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**Meeting**  
**ONC HIT Certification Program**

**Testimony by**  
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**Health Information Technology (CCHIT)**

**Before the**  
**Health Information Technology Policy Committee**

**Panel 4: Private Sector Representatives**

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## **Introduction**

Madam Chair, Mr. Co-Chair, and Members of the Committee, thank you for inviting me today. My name is Alisa Ray, and I am here in my capacity as Executive Director of the Certification Commission for Health Information Technology (CCHIT®). I appreciate the opportunity to address this meeting on the “ONC HIT Certification Program”.

## **Background**

CCHIT is a nonprofit organization with a public mission of supporting the adoption of robust, interoperable health information technology by providing educational resources to healthcare stakeholders including healthcare providers, health IT developers and others. Founded in 2004 in response to the Office of the National Coordinator’s (ONC) Strategic Framework, CCHIT competed for and was awarded a Federal contract in 2005 to develop EHR certification criteria as well as a certification testing methodology. CCHIT received Federal recognition in 2006, and during the following three years, over 250 ambulatory and inpatient EHR products were tested and certified.

In February 2009, Congress acknowledged the value of certification in the language of the American Recovery and Reinvestment Act (ARRA) by offering a multi-year series of incentive payments to providers and hospitals for the meaningful use of certified EHR technology.

As authorized by this law, ONC developed new regulations requiring EHR certifying bodies and testing organizations to become accredited. CCHIT was among the

first to become a National Voluntary Laboratory Accreditation Program (NVLAP) Accredited Testing Lab (ATL), and an American National Standards Institute (ANSI) Accredited and ONC Authorized Certification Body (ONC-ACB).

Under the new regulations, EHR certifying bodies did not have the opportunity to engage with stakeholders to develop and refine certification criteria, and EHR testing organizations were no longer involved in developing or validating test procedures. In January 2014, CCHIT determined that its mission would be best served by voluntarily withdrawing from the ONC HIT Certification Program and instead offering its talents in new ways. CCHIT's future plans include offering direct counsel to both healthcare providers and health IT developers on the requirements for certified EHR technology and how to best satisfy HIT regulations published by organizations and governments. With a more global focus, and in alliance with HIMSS, CCHIT will also develop new programs and policy guidance aimed at achieving interoperability and supporting change in the way providers and patients around the world use IT to positively transform health and healthcare.

### **Comparing CCHIT's independently developed certification with the ONC HIT certification program**

CCHIT was originally created with the mission of accelerating adoption as a private sector collaborator to ONC contributing to the adoption component of the federal HIT strategic plan. From 2005 to 2010 CCHIT worked in this capacity with an emphasis on engaging the community of provider, vendor, payer and government stakeholders to develop criteria and testing processes that established the benchmark for system

capabilities and also published a forward-looking roadmap of future requirements. This independent development process included a high degree of transparency during the development phase supported by multiple rounds of public comment and a rigorous pilot testing of both the criteria and the test methods. CCHIT's full certification also included a validation of successful provider implementation of EHR products at several live sites.

CCHIT pioneered testing and certification methodologies which form the basis of today's ONC program. This includes use of remote testing methods via observation of capabilities, open-source development of tools to encourage and validate interoperability, a volunteer expert juror program to witness testing, and the first introduction of EHR usability testing.

The following chart illustrates the differences between the original CCHIT certification approach and the ONC HIT Certification program introduced with the passage of the HITECH Act and ONC's Certification Program.

<b>Program</b>	<b>CCHIT Certified</b>	<b>ONC HIT Certification</b>
Driver of certification	Voluntary	Mandatory for the collection of incentives and avoidance of penalties
Certification criteria development	Developed by volunteer subject matter expert panels. Panel composition to represent a broad range of healthcare stakeholders. Multiple public comment rounds. Forward-looking roadmaps published.	Federal government with FACA committee and work group input.
Testing tool development	Test scenarios developed by panels with multiple rounds of public comment. Testing tools open-sourced. Test procedures pilot tested with rigorous validation requirements.	Test procedures and testing tools written by NIST with contractor assistance. No formal comment process or validation steps.

Program	CCHIT Certified	ONC HIT Certification
Providers served	A wide range of providers seeking greater assurance when investing in new EHRs; special population, special setting and specialty medicine programs available	Only Medicare and Medicaid eligible providers and hospitals seeking incentive payments
Technology certified	Only comprehensive, integrated EHRs	Broad array of EHR technologies including complete EHRs and EHR modules
Accountable to	Healthcare providers	Federal government
Goals	Assurance of integrated functionality, interoperability and security; meet provider needs for clinical care.	Support Meaningful Use (as defined by CMS) to improve outcomes of care and support healthcare reform

Today, we believe the community views certification more as a necessary technical compliance task associated with administration of incentives, and less as an assurance mechanism for providers purchasing health IT.

**Lessons learned as a pioneer certification organization**

**Lesson 1:** *Don't launch a program until all aspects are tested and ready.* Make sure all components – criteria, standards and test procedures and tools – have undergone quality testing and are error free at program launch. Many of the 2014 test methods and tools have already undergone many updates and revisions. This adds another layer of complexity and confusion to the process that wastes resources and diminishes credibility.

**Lesson 2:** The federal government is eager for adoption to occur as rapidly as possible. *Today, however, we hear from all stakeholders that adequate time for implementation is the biggest challenge.* Providers need more time to successfully implement a new or upgraded EHR, more time to gather data and more time to prepare reports. Vendors need

more time to program their systems to new requirements once the *final* requirements and test methods are locked down. ATIs and ACBs need predictable timelines within which they can adapt to new testing and certification program requirements and retool their businesses.

This calls for a different approach to the regulatory and technical development components. Every developer knows that a waterfall approach takes the most time; that's what the ONC process has followed. CCHIT learned from its independent development programs that drafting and developing test methods simultaneously with the criteria development process is inherently more efficient. It also highlights early on which criteria may be more or less difficult to test – this makes prioritization and alignment with strategic goals easier.

**Lesson 3:** *Create more room for involving community experts in program development, including criteria, testing processes and pilot testing, and certification processes.*

**Lesson 4:** *Through its early work CCHIT learned that a “one size fits all” approach to certification won't work. Beyond ambulatory or acute inpatient distinctions, providers seek assurance programs specific to their patients, their medical specialties and the care settings in which they practice. CCHIT engaged industry experts to develop programs for child and women's health, long term and post-acute care, behavioral health, emergency departments, and several medical specialties.*

## **Conclusion**

CCHIT, again, thanks the Health Information Technology Policy Committee for the opportunity to comment today. We would also like to acknowledge the challenge that EHR testing and certification poses for those developing new programs, health IT developers responding to them, authorized bodies that must objectively test EHRs, and, most importantly, the clinicians using them. Our own experience suggests that it requires broad input and collaboration from the health IT community, in an atmosphere of transparency and reliability, to successfully design certification programs that will demonstrably improve the effectiveness and satisfaction associated with use of EHRs, thus removing one of the major barriers to widespread adoption.