earning the Certification
- The year for which CCHIT has certified the EHR product
- The category of Certification

The form of such a reference shall be as follows: "(Vendor name) is CCHIT CertifiedSM for their product, (product name and version), for (CCHIT year), (category)." An example of such a reference would appear as follows: "XYZ Systems is CCHIT CertifiedSM for their product, XYZ Software Version 1.2.3, for CCHIT Ambulatory EHR 2006."

Use of Seals and Certification:

CCHIT issues Seals for vendors achieving CCHIT Certification. Only vendors achieving a CCHIT Certified status may display the Seal in marketing and advertising material, in accordance with the following guidelines:

The CCHIT Certified Product Certification Seal:



CCHIT grants each vendor that is given a CCHIT Certified status a nonexclusive right to use the CCHIT Certified Product Certification Seal on, or in connection with, the vendor's promotional activities for the shorter of: (i) the time period that the CCHIT Certified version is commercially available; or (ii) the Certification term, which is three (3) years from the date of Certification plus any renewal term. CCHIT's revocation of a vendor's Certification status shall immediately terminate a vendor's right to use the Seal. The CCHIT Certified Product Certification Seal is the property of CCHIT, and the vendor may use the Seal only in accordance with these Marketing Guidelines.

Vendors shall display the CCHIT Certified Product Certification Seal in a readable format and the overall depiction shall be consistent with CCHIT's graphical image, typography and designated colors for such Seal.

The CCHIT Certified Product Certification Seal must not be reshaped, resized or manipulated in any way. The CCHIT Certified Product Certification Seal may be printed in one-color or two-color formats.

The CCHIT Certified Product Certification Seal must never appear more prominently than the name of the vendor. If the Seal is used on a web site, visitors to the site must be able to clearly identify which products have been Certified by CCHIT and which have not. No degree of acceptability, level of safety or protection should be implied in the vendor's promotional materials.

Graphic standards for use of the Seal are included in Policies for Use at www.cchit.org.

Use of Statements:

CCHIT Certified Vendors may use the following statements, alone or in combination, to identify or describe CCHIT, CCHIT's Certification Criteria or its inspection process. Vendors may also reference the CCHIT web site at www.cchit.org for additional information.

Approved Descriptions about CCHIT

- "The Certification Commission for Healthcare Information Technology (CCHITSM) is a nonprofit, independent initiative to certify healthcare information technology (HIT) products."
- "CCHIT is a Recognized Certification Body for EHRs."
- "CCHIT was founded in July 2004 by three healthcare information technology (HIT) industry associations – the American Health Information Management Association (AHIMA), the Healthcare Information and Management Systems Society (HIMSS) and The National Alliance for Health Information Technology (Alliance)."
- "CCHIT's mission is to accelerate the adoption of robust, interoperable healthcare information technology throughout the United States by creating an efficient, credible, sustainable mechanism for the certification of healthcare IT products."
- "The U.S. Department of Health and Human Services (HHS) awarded CCHIT a three-year contract in September 2005 to develop and evaluate certification criteria and an inspection process for ambulatory (office and clinic) EHRs, inpatient (hospital) EHRs and the networks through which they interoperate."
- "The goals of CCHIT product certification are to:
 - "Reduce the risk of HIT investment by providers
 - "Ensure interoperability (compatibility) of HIT products
 - "Enhance the availability of HIT adoption incentives from purchasers and payers
 - "Protect the privacy of personal health information"
- "CCHIT operates under the direction of a 21-member Board of Commissioners led by Chairman Mark Leavitt, M.D., Ph.D. Commissioners represent a range of stakeholders

including providers, vendors, payers and purchasers, public health agencies, quality improvement organizations, clinical researchers, informatics experts, government agencies and consumers.”

- “For more information, visit www.cchit.org.”

Approved Descriptions about CCHIT’s Certification Program

- “CCHIT’s certification compliance criteria and its design for a certification inspection process have been thoroughly researched, taking into account the state of the art of EHRs and available standards, and comparing certification processes in other industries and other countries.”
- “CCHIT’s certification program is reflective of the broad constituency base of CCHIT’s all-volunteer Work Groups and Board of Commissioners.”
- “CCHIT’s Certification program sets the health IT industry bar for:
 - “Functionality – setting features and functions to meet a basic set of requirements
 - “Interoperability – first steps in enabling standards-based data exchange with other sources of healthcare information
 - “Security – ensuring data privacy and robustness to prevent data loss”
- “CCHIT’s inspection process is based on real-life medical scenarios designed to test products rigorously against the clinical documentation needs of providers and the quality and safety needs of healthcare consumers and payers.”
- “CCHIT’s certification program will improve healthcare information technology adoption by physicians and other clinicians who are not technology experts, and will, in turn, improve the quality and safety of care that they deliver to healthcare consumers.”

Approved Descriptions about CCHIT EHR Certification

- “CCHIT CertifiedSM product certification designates that a healthcare information technology product has been tested against a comprehensive set of functionality, interoperability and security criteria and has passed inspection of 100 percent of the criteria.”
- “CCHIT CertifiedSM product certification provides an objective set of criteria against which health information technology products can be measured to enable purchasers to reliably make an investment in those products and to assure healthcare consumers that they can trust their healthcare information to be stored in those products.”

Approved Descriptions about “CCHITSM”

“CCHITSM” is a service mark of the Certification Commission for Healthcare Information Technology.

The service mark symbol SM should be applied directly after the acronym “CCHIT.” The vendor need only apply the service mark to the first reference of the term “CCHIT” within the written material.

At the bottom of the page where the service mark first appears there should be a footnote which states:

“CCHITSM is a service mark of the Certification Commission for Healthcare Information Technology.”

Approved Descriptions about “CCHIT CertifiedSM”

“CCHIT CertifiedSM” is a service mark of the Certification Commission for Healthcare Information Technology.”

The service mark symbol SM should be applied directly after the word “CCHIT Certified.” The vendor need only apply the service mark to the first reference of the term “CCHIT Certified” within the written material.

At the bottom of the page where the service mark first appears there should be a footnote which states:

“CCHIT CertifiedSM is a service mark of the Certification Commission for Healthcare Information Technology.”