



Office of the National Coordinator for Health Information Technology (ONC) Interim Guidance Regarding the Recognition of Certification Bodies

I. Introduction:

The certification of electronic health record software is recognized to be a two part process; 1) the Secretary of the Department Health and Human Services (the Secretary) recognizing specific enumerated criteria for the certification of electronic health record (EHR) software, and 2) certification to the criteria and standards so recognized by the Secretary. This document introduces the process for the Secretary recognizing one or more certification bodies to certify EHR software in fulfillment of the second step in this process (#2) listed above. An organization/entity recognized to carry out the second step of this process is to be referred to as a Recognized Certification Body (RCB).

II. Purpose:

The purpose of this Certification Guidance Document (CGD) is to explain the factors ONC will use to determine whether or not to recommend to the Secretary a body for RCB status. This CGD will serve as a guide for ONC as it evaluates applications for RCB status and seeks to provide all of the information a body would need to apply for and obtain such status.

III. Background:

To encourage a more widespread adoption of interoperable health information technology, the Department of Health and Human Services (HHS) published in August 2006 two final rules in which the Centers for Medicare & Medicaid Services (CMS) and Office of Inspector General (OIG) promulgated an exception to the physician self-referral prohibition and a safe harbor under the anti-kickback statute, respectively, for certain arrangements involving the donation of interoperable EHR technology to physicians and other health care practitioners or entities. The exception and safe harbor provide that EHR software will be “deemed to be interoperable if a certifying body recognized by the Secretary has certified the software no more than 12 months prior to the date it is provided to the [physician/recipient].” Both rules become effective 60 days after publication.

The Department will formalize through notice and comment rulemaking the procedure for becoming an RCB by the Secretary. In the meantime, this guidance document identifies the factors to be considered by the Secretary in granting such recognition. In addition, this document sets forth an interim procedure that certifying bodies should follow in obtaining recognition by the Secretary. Until such time as the Department formalizes the procedure, a certifying body will be considered “recognized by the

Secretary” if it has become an RCB in accordance with this interim guidance. This guidance document seeks to reduce uncertainty about key aspects of the certification body recognition process.

IV. Policy:

A) **ONC will:**

- 1) Develop and maintain the characteristics an RCB must possess and to which it must adhere to be “recognized by the Secretary”;
- 2) Receive and review:
 - a. applications for obtaining RCB status; and
 - b. RCB renewal requests;
- 3) Recommend to the Secretary an RCB applicant for recognition;
- 4) Reconsider denied:
 - a. applications; and
 - b. renewal requests; and
- 5) Make publicly available the name and date of any recognized RCB(s) on our website at <http://www.hhs.gov/healthit/>

- B) **ONC strives to achieve a consistent and fair application review process and this CGD will be used to govern this effort. Upon receipt of an application, ONC will within 60 days, notify the applicant that its application has been denied or the Secretary has recognized the applicant as an RCB.**

ONC will accept applications and will follow this CGD for making RCB determinations until a final rule is promulgated and becomes effective. When a final rule has been promulgated that governs the process by which an RCB is determined, entities that are RCBs under this CGD will be required to complete new applications and successfully demonstrate compliance with all requirements of the final rule prior to the rule’s effective date.

V. Application Process:

ONC will consider such a body for review and recommendation to the Secretary as an RCB only after a completed application has been received.

A) **Applicants:**

A body making a request for RCB status must submit to ONC in writing or in electronic format:

- 1) A letter signed by a senior officer of the body with authority to commit the body to fulfilling the obligations of an RCB and to make representations about the body’s characteristics and operations; and
- 2) Explanations as to how the body meets each of the characteristics specified with the most recent version of the CGD.

Applications that contain deficiencies will be returned to the body and will not be accepted until such deficiencies are addressed to the satisfaction of ONC. A revised application must be submitted in conformance with the process above.

B) Characteristics:

The applicant must demonstrate to the satisfaction of ONC that it meets all of the following characteristics. Wherever possible, the applicant is encouraged to provide specific examples or descriptions to clearly display its abilities.

- 1) Has a transparent and well-documented testing and certification process;
- 2) Has a demonstrated process for, and experience in, certifying EHR software to criteria recognized by the Secretary, as discussed in section I (“Introduction”) of this CGD;
- 3) Publishes a list of all certified products that is freely and publicly available;
- 4) Makes up-to-date information about certification freely and publicly available;
- 5) Can provide a publicly available roadmap for the development of future certification activities;
- 6) Seeks active participation of multiple stakeholders in an open, objective, and consensus-driven process;
- 7) Accepts and responds to public comment on its certification process;
- 8) Can adapt its processes to emerging certification criteria recognized by the Secretary;
- 9) Has developed a method to incorporate all applicable standards and certification criteria recognized by the Secretary into its certification process;
- 10) Has a governing body or executive level steering committee comprised of a diverse set of health care industry stakeholders that must at a minimum represent the following groups:
 - a. Health care providers;
 - b. Employers, unions or other health care payors;
 - c. Health care product vendors;
 - d. Safety net providers;
 - e. Health care consumers;
 - f. Public health agencies;
 - g. Quality improvement organizations;
 - h. Clinical Researchers;
 - i. Standards development and informatics experts; and
- 11) Has a separate committee to advise its board of directors or similar executive level steering committee on business development.

C) Application Submission:

An application can be submitted in the following ways:

- 1) In writing, submitted to the following address:

Steven Posnack
Program Analyst
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
330 C Street SW
Switzer Building, Room 4090
Washington, D. C. 20201

- 2) In electronic format (MS-Word or PDF) emailed to the following address: RCB-submission@hhs.gov

VI. Duration of Recognition as an RCB under this CGD:

Notwithstanding any other provision of this CGD, an RCB's status will expire one year from its date of recognition or upon the effective date of a final rule. Until a final rule has become effective, any RCB that submits a renewal request in accordance with section VII "Renewal" may presume renewal of their status, absent notice from ONC of a denial or request for additional information within 30 days of receipt of a renewal request.

VII. Renewal:

In the absence of a final rule, if an RCB seeks to maintain its status, the RCB must submit a renewal request at least 60 days prior to its expiration.

A) Renewal Request:

A renewal request must:

- 1) State the body's intent to renew its status; and
- 2) Contain any addenda to the RCB's original or previously amended application necessary for it to meet the most recent version of the CGD. A body submitting addenda must submit to ONC for review and approval in writing or in electronic format: explanations as to how the body meets any new characteristics added to the CGD since it was recognized.

B) Renewal Request Submission:

A renewal request can be submitted in the following ways:

- 1) In writing, submitted to the following address:
Steven Posnack
Program Analyst
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
330 C Street SW
Switzer Building, Room 4090
Washington, D. C. 20201

- 2) In electronic format (MS-Word or PDF) emailed to the following address: RCB-submission@hhs.gov

If ONC were to deny a renewal request, we would refer the RCB to the reconsideration process discussed in Section VI of this document.

VIII. Reconsideration:

A) Applicants:

If an applicant is denied RCB status, the applicant may submit a reconsideration request in writing to ONC within 90 days from receipt of the denial notice in order to be reconsidered. If ONC receives the request within the specified timeframe, ONC will contact the body within 90 days to schedule a debriefing meeting. ONC will identify the body's deficiencies and reason(s) for denial, and upon the conclusion of the meeting the body will have up to 30 days to submit to ONC an updated application.

B) Renewal Requests:

If the RCB is denied renewal, the RCB may submit a reconsideration request in writing to ONC no later than 30 days from receipt of the denial notice in order to be reconsidered. If ONC receives the request within the specified timeframe, ONC will contact the RCB within 30 days to schedule a debriefing meeting. ONC will identify the RCB's deficiencies and reason(s) for denial, and upon the conclusion of the meeting the RCB will have up to 30 days to submit to ONC an updated renewal request. An RCB's status may be extended for up to 60 days by ONC if the reconsideration process exceeds the RCB's recognition expiration date.

IX. Public Comment:

Public comment on this CGD will be accepted for 60 days after its publication date and should be submitted as specified below. If this CGD is updated the public will be afforded another period of 60 days to comment. We will accept applications and will follow this guidance when considering an RCB for recommendation to the Secretary until a final rule is promulgated.

Comments may be submitted via email to RCB-comments@hhs.gov or in written form to:

Steven Posnack
Program Analyst
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
330 C Street SW

Switzer Building, Room 4090
Washington, D. C. 20201

Please refer to this guidance document when submitting comments.

For further questions about this guidance, please contact Steven Posnack, at 202-690-7151.

X. Paperwork Reduction Act:

Under the PRA, a “collection of information” means “obtaining, causing to be obtained, soliciting, or requiring the disclosure to an agency, third parties or the public of information by or for an agency by means of identical questions posed to, or identical reporting, recordkeeping, or disclosure requirements imposed on, ten or more persons... .” ONC is currently only aware of one organization/entity that will utilize the application process for RCB status. ONC reasonably does not anticipate that more than 9 organizations/entities will seek RCB status this year or anytime in the near future. As such, the application process is exempt from the Paperwork Reduction Act requirements.