



**Certification Commission
for Health Information
Technology**

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Certification Handbook

CCHIT Certified® 2011
Certification Program

April 7, 2010

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1. OVERVIEW OF CCHIT CERTIFIED® 2011 CERTIFICATION PROGRAMS

The **CCHIT Certified® 2011** certification program, opening on April 7, 2010, is one of two distinct programs of certification offered by CCHIT:

- CCHIT Certified® 2011
- Preliminary ARRA IFR Stage 1

Current applicants may choose to test under both programs (*see below) when a CCHIT Certified 2011 application is received.

In the CCHIT Certified 2011 program, products are rigorously inspected against integrated EHR functionality, interoperability, and security criteria independently developed by the Commission's broadly representative, expert work groups, using the Commission's published testing methods. The CCHIT Certified 2011 program tests "core" domains plus "optional" add-on certifications. The *Ambulatory EHR*, *Inpatient EHR* and *Emergency Department EHR* certification programs have all been significantly updated from 2008, with additional functionality, interoperability, and security requirements. A completely new offering this year is the certification program for stand-alone *ePrescribing* products. Later this year, new stand-alone CCHIT Certified programs will be introduced for *Behavioral Health EHRs* and *Long Term and Post Acute Care EHRs*.

Applicants bringing an Ambulatory EHR for a core certification may choose to qualify for optional, additional certifications in *Child Health* or in *Cardiovascular Medicine* (with optional *Advanced Reporting*). Optional add-on certifications will also be available later this year for *Behavioral Health*, *Clinical Research* and *Dermatology*.

Health IT companies who have products certified in all three domains—Ambulatory, Inpatient, and Emergency Department—can qualify for the additional option of *Enterprise* certification that demonstrates interoperability and integration between the systems in those three settings. The cost for add-on certifications is lower when these optional certifications are performed at the same time as the base certification rather than at a later date.

To increase buyer assurance, all fully certified products in the CCHIT Certified 2011 program are subject to additional testing: key aspects of successful use are verified at live sites, and, for Ambulatory EHR products, basic usability is rated. Only *Conditional* certification is issued until live site verification is complete and, for Ambulatory EHRs, all

electronic prescribing certifications are in place. CCHIT Certified 2011 certification is intended to serve health care providers looking for maximal assurance that a product will meet their complex needs.

The **Preliminary ARRA IFR Stage 1** program tests complete EHRs or EHR modules against criteria and standards published by the US Department of Health and Human Services (HHS) in the Interim Final Rule (IFR) on “Health Information Technology: Initial Set of Standards, Implementation Specifications, and CCHIT Certified Certification Criteria for Electronic Health Record Technology” on January 13, 2010. This program, based on the federal standards for certified EHR technology to support the Stage 1 incentives under the American Recovery and Reinvestment Act of 2009 (ARRA), is designed to demonstrate that a vendor’s product is extremely well prepared to be certified once Office of the National Coordinator (ONC) accredited testing and certification becomes available. The final criteria and test procedures are not yet available, nor has CCHIT been accredited yet by ONC. When those events occur, CCHIT will replace the Preliminary ARRA program with a final, ONC- accredited ARRA certification program.

*For a limited time, applicants under the CCHIT Certified 2011 certification program have the opportunity, for no additional charge, to also test and certify their product in the Preliminary ARRA IFR Stage 1 program. Although applicants must complete their CCHIT Certified testing within the required 90 day window, they may choose to test against the Preliminary ARRA IFR Stage 1 program now, or alternatively, wait and test later under the final ARRA Stage 1 requirements once the final criteria are published by HHS. Applicants who choose to test against the Preliminary requirements will be first in line to schedule any necessary retest against the final Stage 1 requirements at no additional charge. Applicants who successfully complete the Preliminary ARRA IFR Stage 1 requirements can demonstrate that their product has a high level of readiness to meet the final ARRA requirements.

All testing for Preliminary ARRA IFR Stage 1 or final ARRA Stage 1 will be conducted separately from the CCHIT Certified testing. Applicants may schedule ARRA testing to be conducted on the same day as their CCHIT Certified inspection, however, the testing process, procedures and methods utilized for the ARRA testing will follow those described in the Preliminary ARRA IFR Stage 1 Certification Handbook posted on the CCHIT Web site. Please refer to that document for any questions related to the Preliminary ARRA certification program or testing.

Applicants who certify products in both programs receive two separate listings on the CCHIT Web site. Listings include a Certification Facts™ label describing all certifications granted, including optional add-ons for patient populations, care settings or specialty medicine in the CCHIT Certified program and, in a separate listing, an indication of which EHR modules were determined to be compliant with HHS-developed criteria in the Preliminary ARRA IFR Stage 1 or final ARRA program.

1.1. AMBULATORY EHR 2011 CERTIFICATION

CCHIT will offer its Ambulatory EHR 2011 Certification program beginning April 7, 2010. There are new requirements for functionality, interoperability, and security compared with our 2008 program.

There have been several detailed changes to the requirements for interoperability for this certification cycle. We encourage all applicants to carefully review the new CCHIT Certified 2011 Interoperability Test Guide on our Web site for details regarding the changes in this area.

CCHIT offers the option for Ambulatory EHRs who apply for this program to also apply for and test against any or all of the Preliminary ARRA IFR Stage 1 components for Eligible Providers at no additional charge. Ambulatory applicants who are interested in demonstrating compliance with the Preliminary ARRA IFR Stage 1 criteria are encouraged to review the certification materials for Eligible Providers posted on the CCHIT Web site for guidance on the additional test steps that would be required. Alternatively, Ambulatory applicants may choose to complete their CCHIT Certified Ambulatory EHR certification now and wait to test against the final Stage 1 requirements once they are published by the government. CCHIT will quickly adjust our testing materials and offer applicants the opportunity to return on a priority basis and test for full compliance at no additional cost.

Interoperability requirements for the Preliminary ARRA IFR Stage 1 testing can be found in the Preliminary ARRA IFR Stage 1 Interoperability Test Guide on our Web site.

1.2. CHILD HEALTH CERTIFICATION OPTION

Those familiar with CCHIT history are aware that certain functionalities believed to be necessary in providing health care for children were kept out of the Ambulatory EHR requirements because of the concerns of vendors offering products targeted to settings focused exclusively on adult medical care. To resolve this issue, CCHIT began offering an optional Child Health certification in 2008 which can be added onto the base

Ambulatory EHR certification. This certification option addresses the general health care needs of children as a *population*, and does not imply that the EHR system has every capability that might be needed in pediatric subspecialties. The Child Health certification requirements have been expanded for the CCHIT Certified certification to include some additional important areas for care, treatment and well-being of pediatric populations. Applicants that wish to distinguish their products as being suitable for children's general health care needs are invited to apply for and add this certification to their Ambulatory EHR certification.

Applicants are encouraged to apply for this option at the time they apply for the core Ambulatory EHR certification since this is the most convenient and cost-effective approach.

If a product does not successfully pass the Child Health specific test steps but does pass 100% of the remaining Ambulatory steps, the Ambulatory EHR core certification will still be issued.

If you have already obtained your Ambulatory EHR certification and you would like to apply later for the Child Health option, you may do so; however, this will be a higher total cost option as indicated in Fee Schedule (Section 6). In this case, you will be asked to perform any applicable set-up steps and relevant Ambulatory test steps in the scenarios in order to execute the required Child Health specific test steps. Of course, you must ensure that any prerequisite steps are properly executed in order to ensure that the Child Health specific actual results clearly demonstrate the expected results as documented in the Test Scripts.

You will be required to maintain a current Ambulatory EHR core certification in order to maintain your Child Health certification option. If, at any time, your Ambulatory EHR certification expires, is revoked or suspended, the Child Health certification option will also be expired, revoked or suspended accordingly.

1.3. CARDIOVASCULAR MEDICINE CERTIFICATION OPTION

CCHIT is also offering a Cardiovascular Medicine certification option. As with the Child Health option, this optional certification also requires that you achieve and maintain a current Ambulatory EHR certification. This offering addresses the specialty of Cardiovascular Medicine in the ambulatory setting.

The Cardiovascular Medicine Test Script is a separate scenario, but does require that you perform the Ambulatory Test Script set-up procedures prior to its execution. There are additional Cardiovascular Medicine specific set-up requirements, which are outlined in the Ambulatory EHR Test Script set-up information.

In addition to the base Cardiovascular Medicine requirements, there are Advanced Reporting segments included in this Test Script. These Advanced Reporting requirements are highlighted in the script and they are optional for Cardiovascular Medicine certification. Applicants who are able to demonstrate compliance with **all** of the optional Advanced Reporting requirements will receive additional certification recognition for this accomplishment on the CCHIT Web site.

Similar to the Child Health option, you are encouraged to apply for and perform the Cardiovascular Medicine option at the same time as you apply for and perform the core Ambulatory certification.

If a product does not successfully pass the Cardiovascular Medicine test steps but does pass 100% of the remaining Ambulatory steps, the Ambulatory EHR core certification will still be issued.

You also have the option of applying for and performing your Cardiovascular Medicine certification option on a later date; however, this will involve a higher total cost as indicated in the Fee Schedule (Section 5). If you are performing your Cardiovascular Medicine inspection at a later date, you will need to ensure that any relevant set-up steps that are outlined in the Ambulatory Test Scripts are performed to ensure that you can properly execute the Cardiovascular Medicine Test Script and demonstrate the expected results.

Again, you will be required to maintain a current Ambulatory EHR core certification in order to maintain your Cardiovascular Medicine certification option.

If at any time your Ambulatory EHR certification expires, is revoked, or suspended, the Cardiovascular Medicine certification option will also be expired, revoked, or suspended at that time.

1.4. INPATIENT EHR 2011 CERTIFICATION

CCHIT will offer its Inpatient EHR 2011 Certification program beginning April 7, 2010. There are new requirements for functionality, interoperability, and security compared with our 2008 program.

There have been several detailed changes to the requirements for Inpatient interoperability for this certification cycle. We encourage all applicants to carefully review the new CCHIT Certified 2011 Interoperability Test Guide on our Web site for details regarding the changes.

CCHIT offers the option for Inpatient EHRs who apply for this program to also apply for and test against any or all of the Preliminary ARRA IFR Stage 1 components for Hospitals at no additional charge. Inpatient applicants who are interested in demonstrating compliance with the Preliminary ARRA IFR Stage 1 criteria are encouraged to review the certification materials for Hospitals posted on the CCHIT Web site for guidance on the additional test steps that would be required. Alternatively, Inpatient applicants may choose to complete their CCHIT Certified Inpatient EHR certification now and wait to test against the final Stage 1 requirements once they are published by the government. CCHIT will quickly adjust our testing materials and offer applicants the opportunity to return on a priority basis and test for full compliance at no additional cost.

Interoperability requirements for the Preliminary ARRA IFR Stage 1 testing can be found in the Preliminary ARRA IFR Stage 1 Interoperability Test Guide on our Web site.

1.5. EMERGENCY DEPARTMENT EHR 2011 CERTIFICATION

CCHIT will offer its Emergency Department EHR 2011 certification program beginning April 7, 2010. As with our other EHR certification programs, the criteria and Test Scripts for this domain have been updated for functionality, interoperability, and security capabilities.

Since the Emergency Department EHR is a departmental component of an Inpatient electronic health record system, CCHIT offers the option for Emergency Department EHRs who apply for this program to also apply for and test against any or all of the Preliminary ARRA IFR Stage 1 components for Hospitals at no additional charge. Emergency Department applicants who are interested in demonstrating compliance with the Preliminary ARRA IFR Stage 1 criteria are encouraged to review the certification materials for Hospitals posted on the CCHIT Web site for guidance on the additional test steps that would be required. Alternatively, Emergency Department applicants may choose to complete their CCHIT Certified Emergency EHR certification now and wait to test against the Final Stage 1 requirements once they are published by the government. CCHIT will quickly adjust our testing materials and offer applicants the opportunity to return on a priority basis and test for full compliance at no additional cost.

Interoperability requirements for the CCHIT Certified 2011 Emergency Department EHR domain focus on laboratory messaging. For more information regarding how to prepare for the lab messaging component, please refer to the CCHIT Certified 2011 Interoperability Test Guide on our Web site.

Interoperability requirements for the Preliminary ARRA IFR Stage 1 testing can be found in the Preliminary ARRA IFR Stage 1 Interoperability Test Guide on our Web site.

1.6. ENTERPRISE CERTIFICATION OPTION

For applicants offering EHR product(s) in all three 2011 certification domains— Ambulatory, Inpatient, and Emergency Department, CCHIT continues to offer an optional Enterprise certification. This program will be available to any applicant who achieves and maintains current EHR certifications, through a single product or combination of products, in all three domains for the current certification cycle. To obtain the optional Enterprise certification, applicants will be required to execute the Enterprise Test Script that demonstrates interoperability and integration between all three domains.

If at any time any of the core Ambulatory, Inpatient, or Emergency Department certifications expire, are revoked, or suspended, the Enterprise certification option will also be expired, revoked, or suspended at the same time.

1.7. EPRESCRIBING 2011 CERTIFICATION

For applicants offering product(s) for ePrescribing, CCHIT is now offering a stand-alone ePrescribing certification program. This testing process for ePrescribing products contains requirements for functionality, interoperability and security and is new for the 2011 testing cycle.

CCHIT offers the option for ePrescribing EHRs who apply for the CCHIT Certified program to also apply for and test against up to six (6) of the Preliminary ARRA IFR Stage 1 components for Eligible Providers at no additional charge. ePrescribing applicants who are interested in demonstrating compliance with more than six (6) of the Preliminary ARRA IFR Stage 1 criteria are subject to additional fees based on the number of additional modules they wish to test against. The costs for the additional modules are outlined in the Fee Schedule in the Preliminary ARRA IFR Stage 1 Certification Handbook. ePrescribing applicants who are interested in testing against the Preliminary ARRA IFR Stage 1 criteria are encouraged to review the certification materials for Eligible Providers posted on the CCHIT Web site for guidance on the additional test steps that would be required. Alternatively, ePrescribing applicants may choose to complete their CCHIT Certified ePrescribing EHR certification now and wait to test against the final Stage 1 requirements once they are published by the government. CCHIT will quickly adjust our testing materials and offer applicants the opportunity to return on a priority basis and test for full compliance at no additional cost.

Interoperability requirements for the CCHIT Certified 2011 ePrescribing certification are discussed in the CCHIT Certified 2011 Interoperability Test Guide on our Web site.

Interoperability requirements for the Preliminary ARRA IFR Stage 1 testing can be found in the Preliminary ARRA IFR Stage 1 Interoperability Test Guide on our Web site.

2. THE CERTIFICATION PROCESS

After accepting your application for certification, CCHIT arranges to inspect your EHR product for compliance with the current CCHIT Certified® Certification Criteria and Test Scripts for Functionality, Interoperability, and Security. The criteria were developed using available, widely accepted industry standards and refined with input from a wide range of stakeholders in an open, consensus-based process. In addition to the CCHIT Certified testing, you may also choose to test against any or all of the separate Preliminary ARRA IFR Stage 1 modules to demonstrate compliance. The Preliminary ARRA IFR Stage 1 materials were developed using the Interim Final Rule (IFR) on “Health Information Technology: Initial Set of Standards, Implementation Specifications, and CCHIT Certified Certification Criteria for Electronic Health Record Technology” published by the U.S. Department of Health and Human Services (HHS) on January 13, 2010.

Since the criteria and standards for the Preliminary ARRA IFR Stage 1 modules may not be finalized until the federal government publishes a Final Rule in the Federal Register and the National Institute of Standards and Technology (NIST) completes its work on test procedures, test data, and test tools, CCHIT will offer the ability to certify against the current materials, and then quickly test any gaps on a priority basis once the Final Rule and testing procedures are available. There will not be any extra charge for applicants to conduct a retest if one is necessary.

Alternatively, applicants may choose to complete their CCHIT Certified EHR certification now and wait to test against the final ARRA Stage 1 requirements once they are published by the government and CCHIT has adjusted the testing materials.

All testing for Preliminary ARRA IFR Stage 1 or final ARRA Stage 1 will be conducted separately from the CCHIT Certified testing. Applicants may schedule ARRA testing to be conducted on the same day as their CCHIT Certified inspection, however, the testing process, procedures and methods utilized for the ARRA testing will follow those described in the Preliminary ARRA IFR Stage 1 Certification Handbook posted on the CCHIT Web site. Please refer to that document for any questions related to the ARRA certification program or testing.

The CCHIT Certified EHR inspection process employs a combination of the following methodologies:

- Documentation review

- Juror-observed demonstrations
- Technical testing

All inspection processes are accomplished ‘virtually’ using a combination of online forms, electronic mail, telephone and Web-conferencing tools to allow jury observation of demonstrations, and online and downloadable technical testing tools. There is no travel involved for vendors or for the CCHIT inspection team.

Before applying, you should familiarize yourselves with the process and certification requirements by thoroughly reviewing this Certification Handbook, CCHIT Certified 2011 Certification Criteria, CCHIT Certified 2011 Test Scripts, and CCHIT Certified 2011 Interoperability Test Guide documents on the CCHIT Web site (<http://cchit.org>). Review the material carefully, make any necessary adjustments to your product, and practice your demonstration of the Test Scripts before you apply. Applicants that prepare and practice the Test Scripts thoroughly in advance have been found to complete the inspection process more quickly and avoid incurring extra costs for extended testing or retesting. In order to ensure that certified products are solid, market-ready versions, CCHIT strictly forbids modification of products during the testing process; evidence of this activity can result in failure of the inspection and forfeiture of the application fee.

Certification requires 100% compliance with all criteria unless they are designated as Optional (labeled as Optional in the Criteria document and highlighted in yellow in the Test Script). For criteria that are not met on the initial round of inspection, there are retesting procedures as well as an appeal process, described in the Retest and Appeal Mechanisms (Section 2.10).

If an applicant is able to demonstrate that the product meets 100% of the criteria, the inspection staff will take the final step of verifying that the product is in use in at least two live sites for a minimum of forty-five (45) days. This verification is also conducted remotely, by telephone or e-mail. Besides verifying use at two live sites, the staff will verify that the sites are using key functionalities required for CCHIT Certified 2011 Certification. The applicant may submit additional live sites if necessary to verify actual use of key functionalities. It is not necessary for all of the key functionalities to be in use at any one site.

New products not yet in use at two customer sites can receive Pre-Market Conditional Certification. Products in use at one live site will remain at Pre-Market status until two reference sites have been verified. This fact will be clearly displayed in the CCHIT online product directory. As soon as the product is in use at 2 sites for the minimum forty-five (45) day period and this has been verified by CCHIT, the product will receive a status of Fully Certified. All certified EHR products have one full year from their certification anniversary date to attain Full Production certified status or the product will be removed

from the posted products list on the CCHIT Web site. To re-instate the product listing, the applicant must submit the required reference sites and they must be verified as described above.

When the inspection process is complete, the product will become “CCHIT Certified 2011” for the specific certification domain and version (e.g., CCHIT Certified ® 2011 Ambulatory EHR). CCHIT will issue a Certificate, recognition on the CCHIT Web site (which publicly confirms certification), and the limited rights to use the CCHIT Certified ® Seal for the specific domain and optional additional certifications (if Fully Certified status has been attained). CCHIT also provides instructions on using the Seal in its Marketing Policies – CCHIT Certified 2011 (Section 4) and in Usage Guidelines issued with the Seal.

Once products are certified, applicants may, at their option, notify CCHIT when new versions are released and request to have their version information updated on the Web site. CCHIT will allow subsequent versions of a certified product to be marketed as certified as long as the applicant has not removed capabilities needed for compliance with the CCHIT Certified Certification Criteria. For products offered under an Open Source licensing model, the organization or community submitting the product for certification shall be responsible for determining and enforcing its own policy regarding labeling of subsequent versions of the product as certified. Applicants who would like multiple listings of 2 or more versions of a product on the CCHIT Web site may request this using the Product Update Form, available from the Certification Program Team, and submitting the required fee as described in Section 6.

2.0 Before You Apply

Well before applying; ensure that your development team has had the opportunity to conduct a thorough self-assessment of your product against all of the applicable criteria and steps in the Test Scripts. The Test Scripts are available on the CCHIT Web site to enable you to familiarize yourself with them in preparation for the inspection process. Your product must support 100% of the criteria prior to applying for certification.

Once you are confident that your product can support the criteria, you should begin practicing the set up and execution of the Test Scripts and begin assembling the Self-Attestation materials. For all of the interoperability testing requirements, make sure you have thoroughly practiced using the sample test files and tools provided to assist in that preparation as noted in the CCHIT Certified 2011 Interoperability Test Guide.

Once you are confident that you can execute 100% of the test steps, clearly demonstrate the expected results, and have assembled the Self-Attestation materials, you are ready to submit your application. The following checklist should help you to:

- Prepare complete product evaluation and gap analysis
- Resolve product deficiencies
- Assemble the team
 - Team members have the time to prepare and demonstrate
 - Team members have the requisite experience to adequately prepare and demonstrate the product's compliance
- Verify that the product is stable and will perform during the tests.
- Prepare Self-Attestation materials
- Conduct practice runs
- Verify that the demonstrations can be completed in the allotted times

Please keep in mind that product modifications are not allowed during testing and that application fees are nonrefundable.

2.1. WHEN CAN YOU APPLY?

CCHIT will accept applications on a continuous basis for the CCHIT Certified 2011 Certification program beginning on April 7, 2010. CCHIT will announce certified products by posting them on our Web site as certification is attained. Applicants are welcome to drop Press Releases of their accomplishments following the posting on the CCHIT Web site and in accord with the CCHIT Marketing and Public Relations Policies.

2.2. APPLYING FOR CERTIFICATION

2.2.1. Completing the Application

The CCHIT Certified 2011 Application for certification is available online at <http://cchit.org> under the "Get Certified" tab. Select the appropriate domain (Ambulatory, Inpatient, Emergency Department or ePrescribing) and the application link should be available on the right hand side of the web page. You will be required to access, complete and submit the information in the online form in order to initiate the certification process. You should be prepared to provide the following information when you access the form:

- Contact Information:
 - Company name and address
 - Primary contact information

- Secondary contact information
- Billing contact information
- Marketing contact information
- Certification Program and / or Option
- Production or Pre-Market Certification
- Commercial or Internal use
- Single or Joint Application: if you have multiple vendors co-applying for joint certification, the co-applicant's company name and product information.
- Product Name, Version Number and Release Date
- Co-Applicant Product Name, Version Number and Release Date (if applicable)
- Reference Site Information (if applying for Full Certification)
- Product Configuration Information: you will be asked to provide product specific information for the product configuration you will be bringing for certification. If you are submitting a joint application, you will be requested to provide product information for each product:
 - Product Description
 - Product Architecture
 - Application Hosting Model
 - Database Server OS Support
 - Browser Support
 - Database Support
 - Other Components (describe)
- Organization and Product Information and Metrics:
 - Annual Revenues (in ranges)
 - Core Market Size (in ranges - based on number of physicians in the practice for Ambulatory, number of beds for Inpatient, and number of annual visits for Emergency Department)
 - Number of Live Sites (in ranges - both for the version being certified as well as for all versions of the product)
 - Number of Users (in ranges - on all versions of the product)
 - Number of Employees (in ranges)

- Number of Years in Business (in ranges)
- Check box if you want your Key Company and Product Metrics published in the CCHIT Certified EHR Product Directory
- Request for ARRA Testing (Yes or No)
 - Selection of the ARRA Modules to be Tested

We realize that the application form is quite extensive. Please note that you will have the opportunity to save your form intermittently if you do not complete the process so you can complete the online form in several sessions. After you have finished completing the form, it is important that you carefully review your responses prior to submitting your application at the end. **Once you hit “submit” at the end of the form you will not have the opportunity to access the completed form to change your responses.** When you are confident that your application is complete and accurate, please hit the “Submit” button at the bottom of the page. Once you submit your electronic application you will receive an automatic reply from CCHIT acknowledging receipt and providing a brief outline of the next steps in the certification process.

2.2.2. Reference Site Information

To obtain fully certified status, you will be asked to provide at least two (2) live Reference Sites as noted in Completing the Application (Section 2.3.1). You will need to provide contact information for the installed live sites for purposes of verifying that the tested product is in full production use. The sites must have the system installed for at least 45 days and have no financial relationship with the applicant to be eligible to be used for the Reference Verification.

In the reference checks, we will be verifying the production use of the product for which you are seeking certification. We will be seeking additional information such as when the product was installed, types of users actively using the system, and modules of the system in active use. CCHIT must verify, between all the reference sites provided, that key functionalities tested during the certification process are in use

The applicant may submit additional live sites if necessary to verify actual use of key functionalities. It is not necessary for all of the functionalities to be in use at any one site. CCHIT also reserves the right to validate any functionality that may be in question following the inspection process or for your specific certification domain, such as ePrescribing or use of bar-coded technologies, if applicable for your certification.

All certified EHR products have one full year from their certification anniversary date to attain Full Production certified status or the product will be removed from the posted

products list on the CCHIT Web site. To reinstate the product listing, the applicant must submit the required reference sites or ePrescribing compliance verification, and the references must be verified as described above.

CCHIT retains the right to contact the reference sites initially and at any time during the certification period in order to verify that the live sites are still active and that the product is still in compliance with the criteria and test steps under which the product was certified. We also ask that you notify us in case any of the live reference sites deactivate or de-install the product, and provide alternative sites. (For a product that is not yet in production use, please see the section on Pre-market Conditional Designation, Section 3.7)

2.2.3. Annual Renewal Process

CCHIT will initiate the annual certification renewal process for any successfully certified product on or about the yearly certification anniversary date. The applicant will receive an invoice for the annual renewal fee, which will be due within 30 days. CCHIT will also contact at least one of the initial reference sites and at least one new reference site for verification of continued use of the certified product. CCHIT must verify that, between the sites, key functionalities tested during the certification process are in use.

Upon verification of the reference sites and receipt of the annual renewal fee, CCHIT will extend the certification for an additional year. Failure to submit the annual renewal fee by the due date or failure to validate the active use of the system by at least two sites for key functionalities will result in the certification being suspended and the product being removed from the CCHIT Web site until the deficiencies can be resolved.

2.2.4. Purchaser Information

Potential EHR purchasers continue to have concerns about the robustness and longevity of vendors. While there is no way to guarantee outcomes for EHR customers, CCHIT continues to collect company information to provide additional information upon which buyers can base their decisions. When you apply for certification, the application form will request information such as the number of employees at your company, years in business, and number of live sites. When supplied, we will publish this information with the listing for your certified product and include it in a faceted product search at <http://cchit.org>, "Find Products" that helps potential customers locate your technology and understand its fit for them. You may, however, choose to opt out from having this specific information displayed or made available for search, and you have the ability to opt in or opt out at any time. (To change your election later, simply contact CCHIT). If

you opt out of publishing this information, CCHIT will manage this information as confidential and will only use it in aggregate form as de-identified data.

IMPORTANT NOTICE: If you opt out of publishing this information, your product may not show up in faceted search results generated by potential purchasers through our online CCHIT Certified EHR Product Directory.

We also ask that you maintain a current primary contact and respond to periodic requests for updates to information provided in the application such as additional contacts, company information and key product-related metrics, as discussed above.

2.2.5. Applying for Optional Additional Certifications

The Child Health and Cardiovascular Medicine optional additional certifications each require a current Ambulatory certification and are generally performed by the applicant at the same time as the Ambulatory certification. You may, however, apply for and obtain the optional certifications at a later date than the main domain certification. You will be required to submit a new application indicating the optional certifications being applied for. Note that the total cost is typically higher when optional certifications are added at a later date.

2.2.6. Initial Processing of Your Applications

Once we receive your online application, you will receive an email confirmation within one business day. If there is any missing, incomplete, or inaccurate information on the application, we will work with you to make corrections. We do ask that you make available personnel and facilities requested by CCHIT to verify the accuracy of information provided in the application and to respond to requests requiring follow-up.

2.3. SUBMITTING YOUR MATERIALS

After receiving the email confirming your application, you will now need to submit the remaining Certification Materials. These must be submitted within five (5) business days of the Certification Application and must include all of the following:

- Two (2) signed originals of the CCHIT Certified Certification Agreement
- Two signed originals of the Preliminary ARRA IFR Stage 1 Certification Agreement if you have chosen to test against this additional program
- Full payment of the applicable certification fees

- Completed Self-Attestation materials
- Completed CCHIT Certified 2011 Lab Test Form, if applicable.
- Ambulatory, Inpatient and ePrescribing EHR's:
 - Documentation of certification by a pre-approved ePrescribing network (SureScripts) as follows:
 - Ambulatory EHR certification requires proof of **Basic** (NewRx, Renew/Refill) ePrescribing certification before the CCHIT Certified 2011 inspection and proof of **Advanced** (Formulary, Eligibility and Medication History checking) ePrescribing certification before any Preliminary ARRA inspection can be scheduled.
 - Inpatient EHR certification requires proof of **Basic** (NewRx, Renew/Refill) ePrescribing certification
 - ePrescribing EHR certification requires proof of **Basic** (NewRx, Renew/Refill) **and Advanced** (Formulary, Eligibility and Medication History checking) ePrescribing certification

OR

- Documentation of a business relationship with a 3rd party ePrescribing product, and a copy of the 3rd party product's certification with a pre-approved ePrescribing network (SureScripts). (Evidence that the product is fully integrated within the EHR system must also be demonstrated during the inspection process.)

OR

- Alternative documentation of ePrescribing capability as explained in the CCHIT Certified 2011 Security Test Scripts, Step 6.22. (There may be a delay in the certification process if CCHIT must perform any due diligence to verify compliance for this option).

2.3.1. Submitting Your Signed Certification Agreement and Application Fee

You will be required to submit two (2) signed originals of the CCHIT Certified 2011 Certification Agreement, which can be found on our Web site at http://www.cchit.org/get_certified.

You will also be required to submit two (2) signed originals of the Preliminary ARRA IFR Stage 1 Certification Agreement if you have elected to test against this additional

program. This agreement can also be found on our Web site at http://www.cchit.org/get_certified under the appropriate Preliminary ARRA domain.

By executing the Agreement(s), your organization is agreeing to be bound by the terms and conditions of the CCHIT Certification Program as described in this Handbook and/or the Preliminary ARRA IFR Stage 1 Handbook. The Agreement(s) must be executed by an executive of each Applicant organization who is authorized to execute binding contracts. The signed Agreement(s) must also be accompanied by a check for the full amount of the first year certification fee. Please ensure that CCHIT receives **two** original signed Certification Agreements for each program (2 for CCHIT Certified and 2 for Preliminary ARRA) and Full payment of the fees within five (5) business days of your application submission date.

2.3.2. Submitting Your Self-Attestation Materials

As part of this process, you will be required to submit materials supporting those elements designated in the Self-Attestation sections of the CCHIT Test Scripts. Your Self-Attestation materials are due no later than five (5) business days after submitting the application for Certification. Since the information required in the Self-Attestation materials is quite extensive, it is critical that you have this information compiled prior to submitting your application.

It is also important to note that you must provide specific references from your user guides and product documentation that specifically address the requirements in the Self-Attestation steps of the Test Scripts. Simply providing all user guides and product documentation without specific references to the location of the appropriate materials within them will **not** be deemed sufficient.

You will need to provide the following information for Self-Attestation:

- Clear identification of the assignable functions that you are assigning to a third party tool or component, as outlined in the Test Scripts
- A brief statement explaining how the product satisfies each procedure tested through Self-Attestation
- Supporting documentation for each procedure as evidence that the product satisfies the CCHIT Certified Certification Criteria tested through Self-Attestation
- Attestation that your system is 100% compliant with CCHIT Certified Certification Criteria that is no longer being tested through demonstration

As mentioned above, you will receive a confirmation email following the submission of your application. You will also receive a second email which will include a customized link

specifically for materials related to your Certification Application. You will use this link as the location where you will upload all of your Self-Attestation materials, including your Self-Attestation Form. By uploading your Self-Attestation materials to this link, you will be populating our secure internal Web site for our internal staff and juror review.

Applicants that are unable to submit Self-Attestation materials by posting to our secure site may send materials on CD-ROM with instructions via courier to CCHIT at 200 S. Wacker Drive, Suite 3100, Chicago, Illinois 60606.

CCHIT shall retain Self-Attestation materials as long as is necessary to maintain the Certification of that product. This information will be held in confidence and kept secure.

CCHIT will not accept the Certification Application or schedule an inspection until all Certification Materials, including Self-Attestation materials, are received and they pass the Desktop Review process outlined below.

You can find the CCHIT Certified 2011 Self-Attestation Guidance document and the CCHIT Certified® 2011 Self-Attestation Submission Form on the CCHIT Web site (<http://cchit.org>).

2.4. COMPLETING YOUR LAB TEST FORM

All Ambulatory and Emergency Department applicants must submit a completed CCHIT Certified 2011 Lab Test Form to CCHIT within five (5) business days of submitting the Certification Application. You should use this form to confirm that the sample message files work for your system and to identify any specific values that CCHIT might need to customize on the test files (as allowed per the CCHIT Certified 2011 Interoperability Test Guide). CCHIT has identified the elements that may be modified and exercises the discretion necessary to determine whether requested changes comply with the CCHIT Certified Certification Criteria.

For details, see the CCHIT Certified 2011 Interoperability Test Guide posted on the CCHIT Web site (<http://cchit.org>).

2.5. FINALIZING YOUR APPLICATION

CCHIT will finalize processing your application upon receipt of the completed Certification Materials as described above.

CCHIT reserves the right to reject applications for certification when:

- The application is not complete or has incorrect information
- Products are ineligible for certification
- Certification Materials are incomplete

CCHIT application fees are non-refundable upon CCHIT's official acceptance of the Certification Application. CCHIT will notify the applicant when we complete a review of the materials and accept or reject the application.

2.6. DESKTOP REVIEW OF CERTIFICATION MATERIALS

Once you have submitted all of your Certification Materials, CCHIT staff will conduct a "Desktop Review" of those materials. If CCHIT is unable to complete the review within twenty business days of receipt, we will notify you as to the status of such review. The review involves the following:

- Reviewing the Certification Materials, including Self-Attestation, to assess their completeness or readiness for the inspection process
- Informing you of any clarifications or information needed in the Certification Materials in order to begin the inspection
- Notifying you upon successful completion of the Desktop Review

Please note that you must provide clarifications or additional information requested by CCHIT within five (5) business days of CCHIT's request. If your initial response does not resolve all the deficiencies, we will inform you and issue a second request.

If your materials pass the Desktop Review process, we will allow you to reserve your inspection date.

If you fail to resolve all deficiencies in the Certification Materials to CCHIT's satisfaction within the required timeframe and after two requests for additional information, CCHIT will reject the application as incomplete. In this case, CCHIT will retain 15% of the application fee as a nonrefundable service charge. You may reapply in the future by resubmitting an application and the full application fee.

2.7. SCHEDULING YOUR INSPECTION DATE

Once you have received notice that your application has been accepted and passed Desktop Review, you will be notified of available inspection dates, and you will need to reserve a specific date for your test. Inspection dates will be confirmed on a first-come-

first-served basis following the order in which applicants have completed the Desktop Review process.

The jury-observed inspection for all aspects of the product demonstration will generally occur on the same day, including the core program certification, any optional certifications if applicable, interoperability, and security. Inspection of Self-Attestation materials may occur before or after the observed demonstration.

Any inspection for the Preliminary ARRA IFR Stage 1 program may be conducted on the same day as the CCHIT Certified inspection, or scheduled separately on a different day. The scheduling of the ARRA inspection will be discussed with you and every attempt will be made to come to an agreement that is acceptable to both parties.

Please keep in mind that we must schedule and complete all CCHIT Certified inspections within 90 calendar days of your application date.

2.7.1. Technical Readiness Check

CCHIT will schedule a teleconference with you to conduct a technical readiness check. The purpose of this meeting is to verify that the Web conferencing service functions properly for all parties, to review the inspection protocol and to verify applicant readiness for the live inspection.

If your certification includes any interoperability-related demonstration, such as lab results or CCD, you will want to prepare by verifying that any relevant practice files are functioning properly. You will also need to confirm your readiness to CCHIT prior to the inspection process. CCHIT staff will request a statement from you (CCHIT Statement of Readiness) asserting that you are prepared to complete the observed demonstration portion of the inspection within the required time allotment, that you have practiced and are ready for all applicable interoperability testing, and that you have reviewed and are compliant with the Security requirements.

2.7.2. Time for Completing CCHIT Certified Inspections

You will have 90 calendar days from your initial application submission date to complete the entire CCHIT Certified certification process. CCHIT may agree to extensions if unexpected delays occur as a result of our efforts or under other extenuating circumstances on a case-by-case basis. (You may delay testing under the Preliminary ARRA IFR Stage 1 program until you are ready.)

When delays are solely caused by applicant’s failure to respond to requests in a timely manner, and inspections are not completed within the 90-day window, CCHIT may require an application extension fee equal to 15% of the application fee to complete the inspection.

Typical times for inspections are usually four (4) hours for the Clinical Inspection, two (2) hours for the Security Inspection, and one (1) hour for any optional certifications. Regardless, all core CCHIT Certified program certifications provide for a maximum of eight (8) hours for the clinical inspection and four (4) hours for the Security inspection, including the Interoperability testing, if applicable. Allow for two (2) hours of total inspection time for optional certifications conducted separately from a core certification.

If you find that you have exceeded the maximum allowed time for your inspection, we do allow you to purchase additional blocks of time to extend your certification inspection time. All pricing information is included in the Fee Schedule (Section 6).

If compliance cannot be demonstrated after exhausting the allotted hours of inspection time, plus any purchased additional time, certification will be denied.

The time for CCHIT Certified inspections is summarized below (For inspection times for the Preliminary ARRA IFR Stage 1 Testing, see the Handbook for that program on the CCHIT Web site):

CCHIT Certified® Certification Program	Typical Time	Maximum Allowed Time	Additional Hours Available for Purchase
Core Programs— Clinical Inspections	Four (4) Hours	Eight (8) Hours	Eight (8) Hours (available for purchase in two (2) hour blocks)
Core Programs— Security Inspections (including CCD/CCR if applicable)	Two (2) Hours	Four (4) Hours	Four (4) Hours (available for purchase in two (2) hour blocks)
Optional Certifications (if Stand-Alone)	One (1) Hour	Two (2) Hours	Two (2) Hours (available for purchase in one (1) hour blocks)

2.7.3. Rescheduling Inspections

Please keep in mind that once a test date is confirmed, and jurors have been scheduled, you will be assessed a monetary penalty to change the inspection date. For details, see the Certification Agreement (Section 5) and the Fee Schedule (Section 6).

2.7.4. Applicant Voluntary Withdrawal

If you elect to discontinue an inspection once it begins, you may voluntarily withdraw. Voluntary withdrawal prior to completing the inspection will result in an automatic failed certification. If you voluntarily withdraw, you will not be eligible for any retests, appeals, or refund of application fees. For details, see the Certification Agreement.

For these reasons, it is critical that you verify that your product meets the CCHIT Certified Certification Criteria, works properly for the test, and that your demonstration team can complete the demonstration in the allotted timeframes in order to avoid issues resulting in costly extensions and cancellations. For details regarding fees, see the Fee Schedule (Section 6) or the Certification Agreement.

2.8. THE INSPECTION

The description of the inspection process in this Handbook is specific to the CCHIT Certified Certification Program. The Preliminary ARRA IFR Stage 1 inspection process is described in the separate Handbook for that program and can be found on the CCHIT Web site at www.cchit.org.

The CCHIT Certified inspection process involves a structured review of the product using up to five testing methods, depending on the certification program or option:

- Jury-observed demonstration to inspect clinical functionality
- Electronic transmission of sample lab results reporting file
- Use of technical tools (LAIKA and others) for interoperability testing
- Jury-observed demonstration to inspect security functionality
- Juror visual inspection of Self-Attestation Materials

CCHIT Certified Test Scripts are used to test a product's compliance with the CCHIT developed Certification Criteria. The Test Scripts help guide the sequence of the demonstration and review of Self-Attestation materials to confirm compliance of the EHR product with the applicable CCHIT Certified Certification Criteria. You may demonstrate steps in a different order than is described in the CCHIT Test Scripts by providing advance notice to CCHIT.

For quality assurance purposes, all portions of the observed demonstration, including the audio and video demonstration for the inspection, may be recorded. New Jury Retests, Correction and Retests and any Appeals for Commission Review are always recorded.

To achieve certification, a product must comply with **100%** of the CCHIT Certified Certification Criteria. Information gathered throughout the inspection and documentation review processes may be used in total to determine a product's compliance with the CCHIT Certified Certification Criteria. In other words, a product is expected to comply every time a function is demonstrated or represented.

2.8.1. Clinical Functionality Inspection

CCHIT has developed an extensive set of functionality criteria, and evaluates product compliance with these criteria through a jury-observed demonstration. A CCHIT functionality inspection team observes the demonstration and determines whether the product complies with the CCHIT Certified Certification Criteria. The inspection team consists of a CCHIT Staff Proctor (a non-voting facilitator), and a jury comprising three clinical experts, at least one of whom must be a practicing physician. For the Inpatient certifications, one of the clinical jurors must be a nurse in addition to the physician and provider jurors. The inspection team witnesses a live demonstration of the product conducted by your team using a web demonstration system and facilitated by the CCHIT Staff Proctor, following the CCHIT Certified Test Scripts. These Test Scripts contain a closely defined series of test steps to be executed by the applicant.

During the demonstration, your team will conduct the demonstration of your product at your own facility, while the CCHIT functionality inspection team witnesses the demonstration via Web conferencing technology and a simultaneous audio teleconference circuit. Each member of the functionality inspection team—including the CCHIT Staff Proctor, each juror, and the applicant—can observe the demonstration from a different location.

The CCHIT Staff Proctor will monitor the progress of the demonstration and verify that your team has an opportunity to demonstrate each step in the applicable Test Scripts and that each step is observed by each juror.

Jurors may ask the following types of questions, among others, to assess the product's compliance:

- Clarifying questions to verify that the applicant has demonstrated according to the test procedure
- Clarifying questions needed to validate that the actual result matches the expected result
- Clarifying each element/requirement outlined in the expected result

- Asking applicants to repeat a step if the applicant went too fast or to clarify how they executed the test procedure
- Clarifying if there is missing information or a missed part of the step
- Clarifying where to find something on the screen
- Other questions may be facilitated by the CCHIT Staff Proctor if determined to be within the scope of demonstrating the certification requirements

The CCHIT Staff Proctor helps to facilitate the inspection and voting process, including questions posed by jurors, but does not vote on the product's compliance. Jurors cast their official votes at the end of the clinical scenarios. Each juror will vote and record his or her individual determination of compliance/non-compliance for each test step using a CCHIT scoring sheet.

Jurors may not confer or discuss their votes during the demonstration or voting phases of the Functionality Inspection. Each juror is required to clearly document his or her reason for each vote for non-compliance for any step. CCHIT will retain juror scoring sheets and worksheets as part of the official record of the inspection process.

2.8.2. Usability Rating System

As part of the CCHIT Certified 2011 Ambulatory EHR Certification Program, CCHIT will rate perceived system usability. CCHIT will utilize the clinical juror observations during the regular inspection process to gather data on the perceived system usability. The Usability Rating will **not** affect the outcome of the certification process and will result in an overall assignment of between 1 to 5 stars after the detailed results are compiled. This rating exercise will provide the applicant with valuable detailed feedback regarding the perceived usability of their system. The applicant will be informed of the rating at the end of the inspection process and will have the option to opt in or opt out of publishing the final Usability Rating on the CCHIT Web site. The decision to opt in or opt out can be updated at any time during the certification cycle by contacting CCHIT to make a change. Applicants wishing to retest the Usability portion of the inspection process may return and apply to do so after 90 days from the last Usability Rating. CCHIT will use a subset of the test steps from each Scenario of the Ambulatory Test Script for the Usability retesting process. A Usability retest fee applies each time an applicant returns to perform the Usability testing process as outlined in the Fee Schedule (Section 6). The detailed questions and rating methods, published references and scoring algorithms are included in the Usability Testing Guide posted on the CCHIT Web site for use by applicants in preparation for the inspection process.

2.8.3. Collation of Votes

After completing a first pass through the CCHIT Certified Test Scripts, you will be asked to exit the teleconference to allow the CCHIT Staff Proctor to facilitate the voting process. The CCHIT Staff Proctor will ask jurors to independently cast their votes using a CCHIT scoring sheet and submit the scoring sheet directly to the Proctor. Once received, the Proctor will collate the votes and determine the outcome of the initial inspection. CCHIT uses a simple majority-voting rule; therefore, a step will be considered noncompliant only if two or more of the jurors marked it as “Failed”. The proctor will compile the votes and will determine whether retesting is required for steps that the applicant was unable to demonstrate or for steps that jurors found noncompliant by majority vote. Once the votes are collated, the proctor will invite your team to rejoin the teleconference. The proctor will inform you of steps that qualify for retesting with the jury under the Same-Day Retest policy (described below). If retesting with the same jury is not required, this will conclude the functionality inspection.

2.8.4. Same-Day Retest

CCHIT gives your team an opportunity to demonstrate your product’s compliance with the CCHIT Certified Certification Criteria during the inspection and provides for some retesting on the inspection date (Same-Day Retest). The Same-Day Retest is intended to give you an opportunity to clarify or demonstrate items you may have failed to clearly demonstrate that day.

After the voting concludes, the CCHIT Staff Proctor will notify your team of any steps which were noncompliant by majority vote and will give you an opportunity to repeat those individual steps. CCHIT may request that you include other related steps in this demonstration if necessary to adequately demonstrate the noncompliant steps. You may retest that same day as long as no significant modifications (no coding changes) to the product are necessary and only if time allows.

Jurors must render a decision based upon the information presented during the inspection and Same-Day Retest. You may not retest that same day if significant modifications (coding changes) to the product are required to demonstrate compliance with the CCHIT Certified Certification Criteria or if you have exhausted the time limit. CCHIT may allow minor adjustments to interface configuration files to allow you to complete the interoperability portions of the demonstration (Lab Test File and CCD for example). At the discretion of the CCHIT Staff Proctor, you may be allowed to make minor changes to the system interface or configuration files on the day of your test, if time allows, however, there will be a penalty fee for these types of changes during a test as outlined in the Fee Schedule (Section 6).

After completion of the Same-Day Retest, the CCHIT Staff Proctor will review the juror scoring for the retested steps. The Proctor will then share the Same-Day Retest results with you and conclude the inspection process.

Once the inspection concludes, CCHIT renders an official decision regarding the product's compliance based upon the information and functionality presented that day. After completion of the Same-Day Retest, the CCHIT Staff Proctor will inform you that the functionality inspection has been completed.

CCHIT reserves the right to evaluate all inspection results in aggregate before communicating the official results to the applicant. CCHIT will not inform the applicant about the certification results until all inspections have concluded, including the inspection of Self-Attestation materials. Results will be communicated in the form of an Inspection Results Report as described (Section 2.9).

2.8.5. Lab Results Interoperability Inspection

If you are seeking certification for Ambulatory, Inpatient or Emergency Department, you will find that your Test Scripts contain criteria and test steps to demonstrate lab results interoperability.

For the Lab Results Interoperability inspection for Ambulatory and Emergency Department, CCHIT will provide practice test files simulating submission of electronic lab results, as well as instructions that explain how the lab results test process will work. You should utilize the practice files provided to validate the data required to successfully process lab results messages. Sample values have already been provided in our lab results practice files; however, CCHIT anticipates that you may need to modify identifying information provided in the files to match your EHR system values and you may do so utilizing any text editor software program during your practice sessions. You must inform CCHIT ahead of time of any required customizations of the lab test file for the day of your inspection, since no changes to the file will be allowed during the live test. You may submit allowable customization requests using the CCHIT Lab Test Form.

Please see the CCHIT Certified 2011 Interoperability Test Guide for additional clarification and guidance.

Download the current version at <http://cchit.org> in the "Get Certified" section.

2.8.6. ePrescribing Interoperability Attestation and Functional Inspection

If you are seeking **ePrescribing Stand Alone certification**, you will be required to provide proof of **both** the **Basic** (NewRx, Renew/Refill) **and Advanced** (Medication History, Formulary and Eligibility Checking) ePrescribing certification from a pre-approved ePrescribing network at the time of application.

If you are seeking **Ambulatory certification**, you will be required to provide proof of at least **Basic** (NewRx, Renew/Refill) ePrescribing certification from a pre-approved network at the time of application. Ambulatory applicants that have not achieved **Advanced** (Medication History, Formulary and Eligibility Checking) ePrescribing certification from a pre-approved network at the time of their inspection will receive **ePrescribing “Conditional” Certification (eRx Conditional)**. Ambulatory applicants granted “eRx Conditional” certification have one year from the certification anniversary date to attain full Advanced ePrescribing certification from a pre-approved ePrescribing network. Failure to obtain Advanced ePrescribing certification and submit proof to CCHIT by the one year certification anniversary date will result in the certification being revoked and the product being removed from the certified product list on the CCHIT web site. Ambulatory applicants who wish to also conduct the ARRA testing **may not schedule their ARRA inspection until such time as proof of Advanced ePrescribing certification from a pre-approved ePrescribing network has been received**. This is based on new requirements in the IFR Stage 1 criteria published on January 13, 2010, requiring the capability of Formulary checking for the Drug Decision Support module.

If you are seeking **Inpatient certification** you must submit proof of **Basic** (NewRx, Renew/Refill) ePrescribing certification from a pre-approved ePrescribing network at the time of application.

For all of the above domains, the following alternative methods may also be considered to demonstrate proof of compliance with the ePrescribing certification criteria:

- Provide documentation of current, valid certification by a **non**-pre-approved ePrescribing network. In this situation, either you or your ePrescribing network must provide additional documentation that the network fully complies with the standards in the CCHIT Certified Certification Criteria. (Depending on the amount of time required for CCHIT to perform due diligence for this option, there may be a delay in the certification process)
- Provide documentation that the product is only marketed to and used by integrated health care enterprises in which dispensing of all prescriptions are performed within that enterprise. You must then provide additional documentation that there is functional integration such that the transactions described in the CCHIT

Certified Certification Criteria are accomplished electronically following the specified standards.

- Provide documentation of a contractual relationship with an ePrescribing product vendor. The ePrescribing product vendor provides the required documentation of a current valid certification by a CCHIT pre-approved ePrescribing network. This is referred to as a 3rd Party ePrescribing partner product. You will be required to demonstrate the ePrescribing functionality as indicated in the Test Scripts and prove that the 3rd Party ePrescribing product is integrated fully in the EHR (i.e. no separate sign in or double entry of data is required).

Please read the ePrescribing sections of the Test Scripts carefully to make sure you understand the nuances in this area.

2.8.7. Patient Summary Interoperability Testing

If you are seeking certification for the Ambulatory or Inpatient programs, you will find that your functional CCHIT Certified Test Scripts include criteria and test steps requiring you to demonstrate the interoperability of your product by sending a Patient Summary document following the HITSP C32 (CCD) format to CCHIT for validation and then show that you can receive and display the C32 document in a human readable form and file it in a patient record.

Whereas these test steps are found at the end of your functional Test Scripts, these specific test steps will be performed at the beginning of your Security Inspection since we use the more technical skill set of our Security Inspector to assess the outcomes of this test. You will want to use our LAIKA testing tool to help you in preparing for this component of the inspection process as well as the CCHIT Certified 2011 Interoperability Test Guide.

2.8.8. The LAIKA Tool

In order to support the interoperability testing, we are providing an updated version of our testing tool called "LAIKA". LAIKA is the name of a suite of interoperability testing tools used by CCHIT in the process of certifying EHRs. This same set of tools is available free of charge for anyone to use during product development, and in preparing for certification testing.

The LAIKA tool will aid you in preparing for the file and display as well as generate Patient Summary test cases. With the LAIKA tool, you can create your own file and display test cases by selecting a pre-built patient template in our test tool. These patient

templates are simply pre-populated patient charts containing registration and clinical information. You can then use the tool to simulate an external organization sending you a Patient Summary document. Once you receive a Patient Summary document from our LAIKA tool, you can then proceed to file the document to the corresponding patient and display that document in a human readable format.

The LAIKA tool will also be used to simulate your organization sending a Patient Summary document that you have generated to an external organization. This is essentially the reverse case of the file and display test. To practice the simulation of the test step, you can use the LAIKA tool to generate a patient template within LAIKA. This patient template is simply a pre-designed patient chart containing registration and clinical information.

There will be existing templates in our LAIKA tool library that you can use. These templates will already be set up for patients that you should have already created in your test system as part of the set-up and execution of the CCHIT Test Scripts. You can also modify or create additional patient record templates if you so desire. This will allow you to simulate an external organization receiving the care document file for a patient in your system. You can then generate and send out the Patient Summary document for this patient to the LAIKA tool, which represents an external organization requesting a Patient Summary document for that patient.

You can practice the execution of the Generate and Format test case by using LAIKA to prompt for the Patient Summary document file generated by your EHR system. In the live inspection, the Proctor will forward your Patient Summary document file to our technical team for evaluation in LAIKA. LAIKA will receive your Patient Summary document and begin an automated validation process.

Please see the CCHIT Certified 2011 Interoperability Test Guide for more details on the use of the LAIKA testing tool and the requirements for Interoperability testing.

2.8.9. Security Inspection

If you are seeking certification of any of the core domain certification programs, including Ambulatory, Inpatient, or Emergency Department, you will be required to perform the Security inspection. CCHIT provides a separate, common, Security Test Script that you must execute for this part of the inspection. If you are seeking certification of an ePrescribing Stand Alone system, CCHIT has a separate Security Test Script for use with this domain. Please ensure that you have downloaded the appropriate Security Test Script for the domain you have applied for.

The Security Inspection Team consists of the CCHIT Staff Proctor and a Security Inspector. The CCHIT Staff Proctor facilitates the inspection and voting process, but does not vote on the product's compliance with the CCHIT Certified Certification Criteria.

The Security Inspection Team will observe a demonstration of the applicant's product following the appropriate CCHIT Certified Security Test Script as well as the demonstration of the HITSP C32 (CCD) Patient Summary test steps in the applicable domains. This demonstration occurs in the same remote demonstration environment described earlier for the functionality inspection.

Once the Security inspection concludes, the CCHIT Staff Proctor will facilitate the voting process. This process works much like the voting process described in the functional inspection process above.

Since there is no need for collation of votes, the inspection team may request an immediate Same-Day Retest for noncompliant steps. The Same-Day Retest works the same as described in Section 2.8.4 with the single Security Inspector.

2.8.10. Self-Attestation Inspection

CCHIT assesses compliance for certain criteria through Self-Attestation and inspection of related product information. Inspection of Self-Attestation materials is conducted offline by the CCHIT Inspection Team without a Web or audio conference session.

The Self-Attestation Inspection Team includes CCHIT Staff for the Desktop Review and clinical assessment and a Security Inspector for the security-related assessment.

The following describes the Self-Attestation inspection process in more detail:

- CCHIT Staff will inspect the Self-Attestation materials and will determine whether the responses and supporting materials adequately demonstrate the product's compliance with the CCHIT Certified Certification Criteria and are ready for review by the Security Inspector. Deficiencies will be reported to the applicant with a request for a revised submission of the documentation.
- The Security Inspector will inspect the security Self-Attestation materials and will determine whether the responses and supporting materials adequately demonstrate the product's compliance with the CCHIT Certified Certification Criteria.
- CCHIT Staff will evaluate the sufficiency of the ePrescribing materials to determine whether the responses and supporting materials adequately demonstrate the product's compliance with the CCHIT Certified Certification Criteria.

- The CCHIT Security Inspectors notify CCHIT Staff when the materials have been evaluated, noting compliant and noncompliant steps.
- Staff will follow up with you as needed to obtain additional clarifications to Self-Attestation materials following the Inspection Team's review.
- You must respond within three (3) to five (5) business days of CCHIT's request for additional information and clarifications.
- Once the Security Inspector has obtained sufficient information to render a decision regarding the product's compliance with the CCHIT Certified Certification Criteria, CCHIT Staff will facilitate the final votes from the Security Inspector and notify your team that the Self-Attestation Inspection process has concluded.

CCHIT Staff will communicate with your team to resolve questions and request additional materials as needed. For items judged incomplete or noncompliant, the inspection team may request additional information or clarification. You will have an opportunity to provide additional information or clarification to demonstrate compliance with the test steps. However, CCHIT reserves the right to assess when sufficient information has been requested or gathered to render a decision.

You may request a New Jury Retest and Appeal for Commission Review for Self Attestation test steps found to be "noncompliant" as described in the Retest and Appeal Mechanisms (Section 2.10).

2.8.11. Product Modifications Not Allowed During Inspection

Modification of the product during the inspection process—including Same-Day Retests and New Jury Retests—is strictly forbidden. Modifications to one part of a product may affect the product's compliance in other areas tested in another part of the inspection process. The following rules apply:

- Set-up and configuration changes (e.g., adding users, changing selection lists, etc.) are not considered product modifications, and are allowed. Permitted set-up and configuration changes that need to be made during an inspection must be observed by the proctor and jurors and must be able to be completed within the time limits of the inspection.
- Errors in Test Script execution (e.g., entered the wrong patient, logged on as wrong user, entered incorrect diagnosis, etc.) may be corrected and are not considered product modifications. Repeating of test steps to enter the correct Test Script data is allowed but must be observed by the proctor and jurors.
- Changes to the product/system source code are not permitted during the inspection process. CCHIT will make no distinction between 'minor' and 'significant' changes to

product code during an inspection process. You may not make any coding changes to a product once an inspection commences. You should be sure of the product's ability to comply with the criteria and test scripts before applying for certification.

Changing product source code during the test will disqualify you immediately from the entire certification testing process with no opportunity for appeals. The CCHIT Staff Proctor will inform you of the disqualification and will stop the inspection process. No refund will be issued to applicants that are disqualified due to source code changes during the live inspection process.

If you are unable to execute the test procedure or demonstrate compliance with the expected results and/or CCHIT Certified Certification Criteria, you will be given an opportunity to demonstrate that function the same day of the inspection within the allotted time (See Same-Day Retest Section 2.8.4). However, you may not modify the source code of the product in between the initial inspection and any Same Day Retesting, or New Jury Retesting. The only possible exception pertains to limited modification of the interface configuration files during the lab or C32/CCD Patient Summary Interoperability testing as described in the next section.

2.8.12. Same Day Modified Product Retest - Lab or C32/CCD Patient Summary Interoperability Only

Modification to the interface configuration files during the interoperability testing may be allowed at the discretion of the Proctor (not to exceed 30 minutes); however, any changes of this type to meet the expected results for lab interoperability or for C32/CCD Patient Summary file and display are considered an immediate Modified Product Retest (Correct and Retest) and the applicant will be subject to a \$5,000 fee, as indicated in the Fee Schedule (Section 6) and the Certification Agreement.

2.8.13. Technical Issues

Products must be stable and functional during the inspection. The CCHIT Staff Proctor may, at his or her sole discretion, exercise judgment on the appropriateness of continuing an inspection or permitting breaks during an observed demonstration when your team encounters technical problems or requests a break for configuration or set-up changes. This discretion enables the proctor to moderate the observed demonstration in a manner that protects the integrity of the test. CCHIT does not permit extended breaks or continuation of inspections on other days to address technical issues encountered.

Should the CCHIT Staff Proctor stop an inspection due to the extreme instability of the applicant's product/system, a Test Cancellation fee may be assessed as per the Fee Schedule (Section 6) and the Certification Agreement.

2.9. OBTAINING YOUR RESULTS

CCHIT will combine the results from any applicable CCHIT Certified Functionality, Interoperability, Security and Self-Attestation inspections and prepare an Inspection Results Report. The Inspection Results Report will indicate which, if any, CCHIT Certified Test Script steps were judged as noncompliant and could not be resolved during the Same-Day Retest. This report reflects the decision rendered by the inspection teams regarding the product's compliance with the CCHIT Certified Certification Criteria on the day of the initial test.

(Results for any Preliminary ARRA IFR Stage 1 testing will be handled as per the separate Certification Handbook for that program found at:

http://www.cchit.org/get_certified.)

2.10. RETEST AND APPEAL MECHANISMS

CCHIT provides retest and appeal mechanisms to reduce the risk of a juror error or bias affecting the inspection outcome. These are available if the product was found noncompliant during the initial test, and the noncompliant items were not all resolved during the Same-Day Retest. Retest and appeal procedures are described below and in Appendix C.

(Retest and appeal mechanisms for the Preliminary ARRA IFR Stage 1 testing can be found in the separate Certification Handbook for that program at:

http://www.cchit.org/get_certified.)

2.10.1. Retesting with a New Jury

You may request a New Jury Retest if:

- You believe, in good faith, that jurors rendered an incorrect decision about the product's compliance based upon how the product was demonstrated during the inspection due to juror bias or juror error; and
- The inspection process results do not accurately reflect the compliance of the applicant's EHR product with the CCHIT Certified Certification Criteria based upon how the product was demonstrated during the inspections.

You do not qualify for a New Jury Retest or an Appeal for Commission Review if:

- You were unable to complete the test in the allotted time, including extensions; or

- Your team refrained from demonstrating a required functionality, or stated that the product does not include the required functionality; or
- Your organization modified the product, or stated intent to modify the product in order to bring the product into compliance, at any point once inspection had begun; or
- You took any other action which compromised the integrity of the test (e.g., adding data directly to an audit log to create a misleading appearance that the product has logged events).

If you wish to request a New Jury Retest and we determine that you are eligible, you must submit the request in writing within five (5) business days of receipt of the written CCHIT Inspection Results Report. The New Jury Retest Request must state the specific steps that you are contesting, including the reasons that you disagree with the jury's decision. In addition, you must attest that no product modifications have been or will be made since the inspection started.

The New Jury Retest will test noncompliant items and may require retesting an entire scenario. CCHIT records the audio and video demonstration for all New Jury Retests and Appeals.

The New Jury may evaluate the product's compliance for any function and step demonstrated during the retest.

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 an additional fee. See the Fee Schedule (Section 6) and Certification Agreement for details.

CCHIT will send you a New Jury Retest Inspection Results Report within five (5) business days of completing the New Jury Retest.

If your EHR product is found noncompliant by the New Jury Retest, and you believe, in good faith, that the New Jury Retest results do not accurately reflect the compliance of your EHR product as presented during the retest, you may file an Appeal for Commission Review.

2.10.2. Appeal for Commission Review

If your EHR product is found noncompliant after a New Jury Retest and you believe that the results do not accurately reflect your product's compliance, you may submit an Appeal for Commission Review (See Appendix C – CCHIT Appeal and Compliance

Policy, Section 7). You may not appeal disqualifications that result from product modifications or the other disqualifying conditions as described in this Handbook.

If you are eligible for and wish to Appeal for Commission Review, you must submit the request in writing within five (5) business days of receiving the New Jury Retest Inspection Results Report or being notified of revocation, as applicable. The appeal must state the specific steps or decisions that you contest, including, if applicable, the reasons that you disagree with the decision rendered during the New Jury Retest.

CCHIT's complete Appeal and Compliance Policy is included (See Appendix C – CCHIT Appeal and Compliance Policy (Section 7)

2.10.3. Certification Outcomes

After completion of the inspection process including the review of Self-Attestation materials and any potential New Jury Retests or Appeals for Commission Review, CCHIT will reach its decision regarding Certification of the applicant's EHR product. We will notify your designated point of contact via email within five (5) business days of our decision.

2.10.4. Products Achieving Certification

CCHIT will verify production use for any EHR products that pass all inspections. To qualify for Full certification, products must be in production use in at least two reference sites for a minimum of forty-five (45) calendar days and between all sites be using key functionalities tested during the certification process. Products that pass all inspections, but that are not verified to be in production use, qualify for Pre-market Conditional Certification Designation (Section 3.7).

If your EHR product has successfully achieved CCHIT Certified 2011 certification, CCHIT will issue you a Certification Document. If your EHR product has met the requirements for full production certification, you will also be provided with the CCHIT Certified Seal to use in your marketing and communications. CCHIT will add your product to the list of CCHIT Certified 2011 Products on the CCHIT Web site, including information about your EHR product (such as name, version, and key metrics). You may make public announcements regarding certification of your EHR product after your product has been posted on the CCHIT web site. You may prepare sales and marketing materials at any time after achieving certification, but not distribute press releases until you have submitted them for review and approval by the CCHIT communications staff as stated in the Certification Agreement. All such materials must comply with requirements of the Marketing Policies – CCHIT Certified 2011 (Section 4).

CCHIT, in accordance with its communication plan, will be actively engaged in efforts to communicate the benefits of investing in CCHIT Certified 2011 products to the provider community through multiple communication channels.

Products that also become Preliminary ARRA IFR Stage 1 certified or Final ARRA Stage 1 certified will have a separate listing on the CCHIT Web site which supports the specific modular components that were successfully demonstrated and found compliant during your ARRA inspection.

2.10.5. Products Failing to Achieve Certification

If your EHR product is found noncompliant with the CCHIT Certified ® Certification Criteria, CCHIT will issue a confidential report to you regarding the test items that led to such result. You may choose to promptly correct and retest the product as described in the next section, or may simply choose to reapply for certification at a later date.

If you conducted a Preliminary ARRA IFR Stage 1 inspection, your product may be listed as Preliminary ARRA IFR Stage 1 certified for any modules that were successfully demonstrated during the separate ARRA testing process.

CCHIT will not make any public report on the noncompliance of your EHR product with the CCHIT Certified ® Certification Criteria.

2.10.6. Product Correction and Retest

The correction and retest option is available for the CCHIT Certified applicant regardless of the reason(s) for noncompliance or disqualification during the original inspection process.

If you are unable to demonstrate complete product compliance during the CCHIT Certified inspection process, you do have the option to make corrections to the product (including source code changes) and re-apply to test again at a discounted fee as long as the following procedure is observed.

To reapply, follow these steps:

- Notify CCHIT in writing of intent to do a Correction and Retest within thirty (30) business days after receiving the CCHIT Inspection Results Report.
- Submit a new Certification Application for the modified product, citing the specific version number and release for the modified product within 120 days after receiving

the CCHIT Inspection Results Report. (The same testing materials must be in effect as during the initial testing).

- Execute a new Certification Agreement and pay the required fees within the required timeframes. For details regarding the fees for Correction and Retest procedure, see the Certification Agreement or the Fee Schedule (Section 6).
- Test the corrected product within the required timeframe (90 days).

You may make any changes you wish to the product before retesting under the Correction and Retest policy. The retest will be a complete inspection of all Scenarios, and will not be limited to the items previously found noncompliant.

The corrected version of the product must also be verified in use at two live sites, as previously described, to qualify for Full certification. Otherwise, the corrected product will qualify for Pre-Market Conditional Certification Designation and can later be granted Full certification upon verification.

The retest must be against the criteria in effect at the time of the initial test. You should be aware that the option for Correction and Retest may not be available due to time constraints at the end of a certification cycle (the current cycle will end in 2014).

2.11. ADDITIONAL LISTINGS FOR PRELIMINARY ARRA IFR STAGE 1 CERTIFIED PRODUCTS

Applicants that have completed the Preliminary ARRA IFR Stage 1 certification testing successfully will be provided a separate product listing under the Preliminary ARRA certified technology on the CCHIT web site. The listing will include the individual modules in the Preliminary ARRA IFR Stage 1 test that were demonstrated successfully and found compliant. Applicants will be issued verification documentation to support the specific ARRA modular components they successfully demonstrated.

2.12. COMPANY AND PRODUCT NAME CHANGES

If you are actively seeking product certification, you may notify CCHIT of organization and product name changes during the certification process. Because these changes reflect amendments to the Certification Application and Agreement and affect the product tested for certification, requests to modify the organization or product name or to correct a version number or other information found in the Certification Materials must be made in writing as follows:

- The notice must be submitted in writing on organization letterhead and signed by an authorized official of the organization.

- CCHIT will modify the information only after receiving the proper written notice and verifying that the product and version presented and tested for certification matches the new information.

Organizations with products that have already achieved certification may notify CCHIT of company and product name changes, as follows:

- Organizations must submit a notice in writing on organization letterhead and signed by an official of the organization.
- CCHIT will update the information only after receiving the proper written notice.

Note that this policy only applies to **simple name changes**. When products themselves are modified or updated, the policies described in the Marketing Policies (Section 4) will apply.

If a company is changing names due to a merger, sale or other third party transaction, the policies described in the Marketing Policies (Section 4) apply. Please contact CCHIT if you have questions regarding how to document acquisitions, mergers and other third party transactions.

2.13. PREPARING FOR 2012 AND BEYOND

CCHIT has launched an effort to expand certification to address additional areas of focus in 2010 including Behavioral Health, Dermatology, Clinical Research and Long Term and Post Acute Care. CCHIT may add new areas to the development process on an accelerated basis for the next certification cycle. In addition, CCHIT will continue to expand the criteria for existing certifications.

2.14. OUR JURORS

2.14.1. Juror Qualifications, Selection and Assignment

The jury panel for the observed clinical demonstration consists of three clinical experts, at least one of whom must be a practicing physician. In addition, for the Inpatient Inspection, one of the jurors must be a nurse. The inspector for Security testing is an Information Security expert.

CCHIT maintains a pool of trained and ready jurors that is adequate for the volume of vendors seeking certification at any time.

When additional jurors are needed, CCHIT invites candidates to apply and submit an on-line application. CCHIT Staff review and assess the juror applicants' qualifications and experience. This includes screening candidates against Commission-approved job descriptions and rejecting any potential jurors because of inadequate qualifications, background and experience, conflict of interest, or actual, potential or perceived bias. CCHIT may also request that jurors provide reference letters.

CCHIT maintains a list of active jurors on the Web site.

CCHIT jurors are paid a nominal amount and must execute a contract with CCHIT covering Conflict of Interest and Confidentiality. All jurors 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 addresses the CCHIT Certified Certification Criteria, CCHIT Test Scripts, CCHIT Inspection Process, and methods by which CCHIT works to avoid juror errors or bias. CCHIT will endeavor to recruit and retain a core of experienced jurors to serve on multiple inspections over the course of the year.

Once fully qualified, CCHIT will assign jurors from the jury pool to participate in Inspections based upon their availability.

Juror performance will be monitored by CCHIT for consistency, reliability and lack of bias.

2.14.2. Juror Quality Oversight

CCHIT undertakes a number of juror quality assurance and oversight activities, which may include but are not limited to the following:

- Staff oversight during juror training and juror audits of live inspections
- Proctor monitoring juror questions during inspections
- Staff review of Self-Attestation materials
- Retrospective results review
- Juror debriefing sessions to improve the process
- Applicant and juror surveys

CCHIT may employ other measures to evaluate juror performance on an ongoing basis.

2.15. PURCHASER COMPLAINT PROCESS

CCHIT will respond to complaints from purchasers of a certified EHR product who claim that the product is not compliant with the criteria under which it was certified. The complaint must include the following information:

- The identity of the EHR product that is the subject of the complaint, including the release and version number
- The date on which the product was purchased or licensed by the purchaser
- The specific functionality, interoperability, or security criteria with which the purchaser feels the EHR product is noncompliant
- Documents such as copies of electronic mail or written correspondence that demonstrate diligent attempts by the purchaser to resolve the issue directly with the vendor or its customer support organization

CCHIT will:

- Keep a record of all complaints
- Notify the vendor of the product about the complaint and ask the vendor to respond
- Conduct and document an investigation of the complaint using CCHIT Staff

If the staff investigation indicates a probable and substantial compliance discrepancy between the EHR product submitted for testing and an EHR product being marketed by the organization as CCHIT Certified, CCHIT Staff will refer the complaint, accompanied by CCHIT's investigation documentation, to the Appeal and Compliance Committee to recommend a course of action (Appendix C, Section 7).

If the vendor has been found to have made substantial misrepresentations in its attestations to CCHIT, the vendor could be subject to penalties including having CCHIT certification for its products suspended or withdrawn and being prohibited from reapplying for certification for a period of one (1) year.

In addition, for products that are no longer being actively supported by a vendor due to issues such as acquisition, bankruptcy etc., CCHIT reserves the right to suspend or revoke certification until such issues are resolved.

2.16. CERTIFICATION SUSPENSION AND REVOCATION

CCHIT may suspend a product's certification, upon notice to you, if:

- CCHIT determines, in accordance with the Appeals and Compliance Policy, that there is a substantial compliance discrepancy between the certified EHR product and the EHR product being marketed and you do not provide, within 15 days after notice from CCHIT, an explanation that is reasonably satisfactory to CCHIT
- CCHIT determines that you are no longer actively supporting the certified EHR product
- CCHIT determines you have not met the obligations to provide the required reference sites to move your certification status from “Pre-Market Conditional” to “Full Production” within one year from the anniversary date of certification
- You or a reseller are in material breach of any term of the Certification Agreement or you or a reseller are in breach of any of the obligations, terms and conditions of this handbook and you fail to cure such breach within 15 days after notice from CCHIT or, in the reasonable determination of CCHIT, such breach is not capable of cure

CCHIT may, subject to your right to appeal pursuant to the Appeals and Compliance Policy, permanently revoke a product’s certification, upon notice to you, if your certification has remained suspended for a period of more than 30 days.

3. CERTIFICATION TERMS AND CONDITIONS

3.1. CERTIFICATION AGREEMENT

As part of the application process, you are required to review and sign two (2) original copies of the CCHIT Certified® 2011 Certification Agreement. For those applicants also wishing to test under the Preliminary ARRA IFR Stage 1 program, CCHIT also requires that you review and sign two (2) original copies of the Preliminary ARRA IFR Stage 1 Certification Agreement.

3.2. PRICING AND PAYMENT SCHEDULE

All pricing and payment terms are described in the CCHIT Certified 2011 Certification Agreement (see Section 5) and Fee Schedule (see Section 6).

3.3. TERM OF CERTIFICATION

The term for all CCHIT Certified 2011 Certifications, regardless of certification date, will extend to December 31, 2014.

3.4. PRODUCTS AND CONFIGURATIONS

3.4.1. EHR Products Eligible for Certification

CCHIT has developed its test materials to cover EHR products targeted for the domains of Ambulatory, Inpatient, Emergency Department or ePrescribing. To qualify for full certification, the product must be capable of meeting all CCHIT Certified Certification Criteria, be identified with a specific product name, version/release level, and release date, be in production use at two or more live sites for a minimum of forty-five (45) calendar days, and the sites must verify using key functionalities of the EHR product. The product must also be available in the U.S. marketplace.

3.4.2. Defining the Product and Configuration to be Certified

You will be prompted to identify the Certification Domain and any optional additional certifications you wish to pursue on the online Certification Application.

You must complete a separate Certification Application for each Certification Domain (Ambulatory, Inpatient, Emergency Department, or ePrescribing). You must also indicate if you are seeking any optional additional certifications in Child Health and Cardiovascular Medicine (Ambulatory only).

Vendors that have products certified in all three main domains –Ambulatory, Inpatient, and Emergency Department—may qualify for the additional option of Enterprise certification that demonstrates interoperability among those three settings.

For each product on the application, you must describe and identify the specific EHR product version and release date of the product seeking certification. In addition, you must describe the environment and configuration of the product that will be demonstrated for the CCHIT inspection. CCHIT will test the identified product and validate compliance with the CCHIT Certified Certification Criteria in the environment specified on the Certification Application. CCHIT may publish the environment and product configuration details when a certified product is added to the certified product list.

The Certification fees under this 2011 program include one product listing on the CCHIT Certified product list, and one listing on the Preliminary ARRA or Final ARRA Stage 1 product list. Additional, separate product listings may be added for additional fees and upon submission of the CCHIT Product Update Form.

We also ask that you provide additional information such as contact information and key company and product metrics. CCHIT reserves the right to publish any self-reported metrics provided on the application, unless you specifically indicate that you wish to opt out of publishing the information. CCHIT also reserves the right to request periodic updates of contact and key metric related information to maintain accurate and up to date certification information.

3.4.3. Extending Certification to Other Configurations and Versions of a Certified Product

CCHIT Certified Certification is completed with a specific configuration and version of a product that was tested by CCHIT and found 100% compliant with the CCHIT Certified Certification Criteria. CCHIT may extend certification to other configurations and versions of a certified product that are added after the product is certified. Other configurations may include, but are not limited to, alternate operating systems, database platforms, and delivery methods.

Applicants are not required to report subsequent versions of a certified product to CCHIT, but at their option, they may notify CCHIT when new versions are released and request to have their version information updated on the Web site. CCHIT will allow subsequent

versions of a certified product to be marketed as certified as long as the vendor has not removed capabilities needed for compliance with the CCHIT Certified Certification Criteria. For products offered under an Open Source licensing model, the organization or community submitting the product for certification shall be responsible for determining and enforcing its own policy regarding labeling of subsequent versions of the product as certified. Applicants may continue to use the CCHIT Certified Seal in conjunction with subsequent versions of the certified product.

You may always request additional listings of new versions or additional configurations of certified products on the CCHIT Web site for an additional fee and upon submission of the CCHIT Product Update Form. For details, see the Appendix or Certification Agreement.

3.4.4. Significant Product Changes

If you modify or update your CCHIT Certified product in a manner that carries a significant risk of affecting compliance, you must follow this procedure. Before marketing the modified or updated product as CCHIT Certified, you must apply for re-testing of the product to verify continued compliance with all published criteria and Test Scripts.

Examples of changes that would be considered to carry significant risk of affecting compliance include, but are not limited to:

- Extensive re-architecting of the user interface of the product (e.g., extensive changes to user screens, their inter-relationship, and the navigational structure)
- Complete removal of any function or module essential to compliance (e.g., removing audit log function).
- Replacement of modules essential to compliance with software from a different source (e.g., removing a third-party supplied drug interaction module and writing it in-house or vice-versa)
- Replacement of infrastructure that was relied upon for security (e.g., changing from an external third-party database subsystem to an in-house coded database subsystem or vice-versa, when certain security criteria were satisfied via assignment to the database subsystem)

Before marketing a product with significant changes as being certified, you must submit the product for re-inspection as follows:

If the CCHIT Certified Certification Criteria used in the inspection process for the earlier, CCHIT Certified version of the applicant's EHR product are still current, you will need to pay a reduced amount (specified in the Certification Agreement) for inspection of the

newer version of your EHR product, and, the certification date will be reset to begin on the date a certification decision was rendered for the re-inspection of such newer version. CCHIT will determine the scope of the testing required.

If CCHIT has updated or modified the applicable CCHIT Certified Certification Criteria since certification of the earlier version of your EHR product, your organization will need to pay the full amount of the application fee for a full inspection of the newer version of your EHR product. The inspection process for such newer version will use the updated or modified CCHIT Certified Certification Criteria, and will encompass all areas of such newer version. Unless you otherwise request, the earlier CCHIT 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).

3.5. CERTIFICATION AND THE STARK AND ANTI-KICKBACK SAFE HARBORS

The certification-based Stark and Anti-Kickback safe harbors for donation of EHRs to physicians currently require that products be certified within 12 months prior to donation. HHS recognition of standards, however, is no longer being done on a 12 month cycle. To resolve this discrepancy, we will be updating the effective certification date for Stark qualification purposes at the time of annual renewal of a product's certification until HHS issues new or clarifying rules.

3.6. JOINT APPLICATIONS FOR CERTIFICATION

If an applicant's EHR product meets only a subset of the CCHIT Certified Certification Criteria associated with the relevant domain, the applicant may seek certification by co-applying for certification with other products or systems that, collectively, make a complete EHR. Joint application may apply to a single vendor where additional products from the same vendor are needed to meet the CCHIT Certified Certification Criteria or it may apply to systems where multiple vendors with separate products are needed to meet the CCHIT Certified Certification Criteria.

Joint applicants must identify one organization to serve as the single point of contact and the primary applicant for such a combination, and as such shall submit the applications, execute the Certification Agreement(s) and pay applicable application fees. In addition, the primary applicant must coordinate the submission of all CCHIT-required materials, including Self-Attestation materials, and coordinate inspections across the organizations that have jointly applied. If the combination achieves CCHIT Certified® Certification, the combination will receive a combined listing on the CCHIT Certified Web site (e.g., "Applicant A/Applicant O Combined EHR Product"). Joint products that were collectively

certified as a complete EHR product may not be marketed separately as CCHIT Certified. Joint products are subject to the same provisions as single certified products.

The primary and all co-applicants will be required to comply with CCHIT Marketing Policies – CCHIT Certified (Section 4) and the terms of the CCHIT Certified 2011 Certification Agreement.

Joint products that were also inspected together under the Preliminary ARRA IFR or final ARRA Stage 1 program would receive a single combined listing under the ARRA certified technology category.

3.7. PRE-MARKET CONDITIONAL CERTIFICATION DESIGNATION

For a product to meet the requirements for Full certification status, CCHIT requires that it be in production use for a minimum of forty-five (45) calendar days at two or more live sites, and that between all the sites combined, the product is being used for key functionalities tested during the certification process for the appropriate domain. If an applicant's EHR product is ready for the marketplace, but not yet in production use for a minimum of forty-five (45) calendar days at two sites, the applicant may apply under Pre-Market status on its application for certification, and pay the full amount of the then-current application fee. In such event, the inspection process would proceed without verification of production use, and, if certification is achieved, the applicant's EHR product will be granted Pre-Market Conditional certification until such time that the requirements for production use are verified.

All certified EHR products have one full year from their certification anniversary date to attain Full Production certified status or the product will be removed from the posted products list on the CCHIT Web site. To reinstate the product listing, the applicant must submit the required reference sites and they must be verified as described above.

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. The conditionally certified product will be listed on the CCHIT Web site as such; however, the organization will not be granted a certificate or the rights to use the CCHIT Certified Seal until the applicant's EHR product achieves Full certification and the conditional status is removed. Once any conditional certification status is removed, 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 Policies – CCHIT Certified (Section 4). There is no additional fee for such conversion to Full certification status.

3.8. INTERNALLY DEVELOPED EHR SYSTEM

For those organizations that have developed EHR systems primarily for their internal use, CCHIT offers its CCHIT Certified 2011 Certification program for EHR products under similar terms and conditions as are offered to commercial applicants. Internally developed systems may also consider the alternative pathways of Preliminary ARRA IFR Stage 1 certification of the applicable modules, or Site Certification when it is launched later in 2010. Both of these alternate program details will be discussed in separate Certification Handbooks.

Under the CCHIT Certified 2011 certification program, applicants with EHR systems developed primarily for their internal use may seek certification of that product by submitting an application for certification and identifying the product as Internally Developed. These systems will be evaluated against the CCHIT Certified Certification Criteria using the same CCHIT Certified Test Scripts as for commercial EHR products. If the inspection will take place on a system being used for live data, CCHIT Staff will work with the applicant to make adjustments to the inspection in order to ensure that patient safety and health information confidentiality are not compromised in any way.

Applicants for these systems will be required to enter into a Certification Agreement and will be subject to the same application and certification maintenance fees and terms as products developed and marketed exclusively for commercial sale.

If an organization with a CCHIT Certified internally developed system later wishes to bring the product to the commercial market and offer it to other organizations, they must first convert the certification to a commercial certification. The applicant would need to provide at least two references that can verify that the system is in production use at two live sites and that between them, they are using key functionalities tested during the certification process. The reference must not be part of the group that developed the system.

For more details regarding production use verification, see Section 2.2.2.

3.9. CERTIFICATION OF PRIVATE-LABELED PRODUCTS

If an applicant's EHR product becomes CCHIT Certified and the applicant wishes to allow a reseller to market such product under an additional brand name (private labeled product) as CCHIT Certified, such applicant and/or reseller must follow the process described in this section. Only versions with equivalent functionality to the certified product qualify for private-labeled product certification. Any other changes to a certified product may require testing in order to certify the private-labeled product. To add a private-labeled product to the CCHIT Certified product list, applicant or reseller must:

- Submit a letter signed by an officer of both the reseller and applicant's organization stating that the private-labeled product (citing the specific new product name and version number) is an authorized private label version of the CCHIT Certified product (citing the CCHIT Certified product name and tested version number.) This letter should also state whether any changes were made to the certified product, other than the name;
- Submit two (2) signed originals of the Private-Labeled Product Certification Agreement, signed by both the applicant (certified product organization) and the reseller; and
- Pay CCHIT a certification confirmation fee.

The terms and fees for private-labeled products are described in the Certification Agreement (Section 5) and on the Fee Schedule (Section 6).

Once CCHIT has received the required materials and fees, the private-labeled product will be listed as a CCHIT Certified product on the CCHIT Web site (<http://cchit.org>).

CCHIT will also issue the private-labeled product unique certification verification documentation.

In order to maintain the private label product listing after the first year of the certification term, the applicant or reseller must pay an annual renewal fee.

If certification is revoked or expired for the CCHIT Certified product, certification will also be revoked or expired for the corresponding private-labeled product.

3.10. TRANSFERABILITY OF CERTIFICATION

Certification of products shall not be assignable by the vendor whether by operation of law or otherwise without the express advance written approval of CCHIT.

For products offered under an Open Source licensing model, the organization or community submitting the product for certification shall be responsible for determining and enforcing its own policy regarding labeling of subsequent versions of the product as certified.

4. MARKETING POLICIES – CCHIT CERTIFIED® 2011

Background

As part of achieving CCHIT Certified 2011 certification, your organization will gain the advantage of partnering with CCHIT's marketing and outreach staff. We want to help you promote your certification as a competitive market advantage. CCHIT has a full-featured public relations and marketing program to educate potential health IT buyers about the value of purchasing CCHIT Certified products or services. Some of the benefits it offers you are:

- Educational outreach to medical professional associations at both the national and local levels
- Participation in meetings and conferences as featured speakers to promote the value of CCHIT Certified certification with potential buyers or those who influence them
- A faceted search function at <http://cchit.org>, "Find Products" (*planned for spring 2010*), that helps potential customers locate your product or service and understand its fit for them
- A Web site, <http://ehrdecisions.com>, aimed at giving providers more information on health IT evaluation, selection and implementation
- Guides and podcasts for your use as sales tools

The objectives of CCHIT's marketing and outreach program include:

- Raising awareness of CCHIT, its mission and the promise that it holds for health care consumers and providers
- Managing acknowledgement of CCHIT as a certification body
- Furthering the perception of CCHIT as a reliable steward of trust that will allow stakeholders to have increased confidence in decisions about health IT adoption
- Delivering knowledge of where and how to access CCHIT's information and resources

CCHIT provides Marketing Policies in this Certification Handbook and, again, at the time of certification to assist you in preparing your public announcements and marketing campaigns in keeping with CCHIT's communication policies. The intent of these Policies is to maintain the credibility and reliability of the CCHIT Certified brand in the minds of potential buyers and those organizations – public or private – providing incentives to providers to purchase and implement health IT.

The CCHIT Certified 2011 certification program aims to assure the health care industry and health care consumers that certification of health IT can be expected to deliver the following benefits:

- Increase the transparency of the marketplace and reduce risk for physicians and hospitals that select, purchase, and implement CCHIT Certified health IT products or services
- Direct investment toward CCHIT Certified health IT products or services that have the necessary functionality to improve the quality, safety, and efficiency of care
- Ensure the interoperability of health IT through standards-based compatibility with the emerging national standards
- Protect the privacy of health information by requiring adequate security standards within health IT products and health information exchanges

To achieve these goals, CCHIT encourages you to use your CCHIT Certified status as a visible part of your own public relations and marketing program materials.

These Marketing Policies are part of the CCHIT Certified 2011 certification program Policies. The terms and conditions for CCHIT certification and administration of these Policies may be revised by CCHIT in its sole discretion. All marketing promotion that refers to CCHIT or CCHIT certification must be clear and factual. Compliance with these Policies ensures a level playing field in the competitive health IT marketplace and protects the integrity of the CCHIT Certified 2011 certification programs. CCHIT vigorously enforces these policies for the benefit of both your organization and your potential customers. CCHIT encourages you to protect your certification status by complying with these policies.

Important Policy Notes

- **Without the prior written consent of CCHIT, organizations participating in any CCHIT certification program are prohibited from publicly disclosing any of the results of their participation, including, but not limited to, any written or oral comments made about the organization or its health IT products or services by CCHIT or its jurors.**
- **Organizations are required to submit to the Certification Commission, for its prior review and written approval, all press releases mentioning the Certification Commission, CCHIT's certification programs or products or services with CCHIT certification. Organizations are not required to submit other promotional materials to the Certification Commission for approval but have the option of doing so if they are unsure if materials meet these Policies. Organizations will be held accountable for any violations of this Policy and all other Marketing and Public Relations Policies. Any failure to secure CCHIT's prior written approval for press releases and any variance from pre-approved statements and uses of CCHIT Seals or Certification Facts™ labels in an organization'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 organization's certification status. This Policy extends to any statements made by organizations that are in any way false and misleading, as determined by CCHIT in its sole discretion.**

4.1. CERTIFICATION MARKETING POLICY APPLICATION

References to the terms "marketing and/or advertising materials," "advertising" or "promotional materials" in these Policies 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, business papers
- Electronic: Web content, e-newsletters, online advertising, blogs and other social media, downloadable material, Flash animations, Web seminars or presentations, email promotions, search-engine optimization, CDs, photography, video
- Broadcast: radio, television

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

You should read and examine these Marketing Policies prior to producing any promotional material that refers to the Certification Commission or the CCHIT Certified 2011 certification program.

You may contact CCHIT's Marketing Coordinator, Diana Coniglio at dconiglio@cchit.org, or 312.674.4926 for additional information or clarification about these Policies.

Only organizations that have received a Certification Document and CCHIT Certified® Seal from the Certification Commission indicating they have successfully met all CCHIT Certified Certification Criteria within an identified program category and have completed the appropriate agreements to earn CCHIT certification can promote or advertise a product or service as CCHIT Certified.

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

4.2. REFERENCE TO CCHIT CERTIFIED® STATUS

In reference to your product's status as CCHIT Certified®, you must clearly indicate:

- The name of your organization (or the prime organization if applying jointly)
- The name and version of the product or service tested and earning the certification
- The program period for which the CCHIT has certified the product or service
- The domain (care setting) and options (if applicable) of certification
- Any *Conditional* status pending either site verification ("Pre-market conditional") or advanced ePrescribing certification ("ePrescribing conditional")
- If also certified in the Preliminary ARRA IFR Stage 1 program, the product's level of compliance with the HHS IFR requirements for certified EHR technology

The form of such a reference shall be as follows:

“(Organization name)’s, (product or service name and version) is a (any conditional status) CCHIT Certified® 2011 (domain) additionally certified for (optional add-on).

If certified in the Preliminary ARRA program add: “(Product name and version number) also preliminarily meets (number) of (applicable number for Eligible Provider or Hospital) requirements for Eligible Providers (or Hospitals) published by the U.S. Department of Health and Human Services (HHS) in the Interim Final Rule. Inspection information is available at <http://www.cchit.org/products>. For the purpose of qualifying products for ARRA incentives, CCHIT anticipates, but has not yet received, accreditation by HHS.”

Examples of approved references to these certifications in vendor press releases or promotional material are:

“XYZ Inc.’s, XYZ EHR 1.2.3, is a CCHIT Certified® 2011 Ambulatory EHR, additionally certified for Child Health and Cardiovascular Medicine with Advanced Reporting.” *And if certified in the Preliminary ARRA program:* “XYZ EHR 1.2.3 also preliminarily meets 24 of 24 requirements for Eligible Providers published by the U.S. Department of Health and Human Services (HHS) in the Interim Final Rule. Inspection information is available at <http://www.cchit.org/products>. For the purpose of qualifying products for ARRA incentives, CCHIT anticipates, but has not yet received, accreditation by HHS.”

Or for Inpatient EHRs:

“QRS Inc.’s, QRS EHR 1.2.3, is a premarket conditionally CCHIT Certified® 2011 Inpatient EHR.” *And if certified in the Preliminary ARRA program:* “QRS EHR 1.2.3 also preliminarily meets 22 of 22 requirements for Hospitals published by the U.S. Department of Health and Human Services (HHS) in the Interim Final Rule. Inspection information is available at <http://www.cchit.org/products>. For the purpose of qualifying products for ARRA incentives, CCHIT anticipates, but has not yet received, accreditation by HHS.”

Or for Emergency Department EHRs:

“GHI Inc.’s, GHI ED 1.2.3, is a CCHIT Certified® 2011 Emergency Department EHR. *And if certified in the Preliminary ARRA program:* GHI ED 1.2.3 also preliminarily meets 8 of 22 requirements for certified EHR technology for Hospitals published by the U.S. Department of Health and Human Services in the Interim Final Rule. Inspection information is available at <http://www.cchit.org/products>. For the purpose of qualifying products for ARRA incentives, CCHIT anticipates, but has not yet received, accreditation by HHS.”

Or for ePrescribing products:

“ABC Inc.’s, ABC eRx 1.2.3, is a CCHIT Certified® 2011 ePrescribing product (or service). *And if certified in the Preliminary ARRA program:* ABC eRx 1.2.3 also preliminarily meets 5 of 24 requirements for certified EHR technology for Eligible Providers published by the U.S. Department of Health and Human Services in the Interim Final Rule. Inspection information is available at <http://www.cchit.org/products>. For the purpose of qualifying products for ARRA incentives, CCHIT anticipates, but has not yet received, accreditation by HHS.”

If two technologies are combined to achieve certification, an example would appear as follows:

“ABC Inc.’s, ABC Software Version 4.5.6, in combination with DEF Software Version 7.8.9, is a CCHIT Certified® 2011 Ambulatory EHR additionally certified for Child Health. *(In this case, only the health IT company applying as the prime vendor may claim certification for the combined product or service.)*

4.3. THE CCHIT CERTIFIED® SEAL



The CCHIT Certified® Seal is the official designation for products which have achieved certified status in the CCHIT Certified 2011 certification program.

The Seal and specific graphic standards for use of the Seal are provided to you upon successful completion of the **full** CCHIT Certified 2011 certification process, including verification of site references. Initial guidelines on the seal are provided here for clarification.

4.3.1. Use of the CCHIT Certified® Seal

CCHIT grants the organization of a product or service that achieves CCHIT Certified status a nonexclusive right to use the CCHIT Certified Certification Seal on, or in connection with, the product promotional activities for the shorter of: (i) the time period that the CCHIT Certified product is commercially available and maintains payment of Certification Program fees; or (ii) the certification term, plus any renewal term. CCHIT’s

revocation of an organization's certification status shall immediately terminate an organization's right to use the Seal. The CCHIT Certified Certification Seal is the property of CCHIT, and the organization may use the Seal only in accordance with these Marketing and Public Relations Guidelines.

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

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

The CCHIT Certified Certification Seal must never appear more prominently than the name of the organization or product. If the Seal is used on a Web site, visitors to the site must be able to clearly identify which product or service has been certified by CCHIT and which have not. The Seal should never appear in an animated banner of a Web site. No degree of acceptability, level of safety or protection should be implied in the organization's promotional materials.

4.3.2. Use of the CCHIT Certified® Seal with Multiple Certifications

If the organization has pursued additional domains of certification, the organization may use or eliminate the additional domains at its discretion. Organizations are given this freedom to allow them to market products in the most appropriate way for a given market.

For example, a product that is CCHIT Certified 2011 Ambulatory EHR, additionally certified for Cardiovascular Medicine and Child Health, may use the 2011 Seal with a CCHIT Certified 2011 Ambulatory EHR; CCHIT Certified 2011 Ambulatory EHR, additionally certified for Cardiovascular Medicine; CCHIT Certified 2011 Ambulatory EHR, additionally certified for Child Health; or CCHIT Certified 2011 Ambulatory EHR, additionally certified for Cardiovascular Medicine and Child Health.

4.4. USE OF THE CERTIFICATION FACTS™ LABEL

Each certified product or service listed on <http://cchit.org> will have a link to a page describing the product and the company. That page will contain the Certification Facts™ label which will indicate the CCHIT Certified 2011 program domains and options for the certified product or service.

If the product is also certified in the Preliminary ARRA program, the product will also have a separate page listing with a Certification Facts label indicating which of the government required modules are supported by the technology. Health IT companies certified in the Preliminary ARRA program are required to disclose this information to their current and potential customers so providers are aware of any gaps in certified technology that they will need to fill to qualify for ARRA incentive funding.

The CCHIT Certified and Preliminary ARRA Certification Facts labels provide a cross reference to the other certification if a product is certified in both programs.

In addition to the Certification Facts™ label, that page will include, for CCHIT Certified products and services only, an optional Usability Rating, information about your product or service, information about your company and a brief 250 word description. This additional optional data will be used in the search parameters in our faceted product search function at <http://cchit.org>.

4.5. USE OF STATEMENTS

Upon achieving certification for your product or service, you may use the following statements, alone or in combination, to identify or describe CCHIT and the CCHIT Certified 2011 certification program. You may also reference the CCHIT Web site at <http://cchit.org> for additional information. You must cite that source when you reprint information from <http://cchit.org> and abide by the Terms of Use at <http://cchit.org/terms-of-use>.

4.5.1. Approved Descriptions about CCHIT

CCHIT should be referred to in the entirety, “the Certification Commission for Health Information Technology (CCHIT®)”, as “the Certification Commission” or as “CCHIT®” (pronounced C-C-H-I-T).

Other statements you may use in writing or speaking about CCHIT are:

“The Certification Commission for Health Information Technology (CCHIT®) is an independent, 501(c)3 nonprofit organization with the public mission of accelerating the adoption of robust, interoperable health information technology. The Certification Commission has been certifying electronic health record technology since 2006. More

information about CCHIT, CCHIT Certified® products and Preliminary ARRA certified technology is available at <http://cchit.org> and <http://ehrdecisions.com> .”

4.5.2. Approved Descriptions about the CCHIT Certified® 2011 Certification Program

“The CCHIT Certified® program is an independently developed certification that includes a rigorous inspection of an EHR’s integrated functionality, interoperability and security using criteria developed by CCHIT’s broadly representative, expert work groups.”

“The Certification Commission for Health Information Technology’s (CCHIT®) inspection process is based on real-life medical scenarios designed to test products rigorously against the complex needs of health care providers. As part of the process, successful use is verified at live sites.”

4.5.3. Approved Descriptions about “CCHIT®”

“CCHIT®” is a registered mark of the Certification Commission for Health Information Technology.

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

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

“CCHIT® is a registered mark of the Certification Commission for Health Information Technology.”

4.5.4. Approved Descriptions about “CCHIT Certified®”

“CCHIT Certified®” is a registered mark of the Certification Commission for Health Information Technology.

The registered mark symbol ® should be applied directly after the word “CCHIT Certified.” You need only apply the registration mark to the first reference of the term “CCHIT Certified®” within the written material.

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

“CCHIT Certified® is a registered mark of the Certification Commission for Health Information Technology.”

4.6. PRODUCT OR COMPANY RENAMING

In executing your organization’s marketing plan, you may decide to rename your company or your CCHIT Certified product or service. CCHIT’s policy is to publicly list your company name, product or service name and version number **exactly** as it appears on your Certification Application. The marketing staff will not approve any promotional material referencing your Certification status that varies from the Certification application information that you supplied.

If you wish to change that information for your company or your product, you may do so by sending a letter on your company’s letterhead signed by a company executive, requesting this change. This letter may be sent electronically to certify@cchit.org, followed by a hard copy sent to the Certification Commission’s address to the attention of the Certification Manager. Your listing will be changed only after we have received that official notification.

See Section 2.12 for additional information regarding company and product name changes as well as assignment or transfer requirements.

4.7. DISTRIBUTION OF CCHIT CERTIFIED® PRODUCTS BY OTHERS

In the health IT marketplace, it is common practice for a developer of health IT to increase channels of product distribution through arrangements with Value Added Resellers (VARs) who typically resell the developing company’s product using the original name and version number, or through contracts as an Original Equipment Manufacturer (OEM) allowing another company to resell the product with a private label which bears a different name and version number than the original product. In circumstances where these arrangements involve the promotion and sale of a CCHIT Certified product, the company which originally sought Certification bears the responsibility for managing the promotion of Certification for its product according to the following guidelines:

4.7.1. Reselling a CCHIT Certified® Product with VARs

If you plan to resell your CCHIT Certified product through arrangements with VARs using the original name and version number of your product, you are responsible for assuring that the VAR conforms to all Certification Commission Marketing Policies provided in this Handbook and any updates received by you at the date of your product's Certification. You are responsible for providing the VAR with these Policies and your Seal if you should choose to allow them to use it. Any violation of Marketing Policies or Seal usage by the VAR will jeopardize your product's Certification status.

Failure to adequately manage the marketing practices of your resellers may result in the revocation of your certification and the delisting of your product on CCHIT's Web site.

CCHIT's marketing staff will contact you directly for remediation of any Policy violation by your VAR. All such instances will be reported to CCHIT's Executive Director and its Certification Program Director.

4.7.2. Reselling a CCHIT Certified® Product under a Private Label

If you plan to allow another company to license your CCHIT Certified product for rebranding under their own company name with a privately labeled product name, you are responsible for executing an additional Certification Commission agreement, in cooperation with them, allowing them to reference the product's Certification status. Your OEM partner must then execute a separate agreement with CCHIT, described in Section 3.9.

Under this circumstance, your partner is directly responsible for meeting CCHIT's Marketing Policies. You bear no responsibility for monitoring and correcting their marketing practices.

4.8. OPEN SOURCE LABELING

For products offered under an Open Source licensing model, the organization or community submitting the product for certification shall be responsible for determining and enforcing its own policy regarding labeling of subsequent versions of the product it certified.

5. APPENDIX A – FORMS AND DOCUMENTS

All forms and documents referenced in this Certification Handbook are available at http://cchit.org/get_certified within the designated program (i.e., CCHIT Certified ® 2011), and domain categories (i.e., Ambulatory, Inpatient, Emergency Department or ePrescribing). Additional forms for private labeling and product updates are available through the Certification Program team.

- 5.1. CCHIT CERTIFIED® 2011 CERTIFICATION AGREEMENT
- 5.2. CCHIT CERTIFIED® 2011 SELF-ATTESTATION GUIDANCE
- 5.3. CCHIT CERTIFIED® 2011 SELF-ATTESTATION SUBMISSION FORM
- 5.4. CCHIT CERTIFIED® 2011 LAB TEST FORM
- 5.5. CCHIT CERTIFIED® 2011 LAB TEST SAMPLE FILES
- 5.6. CCHIT CERTIFIED® 2011 INTEROPERABILITY TEST GUIDE
- 5.7. CCHIT CERTIFIED® 2011 USABILITY TEST GUIDE FOR AMBULATORY EHRs

6. APPENDIX B – FEE SCHEDULE FOR CCHIT CERTIFIED® 2011

Exhibit A - CCHIT Certified 2011 Certification Program Pricing

	Ambulatory	Ambulatory Add-On Child Health	Ambulatory Add-On Cardio	Inpatient	Emergency Department	Amb+IP+ED Add-On Enterprise	ePrescribing Stand Alone
Standard Fees							
Certification (due with application)	\$37,000	\$8,000 (1)	\$16,000 (2)	\$49,000	\$37,000	\$35,000 (3)	\$18,000
Annual Renewal	\$9,000	\$1,500	\$2,500	\$9,000	\$9,000	\$9,000	\$7,000
Resellers of Private Label Products (Year1/Year 2)	\$2,000/\$1,000			same	same	same	same
Additional Web Listings (Year1/Year 2)	\$2,000/\$1,000			same	same	same	same
Service Charges							
Incomplete Applications	15% of Application Fee	same	same	same	same	same	same
Inspection Extension (beyond 90 days)	15% of Application Fee	same	same	same	same	same	same
Test Cancellations	\$7,000			\$10,000	\$7,000	\$7,000	\$5,000
Correct and Retest							
Configuration Modification During Lab or CCD Interoperability Test	\$5,000						
Certification Fee (due with application)	\$32,000			\$44,000	\$32,000	\$30,000	\$15,000
Additional Inspection Time (if required) (2 hour blocks)	\$4,000			\$5,000	\$4,000	\$4,000	\$0
Options							
Fee to Reinspect and Update Usability Rating	\$4,000						

Notes for Fee Schedule:

- (1) Assumes inspection done at same time as Ambulatory EHR. If inspection is done at a different time, price is \$13,500.
- (2) Assumes inspection done at same time as Ambulatory EHR. If inspection is done at a different time, price is \$21,500.
- (3) Requires inspection of Ambulatory, Inpatient and Emergency Department, not on same day, plus execution of add-on Enterprise Test Script.

7. APPENDIX C – CCHIT APPEAL AND COMPLIANCE POLICY

This Appeal and Compliance Policy is specific to the CCHIT Certified® Certification Program. The Appeal policies for the Preliminary ARRA IFR Stage 1 Program can be found in the separate Handbook for that program posted on the CCHIT Web site at: www.cchit.org.

CCHIT has developed a one-level internal procedure to provide expedited review of denials and revocations of certification and of purchaser complaints about CCHIT Certified EHR products. These CCHIT Certification Appeal and Compliance Policies and Procedures (the “Appeal and Compliance Policy”) are designed to resolve disputes concerning certification raised by vendors and purchasers and enhance the integrity and fairness of the certification program.

This Appeal and Compliance Policy is subject to and incorporated by reference into the Certification Agreement. All capitalized terms not defined in this Section 7.0 have the meanings set forth in the Certification Agreement, which governs this Appeal and Compliance Policy; provided, however, that terms defined in both the Certification Agreement and this Section 7.0 shall, for the purposes of this Section, have the meanings ascribed to them herein.

(a) Appeal and Compliance Committee. The purpose of the Appeal and Compliance Committee (also referred to as the “Committee”) is to review and resolve:

- (i) each Appeal for Commission Review filed by a vendor after a finding through the Inspection Process and New Jury Retest that such vendor’s EHR product is not compliant with applicable CCHIT Certified Certification Criteria;
- (ii) each Appeal for Commission Review filed by a vendor after a decision by CCHIT to revoke such vendor’s certification;
- (iii) complaint(s) submitted to CCHIT by a purchaser of a CCHIT Certified EHR product, and referred to the Committee after staff investigation because of a probable and substantial compliance discrepancy between the EHR product submitted for testing and an EHR product being marketed by the applicant as CCHIT Certified; or

- (iv) questions, issues, exceptions or disputes relating to specific provisions of this Certification Handbook or the Certification Agreement.

When CCHIT receives an Appeal for Commission Review, a purchaser complaint or a request for interpretation of, or an exception to, a provision of this Handbook or the Certification Agreement, the Chair of CCHIT shall appoint at least three (3) CCHIT Commissioners as members of the Appeal and Compliance Committee for such issue.

Any vendor whose EHR product is the subject of an appeal or complaint that is to be reviewed by the Appeal and Compliance Committee may submit a written request to the Chairman requesting a change in one or more members of the Committee, if such vendor has reason to believe that such member(s) may have a conflict of interest or bias with respect to such appeal or complaint. Such request must be received by the Chair at least thirty (30) days prior to the scheduled hearing for such appeal or complaint and must identify the Committee member(s) at issue and explain in reasonable detail vendor's reasons for requesting that such member(s) be replaced for the review of such appeal or complaint. CCHIT's Chair shall respond to such request within a reasonable period of time prior to the consideration by the Committee of the appeal or complaint at issue and may appoint other member(s) to the Committee, in the Chair's sole discretion.

(b) Procedure

- (i) **Initiation of Appeal for Commission Review of Certification Decision.** If a vendor's EHR product fails to achieve Certification through the original Inspection Process and a subsequent New Jury Retest or upon receipt of notice from CCHIT that a vendor's Certification of its EHR Product is being revoked, the vendor may appeal such decisions by submitting to CCHIT, by mail, fax or e-mail, an Appeal for Commission Review within five (5) business days of its receipt of notice that its EHR Product failed the New Jury Retest or that its certification has been revoked. Appeals for Commission Review are managed by a CCHIT staff member who was not directly involved in the product evaluation.

The Appeal for Commission Review should include the following information:

- (A) the reasons the vendor believes that the denial or revocation of Certification should be reversed, including any objections, corrections, and factual information the vendor believes to be relevant to the appeal;

- (B) if relevant, the elements of the Certification Program the vendor plans to address in the appeal;
 - (C) whether the vendor plans to be present at the hearing;
 - (D) the contact information of any person the vendor plans to bring to the hearing in order to present factual information relevant to the appeal, with a clear description of the factual information available from these persons; and
 - (E) a list and copies of all relevant documents, exhibits, or other information the vendor intends to submit in support of the appeal.
- (ii) **Request for Extension of Time Period for Submitting Appeal.** CCHIT may, in its sole discretion, extend the time period for filing the Appeal for Commission Review, pursuant to a written extension request by the vendor that is received by CCHIT prior to the appeal request deadline. Such extension request will be handled by a CCHIT reviewer who was not involved in the decision to deny certification. Denials of time extension requests are not subject to appeal.
- (iii) **CCHIT Acknowledgement of Appeal.** CCHIT will acknowledge receipt of an Appeal for Commission Review, notify the vendor if it is incomplete and permit the vendor to provide any missing information within a reasonable period of time after such notice. CCHIT will forward each complete Appeal for Commission Review to the Appeal and Compliance Committee.
- (iv) **Initiation of Purchaser Complaint and Preparation for Hearing.** If a purchaser of a CCHIT Certified EHR Product has a specific complaint that such product is not compliant with the criteria under which it was certified, the purchaser should submit its complaint through the complaint intake process on the CCHIT Web site. The complaint must include the following information:
 - (A) the identity of the EHR product that is the subject of the complaint, including the release and version numbers;
 - (B) the date on which the product was purchased or licensed by the purchaser;

- (C) the specific functionality, interoperability, or security criteria with which the purchaser feels the EHR product is noncompliant; and
 - (D) documents such as copies of electronic mail or written correspondence that demonstrate diligent attempts by the purchaser to resolve the issue directly with the vendor or its customer support organization.
- (v) **CCHIT initially processes each purchaser complaint by:**
- (A) recording the complaint as part of a permanent record of all such complaints;
 - (B) notifying the vendor of the product about the complaint and requesting the vendor to respond;
 - (C) conducting and documenting an investigation of the complaint using CCHIT staff; and
 - (D) if the staff investigation indicates a probable and substantial compliance discrepancy between the EHR product submitted for testing and an EHR Product being marketed by the Applicant as CCHIT Certified, referring the complaint, accompanied by CCHIT's investigation documentation, to the Appeal and Compliance Committee.

(c) **Hearings.**

- (i) **Scheduling.** Generally, the Appeal and Compliance Committee will meet at the same time as CCHIT's bimonthly in-person meetings, but may schedule hearings on an as needed basis. Following receipt of (x) a complete Appeal for Commission Review, (y) a referral of a purchaser complaint together with the investigation report of CCHIT's staff or (z) a request for interpretation of, or an exception to, a provision of this Handbook or the Certification Agreement, the Appeal and Compliance Committee will schedule its review of such appeal, complaint or request for the next available hearing date, and will notify each vendor involved in the appeal or complaint of the date and time for the hearing.
- (ii) **Supplemental Information for Appeals.** The Appeal and Compliance Committee Chair may require the vendor to clarify, supplement, or amend

an Appeal for Commission Review. Also, where the vendor has requested participation in the hearing, the vendor may be required to provide additional information concerning hearing presentation requirements prior to the hearing date. The appeal may be delayed if the vendor does not provide necessary information for the appeal.

- (iii) **Supplemental Information for Complaints.** The Appeal and Compliance Committee Chair or the CCHIT staff will request the vendor to respond to the complaint and provide any clarification or supplemental information that the vendor believes will assist the Committee in its consideration of the complaint. Also, if the vendor recommends the participation of other individuals in the investigation or hearing, such as other purchasers of the product, the Committee, in its sole discretion, may include such individuals either in the staff's investigation or the hearing.
- (iii) **Hearing Participants.** If a vendor stipulates in its Appeal for Commission Review that it desires to participate in the informal hearing of such appeal, it will be invited by the Committee to attend the hearing. In the event that the vendor does not request to participate in the hearing, the appeal will be resolved and decided based on the appropriate written record and review of the recorded New Jury Retest, as determined by the Appeal and Compliance Committee.

The Committee, in its sole discretion, may invite the vendor of the EHR product that is the subject of the purchaser complaint to attend the hearing about such complaint, as well as any other individual considered by the Committee to be relevant to its review of the complaint. A list of every person invited to the hearing will be provided to the vendor prior to the hearing date.

(d) Decision of the Appeal and Compliance Committee.

- (i) **Appeals for Commission Review.** Prior to the hearing of an Appeal for Commission Review, the Appeal and Compliance Committee will review the information submitted by the vendor and, if applicable, the recorded New Jury Retest. If the vendor chooses to be present at the hearing, the vendor will be given the opportunity to make a statement. The Appeal and Compliance Committee, and such additional members of CCHIT as are available to attend the hearing, will resolve and decide the appeal based on the record, including, if applicable, the recorded New Jury Retest, relevant

and credible information presented by the vendor, CCHIT policies, and, if applicable, the action or decision of the CCHIT Executive Director. The Appeal and Compliance Committee will issue a written decision to the vendor within five (5) days after the hearing that either the vendor's EHR product is CCHIT Certified or that certification has been denied.

- (ii) **Purchaser Complaints.** Prior to a hearing concerning a purchaser complaint, the Appeal and Compliance Committee will review the information submitted by the purchaser and the results of the investigation by the CCHIT staff. If the vendor has been invited to be present at the hearing and chooses to attend, the vendor will be given the opportunity to make a statement. The Appeal and Compliance Committee, and such additional members of CCHIT as are available to attend the hearing, will determine which actions, if any, should be taken in response to the complaint based on the CCHIT staff report, relevant and credible information presented by the vendor, CCHIT policies, and, if applicable, the action or decision of the CCHIT Executive Director. All vendors involved with the product (e.g., the OEM, resellers, etc.) will be notified of the Committee's recommendations and of all actions taken based on those recommendations.
- (iii) **Contract Interpretations, Disputes and Exceptions.** The Appeal and Compliance Committee, and such additional members of CCHIT as are available to participate, will review vendor requests for interpretation of, or exceptions to, the provisions of this Handbook or the Certification Agreement. The Appeal and Compliance Commission will make a determination based on CCHIT policies, relevant and credible information presented by the vendor, and, if applicable, the action or decision of the CCHIT Executive Director. All such determinations are final and are not subject to appeal.
- (iv) **Majority Rule.** All decisions by the Committee, which shall for purposes of this Section be deemed to include any additional members of CCHIT as may be voting on a particular matter, will be reached by a vote of the Committee members, using a simple majority voting rule.

(e) **Finalizing and Closing Appeals and Complaints.** An appeal or complaint will be closed, and all proceedings ended, when either of the following occurs:

- (i) The appeal or complaint has been resolved and decided by the Appeal and Compliance Committee; or
- (ii) The appeal has been withdrawn or terminated by the vendor or the complaint has been withdrawn by the purchaser.

General Provisions

- (i) **Nature of the Process.** All challenges of CCHIT Certification decisions and consideration of purchaser complaints shall be governed exclusively by the rules contained in this Appeal and Compliance Policy. This process is the only way to resolve challenges to or complaints regarding denial of certification and complaints by purchasers concerning CCHIT Certified EHR products. With respect to certification, only denial of certification decisions are subject to review and only by the submission of an Appeal for Commission Review by the vendor. Because these informal procedures are not legal proceedings, they are designed to operate without the assistance of attorneys. While a party may choose to be represented by an attorney, vendors are encouraged to communicate directly with CCHIT. If a party has retained an attorney, that attorney will be directed to communicate with CCHIT through CCHIT's legal counsel.
- (ii) **Time Requirements.** CCHIT will make every effort to resolve appeals and complaints in accordance with the time requirements noted in this Appeal and Compliance Policy. However, CCHIT's failure to meet a time requirement will not prohibit the consideration or final resolution of any matter arising under these procedures. Vendors are required to comply with all time requirements specified in this Appeal and Compliance Policy. Unless provided otherwise, time extensions or postponements may be granted by CCHIT if a timely, written request explaining a reasonable cause is submitted, consistent with this Appeal and Compliance Policy.
- (iii) **Confidentiality.** In order to protect the confidentiality of information of parties involved in matters arising under this Appeal and Compliance Policy, all material prepared by, or submitted to, CCHIT will be confidential in accordance with the confidentiality provisions of the Certification Agreement.

Notwithstanding anything in the Certification Agreement to the contrary, the following materials and documents shall not be considered to be confidential:

- (A) Published Certification and eligibility criteria;
 - (B) Records and materials that are disclosed pursuant to a legal requirement, to the extent their confidentiality is not protected by a court order or similar means of protection; and,
 - (C) Upon the written request of the vendor, to the extent any information concerning Certification status or application materials are made available to other credentialing agencies, professional organizations, or similar bodies.
- (iv) **Final Decisions.** All decisions and orders of the Committee are considered final and closed, consistent with this Appeal and Compliance Policy and the Certification Agreement.
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