Certification Commission
for Health Information
Technology

200 S. Wacker Drive, Suite 3100
Chicago, Illinois 60606
Tel 312.674.4930 Fax 312.896.1466
cchit.org

Certification Handbook

Preliminary ARRA IFR Stage 1

Certification Program

April 7, 2010

Table of Contents

1. OVERVIEW OF PRELIMINARY ARRA IFR STAGE 1 CERTIFICATION PROGRAM

The Preliminary ARRA IFR Stage 1 Certification Program is a certification program developed by the Certification Commission for Health Information Technology (CCHIT®) in response to the requirements of the American Recovery and Reinvestment Act of 2009 (ARRA). The updated program incorporates the Interim Final Rule (IFR) on "Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology" published by the Department of Health and Human Services (HHS) on January 13, 2010. The program is based on the federal standards for certified EHR technology to support the Stage 1 incentives under ARRA and 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 yet been accredited by the ONC. When those events occur, CCHIT will replace the Preliminary ARRA program with a final, ONC-accredited ARRA certification program. Vendors with Preliminary ARRA certification will be eligible to undergo retesting by CCHIT for no additional cost to receive a fully-accredited certification against Final Rule requirements once they are available.

In comparison to the CCHIT Certified® 2011 program, which seeks to assure providers of a higher level of integrated functionality, the Preliminary ARRA IFR Stage 1 program is intentionally limited to assessing compliance with government-developed criteria and standards. The Preliminary ARRA program tests and certifies EHR technologies developed for "Eligible Providers" or "Hospitals" against these federal minimum requirements. Applicants who wish to attain certification for their technology must select one of these two domains first, and then apply for 1 to 25 of the EHR modules for inspection. All applicants must successfully demonstrate compliance with the Security and Privacy module of this certification program before any other modular certifications will be granted. The results of the inspection are reported in a Certification Facts™ label designating which requirements were successfully demonstrated. Certification Facts™ labels are published at http://cchit.org and updated with any additional modules that attain certification at later dates.

Health Information Exchange (HIE) and Personal Health Record (PHR) vendors are invited to certify under the Preliminary ARRA certification program. Although all products must meet the Security criteria, vendors have the freedom to determine which other government-required modular criteria their products support.

All Preliminary ARRA IFR Stage 1 certifications will remain effective through December 31, 2014 as long as the required annual maintenance fees are paid.

This certification program only tests to the federal minimum standards necessary to qualify the technology to be certified under the IFR Stage 1 requirements. It does not test any additional functionality, interoperability or security that providers may seek to reduce risk and fully document patient care. Applicants interested in a more robust certification process for fully integrated EHR systems should review the separate CCHIT Certified ® 2011 Certification Handbook posted on the CCHIT Web site for additional details. 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.

1.1. Preliminary ARRA IFR Stage 1 Eligible Provider Certification

CCHIT began offering Eligible Provider Preliminary ARRA IFR Stage 1 certification on February 12, 2010. This domain addresses EHR technology used in an **ambulatory care** (doctor's office) setting. Applicants wishing to test against the requirements in the Eligible Provider domain should select this option during the application process and indicate which of the EHR modular tests they wish to demonstrate during the inspection process. Applicants are required to select Security and Privacy as the base module and may then add other modules to be inspected.

The Eligible Provider modular certification allows providers who prefer to combine technologies from multiple sources, or self develop an EHR, to qualify for the federal incentive payments established under ARRA.

The current criteria for testing Eligible Provider technology is based on the updated Interim Final Rule published by HHS in the Federal Register on January 13, 2010. CCHIT will quickly evaluate our materials against the government's Final Rule, when available, and adjust our testing materials to offer applicants the opportunity to return and test for full compliance with the Final Stage 1 requirements at no additional cost. Applicants applying before the Final Rule and requirements are published by the government will have priority in scheduling their retesting.

Applicants selecting any of the Interoperability modules for testing are encouraged to carefully review the new Preliminary ARRA IFR Stage 1 Interoperability Test Guide at http://cchit.org for details regarding the requirements.

CCHIT will publish the outcome of all successfully demonstrated modules in a Certification Facts™ label on our Web site for each EHR technology undergoing testing. If an applicant does not successfully demonstrate a specific modular test during their inspection, the result would not be reflected on the Certification Facts™ label.

If you wish to test some of the modules under the Preliminary ARRA IFR Stage 1 certification program now, and then test others at a later date, you may; however, you must test Security and Privacy during the first test and pass that module to be eligible to test additional modules later in the same certification cycle (Stage 1). To test additional modules at a later date you must submit a new Application Form and the appropriate fees associated with the number of additional modules you select per the Preliminary ARRA IFR Stage 1 Fee Schedule (Section 6).

1.2. PRELIMINARY ARRA IFR STAGE 1 HOSPITAL CERTIFICATION

CCHIT began offering Preliminary ARRA IFR Stage 1 Hospital certification on February 12, 2010. This domain addresses EHR technology used in an **inpatient** setting (acute care hospital). Applicants wishing to test against the requirements in the Hospital domain should select this option during the application process and indicate which of the modular tests they wish to demonstrate during the inspection process. Applicants are required to select Security and Privacy as the base module and may then add other modules to be inspected.

The Preliminary ARRA IFR Stage 1 Hospital certification allows providers who prefer to combine technologies from multiple sources, or self develop an EHR, to qualify for the federal incentive payments established under ARRA.

The current criteria for testing Hospital technology is based on the updated Interim Final Rule published by HHS in the Federal Register on January 13, 2010. CCHIT will quickly evaluate our materials against the government's Final Rule, when available, and adjust our testing materials to offer applicants the opportunity to return and test for full compliance with the Final Stage 1 requirements at no additional cost. Applicants who test before the Final Rule and requirements are published by the government will have priority in scheduling their retesting.

Applicants selecting any of the Interoperability modules for testing are encouraged to carefully review the new Preliminary ARRA IFR Stage 1 Interoperability Test Guide at http://cchit.org for details regarding the requirements.

CCHIT will publish the outcome of all successfully demonstrated modules in a Certification Facts™ label on our Web site for each EHR technology undergoing testing. If an applicant does not successfully demonstrate a specific modular test during their inspection, the result would not be reflected on the Certification Facts™ label.

If you wish to test some of the modules under the Preliminary ARRA IFR Stage 1 certification program now, and then test others at a later date, you may; however, you must test Security and Privacy during the first test and pass that module to be eligible to test additional modules later in the same certification cycle (Stage 1). To test additional

modules at a later date you must submit a new Application Form and the appropriate fees associated with the number of additional modules you select per the Preliminary ARRA IFR Stage 1 Fee Schedule (Section 6).

2. THE CERTIFICATION PROCESS

After accepting your application for certification, CCHIT arranges to inspect your EHR technology for compliance with the then current Preliminary ARRA IFR Stage 1 Certification Criteria for the Security and Privacy modules and the additional modules selected.

These criteria were developed by the federal government and were published in the Interim Final Rule by HHS on January 13, 2010. CCHIT has developed test steps and Test Scripts against which applicants may demonstrate compliance with these criteria. Since the criteria will not be finalized until the federal government publishes a Final Rule in the Federal Register, CCHIT will offer the ability to certify against the current materials, and then quickly update our materials and test any gaps on a priority basis when a Final Rule is published. There will not be any extra charge for applicants to conduct a "gap test" if one is necessary to meet the final Stage 1 requirements.

The Preliminary ARRA IFR Stage 1 inspection process employs a combination of the following methodologies:

- Documentation review
- Jury-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 submission of any necessary documentation. There is no travel involved for applicants or for the CCHIT inspection team.

Before applying, you should familiarize yourselves with the process and certification requirements by thoroughly reviewing this Handbook, IFR Stage 1 Criteria, appropriate domain Test Scripts, and the Preliminary ARRA IFR Stage 1 Interoperability Test Guide documents on the CCHIT Web site (http://cchit.org). Review the material carefully, make any necessary adjustments to your technology, 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.

Certification requires 100% compliance with all applicable required criteria and test steps. Optional criteria and test steps do not affect the certification outcome. For required

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 2.9).

If an applicant is able to demonstrate that the technology meets 100% of the criteria for the selected modules, the inspection staff will take the final step of completing the certification results report and posting the results on the CCHIT Web site.

When the inspection process is complete, the technology will become "Preliminary ARRA IFR Stage 1 certified" for the specific certification domain and modules that were successfully tested. CCHIT will issue a Certificate and post the completed Certification Facts™ table as recognition on the CCHIT Web site (which publicly confirms certification).

CCHIT will indicate the version of the technology that was tested on our Web site; however, once technology is 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 technology to be marketed as certified as long as the applicant has not removed capabilities needed for compliance with the certification criteria. For technology offered under an Open Source licensing model, the organization or community submitting the technology for certification shall be responsible for determining and enforcing its own policy regarding labeling of subsequent versions of the technology as certified. Applicants that would like multiple listings of 2 or more versions of a technology on the CCHIT Web site may request this using the Product Update Form and submitting the required fee as per Section 6.

2.1. BEFORE YOU APPLY

Well before applying, ensure that your development team has had the opportunity to conduct a thorough self-assessment of your technology against all of the applicable criteria and steps in the appropriate domain 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 technology must support 100% of the criteria for the appropriate modules prior to applying for certification.

Once you are confident that your technology can support the criteria, you should begin practicing the set-up and execution of the Test Scripts. If you will be conducting any of the modules that require interoperability and file structure validation, make sure you have thoroughly practiced using sample test files and tools. To assist in that preparation, refer to the Preliminary ARRA IFR Stage 1 Interoperability Test Guide posted on the CCHIT Web site.

Once you are confident that you can execute 100% of the test steps for the appropriate modules and can clearly demonstrate the expected results, you are ready to submit your application. The following checklist should help you to prepare:

- Complete technology evaluation and gap analysis
- Resolve any deficiencies
- Assemble the team
  - Team members have the time to prepare and practice the demonstration
  - Team members have the requisite experience to adequately prepare and demonstrate the technologies' compliance
- Verify that the technology is stable and will perform during the tests
- Conduct practice runs
- Verify that the demonstrations can be completed in the allotted times

2.2. When Can You Apply?

CCHIT began accepting applications for Preliminary ARRA IFR Stage 1 certification on February 12, 2010. CCHIT will announce certified technology 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 Policies (Section 4).

2.3. Applying for Certification

2.3.1. Completing the Application

The Application for Preliminary ARRA IFR Stage 1 certification is available online at http://cchit.org under the "Get Certified" tab. Select the appropriate certification type and scroll down to find the application link. 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 Domain
- ARRA Components to be Tested
- Interoperability specifications for any files created (if applicable)
- Licensing Model (Open Source or Proprietary)
- Single or joint application: if you have multiple vendors co-applying for joint certification of any module, the co-applicant's company name and technology information
- Technology Name, Current Version and Release Date
- Co-Applicant Technology Name, Current Version Number and Release Date (if applicable)
- Technology description

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 submit the form you will not have the opportunity to access the completed form to correct your responses.** When you are confident that your application is complete and accurate, please hit the "Submit" button at the bottom of the page.

2.3.2. Annual Renewal Process

CCHIT will initiate the Annual Certification Renewal process for any successfully certified technology 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. Upon receipt of the fee, CCHIT will extend the certification for an additional year. Failure to submit the annual renewal fee by the due date may result in the certified technology being removed from the CCHIT Web site and certification status will be expired.

2.3.3. Initial Processing of your Application

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.

2.4. 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 Certification Agreement
- Full payment of the certification fees
- ePrescribing applicants must submit:
  - Documentation of direct certification by a pre-approved ePrescribing network (SureScripts) for the transactions of at least New Prescription (NewRx) and Formulary, or;
  - Documentation to support integration of a 3rd party ePrescribing product, including a copy of the business agreement and the ePrescribing network certification documentation for the 3rd party system.

2.4.1. Submitting your Signed Certification Agreement and Application Fee

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

By executing the Agreement, your organization is agreeing to be bound by the terms and conditions of the CCHIT Certification Program as described in this Handbook. The Agreement must be executed by an executive of each applicant organization who is authorized to execute binding contracts. The signed Agreement 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 and full payment of the fees within five (5) business days of your application submission date.

2.4.2. Laboratory Interoperability Testing

All applicants wishing to test the Lab Test Results module will be responsible for creating their own lab files for the inspection process. Applicants must demonstrate that they can receive an electronic lab result and that the results are stored as discrete data in the patient's medical record. Applicants do not need to submit the file to CCHIT.

2.4.3. Submitting Your ePrescribing Documentation

All applicants wishing to apply for the ePrescribing module must submit the required ePrescribing documentation within five business days of the Application Date. Documentation requirements are specified in Section 2.4 above.

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
- Technology is determined 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 and accept or reject the application.

2.5.1. 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 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 process
- 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 schedule 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.

2.6. 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 date at this point in time. Inspection dates will be confirmed on a first-come-first-served basis, based upon the order in which applicants have completed the Desktop Review process.

The juror-observed inspections for all modules will generally occur on the same day, including the Security and Privacy Inspection which must be demonstrated first, any Interoperability inspection, and any other optional modules.

Please keep in mind that we must schedule and complete all inspections within 90 calendar days of your Application Date.

2.6.1. Technical Readiness Check

CCHIT will schedule a teleconference with you to conduct a Technical Readiness Check prior to your inspection date. 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/CCR, you will want to prepare by verifying that any relevant practice files for lab results or technical tools provided to test the CCD/CCR are functioning properly. You will also need to confirm your readiness to CCHIT prior to the Technical Readiness Check. CCHIT staff will request a statement from you 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, lab file and ePrescribing testing, and that you have reviewed and are compliant with all Security and Privacy requirements.

2.6.2. Timeframe for Completing All Inspections

You will have 90 calendar days from your initial Application Submission Date to complete the entire 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.

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 of 15% of the application fee to complete the inspection.

Number of Modules Selected	Typical Time	Maximum Time Allowed	Additional Hours Available for Purchase (1 hour increments)
Security and Privacy Module (required as foundation)	1 hr.	3 hr.	3 hr.
2-5 Additional Modules (with Security)	2 hr.	4 hr.	3 hr.
6-10 Additional Modules (with Security)	3 hr.	5 hr.	3 hr.
11-20 Additional Modules (with Security)	4 hr.	6 hr.	3 hr.
>20 Additional Modules (with Security)	5 hr.	7 hr.	3 hr.

The table above reflects the typical times and maximum allowed times for demonstrating a specific number of modules for the Preliminary ARRA IFR Stage 1 certification testing. Up to three (3) additional hours are available for purchase, if necessary, in 1 hour increments. If compliance cannot be demonstrated after exhausting the allotted hours of inspection time, plus any purchased additional time, certification will be denied.

2.6.3. 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 and the Preliminary ARRA IFR Stage 1 Fee Schedule.

2.6.4. 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 technology meets the 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 or Certification Agreement.

2.7. THE INSPECTION

CCHIT's inspection process involves a structured review of the technology using up to three testing methods, depending on the modules being demonstrated:

- Jury-observed demonstrations to inspect for clinical and security compliance
- Electronic transmission of files
- Use of technical tools (LAIKA and others) for Interoperability testing

CCHIT Test Scripts are used to test the technology compliance with the IFR criteria. The Test Scripts help guide the sequence of the demonstration and review of the technology to confirm compliance of the technology with the applicable IFR criteria. You may demonstrate steps in a different order than numbered in the Preliminary ARRA IFR Stage 1 Test Script 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 and Correction and Retests are always recorded.

To achieve certification of a module, a technology must comply with **all** of the certification criteria **within** each module selected. Information gathered throughout the inspection process may be used in total to determine technology compliance with the criteria. In other words, a technology is expected to comply every time a function is demonstrated.

2.7.1. Juror Observed Demonstration

CCHIT has developed specific test steps to be carried out by the applicant during the inspection process. The steps in the Test Script are designed to test the technology against the criteria statements developed by the federal government. The CCHIT inspection team evaluates technology compliance with these criteria through jury-

observed demonstration. The inspection team consists of a CCHIT Staff Proctor (a non-voting facilitator), and jurors comprising one clinical expert and one Security expert. The inspection team witnesses a live demonstration of the technology conducted by your team using a Web demonstration system and facilitated by the CCHIT Staff Proctor, following the CCHIT 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 technology at your own facility, while the CCHIT Inspection Team witnesses the demonstration via Web conferencing technology and a simultaneous audio teleconference circuit. Each member of the Inspection Team—including the CCHIT Staff Proctor, the 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 the appropriate juror.

Jurors may ask the following types of questions, among others, to assess the technology 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 technology compliance. Jurors cast their official votes at the end of the appropriate scenarios. Each juror will vote and record his or her individual determination of compliance or non-compliance for each test step using a CCHIT Scoring Sheet for the appropriate modules being tested.

Jurors may not discuss their votes during the demonstration or voting phases of the inspection. Jurors are 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.

2.7.2. Juror Scoring

After completing a first pass through the Test Scripts, you will be asked to exit the teleconference to allow the CCHIT Staff Proctor to facilitate the scoring 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 review the votes and determine the outcome of the initial inspection. For the modular testing, CCHIT uses a single Security expert juror to evaluate the foundation Security and Privacy demonstration and a separate single clinical expert juror to evaluate the other modular component demonstrations; therefore, the score of the appropriate juror will determine the compliance of the technology with each step and criteria statement. The Proctor will determine if any steps require retesting based on non-compliant scores and will invite your team to rejoin the teleconference. The Proctor will inform you of steps that qualify for retesting immediately under the Same-Day Retest policy (described below). If no retesting is required, this will conclude the inspection.

2.7.3. Same-Day Retest

CCHIT gives your team an opportunity to demonstrate your technology's compliance with the criteria and test steps during the inspection and provides for some retesting on the inspection date (Same-Day Retest) if necessary. 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 scoring concludes, the CCHIT Staff Proctor will notify your team of any steps which were non-compliant and will give you an opportunity to either repeat individual steps or the entire Scenario with the non-compliant steps. CCHIT may request that you include other related steps in this demonstration if necessary to adequately demonstrate the non-compliant steps. You may retest that same day as long as time allows. The Proctor may allow a set period of time for the applicant to fix any set up issues or configuration issues prior to conducting the Same Day Retest but only as 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 lengthy modifications to the technology are required to demonstrate compliance with the Certification Criteria or if you have exhausted the time limit. The only exception to this is in regard to minor configuration adjustments or interface changes for Interoperability. Minor changes of this type may be allowed if time permits at the Proctor's discretion.

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.

CCHIT reserves the right to evaluate all inspection results thoroughly, including recordings, before communicating the official results to the applicant. CCHIT will make every effort to inform the applicant of the outcome at the end of the demonstration process; however, this may not always be possible. CCHIT will not inform the applicant about the certification results until all inspections have concluded, including the inspection of any written materials. Official results will be communicated to the applicant in the form of an Inspection Results Report as described in Section 2.8.

2.7.4. Lab Test Results Interoperability Inspection

If you are seeking certification for the Lab Test Results module, you will find that your Test Scripts contain criteria and test steps to demonstrate lab results Interoperability. For the Lab Test Results Interoperability Inspection, CCHIT will observe the process of lab test files being received by the system and then the results displayed from within a patient record. The applicant will be responsible for creating their own files; CCHIT will not send lab files to the applicant.

2.7.5. ePrescribing Interoperability Attestation and Inspection

If you are seeking certification for the ePrescribing module, you will be required to provide attestation and demonstrate your ePrescribing capability. CCHIT will evaluate a product's compliance with the ePrescribing interoperability criteria based on documentation submitted for attestation and the live demonstration. All applicants must meet at least the New Prescription (NewRx) and Formulary ePrescribing certification requirements and submit a copy of the certification documents from the ePrescribing network (SureScripts) or document the integration of a 3rd party ePrescribing product within their technology. Applicants using a 3rd party ePrescribing product must submit a copy of the business agreement and the ePrescribing network (SureScripts) certificate for the 3rd party product. CCHIT maintains a "CCHIT Test Pharmacy Two" on the SureScripts Staging system to verify compliance with the live testing of a new prescription. Applicants must ensure that they have set up the appropriate participating provider (specified in the Test Scripts) and that they have loaded the CCHIT Test Pharmacy Two NCPDP information in their system ahead of their inspection. Applicants are strongly encouraged to practice sending a prescription to the test pharmacy before their test; however, you must contact CCHIT to approve this practice so as not to disrupt other live testing.

Alternatively, the applicant may provide documentation of current, valid certification by a NON-pre-approved ePrescribing network. In this situation, the applicant or the ePrescribing network must provide additional documentation that the network fully complies with the standards in the certification criteria. Due to the additional time

required for CCHIT to validate a new ePrescribing network, the certification process may be delayed if this option is selected.

2.7.6. Exchange Clinical Information, Immunization Registries, Reportable Lab Submission and Electronic Syndromic Surveillance Interoperability Testing

If you are seeking certification for the Exchange Clinical Information, Immunization Registries, Reportable Lab Submission or Electronic Syndromic Surveillance (the term used to describe biosurveillance) modules, you will find that the Test Scripts include criteria and test steps requiring you to demonstrate the ability to create and send specific file types following the required specified standards in the IFR. CCHIT will require you to complete detailed information on the Application Form if you select any of these Interoperability modules regarding the standards, file formats or templates that will be used to demonstrate each of these capabilities. This documentation will allow CCHIT to validate that the files created for the "Exchange Clinical Information", "Immunization Registry", "Reportable Lab Submission" or "Electronic Syndromic Surveillance" steps meets the requirements of the criteria. The document that is created for each modular test should be formatted to match the specifications submitted on the Application Form. (If you change the file specifications from the information submitted on your Application Form before your inspection date please inform CCHIT so that your documentation can be updated.) Please review the Interoperability sections of the Test Scripts and Preliminary ARRA IFR Stage 1 Interoperability Test Guide carefully to make sure you understand the nuances in this area. You may want to use our LAIKA testing tool to help you in preparing for this component of the inspection process (see the next section).

2.7.7. The LAIKA Tool

In order to support the required Interoperability testing, CCHIT is 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 technology development, and in preparing for certification testing.

The LAIKA tool will aide you in preparing for the Exchange Clinical Information module, which requires both the display and generation of electronic care documents containing specific elements. There will be existing templates in our LAIKA tool library that you can use during practice. 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 care document for this patient to the LAIKA tool, which represents an external organization requesting an electronic care document for that patient.

You can practice the execution of the Generate and Format test case by using LAIKA to prompt for an XML file generated by your system. In the live inspection, the Proctor will

forward your created electronic care document file to our technical team for evaluation and validation.

Please see the Preliminary ARRA IFR Stage 1 Interoperability Test Guide for more details on the use of the LAIKA testing tool and the requirements for Interoperability testing.

2.7.8. Technology Modifications During the Inspection

Significant modification of the technology during the inspection process—including Same-Day Retests and New Jury Retests—will generally not be allowed. Modifications made to one part of a technology may affect the technology's compliance in other areas tested during the inspection process; therefore, the following rules apply:

- Setup and configuration changes (e.g., adding users, changing selection lists, etc.) are not considered technology modifications, and are allowed. Permitted setup 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 allotted time provided by the CCHIT Staff Proctor.
- Errors in Test Script execution (e.g., entered the wrong patient, logged on as wrong user, entered incorrect diagnosis, etc.) are not considered technology modifications, and applicants are allowed to correct data entry mistakes or repeat steps.
- Changes to the technology source code are not permitted during the inspection process. CCHIT will make no distinction between 'minor' and 'significant' changes to technology code during an inspection process. You may not make any coding changes to a technology once an inspection commences. You should be sure of the technology's ability to comply before applying for certification.

Changing technology source code during a live inspection will result in a "failed" inspection outcome, not only for the module being tested at the time, but for all the modules that were applied for. Changing technology source code during the test will disqualify you immediately from the entire certification testing process. The CCHIT Staff Proctor will inform you of the disqualification and will stop the inspection process. No refund will be issued to applicants who 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 Certification Criteria during the initial inspection, you will be given an opportunity to re-demonstrate that function during the Same-Day Retest (Section 2.7.3). However, you may not modify the source code of the technology 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 or configuration files during the

Interoperability testing process at the discretion of the CCHIT Staff Proctor and based on time available.

2.7.9. Technical Issues

Technology 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 setup 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 technology, a Test Cancellation fee may be assessed as per the Preliminary ARRA IFR Stage 1 Fee Schedule.

2.8. Obtaining Your Results

CCHIT will combine the results from any applicable modular certification tests and prepare an Inspection Results Report. The Inspection Results Report will indicate which, if any, Test Script steps were judged as non-compliant and could not be resolved during the Same-Day Retest. This report reflects the decision rendered by the inspection team regarding the technology compliance with the certification criteria.

2.9. 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 technology was found non-compliant during the initial test, and the non-compliant items were not all resolved during the Same-Day retest. Retest and appeal procedures are described below.

2.9.1. Retesting with a New Jury

You may request a New Jury Retest if:

- You believe, in good faith, that a juror rendered an incorrect decision about the technology compliance based upon how the technology 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 technology with the Preliminary ARRA Certification Criteria based upon how the technology was demonstrated during the inspection.

You do not qualify for a New Jury Retest 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 technology does not include the required functionality; or
- Your organization changed the source code in the technology, or stated intent to change the source code in the technology in order to bring the technology into compliance, at any point once the 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 technology 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 on your letterhead within five (5) business days of receipt of the written CCHIT Inspection Results Report. The New Jury Retest Request letter must state the specific steps that you are contesting, including the reasons that you disagree with the juror's decision. In addition, you must attest that no source code modifications have been or will be made to the technology since the original inspection started.

The New Jury Retest will test non-compliant items and may require retesting an entire scenario. CCHIT records the audio and video demonstration for the original inspection and any Retests.

The New Jury may evaluate the technology'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 for additional inspection time in one (1) hour increments up to three (3) extra hours. See the Certification Agreement and Fee Schedule 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 technology is found non-compliant 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 technology as presented during the retest, you may file an Appeal for Committee Review described in the next section.

2.9.2. Appeal for Committee Review

If the applicant's EHR technology is found non-compliant after a New Jury Retest, then, if the applicant believes, in good faith, that the results do not accurately reflect the compliance of the applicant's EHR technology with the Preliminary ARRA Certification Criteria as developed by the U.S. Department of Health and Human Services due to manifest juror error or demonstrable juror bias, the applicant may submit an Appeal for Committee Review pursuant to the Preliminary ARRA Certification Appeal and Compliance Policy detailed in Appendix C, Section 7.

Applicants may not appeal disqualifications that result from technology modifications or the other disqualifying conditions described in this Handbook.

Applicants that are eligible for and that wish to Appeal for Committee Review must submit the request in writing within five (5) business days of receiving the New Jury Retest Inspection Results Report. The appeal must state the specific steps that the applicant contests, including, with reasonable specificity, the reasons that the applicant disagrees with the decision rendered during the New Jury Retest. Appeals for Committee Review which are not, in the good-faith judgment of the Commission, reasonably specific as to the nature of the appeal will be denied.

CCHIT's complete Preliminary ARRA Appeal and Compliance Policy is included in Appendix C, Section 7.

2.10. Certification Outcomes

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

2.10.1. Technology Achieving Certification

If your EHR technology has successfully achieved Preliminary ARRA IFR Stage 1 Certification, CCHIT will add your technology to the list of certified technology on the CCHIT Web site, including a table of the ARRA modules that were successfully demonstrated, the version of the Certification Criteria used during the inspection process, the certification date, and other information about your EHR technology (such as name, version, etc). You may make public announcements regarding the certification of your EHR technology after your technology has been posted on the CCHIT Web site. You may prepare sales and marketing materials at any time after achieving certification, but may not distribute press releases until you have submitted them for review and approval

by the CCHIT marketing staff as stated in the Certification Agreement. All such materials must comply with requirements of the Marketing Policies (Section 4).

Technology that becomes certified prior to the publication of the Final Rule by U.S. Department of Health and Human Services (HHS) will be considered to have attained compliance with the IFR requirements as published at the time of the program launch on February 12, 2010. Once HHS has finalized the criteria and standards, applicants will be provided the opportunity to quickly close any gaps when the Final Rule is published, subject to Center for Medicare and Medicaid Services (CMS) timelines, and to announce full compliance with all criteria and standards for EHR certification established under ARRA.

Once applicants have met the Final requirements as published by HHS, following any necessary gap testing, CCHIT will issue documentation to certified applicants to support the specific modular components they successfully demonstrated and are certified for by CCHIT. Applicants may **not** share their verification documentation with rebranded Open Source EHR technology recipients. Rebranded technology recipients will receive their own unique verification documentation. (See Section 3.5.2)

2.10.2. Technology Failing to Achieve Certification

If your EHR technology is found non-compliant with the Preliminary ARRA IFR Stage 1 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 technology (described in the next section), or simply reapply for certification at a later date. CCHIT will not make any public report on the non-compliance of your EHR technology with the certification criteria.

2.10.3. Technology Correction and Retest

The Correct and Retest option is available regardless of the reason(s) for non-compliance or disqualification during the original inspection process.

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

If you wish to make corrections (including source code changes) to the technology and retest it, you must resubmit a Certification Application and follow these steps:

- Notify CCHIT, in writing on your letterhead, 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 technology, citing the specific version number and release date within 120 days after receiving the CCHIT Inspection Results Report.
- Execute a new Certification Agreement and pay the required fees within five (5) business days of the application date. For details regarding the fees associated with a Correction and Retest, see the Certification Agreement and the Preliminary ARRA IFR Stage 1 Fee Schedule.
- Test the corrected technology within the required timeframe after submitting the new Certification Agreement (90 calendar days).

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

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.

2.10.4. Certification Descriptions and Disclaimers

On its Web site (http://cchit.org), CCHIT will post disclaimers that caution potential purchasers about the limits of Preliminary ARRA IFR Stage 1 certification. Among these is that the federal criteria only represent broad, basic capabilities, and that these may prove insufficient for some practice specialties, or may be inappropriate for others; the criteria do not assess technology usability, implementation service, technology maintenance, technical and application support; and other facts.

2.11. Company and Technology Name Changes

If you are actively seeking certification, you may notify CCHIT of organization and technology name changes during the certification process. Because these changes reflect amendments to the Certification Application and certification records, requests to modify the organization or technology 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 that organization.
- CCHIT will modify the information only after receiving the proper written notice and verifying that the technology and version presented and tested for certification matches the new information.

Organizations with technology that has already achieved certification may notify CCHIT of company and technology name changes, as follows:

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

Note that this policy only applies to **simple name changes**.

If a company is changing names due to a merger, sale or other third party transaction, refer to the policies described in the Marketing Policies. (Section 4)

2.12. PREPARING FOR 2012 AND BEYOND

CCHIT expects to continue to work with the materials from HHS to develop certification programs to test their criteria in the next cycle and beyond. The anticipated launch date for the Stage 2 certification cycle is anticipated to be early 2012 to allow providers enough time to successfully implement the technology at the next level in time to prove Meaningful Use and be eligible to collect incentive payments under ARRA.

2.13. OUR JURORS

2.13.1. Juror Qualifications, Selection and Assignment

The jury panel for the clinical demonstration will consist of one clinical expert from our experienced juror pool. The juror for Security testing is an Information Security expert from our experienced juror pool.

CCHIT maintains a pool of trained and ready jurors that is adequate for the volume of applicants 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 certification criteria, 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.

2.13.2. 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.

2.14. Purchaser Complaint Process

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

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

CCHIT will:

- Keep a record of all complaints
- Notify the applicant about the complaint and request the applicant 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 technology submitted for testing and an EHR technology being marketed by the organization as certified, CCHIT Staff will schedule a meeting with the applicant to discuss the findings.

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

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

2.15. Certification Suspension and Revocation

CCHIT may suspend your technology certification, upon notice to you, if:

- CCHIT determines, in accordance with our policies, that there is a substantial compliance discrepancy between the certified EHR technology and the EHR technology being marketed and you do not provide, within 15 days after notice from CCHIT, an explanation therefore that is reasonably satisfactory to CCHIT
- CCHIT determines that you are no longer actively supporting the certified EHR technology; or
- You are in material breach of any term of the Certification Agreement or you, or a rebranded recipient (Open Source), 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 revoke a technology's certification, upon notice to you, if your certification has remained suspended for a period of more than 30 days.

3. CERTIFICATION PROGRAM 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 Preliminary ARRA IFR Stage 1 Certification Agreement (Section 5). For any required incremental testing to meet updated criteria from HHS you may be required to sign an addendum to the Certification Agreement prior to testing.

3.2. PRICING AND PAYMENT SCHEDULE

All pricing and payment terms are described in the Certification Agreement (Section 5). A summary of our pricing is provided in the Preliminary ARRA IFR Stage 1 Certification Fee Schedule Section 6.

3.3. TERM OF CERTIFICATION

The term for all Preliminary ARRA IFR Stage 1 certifications, regardless of certification date, will extend to December 31, 2014 (unless extended by a directive of the ONC or HHS). If HHS extends the applicability of the Stage 1 criteria beyond this date, CCHIT will extend the renewability of Stage 1 Certification.

3.4. TECHNOLOGY ELIGIBLE FOR CERTIFICATION

3.4.1. EHR Technology Eligible for Certification

CCHIT has utilized the criteria developed by the federal government in the Interim Final Rule to construct the modular Test Scripts for use in the Preliminary ARRA IFR Stage 1 certification testing process. EHR technology, products or systems targeted for the domains of Eligible Providers (used in an Ambulatory care setting) or Hospitals (used in an Inpatient care setting) that can meet the requirements of the foundational Security and Privacy criteria plus 1 or more additional ARRA modules are invited to participate in the certification process. Virtually any type of EHR technology is eligible to apply including, but not limited to, Open Source, registries, networks, handheld device applications, portals, etc., as long as they can qualify for certification by demonstrating 100% compliance with the foundational Security and Privacy criteria and 1 or more additional components. The EHR technology, product or system should be identified by a specific name, version/release level, and release date (or expected release date), and be available in the United States.

3.4.2. Open Source Technology

All Open Source EHR technology is welcome to apply for the Preliminary ARRA IFR Stage 1 certification, CCHIT Certified® 2011 certification, or the IFR Stage 1 Site certification when it is launched later in 2010. CCHIT has updated our processes to accommodate the changing nature of Open Source technology, such as allowing subsequent versions to "inherit" the certification status from the base system that was tested (Section 3.5.1). CCHIT acknowledges that Open Source code is often shared and policies have been developed to accommodate rebranding of certified Open Source technology and still maintain the certified status of the underlying technology (Section 4.8).

CCHIT is in the process of exploring ways to obtain cost-deferral grant funds for Open Source applicants. CCHIT may be able to apply any grant monies received for this purpose retroactively if approved by the authorizing source.

3.4.3. Internally Developed EHR Systems

For those organizations that have developed EHR systems primarily for their internal use, CCHIT offers the Preliminary ARRA IFR Stage 1 certification program under the same terms and conditions as are offered to commercial applicants. Applicants must choose the appropriate domain, licensing model and ARRA modules to be tested against based on the Internally Developed system capabilities. The foundational Security and Privacy module must be included in any application for certification testing. These systems will be evaluated against the federally developed criteria using the same Test Scripts as for commercial EHR technology. 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 renewal fees and terms as technology developed and marketed exclusively for commercial sale.

Internally developed systems may also consider the alternative certification pathways of CCHIT Certified® 2011 certification, or Stage 1 Site certification when it is launched later in 2010. Both of these alternate program details will be discussed in separate Certification Handbooks.

3.4.4. Defining the EHR Technology, Product or System for Certification

You will be prompted to identify the appropriate Domain (Eligible Provider or Hospital), Licensing Model (Open Source or Proprietary) and select the ARRA modules for which you are seeking certification on the online Certification Application. If you are applying for any of the Interoperability modules (Lab Test Result, Exchange Clinical Information, Immunization Registries, Reportable Lab Submission or Electronic Syndromic Surveillance) you will be prompted to enter the specific standards you utilize to comply with the listed criteria applicable to each module you select.

You must complete a separate Certification Application for each Domain (*Eligible Provider or Hospital*) and submit the fees associated with each application. Each Domain must be tested in its entirety following the appropriate Test Script since the requirements are each based on separate criteria sets as published by HHS in the Federal Register.

On each application for certification, you must describe and identify your specific EHR technology name, version and release date (or expected release date). You may update the version information at any point up to the scheduled inspection date by simply notifying CCHIT. CCHIT will test the identified technology and validate compliance with the criteria. CCHIT will include the version and release date information for the technology that was successfully tested when it is added to the CCHIT Web site.

We also ask that you provide additional information such as primary and secondary contact information. CCHIT reserves the right to request periodic updates of contact information to maintain accurate and up to date certification information.

3.5. Maintaining Certification Following Updates, Changes or Rebranding

3.5.1. Extending Certification to Subsequent Versions of a Certified Technology

Certification is completed with the specific version of the technology that was tested by CCHIT and found 100% compliant with the relevant criteria.

Once a technology is 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 technology to be marketed as certified as long as the applicant has not irreversibly removed capabilities needed for compliance with the Certification Criteria. For technology offered under an Open Source licensing model, the organization or community submitting the technology for certification shall be responsible for determining and enforcing its own policy regarding labeling of subsequent versions of the technology as certified.

The certification fees currently include a single listing for each certified technology on the CCHIT Web site; however, you may request additional listings of new versions if you wish. Additional, separate version listings may be added to the CCHIT Web site for an additional fee and upon submission of the CCHIT Product Update Form available by contacting the Certification Program team. For details, see the Appendix or the CCHIT Certification Agreement.

3.5.2. Rebranding of Preliminary ARRA IFR Stage 1 Certified Open Source Technology

CCHIT recognizes that the source code of an Open Source certified EHR technology may be shared with other organizations who wish to rename the technology or system. To allow a second organization (recipient) to claim certification of the EHR technology, both organizations must follow the process described in this section. Only versions with the equivalent or higher functionality to the originally certified technology qualify for rebranded Open Source EHR certification. Any other changes or unauthorized "forking" to the code of a certified technology may require testing in order to maintain certification of the rebranded system. To add a rebranded technology or system to the certified technology list, the original applicant and the recipient organization must jointly perform the following:

- Submit a letter, on company letterhead, signed by an officer of both the recipient organization and original applicant's organization stating that the rebranded system (citing the specific new technology name and version number) is an authorized transfer of the original source code of the certified technology (citing the original technology name and tested version number). This letter should also state whether any changes were made to the certified technology since the certification date, other than the name ;
- Submit two (2) signed originals of the Rebranded EHR Technology Certification Agreement, signed by both the original applicant and the recipient organization; and
- Submit payment of the rebranded certification fee to CCHIT. (See Preliminary ARRA IFR Stage 1 Fee Schedule, Section 6)

The terms and fees for rebranded Open Source EHR technology are described in the Rebranded EHR Technology Certification Agreement and on the Preliminary ARRA IFR Stage 1 Fee Schedule.

Once CCHIT has received the required materials and fees, the rebranded EHR technology will be listed on the CCHIT Web site (http://cchit.org). The certification listing and label will **exactly** match the ARRA modules with which the original certified technology demonstrated compliance. CCHIT will also issue the recipient unique certification verification documentation to supply to purchasers or providers of the technology for use as proof of "certified technology" use in their facility or practice to qualify for incentives under ARRA once all criteria and standards requirements are final.

In order to maintain the rebranded EHR technology listing on the CCHIT Web site following the first year, the recipient must pay the annual renewal fee for rebranded EHR technology.

If certification is revoked for the original certified technology, certification will also be revoked for the corresponding rebranded EHR technology.

3.6. JOINT APPLICATIONS FOR CERTIFICATION

If an applicant's EHR technology meets only a subset of the ARRA Certification Criteria associated with the relevant certification, the applicant may seek certification by co-applying with other technologies or systems that, collectively, can meet **all** of the requirements when used together. Joint application may apply to a single applicant where additional technology modules from the same vendor are needed to meet the Certification Criteria or it may apply to systems where multiple applicants with separate technologies or systems are needed to meet the 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 and pay applicable application fees and renewal fees. In addition, the primary applicant must coordinate the submission of all CCHIT-required materials and coordinate inspections across the organizations that jointly applied. If the combination achieves certification, the combination will receive a single combined listing on the CCHIT Web site (e.g., "Applicant A/Applicant O EHR Technology"). Joint technologies or services that were collectively certified may not be marketed separately as meeting the certification requirements and are subject to the same provisions as single technologies or systems.

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

3.7. CERTIFICATION VERIFICATION

Once applicants have met the requirements in the Final Rule as published by HHS, following any necessary retesting, CCHIT will issue documentation to certified applicants to support the specific modular components they successfully demonstrated and for which they are certified. The certification verification will be unique to the certified technology/system and may be provided by the applicant to any purchasers of the technology for use as proof of "certified technology" use in their facility or practice to qualify for incentives under ARRA. Applicants may NOT share their verification documentation with Rebranded Open Source EHR Technology Recipients. Rebranded technology recipients will receive their own unique verification documentation. (See Section 3.5.2)

3.8. TRANSFERABILITY OF CERTIFICATION

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

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

4. MARKETING POLICIES – PRELIMINARY ARRA IFR STAGE 1

Background

As part of achieving Preliminary ARRA IFR Stage 1 certification, your organization will benefit from CCHIT's public relations and marketing program that educates potential health IT buyers about the value of purchasing certified technology. Those programs include:

- Educational outreach to medical professional associations at both the national and local levels
- Participation in meetings and conferences to promote the value of 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
- A Web site, http://ehrdecisions.com, aimed at giving providers more information on health IT evaluation, selection and implementation

CCHIT provides Marketing Policies in this 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 CCHIT's brand in the minds of potential buyers and those organizations – public or private – providing incentives to providers to purchase and implement health IT.

These Policies aim to increase the transparency of the marketplace by differentiating for physicians and hospitals which technology will help them meet the federal minimum requirements for incentive funding under the ARRA. Providers seeking more purchasing assurance than is available in the Preliminary ARRA IFR Stage 1 certification program will be referred to CCHIT Certified® 2011 products.

The Marketing Policies are part of the CCHIT's 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 Preliminary ARRA 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 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 by CCHIT or its jurors.**

- **Organizations are required to submit to CCHIT, for its prior review and written approval, all press releases mentioning CCHIT, CCHIT's certification programs or technology with CCHIT certification. Organizations are not required to submit other promotional materials to CCHIT 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 Policies. Any failure to secure CCHIT's prior written approval for press releases and any variance from pre-approved statements and uses of 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, business papers
- Electronic: Web content, e-newsletters, online advertising, blogs or any other social media, downloadable material, Flash animations, Web seminars or presentations, email promotions, search-engine optimization, CDs, photography, video
- Broadcast: radio, television, Web

- 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 CCHIT or the Preliminary ARRA 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 from CCHIT indicating they have successfully met designated Certification Criteria within an identified program category and have completed the appropriate agreements to earn Certification can promote or advertise technology as certified in CCHIT's Preliminary ARRA certification program.

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 Preliminary ARRA IFR Stage 1 Certification Status

In reference to your technology's status as certified EHR Preliminary ARRA technology, you must clearly indicate:

- The name of your organization (or the prime organization if applying jointly)
- The name and version of the technology tested and earning the certification
- The domain: Eligible Provider or Hospital
- The number of modules for which the technology is certified
- The Preliminary ARRA program period for which CCHIT has inspected the technology

The form of such a reference shall be as follows: "(Organization name)'s, (technology name and version) has been inspected by the Certification Commission for Health Information Technology (CCHIT®) and is certified EHR technology, (program period), preliminarily meeting (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."

An example of a reference to these certifications for Eligible Provider EHR technology is:

"Health Inc.'s, Good EHR version 1.2.3, has been inspected by the Certification Commission for Health Information Technology (CCHIT®) and is certified EHR technology, IFR Stage 1, preliminarily meeting 5 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 Hospital EHR technology is:

"Care Inc.'s, Complete EHR technology version 4.5, has been inspected by the Certification Commission for Health Information Technology (CCHIT®) and is certified EHR technology, IFR Stage 1, meeting 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."

4.3. Use of Seals and Certification Marks

Technology certified under the Preliminary ARRA program is not eligible to use the "CCHIT Certified®" designation in any form or a CCHIT Certified® Certification Seal. "CCHIT Certified®" is a registered mark of the Certification Commission for Health Information Technology and may not be used without permission.

4.4. Use of the Certification Facts™ Label

Each certified EHR technology listed on http://cchit.org will have a link to a page describing the inspection results for that technology. The page contains 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.

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 Preliminary ARRA 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 the Web site and abide by the Terms of Use at http://cchit.org/terms-of-use .

4.5.1. Approved Descriptions about CCHIT

CCHIT may 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 Preliminary ARRA IFR Stage 1 Certification Program

These statements must be used in their entirety.

"The Preliminary ARRA IFR Stage 1 certification program, operated by the Certification Commission for Health Information Technology (CCHIT®)", inspects EHR technology against federal minimum criteria and standards developed by the U.S. Department of Health and Human Services (HHS) and published on January 13, 2010. It is offered now to allow eligible providers and hospitals time to qualify for incentive funding under the American Recovery and Reinvestment Act of 2009 (ARRA). The program is designed to demonstrate that a vendor's product is 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, and health IT companies will have an opportunity to return to complete final certification."

"The Preliminary ARRA IFR Stage 1 criteria and standards used by the Certification Commission for Health Information Technology's (CCHIT®) for EHR technology inspection were published by the U.S. Department of Health and Human Services as an Interim Final Rule (IFR) as an *Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology*. The IFR took effect on February 12, 2010."

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."

4.6. TECHNOLOGY OR COMPANY RENAMING

In executing your organization's marketing plan, you may decide to rename your company or your technology. CCHIT's policy is to publicly list your company name, technology 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 the Certification application information for your company or your technology, 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 any member of the CCHIT Program Team, followed by a hard copy sent to CCHIT's address to the attention of the Certification Manager. Your listing will be changed only after we have received that official notification. See Section 2.11.

4.7. 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.

4.8. Rebranding of Preliminary ARRA Certified Open Source Technology

CCHIT recognizes that the source code of an Open Source certified EHR technology may be shared with other organizations who wish to rename the technology or system. To allow a second organization (recipient) to claim certification of the EHR technology, both organizations must follow the process described in Section 3.5.2.

5. APPENDIX A – FORMS AND DOCUMENTS

All forms and documents referenced in this Certification Handbook are available at http://www.cchit.org/get_certified within the designated program (i.e., Preliminary ARRA IFR Stage 1), and domain categories (i.e., Eligible Provider or Hospital). Additional forms, such as the Product Update Form, are available from the Certification Program team.

6. APPENDIX B – PRELIMINARY ARRA IFR STAGE 1 FEE SCHEDULE

Exhibit A – Preliminary ARRA IFR Stage 1 Certification Program Pricing

Note: Elibible Provider and Hospital Domains are separate inspections and priced as such

		Number of Meaningful Use Objectives Inspected			
Total Dollars	**1 (Security) to 2**	**3 to 5**	**6 to 10**	**11 to 20**	**> 20**
Standard Fees					
Certification (due with application)	$6,000	$10,000	$15,000	$24,000	$33,000
Annual Renewal	$1,000	$2,000	$3,000	$4,000	$5,000
Additional Web Listings (Year1/Year 2)	$2,000/$1,000	same	same	same	same
Rebranded Technology Listing (Open Source only)	$2,000/$1,000	same	same	same	same
Service Charges					
Incomplete Applications	15% of Application Fee	same	same	same	same
Inspection Extension (beyond 90 days)	15% of Application Fee	same	same	same	same
Test Cancellations	$1,000	$2,000	$3,000	$4,000	$5,000
Additional Inspection Time (if required) (1 hour increments)	$1,000	$1,000	$1,000	$1,000	$1,000
Correct and Retest					
Certification Fee (due with application)	$3,000	$5,000	$7,500	$12,000	$16,500

7. APPENDIX C – PRELIMINARY ARRA CERTIFICATION APPEAL AND COMPLIANCE POLICY

CCHIT has developed a one-level internal procedure to provide expedited review of denials of Preliminary ARRA Certification and of purchaser complaints about Preliminary ARRA Certified Technology. These Preliminary ARRA Certification Appeal and Compliance Policies and Procedures (the "Appeal and Compliance Policy") are designed to resolve disputes concerning Preliminary ARRA Certification raised by vendors and purchasers and enhance the integrity and fairness of the Preliminary ARRA Certification Program.

This Preliminary ARRA Certification 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 Preliminary ARRA Certification 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.

1. Appeal and Compliance Committee

(a) Purpose. The purpose of the Preliminary ARRA Appeal and Compliance Committee (also referred to as the "Committee") is to review and resolve:

(i) each Appeal for Committee Review filed by a vendor after a finding through the Inspection Process and New Jury Retest that such vendor's EHR Technology is not compliant with applicable Certification Criteria;

(ii) complaint(s) submitted to CCHIT by a purchaser of a CCHIT Preliminary ARRA Certified Technology, and referred to the Committee after staff investigation because of a probable and substantial compliance discrepancy between the EHR Technology submitted for testing and an EHR Technology being marketed by the Applicant as Preliminary ARRA IFR Stage 1 Certified; and

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

(b) Committee Members. When CCHIT receives an Appeal for Committee Review, a purchaser complaint or a request for interpretation of, or an exception to, a provision of this Handbook or the Certification Agreement, the members of the Preliminary ARRA Appeal and Compliance Committee for such issue shall consist of CCHIT's Executive Director, Certification Program Director and Technology Director. In the event that any member of the Committee is unable to serve in a timely manner with respect to any particular appeal, CCHIT's Executive Director shall select a replacement member of the Committee from among CCHIT's staff.

2. Procedure

(a) Initiation of Appeal/Complaint Process

(i) **Initiation of Appeal for Committee Review**. If a vendor's EHR Technology fails to achieve Preliminary ARRA Certification through the original Inspection Process and a subsequent New Jury Retest, the vendor may appeal this decision by submitting to CCHIT, by mail, fax or e-mail, an Appeal for Committee Review within five (5) business days of its receipt of notice that its EHR Technology failed the New Jury Retest. Appeals for Committee Review are managed by a CCHIT staff member who was not directly involved in the technology evaluation.

The Appeal for Committee Review should include the following information:

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

(B) the elements of the Preliminary ARRA 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 Committee 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 Preliminary ARRA Certification. Denials of time extension requests are not subject to appeal.

(iii) **CCHIT Acknowledgement of Appeal**. CCHIT will acknowledge receipt of an Appeal for Committee 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 Committee Review to the Preliminary ARRA Appeal and Compliance Committee.

(iv) **Initiation of Purchaser Complaint and Preparation for Hearing**. If a purchaser of a CCHIT Preliminary ARRA Certified Technology has a specific complaint that such technology 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 technology that is the subject of the complaint, including the release and version numbers;

(B) the date on which the technology was purchased or licensed by the purchaser;

(C) the specific criteria with which the purchaser feels the EHR technology is non-compliant;

(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.

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 technology 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 Technology submitted for testing and an EHR Technology being marketed by the Applicant as Preliminary ARRA IFR Stage 1 Certified, referring the complaint, accompanied by CCHIT's investigation documentation, to the Preliminary ARRA Appeal and Compliance Committee.

(b) Hearings.

(i) **Scheduling**. The Preliminary ARRA Appeal and Compliance Committee will schedule hearings on an as needed basis. Following receipt of (i) a complete Appeal for Committee Review, (ii) a referral of a purchaser complaint together with the investigation report of CCHIT's staff or (iii) a request for interpretation of, or an exception to, a provision of this Handbook or the Certification Agreement, the 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 Committee may require the vendor to clarify, supplement, or amend a Preliminary ARRA Appeal for Committee 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 Committee or other 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 technology, the Committee, in its sole discretion, may include such individuals either in the staff's investigation or the hearing.

(iv) **Hearing Participants**. If a vendor stipulates in its Appeal for Committee 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 Committee.

The Committee, in its sole discretion, may invite the vendor of the EHR technology 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.

(c) Decision of the Preliminary ARRA Appeal and Compliance Committee.

(i) **Appeals for Committee Review.** Prior to the hearing of an Appeal for Committee Review, the Committee will review the information submitted by the vendor and 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 Committee will resolve and decide the appeal based on the record, including the recorded New Jury Retest, relevant and credible information presented by the vendor, and CCHIT policies. The Committee will issue a written decision to the vendor within five (5) days after the hearing that either the vendor's EHR Technology is Preliminary ARRA IFR Stage 1 Certified or that Preliminary ARRA Certification has been denied.

(ii) **Purchaser Complaints.** Prior to a hearing concerning a purchaser complaint, the 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 Committee 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 and CCHIT. All vendors involved with the technology (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 Committee will review vendor requests for interpretation of, or exceptions to, the provisions of this Handbook or the Certification Agreement. The Committee will make a determination based on CCHIT policies, relevant and credible information presented by the vendor. All such determinations are final and are not subject to appeal.

(iv) **Majority Rule.** All decisions by the Committee will be reached by a vote of the Committee members, using a simple majority voting rule.

3. Finalizing and Closing Appeals and Complaints

Conditions for Closing. An appeal or complaint will be closed, and all proceedings ended, when either of the following occurs:

(a) The appeal or complaint has been resolved and decided by the Committee; or

(b) The appeal has been withdrawn or terminated by the vendor or the complaint has been withdrawn by the purchaser.

4. General Provisions

(a) Nature of the Process. All challenges of Preliminary ARRA Certification decisions and consideration of purchaser complaints shall be governed exclusively by the rules contained in this Preliminary ARRA Certification 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 Preliminary ARRA Certified EHR Technology. With respect to Preliminary ARRA Certification, only denial of Certification decisions are subject to review and only by the submission of an Appeal for Committee 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. Attorneys will not, however, be permitted to attend any hearings. If a party has retained an attorney, that attorney will be directed to communicate with CCHIT through CCHIT's legal counsel.

(b) Time Requirements. CCHIT will make every effort to resolve appeals and complaints in accordance with the time requirements noted in this Preliminary ARRA Certification Appeal and Compliance Policy. CCHIT's failure to meet a time requirement, however, 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 Preliminary ARRA Certification 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.

(c) 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:

(i) HHS published certification and eligibility criteria;

(ii) 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

(iii) 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; and,

(iv) All decisions and orders of CCHIT are considered final and closed, consistent with this Appeal and Compliance Policy and the Certification Agreement.

