for comprehensive guidance on all phases of the submission, application, and award implementation process.

Will D. Spoon,

Program Analyst, Gulf Coast Ecosystem, Restoration Council.

[FR Doc. 2015–32924 Filed 12–30–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations:
Voluntary Reinquishment from the Texas Patient Safety Organization, Inc.

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of Delisting.

SUMMARY: The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b–21 to b–26, (Patient Safety Act) and the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the Federal Register on November 21, 2008, 73 FR 70732–70814, provide for the formation of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The Patient Safety Rule authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be “delisted” if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO’s listing expires. AHRQ has accepted a notification of voluntary relinquishment from the Texas Patient Safety Organization, Inc. of its status as a PSO, and has delisted the PSO accordingly. The Texas Patient Safety Organization, Inc. submitted this request for voluntary relinquishment during expedited revocation proceedings for cause.

DATES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12:00 Midnight ET (2400) on December 15, 2015.

ADDRESSES: Both directories can be accessed electronically at the following HHS Web site: http://www.pso.ahrq.gov/listed.

FOR FURTHER INFORMATION CONTACT:
Eileen Hogan, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Room 06N94B, Rockville, MD 20857; Telephone (toll free): (866) 403–3697; Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; Email: pso@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Background
The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery. HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be “delisted” if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO’s listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs.

AHRQ has accepted a notification from the Texas Patient Safety Organization, Inc., PSO number P0012, to voluntarily relinquish its status as a PSO. Accordingly, the Texas Patient Safety Organization, Inc. was delisted effective at 12:00 Midnight ET (2400) on December 15, 2015. The Texas Patient Safety Organization, Inc. submitted this request for voluntary relinquishment during expedited revocation proceedings for cause.

The Texas Patient Safety Organization, Inc. has patient safety work product (PSWP) in its possession. The PSO has met the requirements of section 3.108(c)(2)(i) of the Patient Safety Rule regarding notification to providers that have reported to the PSO. In addition, according to sections 3.108(c)(2)(ii) and 3.108(b)(3) of the Patient Safety Rule regarding disposition of PSWP, the PSO has 90 days from the effective date of delisting and revocation to complete the disposition of PSWP that is currently in the PSO’s possession.

More information on PSOs can be obtained through AHRQ’s PSO Web site at http://www.pso.ahrq.gov/index.html.

Sharon B. Arnold,
AHRQ Deputy Director.

[FR Doc. 2015–32914 Filed 12–30–15; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3323–NC]

Request for Information: Certification Frequency and Requirements for the Reporting of Quality Measures Under CMS Programs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Request for information.

SUMMARY: This request for information seeks public comment regarding several items related to the certification of health information technology (IT), including electronic health records (EHR) products used for reporting to certain CMS quality reporting programs such as, but not limited to, the Hospital Inpatient Quality Reporting (IQR) Program and the Physician Quality Reporting System (PQRS). In addition, we are requesting feedback on how often to require recertification, the number of clinical quality measures (CQMs) a certified Health IT Module should be required to certify to, and testing of certified Health IT Module(s).

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 1, 2016.

ADDRESSES: In commenting, refer to file code CMS–3323–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to http://www.regulations.gov. Follow the “Submit a comment” instructions.

2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3323–NC, P.O. Box 8013, Baltimore, MD 21244–8013. Please allow sufficient time for mailed comments to be received before the close of the comment period.
3. By express or overnight mail. You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS—3323—NC, Mail Stop C4—26—05, 7500 Security Boulevard, Baltimore, MD 21244—1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses:
   (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)
   b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244—1850.
   If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786—9994 in advance to schedule your arrival with one of our staff members.
   Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT: Lisa Marie Gomez, 410—786—1175.

SUPPLEMENTARY INFORMATION:
  Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments.
  Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1—800—743—3951.

I. Background

The Health Information Technology for Economic and Clinical Health Act (Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) and Title XIII of Division A of the ARRA) authorizes incentive payments under Medicare and Medicaid for the adoption of and meaningful use of certified EHR technology (CEHRT) and downward payment adjustments under Medicare for failure to demonstrate meaningful use. Eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) that seek to qualify for incentive payments or avoid negative payment adjustments under the Medicare and Medicaid EHR Incentive Programs are required to use CEHRT. Some CMS quality reporting programs, such as the Hospital Inpatient Quality Reporting (IQR) Program and Physician Quality Reporting System (PQRS), either require or provide the option to use certified EHR technology, as defined under the EHR Incentive Program, for reporting quality data.

The Office of the National Coordinator for Health Information Technology’s (ONC’s) “2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications Final Rule” (80 FR 62601 (2015 Edition final rule), establishes the capabilities and specifies the related standards and implementation specifications that CEHRT needs to include to support the achievement of meaningful use by EPs, eligible hospitals, and CAHs. ONC’s Health IT Certification Program provides a process by which Health IT Module(s) in order to reduce the burden and further streamline the process for providers and health IT developers while ensuring such products are certified and tested appropriately for effectiveness. The feedback will inform CMS and ONC of elements that may need to be considered for future rules relating to the reporting of quality measures under CMS programs. This request for information is part of the effort of CMS to streamline/reduce EP, eligible hospital, CAH, and health IT developer burden.

A. Frequency of Certification

We conduct an annual analysis of CQM specifications in order to ensure measure efficacy, accuracy, and clinical relevance. Any updates to the calculation of a CQM through this process are released with the annual updates to the electronic specifications for EHR submission published by CMS (https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html). Because we require the most recent version of the CQM specifications to be used for electronic reporting methods (79 FR 67906 and 80 FR 49760), we understand that health IT developers must make CQM updates annually and providers must regularly implement those updates to stay current with the most recent CQM version. To
ensure accuracy of the implementation of these updates, we have considered requiring recertification of already certified EHR products with these annual updates. We understand that standards for electronically representing CQMs continue to evolve, and believe there may be value in retesting certified Health IT Modules (including CEHRT) periodically to ensure that CQMs are being accurately calculated and represented, and that they can be reported as required. However, we have not required this recertification to date. With the continuing evolution of technology and clinical standards, as well as the need for a predictable cycle from measure development to provider data submission, we indicated, in the Fiscal Year (FY) 2016 Hospital Inpatient Prospective Payment Systems (IPPS) and Long-term Care Hospital (LTCH) Prospective Payment System (PPS) final rule (80 FR 49760) (hereinafter referred to as the FY 2016 IPPS/LTCH PPS final rule), that we would be issuing a request for information on the establishment of an ongoing cycle for the introduction and certification of new measures, the testing of updated measures, and the testing and certification of submission capabilities.

While we believe that health IT developers should test and certify their products to the most recent version of the electronic specifications for the CQMs when feasible, we understand the burdens associated with this requirement and therefore, have not historically required re-certification of previously certified products when updates are made to CQM electronic specifications or to the standards required for reporting. During the FY 2016 IPPS/LTCH PPS rulemaking process, we received comments and requests from stakeholders to change this policy. We acknowledge that the certification process can be burdensome to health IT developers and believe that annual certification could compress the timeline for CQM and standard updates. We also acknowledge that stakeholders and providers reporting electronic CQMs have an interest in ensuring that their Health IT Module is tested and certified to the most recent version of electronic CQM specifications. We are soliciting feedback regarding testing and recertification, particularly relating to: The requirement for CEHRT products to be recertified when a new version of the CEHRT is available in order to ensure the accuracy of implementation; and the requirement for Health IT Modules to undergo annual CQM testing through CMS approved testing tools and the ONC Health IT Certification Program.

We are also seeking comment on the following:
- What is the burden (both time and money) of additional testing and recertification?
- What are the benefits of requiring additional testing and recertification?
- How will it affect the timeline for CQM and standard updates?
- What are the benefits and challenges of establishing a predictable cycle from measure development to provider data submission?

B. Changes to Minimum CQM Certification Requirements

The Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 through 2017 final rule (80 FR 62761) specifies the meaningful use criteria that hospitals, and CAHs must meet in order to qualify for Medicare and Medicaid EHR incentive payments and avoid downward payment adjustments under Medicare. We believe EHRs should be certified to more than the minimum number of CQMs as required by the ONC 2014 Edition Base EHR definition of a minimum of 9 CQMs for EPs or 16 for eligible hospitals and CAHs (80 FR 16771, see also 45 CFR 170.102). With health IT developers having EHRs certified to the minimum number of CQMs, EPs, eligible hospitals, and CAHs may have limited CQMs available to them and may not be able to report on CQMs that are applicable to their patient population or scope of practice. As stated in the preamble of the final rule (80 FR 62895), we believe EPs, eligible hospitals, and CAHs should have a choice of which CQMs to report so that they can report on those CQMs most applicable to their patient population or scope of practice. Accordingly, we are soliciting comment on the following policy options that could provide greater choice for EPs, eligible hospitals, and CAHs.

Specifically, we are soliciting comment on: The feasibility of health IT developers complying with the requirements of each option in the first year in which the requirements would become effective; the impact of each option on EPs, eligible hospitals/CAHs, and health IT developers; and what we would need to consider when assessing each of these options.

- **Option 1:** Require EP health IT developers to certify Health IT Modules to all CQMs in the EP selection list; and require eligible hospital/CAH health IT developers to certify to all CQMs in the selection list for eligible hospitals and CAHs.

- **Option 2:** Incrementally increase the number of CQMs required to be certified each year until Health IT Modules are certified for all CQMs available for reporting by EPs, eligible hospitals, and CAHs to meet their CQM reporting requirements. For Option 2, we invite input on the advantages and disadvantages of an incremental increase in the number of CQMs required to be certified each year.

- **Option 3:** Require EP health IT developers to certify health IT products to more than the current minimum number of CQMs required for reporting, but not to all available CQMs.

For Option 3, we invite stakeholders’ input regarding the following approaches that are specific examples of implementation of the policy goal:

- **Option A:** An approach that would set a minimum number of measures health IT developers must certify to for EP settings or eligible hospital/CAH settings that is greater than the minimum number required for provider reporting. For example, EP health IT developers could be required to certify to a minimum of 15 measures, and eligible hospital/CAH health IT developers could be required to certify to a minimum number of 25 measures. We note that these numbers are provided as examples only, and we solicit comment on the appropriate number health IT developers could be required to certify to. Under this approach, health IT developers could choose from any measures in the list of available CQMs.

- **Option B:** An EP-specific approach that would require an EP health IT developer to certify to all the measures in a core/required set and all the measures in at least one specialty measure set relevant to the scope of practice for which the product is intended. We are looking for feedback on the general concept of requiring health IT developers to ensure that they are certified to the types of measures that are most relevant to their client base. For example, if a product serves multiple specialties, then it needs to be certified to the measures that are most likely needed by all of the specialties it serves. On the other hand, if the product is a niche product, such as a dental product, then it only needs to be certified to the measures that are relevant for that particular section of the market. As another example, we have provided a pediatric recommended core set 1 and an adult recommended core

one method of grouping measures could be by those that are invasive (for example, surgical), non-invasive, and cognitive. Another method could be by setting of care/venue.

As stated in the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 through 2017 final rule (80 FR 62895), any specific proposals for the number of measures vendors would be required to certify to would be outlined in separate notice and comment rulemaking such as the Physician Fee Schedule or Inpatient Prospective Payment Systems rules.

C. CQM Testing and Certification

ONC offers health IT certification for CQMs to record and export, import and calculate, and electronically report CQMs through its ONC Health IT Certification Program. This year, ONC has adopted a new edition of certification criteria in the 2015 Edition final rule (80 FR 62601). One objective of testing for the 2015 Edition CQM criteria (80 FR 62651) is to increase testing robustness (for example, increasing number of test records, robustly testing pathways by which a patient can enter the numerator or denominator of a measure), thereby ensuring that all certified products have capabilities commensurate to the increased requirements enumerated in the 2015 Edition final rule.

In the 2011 and 2014 Editions of certification criteria, the certification program sought to test basic capabilities and minimum requirements. Our expectation is that as time progresses and technology improves, EHR systems will have to demonstrate that they can perform to increasing levels of complexity, including requirements to identify errors, consume larger numbers of test cases, and demonstrate stricter adherence to standards. This is to ensure that investments into certified products yield the functionality expected to improve health care.

Certification criteria also includes optional and required elements that allow end users and quality improvement leaders to view, filter, and export quality measure data. These data enable point-of-care, iterative quality improvement efforts to identify patients whose care and conditions are not compliant with evidence-based guidelines, take action to improve their engagement with care processes, and achieve better outcomes.

CMS and ONC’s Health IT Certification Program test CQM functionality (for example, by testing a health IT system’s ability to import, export, capture, calculate, and report CQM data according to certain standards) through the Cypress Testing and Certification Tool by enabling repeatable and rigorous testing of a product’s capability to accurately calculate CQMs.4 There are potential areas of improvement to increase the robustness of that testing. Therefore, we are requesting information on the following:

• What changes to testing are recommended (or are not recommended) to increase testing robustness?
• How could CMS and ONC determine how many test cases are needed for adequate test coverage?
• Are there recommendations for the format of test cases that could be entered both manually and electronically?
• What kind of errors should constitute warnings rather than test failures?
• Are there recommendations for or against single measure testing?
• How could the test procedures and certification companion guides published by ONC be improved to help you be more successful in preparing for and passing certification testing?

CMS and ONC believe that increased testing robustness adds value to the process of certification, but acknowledge that it would increase health IT developer burden in certifying their products. Therefore, we welcome comments on the following:

• How can the CQM certification process be made more efficient and how can the certification tools and resources be augmented or made more useable?
• What, if any, adverse implications could the increased certification standards have on providers?
• What levels of testing will ensure that providers and other product purchasers will have enough information on the usability and effectiveness of the tool without unduly burdening health IT developers?
• Would flexibility on the vocabulary codes allowed for test files reduce burden on health IT developers?
• What are other ways in which the Cypress testing tool could be improved?
• When 45 CFR 170.315(c)(1) requires users to export quality measure data on demand, how would you want that to be accessed by users and what characteristics are minimally required to make this feature useful to end users?
• ONC finalized a 2015 Edition certification criterion for filtering of CQMs (45 CFR 170.315(c)(4)) to the following filters:

http://projectcypress.org/
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–284]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by February 29, 2016.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured reference the document identifier or OMB number, you must mail written comments to the Federal Register documents. To comply with this requirement, CMS is publishing this notice. CMS, Office of Strategic Operations and Regulations Development, Attention: Document Identifier/OMB Control Number __ Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection’s supporting statement and associated materials (see ADDRESSES).

CMS–R–284 Medicaid Statistical Information System (MSIS) and Transformed—Medicaid Statistical Information System (T–MSIS)

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

1. Type of Information Collection Request: Revision of a currently approved collection. Title of Information Collection: Medicaid Statistical Information System (MSIS) and Transformed—Medicaid Statistical Information System (T–MSIS); Use: The data reported in MSIS/T–MSIS are used by federal, state, and local officials, as well as by private researchers and corporations to monitor past and projected future trends in the Medicaid program. These data provide the only national level information available on enrollees, beneficiaries, and expenditures. They also provide the only national level information available on Medicaid utilization. This information is the basis for analyses and for cost savings estimates for the Department’s cost sharing legislative initiatives to Congress. The collected data are also crucial to our actuarial forecasts. Form Number: CMS–R–284 (OMB control number: 0938–0345); Frequency: Quarterly and monthly;