May 10, 2010

David Blumenthal, MD
National Coordinator
Health Information Technology
Office of the National Coordinator for Health Information Technology
Hubert H. Humphrey Building, Suite 729D
200 Independence Avenue, SW
Washington, DC 20201

RE: 45 CFR Part 170; RIN 0991-AB59; Proposed Establishment of Certification Programs for Health Information Technology

Public stakeholder comments specific to the establishment of a permanent certification program.

Dear Dr. Blumenthal:

The Council for Affordable Quality Healthcare (CAQH) appreciates the opportunity to comment on the notice of proposed rulemaking (NPRM) published on March 10, 2010 detailing the proposed processes for certification of electronic health record (EHR) technology (*Federal Register*, Vol 75, No 46). This letter includes our comments specific to the establishment of the permanent certification program, which complement our comments submitted on April 9, 2010 regarding the temporary certification program.

CAQH supports the development of a robust and efficient certification process for EHR technologies to ensure that such technologies provide the functional requirements necessary to support meaningful use. We commend the Office of the National Coordinator for Health Information Technology's (ONC) thoughtful work toward this end. Our comments address:

A. An overview of CAQH:
   ➢ Including the significant expertise CAQH has with regard to developing and overseeing a certification and testing program for health information technologies.
B. A set of recommendations, comments, and requests for clarification regarding provisions of the proposed permanent certification program that focus on:
   ➢ Minimizing disruption during transition from temporary to permanent program;
   ➢ Maintaining flexibility for alternative certification pathways;
   ➢ Assuring quality of testing and certification through an open and transparent process that leverages existing resources; and
   ➢ Establishing transparent processes to encourage shared-learning and minimize system-wide costs.

A. OVERVIEW OF CAQH

CAQH is a nonprofit alliance of health plans and trade associations that serves as a catalyst for industry collaboration on initiatives that simplify healthcare administration. CAQH solutions promote quality interactions between plans, providers, vendors, and other stakeholders, reduce costs and frustrations associated with healthcare administration, facilitate administrative healthcare information exchange, and encourage administrative and clinical data integration. The recommendations in this letter have been informed by the CAQH role in deploying multi-stakeholder, national, health information technology (HIT) initiatives, and tracking their impact across a range of stakeholders; as well as by our extensive experience establishing and operating a successful testing and certification program.

Two notable examples of CAQH initiatives include:

- Universal Provider Datasource® (UPD) has streamlined the country's provider data collection process associated with credentialing healthcare providers, directory maintenance, claims administration, and quality assurance. It is used by over 815,000 providers and over 550 private/public organizations, ranging from state Medicaid plans and large integrated hospitals to private national and regional health plans.

- Committee on Operating Rules for Information Exchange® (CORE) has brought together over 115 organizations to implement the exchange of administrative data through a set of phased requirements. CORE is a national, vendor-neutral initiative that makes it possible for any provider to access consistent and reliable insurance coverage and payment information from any health plan electronically, using the technology of the provider's choice. To quantify the impact of CORE, a study conducted by IBM Global Business Services tracked outcomes affecting over 33 million lives in various provider settings with a range of HIT tools. Results show that providers are saving millions of dollars due to increased efficiency and reliance upon CORE-certified vendors to ensure expected benefits occur. Moreover, there has been a 33% increase in HIT adoption by these providers.

CAQH Experience in Testing and Certification of Health Information Technologies

The CORE Certification process was established to validate voluntary implementation of CORE operating rules by marketplace adopters. To achieve successful certification, entities follow a thorough testing process that requires completion of stakeholder-specific test scripts for health plans, vendors, clearinghouses/electronic health networks, and providers, using a uniform test suite with test data developed and approved by CORE participants. CORE testing is conducted by CORE-authorized, third-party testing vendors that are approved by CAQH via comprehensive alpha and beta testing.

Components of CORE Certification and Testing
The primary components of CORE testing include: transactional-based, simulated testing of data exchange, testing of system functionality (i.e., electronic), and manual uploading of specified documentation (e.g., system logs) to assist with verifying rule requirements. Key steps to certification include:

- Entities submit a report that demonstrates the successful completion of testing based on their stakeholder-type, along with supporting documentation that is required by the CORE Certification Policy and Seal application.
- CAQH staff review completed applications within a 30-day time period for rule applicability, successful test script completion, other required documentation such as HIPAA attestations, and any other statements that demonstrate an entity's appropriate implementation of CORE operating rules.
- If successful, the entity will earn a CORE Certification Seal for the CORE phase for which they applied.

Impact of CORE Certification

CORE operating rules are deliberately introduced to the market in phases. Each CORE phase represents significant collaborative activity to set policy, technical specifications and testing/certification requirements, and builds the foundation for varied forms of information exchange. Established in 2007 to facilitate the implementation of CORE Phase I rules, the CORE Certification process now extends to CORE Phase II (2009) and is anticipated to support market adoption of CORE Phase III in 2010. To date, over fifty organizations – a mix of large vendors, health plans, and providers - have earned the CORE Phase I Seal, and more than half of these entities have already achieved or are committed to achieving Phase II Certification by mid-2010. CORE Phase I certified entities are providing and exchanging robust and consistent data for over 85 million health plan members.

CORE Certification provides entities with useful tools, such as the CORE Seal, that enable them to demonstrate the achievement of streamlined information exchange for all entities with whom they communicate. CORE-certified vendors, in particular, have used the CORE Certification process to improve their time-to-market with new products, streamline their data handling and connectivity processes, and deliver added value to their provider clients. Providers can look to their vendor, or certify directly, to ensure there is robust administrative data in their Emergency, Admitting/Registration, and Patient Financial Services departments.

Coordination with Other Industry Efforts

CORE Certification has been recognized as complementary to accreditation and certification programs offered by organizations such as Electronic Healthcare Network Accreditation Commission (EHNAC). CORE has worked to outline future requirements with entities such as Certification Commission for Healthcare Information Technology (CCHIT). CAQH involvement with these types of organizations has enabled stakeholders to achieve key milestones and meet complementary requirements within a larger industry framework – understanding that certifications will not be overlapping. In just four years, CAQH has established a proven testing methodology that has enabled stakeholders to take the necessary steps toward true interoperability. Demonstrations that included CORE certification by the Medicaid Information Technology Architecture (MITA) and the Nationwide Health Information Network (NHIN) CONNECT Gateway at industry events like the Healthcare Information and Management Systems Society (HIMSS) Integrating the Healthcare Enterprise (IHE) Interoperability Showcase, illustrate the capability for CORE Certification to contribute to the transformation of the marketplace.

B. **CAQH COMMENTS AND RECOMMENDATIONS**

> Minimize disruption during transition from temporary to permanent program.

Recommendation #1: *Enable seamless transition from the temporary to the permanent certification programs.*

> **Rationale:** The potential exists for confusion and duplication of activities during the transition between the temporary and permanent certification programs. ONC should seek to simplify this transition to the greatest extent possible to reduce the burden on providers and minimize overall program costs.

- *Vendors and providers should not be required to recertify solely because the program structure changes.* While CAQH acknowledges that the temporary testing and certification program may not be as rigorous as the permanent program, if Stage 1 criteria remain unchanged providers and/or vendors should not be required to be re-certified after transition to the permanent program. Re-certification is costly and would include unnecessary duplication of processes.

- *The transition from the temporary to the permanent certification programs should align with the transition from Stage 1 to Stage 2 meaningful use criteria.* CAQH recommends that ONC Authorized Testing and Certification Bodies (ONC-ATCBs) be the key authorization bodies for Stage 1 criteria and that these certifications remain valid through 2014 when the incentives are no longer available. ONC-ACBs will then only perform certification against Stage 2 and 3 criteria. Under this scenario, there is no need to "sunset" the ONC-ATCB status since they will naturally expire in 2014. Otherwise, as the NPRM is currently written there may be a time where providers are still eligible for incentives under State 1 of meaningful use, but are required to buy or upgrade to Stage 2-certified EHRs between 2012 and 2014.

Recommendation #2: *Leverage existing and proven programs by grandfathering providers already certified by external programs that have the same criteria used for meaningful use.*

> **Rationale:** Certification and testing for some key components of meaningful use are already well-established in the industry. Significant industry vetting and resources have contributed to current programs and potentially duplicative testing and certification steps should be avoided throughout the permanent program (Stages 1-3). ONC should consider grandfathering entities already certified by external programs under the same criteria used for meaningful use (where overlap occurs). Such a process will allow ONC to focus on the development of testing and certification processes for EHR components without an existing certification/testing methodology.

> Maintain flexibility for alternative certification pathways.

Recommendation #3: *Maintain the proposal to allow for an alternative certification path that permits direct healthcare provider certification, specifically in the case of self-developed provider platforms and integrated systems comprised of multiple technology vendors (Section E.4 of the proposed rule).*

Rationale: Testing and certification must account for the needs of the end-user. Based on the CAQH CORE testing and certification experience, many provider organizations have developed and will continue to develop customized solutions, using tools and software modules from a variety of vendors. Even those hospitals that install a single-vendor enterprise system routinely supplement it with other products to achieve specific needs, such as department-specific systems, billing and coding systems, or business intelligence tools around infection control or bed management. As a result, testing and certification processes should take into account the provider combination of these multiple modules into a Complete EHR that meets the criteria for certification. CORE certification includes a methodology for providers to apply directly for certification rather than reference use of a certified vendor system. As noted in our cost recommendation below, the cost to providers requiring this alternative must be considered.

> Assure quality of testing and certification through an open and transparent process which leverages existing resources.

Recommendation #4: *Clarify where privacy and security exemptions are appropriate for Stage I and include technical specifications to support privacy and security policies in future meaningful use stages.*

Rationale: CAQH has worked successfully with HIPAA covered entities to develop operating rules that support and complement organizations' HIPAA privacy and security compliance efforts, as well as the growing demand for additional security. All CORE participants must submit a HIPAA Attestation Form when applying for the CORE Seal and adhere to specific connectivity requirements that provide technically-based security standards. Based on experience, we agree with ONC that certifying the EHR capability to protect electronic health information is important and it instills provider and patient trust and fosters greater adoption. However, we understand that some exemptions are needed, but any interpretation issues on this critical topic should be avoided. ONC needs to clarify the policies regarding these exemptions and given the significant evolution that will occur in this arena, the process that will be in place to answer questions and provide clear technical guidance. In addition, we support the inclusion of explicit language specifying that using a Certified EHR does not absolve providers and other HIPAA covered entities of the need to comply with HIPAA privacy and security requirements. Finally, we encourage ONC to consider how Stage 2 will increase the focus on the area of privacy and security on a technical level.

Recommendation #5: *Encourage ONC and NIST to embrace an open and transparent process, draw from existing tools and procedures currently adopted in the market, and develop opportunities for stakeholder input for development of testing and certification infrastructure and criteria.*

Recommendation #5a – Establish formal advisory relationships with testing and certification authorities: *ONC and NIST should establish relationships or advisory bodies composed of industry authorities (e.g., CAQH, CCHIT, etc.) to provide input on questions related to testing and certification.*

Recommendation #5b – Clarification needed on open source software: *ONC should clarify how NIST will approach developing testing methodologies for open source solutions and how ONC will ensure those applications result in consistent testing for entities that undergo testing at different times. By definition, open-source software is software in which the source code is*

open and can be modified or changed by the public writ large. ONC has publicly supported open source solutions for meaningful use.

Recommendation #5c – Include the CORE process in testing protocols: *If electronic verification of insurance eligibility and electronic submission of claims are included in the final Stage 1 meaningful use requirements for certified EHRs, CAQH requests the permanent program recognize or incorporate the CORE testing process for these requirements.*

Rationale: Both ONC and NIST would benefit from developing strong advisory relationships with industry authorities on certification and testing to support the program development. ONC proposes that ONC-ACBs would only be "permitted to certify Complete EHRs and/or EHR Modules that have been tested by a National Voluntary Laboratory Accreditation Program (NVLAP) accredited testing laboratory." The HITECH Act also requires that the Director of NIST, in coordination with the HIT Standards Committee, "shall support the establishment of a conformance testing infrastructure, including the development of technical test beds." Congress also indicated that "[t]he development of this conformance testing infrastructure may include a program to accredit independent, non-Federal laboratories to perform testing." While testing is out of the ONC scope for the permanent program, CAQH believes the requirements for NIST to develop testing infrastructure lack clarity, and requests that CMS/ONC provide additional guidance in the final rule regarding the NIST role in the permanent testing process.

- *ONC and NIST should establish formal relationships with existing testing and certification experts.* An advisory panel should be referenced as industry experts in certain functionalities and be actively sought out to provide expertise on testing processes, certification criteria, and standards interpretation. Test scripts and implementation specifications should be approved by these industry authorities in relevant areas. Additionally, these industry authorities can serve as the advisory bodies that advise ONC as to when code sets or operating rules change significantly enough to require changes in the testing or certification process.

- *NIST should leverage existing testing tools and procedures.* As stated throughout our comments for both the temporary and permanent programs, CAQH strongly encourages that NIST consider the adoption of existing tools and procedures currently operational and developed via industry consensus for testing infrastructure. The industry has already invested significant resources in developing and vetting testing and certification processes and building consensus for practical solutions.

- *NIST should develop testing infrastructure and technical test beds through an open and transparent process.* CAQH emphatically endorses NIST use of an open and transparent process that acknowledges public input when developing testing components. Creation of an open process will be a critical component of ensuring that existing knowledge informs testing requirements.

Recommendation #6: *Establish ONC safeguards to ensure National Institute of Standards and Technology (NIST) does not define the certification criteria; instead, the certification criteria - based on policy goals - should drive the testing specifications.*

Rationale: Some of the proposed Stage 1 meaningful use criteria do not provide sufficient specificity to fully describe what should be tested. For example, the eligibility benefits transaction proposed by the CMS meaningful use requirement could be interpreted very differently – unless there is ONC

specification to support the criteria. Without the specifications, presumably NIST could develop its own interpretation of what should be tested. It may elect to test for only the minimum requirements of the HIPAA transaction standard or test for a set of specifications that are more than the minimum required. It is vital that ONC define each meaningful use criteria to support the end-user needs of the industry, and the intended impact of the meaningful use stages, rather than have the testing define the details.

ONC must ensure it consistently confirms that all aspects of its approved certification program meet the policy goals for meaningful use, most especially end-user adoption and impact. Therefore, certification should be a supporting effort versus the defining action.

Recommendation #7: *Leverage lessons learned for development of surveillance and ongoing certification compliance monitoring, and need for recertification.*

Rationale: While CAQH recognizes that the scale of the ONC surveillance and compliance monitoring program will be significantly larger than that for CORE, aspects of our existing efforts can inform the ONC process. Over the past three years, CAQH has issued a combined 67 certifications to health plans, vendors, providers, and clearinghouses for Phase I and Phase II of the CORE operating rules. CORE recognizes that surveillance, monitoring, and recertification are multi-faceted. An important first step is self-regulation, which helps to ensure that organizations take ownership for conforming to requirements. In addition, it is important to establish a sound and fully transparent framework that encourages tracking, prompt disclosure, and correction of any compliance violations. This framework should include policies for documentation of violations, re-testing, and re-certification criteria. As part of its publicly available rules and policies, CORE has a Guiding Principles and Enforcement Policy that includes:

- *Voluntary Self-Discovery steps, such as:*
    - Organizations are encouraged to privately resolve disputes before submitting a formal complaint of non-compliance.
    - Only a CORE-certified entity, a healthcare provider that is an end-user of a CORE-certified product/service, or an organization involved in the alleged non-compliant transactions may file a complaint.

- *Prompt Disclosure if Disputes Cannot be Privately Resolved steps, such as:*
    - A documented formal complaint process with fixed policies and procedures demonstrating the alleged violation was not a one-time occurrence, but occurred in multiple instances. For example,
        - The Request for Review of Possible Non-Compliance Form calls for the violation to be outlined by the organization filing the request, including at least five documented examples of the violation over a 30-day period.
    - CAQH has 30 days to review the documentation, with oversight from an Enforcement Committee (multi-stakeholder industry panel), and verify or dismiss a complaint.
    - The organization in question is given an opportunity to respond to the complaint in writing.
    - Entities are permitted to withdraw a complaint any time during the process.

- *Procedures for Prompt and Appropriate Action to Correct Violations steps, such as:*
    - In the case of a verified complaint, entities found to be out of compliance with the rule(s) will be informed by CORE that they have a defined grace period (40 business days) in

order to remedy the problem by successfully re-testing for compliance with the rule(s), or be de-certified.

- Entities seeking re-certification due to non-compliance will only need to do so for the rule with respect to which they were found to be non-compliant.

Given that the playing field of participants is larger for meaningful use than currently addressed by CORE, some aspects of surveillance may need to be more proactive than the CAQH guidelines. This said, *all aspects of compliance issued need to addressed, policies need to be clear, and staff must be available to adjudicate issues.*

> Establish transparent processes to encourage shared-learning and minimize system-wide costs.

Recommendation #8: *Factor cost considerations into ONC decision-making. As with any major process redesign, it is critical to consider cost burdens on both end-users and the entire healthcare system.*

Rationale: ONC and NIST should be sensitive to the total cost for testing and certification. This goes beyond the unavoidable cost of modifying and enhancing software to meet the criteria, and includes the fees related to testing, certification, and the overhead and indirect costs associated with preparing for the testing and certification process.

- *While the NPRM does not address cost considerations, they remain an important factor in achieving success of the permanent program.* CAQH urges ONC to consider cost as an important factor when detailing the parameters of the permanent program. Cost issues of concern include:
    - Fees for vendors/providers to test with NVLAP-accredited testing labs
    - Fees for vendor/provider certification
    - Changes in software and administrative procedures to meet meaningful use
    - When and if certified vendors need to continue meaningful use criteria by Stage and if there is an expectation that updated modules will mean additional costs for providers

The cost of testing and certification and preparation for both must be a discussion point for the industry in order to assure a successful roll-out.

Recommendation #9: *Evaluate future use of certification programs for health information exchange infrastructure after experiencing Stage 1 of meaningful use.*

Rationale: CAQH supports the ONC interpretation of the HITECH Act requirement that it create "certification programs for Health Information Technology", allowing potential future use of testing and certification processes for health information exchange. However, the lessons learned from meaningful use roll-out will be essential to industry-wide collaboration on other potential arenas of health IT. CAQH leadership offers its extensive experience as a resource and partner to assist the ONC decision-making regarding the final policies for the Establishment of Certification Programs for Health Information Technology.

We welcome the opportunity to meet with you to discuss our comments further. Should you have questions or require additional information, please contact Gwendolyn Lohse, Deputy Director, at (202) 778-1142.

Sincerely,

Robin Thomashauer
Executive Director