Electronic Healthcare Network Accreditation Commission

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Lee B. Barrett
Executive Director

Debra C. Hopkinson
Operations, VP

Dhopkinson@ehnac.org

Commissioners
Paul Calatayud
 Surescripts

Catherine C. Costello, JD
 The Ohio Health Information Partnership

Jay Eisenstock
 Aetna

Jan Estep
 NACHA- The Electronic Payments Association

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 DirectTrust

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 Kaiser Permanente

Deborah Meisner
 Emdeon

Thomas Meyers
 America's Health Insurance Plans

William O'Byrne
 NJ-HITEC, New Jersey's Regional Extension Center

David Sharp
 Maryland Health Care Commission

Robert Tennant
 Medical Group Management Association

TO: Dan Chaput
FROM: Lee Barrett
DATE: 11/5/15
RE: Acceptance and Approval of Test Procedures, Test Tools, and Test Data for Use under the ONC Health IT Certification Program

Mr. Chaput,

This document is in response to your request for additional information from the EHNAC submission of September 10th. It is understood that a subsequent call was held to clarify the intention of your request for the additional information. That call was held on October 14th and included Mark McLaughlin and Stanley Nachimson, two of EHNAC's independent consultants. Resulting from that call you had requested that EHNAC provide additional information as supplied by you and included below as referenced.

EHNAC is an independent, federally recognized, standards development organization and tax-exempt, 501(c)(6) non-profit accrediting body designed to improve transactional quality, operational efficiency and data security in healthcare. While EHNAC understands the differences between ONC's Health IT Certification for EHR's and EHNAC's own accreditation process, EHNAC believes that incorporating some of the EHNAC processes into the ONC process would assist to solidify the validity and value of the ONC Certification applicant once certified.

As noted on the conference call, there are overlapping areas related to privacy and security where EHNAC's criteria and the ONC certification criteria match. It is expected that EHNAC's additional requirements related to those criteria as well as the on-site reviews to validate such controls are in place, would enhance and add value to the ONC Health IT Certification process. Specifically, as documented in an e-mail from you to Mark McLaughlin on October 14, 2015, you requested the following (we have added numbering for ease of referencing):

1. ONC Request: Provide an outline of testing steps, with required and optional steps identified

EHNAC Response:
Each of the following steps are required by EHNAC to complete the accreditation process:

- Candidate files for accreditation and pays the accreditation fees;
- Candidate receives the EHNAC self-assessment package that contains the criteria for self-evaluation related to the EHNAC criteria;
- Candidate documents responses stating how their organization satisfies the EHNAC criteria;
- Candidate supplements these responses with supporting evidence to reinforce the response in satisfaction of the EHNAC criteria;

- Self-assessment package is submitted to EHNAC for review;
- EHNAC site reviewers evaluate the self-assessment package and create an initial report;
- EHNAC site reviewers identify missing evidence and any additional questions related to the responses and evidence submitted;
- EHNAC site reviewers perform an on-site visit for the following purposes:

  1. Candidate Interviews

  Site reviewers interview key personnel including subject matter experts regarding representations made in the self-assessment. The interviews are instrumental in obtaining an understanding of the candidate as a whole and in understanding how specific services under review are delivered.

  2. Inspection of Physical Site

  Each site that is visited must be inspected/reviewed to ensure appropriate security is in place and further that the environment is effective for delivering the services under review.

  3. Verification of Representations

  The site visit will include random testing to ensure that what is represented in the self-assessment is indeed verifiable. This could include, for example, testing employee knowledge for training received, confirmation of physical resources described, policy review cycles, disaster recovery testing, etc.

  4. Consultative Value to Candidate

  A key component of each site visit is the value the site reviewer provides to the candidate. Each EHNAC site reviewer brings a wealth of industry experience that provides valuable insight to the candidate under review.

- EHNAC site reviewers complete the report for the EHNAC Commission;
- EHNAC site reviewers submit the report through an internal EHNAC QA process to validate consistent evaluation amongst site reviewers;
- EHNAC site reviewers send the QA-approved report to the Candidate for approval to move it forward to the EHNAC Commission for an accreditation vote;
- EHNAC site reviewers submit the Candidate-approved report to the EHNAC Commission for a vote;
- EHNAC Commissioners vote on the Candidate's accreditation status;
- If the Candidate is accredited, they are listed on the EHNAC web site (www.ehnac.org) as such and will remain an EHNAC-accredited organization for a period of two years.

2. ONC Request: Provide documentation tracing the testing steps to the certification criteria capabilities requirements

EHNAC Response:

The capabilities requirements are documented in the steps listed above. The Candidate must submit a self-assessment that contains responses stating how their organization satisfies each criterion plus specific evidence in support of each response.

3. ONC Request: Provide an outline of attestation steps, with required and optional steps identified;

EHNAC Response:

The attestation steps are documented in the steps listed above. All steps listed above are required for the Candidate organization. Specifically related to attestation, the Candidate must perform the following:

- Must document all responses and provide evidence in support of the response for all EHNAC criteria;
- Must ensure that all "Required" elements listed in the EHNAC criteria Samples of Acceptable Evidence or Instructional Guidance are met;
- Must ensure that all MANDATORY criteria requirements are fully met;
- Must ensure that all responses and evidence are able to be validated during the on-site review;
- Must perform timely follow up for any outstanding issues after the on-site review.

4. ONC Request: Provide documentation and test data that can be used to verify that:

4.a. ...the testing steps evaluate all mandatory capabilities in the certification criteria

EHNAC Response:

EHNAC does not supply test data for verification purposes. All evaluation of mandatory capabilities must be met through Candidate-documented responses and evidence submitted for each criterion. Site reviewers validate that the responses and evidence submitted are compliant with the intention of the criteria.

4.b. …the required testing steps are limited to those required in the ONC certification criteria (note: optional certification criteria are allowed)

EHNAC Response:

EHNAC's successful accreditation could act as sufficient evidence in support of satisfying ONC criteria where there is overlap between the two programs. Overlap is shown in the attached spreadsheet: ONC Stage 2 Comparison to EHNAC Programs 09152015 Summary Version.xls

5. ONC Request: Documentation of an established versioning process that includes release notes

EHNAC Response:

Please note that all of this information is documented internally by EHNAC and can be sent to ONC if requested:

- EHNAC produces new versions of each of its accreditation programs at least annually;
- Criteria changes are requested through the EHNAC Criteria Committee;
- The EHNAC Criteria Committee votes on the changes requested;
- Approved changes are published for 60 day public comment in accordance with standards development organization requirements;
- Public comments received are addressed by the EHNAC Criteria Committee;
- Final changes are made to the criteria by the EHNAC Criteria Committee and a final vote is conducted;
- After the EHNAC Criteria Committee votes in favor of the changes, the criteria moves to the EHNAC Commission for their vote;

- Once the EHNAC Commission votes to move the criteria forward, the new version of the EHNAC program is published and new applicants receive the latest version of the criteria;
- EHNAC's Criteria Committee also publishes release notes that identify the changes between versions.

6. ONC Request: Documentation of the ability to provide support for users during normal business hours with established downtime procedures.

EHNAC Response:

- Candidates may reach out to EHNAC Operations with questions pertaining to application processes, fees, timing of submissions, general process-related questions;
- Candidate may reach out to their assigned site reviewer for questions related to specific criteria;
- Candidates may either call or e-mail their contacts and responses are provided as soon as possible;
- Downtime procedures during off-hours include leaving voice-mails or having e-mails responded to during the next business day.
- Accreditation guidelines can be found here: https://www.ehnac.org/complete-guidelines/

7. ONC Request: Please document:

7.a. …whether the tool was piloted or is the tool in production? Please provide documentation of a pilot of the test procedure with at least one ATL and one health IT developer

EHNAC Response:

EHNAC currently has 16 programs in production, with two new programs scheduled to be released in January 2016. EHNAC develops each program by creating an advisory committee that includes subject matter experts from across the country. Beta organizations are also identified that test the preliminary release of the program and that provide input for refining the criteria prior to final release. New programs are released through EHNAC's standard release process described in #5, above. A listing of all accredited organizations may be found here: https://www.ehnac.org/accredited-organizations/

7.b. …whether public comment was sought, if so how was it sought and how was it incorporated.

EHNAC Response:

As noted above, EHNAC, as a federally recognized standards development organization, seeks public comment on both the new and the maintenance releases of each EHNAC program. This feedback is incorporated in the following fashion:

- Criteria changes are requested through the EHNAC Criteria Committee;
- The EHNAC Criteria Committee votes on the changes requested;
- Approved changes are published for 60-day public comment in accordance with standards development organization requirements. Public comment is sought by publishing notice on the EHNAC web site (www.ehnac.org) ;
- Public comments received are addressed by the EHNAC Criteria Committee;

- Final changes are made to the criteria by the EHNAC Criteria Committee and a final vote is conducted;
- After the EHNAC Criteria Committee votes in favor of the changes, the criteria moves to the EHNAC Commission for their vote;
- Once the EHNAC Commission votes to move the criteria forward, the new version of the EHNAC program is published and new applicants receive the latest version of the criteria;
- EHNAC's Criteria Committee also publishes release notes that identify the changes between versions.

8. ONC Request: Specifically for the testing tool please supply:

8.a. …documentation on the ability to validate to the Common Clinical Data Set (where applicable)

EHNAC Response:

EHNAC's criteria validate that the organization utilizes industry-approved standards relative to the program accreditation being sought. EHNAC specifically supports the interoperability standard requirements in its Accountable Care Organization (ACOAP) and Data Registry (DRAP) criteria. In such instances, evidence must be presented in support of an affirmative response showing how the Candidate satisfies the criterion. Samples of files as well as any proof of testing tool compliance would suffice as satisfactory evidence.

8.b. …any content exchange standards utilized

EHNAC Response:

EHNAC programs support the standard ONC Applicability Statement for Secure Health Transport and the ONC Applicability Statement for Secure Health Transport and ONC XDR and XDM for Direct Messaging Specification through many of the programs supported. Additionally, encryption and hashing standards are more generally reviewed in all other EHNAC programs.

8.c. …any implementation specifications utilized

EHNAC Response:
- Implementation specifications utilized are dependent on the standards being reviewed. The standards being reviewed are different depending on the accreditation program being sought.
- In general EHNAC utilizes the following implementation guides:
  - ASC X12N – HIPAA related transactions;
  - HL7 CDA and CCD;
  - HL7 Clinical messaging;
  - NIST;
  - ONC standards noted in the response above.

8.d. …access to a downloadable version of the tool

EHNAC Response:

Access to EHNAC criteria is available at the following link: https://www.ehnac.org/program-criteria/

8.e. …access to a practice instance or sandbox version of the tool;

EHNAC Response
The criteria link noted above is the appropriate link for downloadable instances of the EHNAC criteria.

8.f. …"User guide" type documentation that illustrates (8g-8j below):
EHNAC Response:
Candidates receive a user's guide that guides them through the accreditation process. The documentation is provided as supplemental information to this documentation.

8.g. …the automated validation performed;

EHNAC Response:
EHNAC does not provide for automated validation of any criteria.

8.h. …the test tool workflow instructions;

EHNAC Response:
The user's guide is titled READ THIS FIRST and is a PDF with instructions as to how to go about putting together the self-assessment.

8.i. …the standards and criteria that are validated using the test tool;

EHNAC Response:
All standards are noted within the criteria itself.

8.j. …any validation not performed by the test tool that must be visually inspected.

EHNAC Response:
EHNAC site reviewers will visually inspect all responses and evidence submitted and perform a physical site visit to further validate the organization meets the EHNAC requirements.

9. ONC Request: Specifically for test data please supply appropriate and clinically relevant test data that tests both positive and negative outcomes.
EHNAC Response:

EHNAC does not have a tool to evaluate positive and negative outcomes related to clinical test data.

In summary, it is expected that EHNAC may act as a supplemental verification of specific criteria within the ONC Health IT Certification Program. EHNAC would like ONC to consider the following:

- Allowing ONC Health IT Certification candidates the ability to show compliance with certain criteria that have already been validated by an EHNAC accreditation. EHNAC has evaluated ONC's criteria and found some to be very similar to EHNAC's own

criteria. A spreadsheet has been provided along with this communication to support the evaluation noted. The spreadsheet is called ONC Stage 2 Comparison to EHNAC Programs 09152015 Summary Version.xls;

- If, at some point, ONC would require a more in-depth physical review of certification candidate facilities and datacenters, EHNAC would be interested in conducting such a review on behalf of ONC's Health IT Certification program.

EHNAC would be happy to discuss any of the information contained in this communication in more detail. Please let us know if a follow up call would be preferred and we will arrange it.

Respectfully Submitted,

Lee Barrett
Executive Director, EHNAC

Cc: Regulatory Compliance WG