respect to wording, we provided a combined objective and referenced the full proposed objective in a footnote. All certification criteria are prefaced with the statement "A Complete EHR or EHR Module must include the capability to:" in order to create uniformity in the way each certification criterion is read.

Finally, we understand that certain types of standards, specifically code sets, must be maintained and frequently updated to serve their intended purpose effectively. Code sets are typically used for encoding data elements, such as medical terms, medical concepts, diagnoses, and medical procedures. As new medical procedures, technologies, treatments, or diagnostic methods are developed or discovered, additional codes must be added or existing codes must be revised. In some cases, new codes are necessary to reflect the most recent changes in medical practice, involving perhaps revised medication dosage, updated treatment procedures, or the discovery of new diseases. In many cases, the new codes must be disseminated and implemented quickly for patient safety and significant public health purposes.

To address this need and accommodate industry practice, we have in this interim final rule indicated that certain types of standards will be considered a floor for certification. We have implemented this approach by preceding references to specific adopted standards with the phrase, "at a minimum." In those instances, the certification criterion requires compliance with the version of the code set that has been adopted through incorporation by reference, or any subsequently released version of the code set. This approach will permit Complete EHRs and EHR Modules to be tested and certified, to, "at a minimum," the version of the standard that has been adopted or a more current or subsequently released version. This will also enable Certified EHR Technology to be updated from an older, "minimum," adopted version of a code set to a more current version without adversely affecting Certified EHR Technology's "certified status." We intend to elaborate in the upcoming HIT Certification Programs proposed rule on how testing and certification would be conducted using standards we have adopted and designated as "minimums" in certain certification criteria.

Because we expect to adopt additional code set standards in the future, we believe this approach is necessary. Moreover, we believe the certification of Complete EHRs and EHR Modules should be flexible enough to accommodate current code sets that are regularly maintained and updated. We also believe that this approach will enable and encourage eligible professionals and eligible hospitals to adopt Certified EHR Technology and keep it current, which will promote patient safety, public health safety, and more broadly, improve health care quality.

That being said, we understand that this approach has certain limitations. In some cases, for instance, rather than simply maintaining, correcting, or slightly revising a code set, a code set maintaining organization will modify the structure or framework of a code set to meet developing industry needs. We would consider this type of significant revision to a code set to be a "modification," rather than maintenance or a minor update of the code set. An example of a code set "modification" would be if a hypothetical XYZ code set version 1 were to use 7-digit numeric codes to represent health information while XYZ code set version 2 used 9-digit alphanumeric codes to represent health information. In such cases, interoperability would likely be reduced among Complete EHRs and EHR Modules that have adopted different versions of the structurally divergent code sets. If a code set that we have adopted through incorporation by reference is modified significantly, we will update the incorporation by reference of the adopted version with the more recent version of the code set prior to requiring or permitting certification according to the newer version.

The following provides an example of how our approach will work. A proposed meaningful use Stage 1 objective specifies the capability to submit electronic data to immunization registries and, accordingly, we have adopted a certification criterion to assure that a Complete EHR or EHR Module is capable of electronically recording, retrieving, and transmitting immunization information to immunization registries in accordance with the standards specified in Table 2A row 8. Table 2A row 8 references, as a vocabulary standard (code set), the CDC maintained HL7 standard code set CVX-Vaccines Administered. The current version of the CVX code set was published July 30, 2009, and includes new vaccine codes related to the "Novel Influenza-H1N1." Continuing our CVX example, if the CDC were to publish a new version of CVX on February 1, 2010, we would permit a Complete EHR or EHR Module to be tested and certified according to the minimum adopted version of the standard, the July 30, 2009, version of CVX or the February 1, 2010 version that was subsequently issued as part of the code set's maintenance.

For certain certification criteria in Table 1 below, we include a percent symbol "%" superscript to indicate instances where the version of an adopted standard (specified in the regulation text) will be "at a minimum" the version to which a Complete EHR or EHR Module must be tested and certified in order to be considered compliant with the adopted standard.

TABLE 1—CERTIFICATION CRITERIA

| Proposed meaningful use Stage 1 objectives | Certification criteria to support the achievement of meaningful use Stage 1 by eligible professionals | Certification criteria to support the achievement of meaningful use Stage 1 by eligible hospital |
|---|---|---|
| | A Complete EHR or EHR Module must include the capability to: | |
| Use Computerized Provider Order Entry (CPOE)[3]. | Enable a user to electronically record, store, retrieve, and manage, at a minimum, the following order types:<br>1. Medications;<br>2. Laboratory;<br>3. Radiology/imaging; and | Enable a user to electronically record, store, retrieve, and manage, at a minimum, the following order types:<br>1. Medications;<br>2. Laboratory;<br>3. Radiology/imaging; |

TABLE 1—CERTIFICATION CRITERIA—Continued

| Proposed meaningful use Stage 1 objectives | Certification criteria to support the achievement of meaningful use Stage 1 by eligible professionals | Certification criteria to support the achievement of meaningful use Stage 1 by eligible hospital |
|---|---|---|
| | 4. Provider referrals. | 4. Blood bank;<br>5. Physical therapy;<br>6. Occupational therapy;<br>7. Respiratory therapy;<br>8. Rehabilitation therapy;<br>9. Dialysis;<br>10. Provider consults; and<br>11. Discharge and transfer. |
| Implement drug-drug, drug-allergy, drug-formulary checks. | 1. Automatically and electronically generate and indicate (*e.g.,* pop-up message or sound) in real-time, alerts at the point of care for drug-drug and drug-allergy contraindications based on medication list, medication allergy list, age, and CPOE.<br>2. Enable a user to electronically check if drugs are in a formulary or preferred drug list in accordance with the standard specified in Table 2A row 2.<br>3. Provide certain users with administrator rights to deactivate, modify, and add rules for drug-drug and drug-allergy checking.<br>4. Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user. | |
| Maintain an up-to-date problem list of current and active diagnoses based on ICD–9–CM or SNOMED CT®. | Enable a user to electronically record, modify, and retrieve a patient's problem list for longitudinal care (*i.e.,* over multiple office visits) in accordance with the applicable standards[4 5] specified in Table 2A row 1. | |
| Generate and transmit permissible prescriptions electronically (eRx). | Enable a user to electronically transmit medication orders (prescriptions) for patients in accordance with the standards specified in Table 2A row 3. | No Associated Proposed Meaningful Use Stage 1 Objective. |
| Maintain active medication list | Enable a user to electronically record, modify, and retrieve a patient's active medication list as well as medication history for longitudinal care (*i.e.,* over multiple office visits) in accordance with the applicable standard specified in Table 2A row 1. | |
| Maintain active medication allergy list | Enable a user to electronically record, modify, and retrieve a patient's active medication allergy list as well as medication allergy history for longitudinal care (*i.e.,* over multiple office visits). | |
| Record demographics[4 5] | Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, insurance type, gender, race, ethnicity, and date of birth. | Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, insurance type, gender, race, ethnicity, date of birth, and date and cause of death in the event of mortality. |
| Record and chart changes in vital signs:<br>• Height<br>• Weight<br>• Blood pressure<br>• Calculate and display: BMI<br>• Plot and display growth charts for children 2–20 years, including BMI. | 1. Enable a user to electronically record, modify, and retrieve a patient's vital signs including, at a minimum, the height, weight, blood pressure, temperature, and pulse.<br>2. Automatically calculate and display body mass index (BMI) based on a patient's height and weight.<br>3. Plot and electronically display, upon request, growth charts (height, weight, and BMI) for patients 2–20 years old. | |
| Record smoking status for patients 13 years old or older. | Enable a user to electronically record, modify, and retrieve the smoking status of a patient to: current smoker, former smoker, or never smoked. | |
| Incorporate clinical lab-test results into EHR as structured data. | 1. Electronically receive clinical laboratory test results in a structured format and display such results in human readable format.<br>2. Electronically display in human readable format any clinical laboratory tests that have been received with LOINC® codes.<br>3. Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).[6]<br>4. Enable a user to electronically update a patient's record based upon received laboratory test results. | |
| Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach. | Enable a user to electronically select, sort, retrieve, and output a list of patients and patients' clinical information, based on user-defined demographic data, medication list, and specific conditions. | |
| Report quality measures to CMS or the States[7 8]. | 1. Calculate and electronically display quality measure results as specified by CMS or states.<br>2. Enable a user to electronically submit calculated quality measures in accordance with the standard specified in Table 2A row 5. | |

TABLE 1—CERTIFICATION CRITERIA—Continued

| Proposed meaningful use Stage 1 objectives | Certification criteria to support the achievement of meaningful use Stage 1 by eligible professionals | Certification criteria to support the achievement of meaningful use Stage 1 by eligible hospital |
|---|---|---|
| Send reminders to patients per patient preference for preventive/follow up care. | Electronically generate, upon request, a patient reminder list for preventive or follow-up care according to patient preferences based on demographic data, specific conditions, and/or medication list. | No Associated Proposed Meaningful Use Stage 1 Objective. |
| Implement 5 clinical decision support rules [9] [10] | 1. Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) according to specialty or clinical priorities that use demographic data, specific patient diagnoses, conditions, diagnostic test results and/or patient medication list.<br>2. Automatically and electronically generate and indicate (*e.g.,* pop-up message or sound) in real-time, alerts and care suggestions based upon clinical decision support rules and evidence grade.<br>3. Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user. | 1. Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) according to a high priority hospital condition that use demographic data, specific patient diagnoses, conditions, diagnostic test results and/or patient medication list.<br>2. Automatically and electronically generate and indicate (*e.g.,* pop-up message or sound) in real-time, alerts and care suggestions based upon clinical decision support rules and evidence grade.<br>3. Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user. |
| Check insurance eligibility electronically from public and private payers. | Enable a user to electronically record and display patients' insurance eligibility, and submit insurance eligibility queries to public or private payers and receive an eligibility response in accordance with the applicable standards specified in Table 2A row 4. | |
| Submit claims electronically to public and private payers. | Enable a user to electronically submit claims to public or private payers in accordance with the applicable standards specified in Table 2A row 4. | |
| Provide patients with an electronic copy of their health information upon request [11] [12]. | Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures in: (1) Human readable format; and (2) accordance with the standards% specified in Table 2A row 1 to provide to a patient on electronic media, or through some other electronic means. | Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, discharge summary, and procedures in: (1) Human readable format; and (2) accordance with the standards% specified in Table 2A row 1 to provide to a patient on electronic media, or through some other electronic means. |
| Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request. | No Associated Proposed Meaningful Use Stage 1 Objective. | Enable a user to create an electronic copy of the discharge instructions and procedures for a patient, in human readable format, at the time of discharge to provide to a patient on electronic media, or through some other electronic means. |
| Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, allergies) within 96 hours of the information being available to the eligible professional. | Enable a user to provide patients with online access to their clinical information, including, at a minimum, lab test results, problem list, medication list, medication allergy list, immunizations, and procedures. | No Associated Proposed Meaningful Use Stage 1 Objective. |
| Provide clinical summaries for patients for each office visit. | 1. Enable a user to provide clinical summaries to patients (in paper or electronic form) for each office visit that include, at a minimum, diagnostic test results, medication list, medication allergy list, procedures, problem list, and immunizations.<br>2. If the clinical summary is provided electronically (*i.e.,* not printed), it must be provided in: (1) Human readable format; and (2) accordance with the standards% specified in Table 2A row 1 to provide to a patient on electronic media, or through some other electronic means. | No Associated Proposed Meaningful Use Stage 1 Objective. |

TABLE 1—CERTIFICATION CRITERIA—Continued

| Proposed meaningful use Stage 1 objectives | Certification criteria to support the achievement of meaningful use Stage 1 by eligible professionals | Certification criteria to support the achievement of meaningful use Stage 1 by eligible hospital |
|---|---|---|
| Capability to exchange key clinical information among providers of care and patient authorized entities electronically [13] [14].<br>Provide summary care record for each transition of care and referral. | 1. Electronically receive a patient summary record, from other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures and upon receipt of a patient summary record formatted in an alternative standard specified in Table 2A row 1, displaying it in human readable format.<br>2. Enable a user to electronically transmit a patient summary record to other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures in accordance with the standards% specified in Table 2A row 1. | 1. Electronically receive a patient summary record, from other providers and organizations including, at a minimum, discharge summary, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures and upon receipt of a patient summary record formatted in an alternative standard specified in Table 2A row 1, displaying it in human readable format.<br>2. Enable a user to electronically transmit a patient summary record, to other providers and organizations including, at a minimum, discharge summary, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures in accordance with the standards% specified in Table 2A row 1. |
| Perform medication reconciliation at relevant encounters and each transition of care. | Electronically complete medication reconciliation of two or more medication lists (compare and merge) into a single medication list that can be electronically displayed in real-time. | |
| Capability to submit electronic data to immunization registries and actual submission where required and accepted. | Electronically record, retrieve, and transmit immunization information to immunization registries in accordance with the standards% specified in Table 2A row 8 or in accordance with the applicable state-designated standard format. | |
| Capability to provide electronic submission of reportable lab results (as required by state or local law) to public health agencies and actual submission where it can be received. | No Associated Proposed Meaningful Use Stage 1 Objective. | Electronically record, retrieve, and transmit reportable clinical lab results to public health agencies in accordance with the standards% specified in Table 2A row 6. |
| Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice. | Electronically record, retrieve, and transmit syndrome-based (*e.g.,* influenza like illness) public health surveillance information to public health agencies in accordance with the standards specified in Table 2A row 7. | |
| Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities. | 1. Assign a unique name and/or number for identifying and tracking user identity and establish controls that permit only authorized users to access electronic health information.<br>2. Permit authorized users (who are authorized for emergency situations) to access electronic health information during an emergency.<br>3. Terminate an electronic session after a predetermined time of inactivity.<br>4. Encrypt and decrypt electronic health information according to user-defined preferences (*e.g.,* backups, removable media, at log-on/off) in accordance with the standard specified in Table 2B row 1.<br>5. Encrypt and decrypt electronic health information when exchanged in accordance with the standard specified in Table 2B row 2.<br>6. Record actions (*e.g.,* deletion) related to electronic health information in accordance with the standard specified in Table 2B row 3 (*i.e.,* audit log), provide alerts based on user-defined events, and electronically display and print all or a specified set of recorded information upon request or at a set period of time.<br>7. Verify that electronic health information has not been altered in transit and detect the alteration and deletion of electronic health information and audit logs in accordance with the standard specified in Table 2B row 4.<br>8. Verify that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information.<br>9. Verify that a person or entity seeking access to electronic health information across a network is the one claimed and is authorized to access such information in accordance with the standard specified in Table 2B row 5.<br>10. Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in Table 2B row 6. | |

We reiterate that adopted certification criteria identify the required capabilities for a Complete EHR or EHR Module to be certified. Adopted certification criteria do not apply to, or require actions by, eligible professionals or eligible hospitals. For example, to be certified, a Complete EHR or EHR Module must be capable of plotting and displaying growth charts for patients. By

[3] For eligible hospitals the full proposed meaningful use Stage 1 objective is: "Use CPOE for orders (any type) directly entered by authorizing provider (for example, MD, DO, RN, PA, NP)."

[4] For eligible professionals the full proposed meaningful use Stage 1 objective is: "record demographics: preferred language, insurance type, gender, race, ethnicity, date of birth."

[5] For eligible hospitals the full proposed meaningful use Stage 1 objective is: "record demographics: preferred language, insurance type, gender, race, ethnicity, date of birth, date and cause of death in the event of mortality."

[6] 42 CFR 493.1291(b) specifies that "[t]he test report information maintained as part of the