HIMSS Electronic Health Record Association

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February 12, 2016

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3323-NC
Baltimore, MD 21244-8016

Dear Acting Administrator Slavitt:

On behalf of the more than 30 member companies of the Electronic Health Record Association (the Association), we are pleased to submit comments on the Centers for Medicare and Medicaid's (CMS) Request for Information (RFI): Certification Frequency and Requirements for the Reporting of Quality Measures under CMS Programs. We believe that EHRs and other health information technologies are foundational to advancing quality measurement and reporting by providing access to information not previously available and by automating data collection – all necessary in the transition to value-based care and alternative payment models (APMs).

These comments reflect the collective experience and expertise of health IT developers and are a result of our collaborative efforts working with policymakers, other stakeholders, and most importantly, our customers.

The EHR Association appreciates the opportunity to provide our recommendations to CMS and ONC on the certification frequency and requirements for the reporting of clinical quality measures (CQMs), and we have provided detailed feedback and recommendations to the specific questions asked in the RFI in the attached table. However, we are concerned that the areas focused on in this RFI will provide little improvement to the actual quality of the submission of the CQM data to CMS, nor will it streamline or

reduce the burden of electronic quality measurement on providers, hospitals, and health IT developers, both mentioned as CMS goals in the RFI and the accompanying CMS blog[1].

In previous comments, letters, and discussions with CMS and the Office of the National Coordinator for Health IT (ONC), the Association has voiced our concerns regarding the disconnect between the CQM certification process and the requirements for successful CQM data submission to CMS. Specifically, we believe that it is problematic that a provider who possesses certified software that has been tested using the most recent certification tools and data cannot be assured that their CQM data can be successfully submitted to CMS, due to the differences in the ONC certification and CMS submission requirements. In our detailed comments to the RFI questions, we recommend that CMS should work closely with ONC to close the gap between certification testing and the CMS submission requirements, ensuring that certification can become an incremental step towards successful CQM submission for our customers, and is not wasted software development for vendors as it is today.

In addition, we feel that it is crucial to recognize that the industry is still in the early stages of migrating from claims-based measures to eCQMs, as well as from process-based to outcomes-oriented measures. We have previously commented on some of the fundamental challenges inherent with the current processes around electronic quality measurement, as well as issues with the measures themselves. The pending implementation of the Merit-based Incentive Program System (MIPS) and Alternative Payment Models (APMs) underscores the urgency of improving the quality measurement process as we move towards a system where providers are reimbursed on the value that they provide to their patients.

We urge CMS to prioritize the work to improve the CQM process before expanding the certification program and adding new requirements. Focusing on certification does not address the fundamental deficiencies that all stakeholders have experienced with the CQMs. As we have commented on previously, electronic clinical quality measurement is not yet captured as a "byproduct" of care delivered, and providers are often frustrated with the documentation efforts necessary to satisfy the CQMs. Providers are also concerned over the quality and relevancy of the measures themselves, and feel the CQMs are not much more than a "check the box" requirement today. At the same time, health IT software developers and providers alike are spending an inordinate amount of resources implementing the CQMs, at the expense of other high priority software enhancements that are crucial to support the transition to APMs and value-based care.

In order to improve the fundamental components of this transition to electronic quality measurement, the EHR Association reiterates recommendations we have made previously in order to improve CQM development, endorsement, and implementation:

- More time must be devoted to ensure the reliability, validity, and feasibility of both the current CQMs, as well as any new CQMs. This must include allocating more time and resources to testing both the accuracy of the CQM specifications, as well as the feasibility of the data collection requirements. In addition, these components should be considered part of the CQM endorsement process.
- Conduct pilots for all new CQMs that replicate real-world usage by providers, in all settings of care applicable, before requiring the use of the CQM in a CMS program.
- Reduce the number of revisions to the requirements, tools, and documentation for CQM certification, validation, and submission in a given calendar year. These numerous revisions lead to missed information by vendors and providers, which result in errors like the ones identified in

[1] Goodrich, K. (2015) *Improving the submission of quality data to CMS quality reporting programs* available at: http://blog.cms.gov/2015/12/30/improving-the-submission-of-quality-data-to-cms-quality-reporting-programs/

the 2014 CQM submission data. In addition, at least 18 months must be allowed for full implementation of any major changes by vendors and providers.

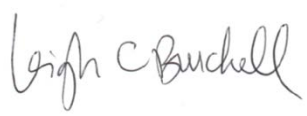
The transition to CQMs that are longitudinal, outcome-based, and patient-centered will be critical to ensuring a successful path towards value-based care. Focusing on improving the fundamental components of the CQM process, and working with all stakeholders to achieve advances in the areas noted above will facilitate this transition.

Specific to our responses to the questions posed in this RFI, we would like to highlight a number of key points made in the attached table.

- *Frequency of Certification:* The Association does not support annual certification, including recertification of the annual measures updates, as the burden on both vendors and providers exceeds any benefits, especially given that this would still not ensure that the CQM submission would be accepted by CMS.
- *Frequency of Certification:* As we have noted many times in the past, we and our customers need *at least* 18 months between the time that the measure specifications, implementation guides, and test tools are released (together) and the date when reporting is required. Inadequate time to perform all the design, testing, implementation, and training required for both revised and new eCQMs results in frustrating provider workflows as well as usability issues. We reiterate our past recommendation that the annual measure updates be limited to changes that do not have a significant impact on clinician workflow or provider implementation time, or require extensive software code changes or recertification.
- *Changes to Minimum CQM Certification Requirements:* We do not believe that there is any advantage to requiring health IT developers to implement *all* eCQMs if their respective customer base does not need and will not use them. This burdens not only providers, but also vendors who would then be required to recertify for each new eCQM implemented in their EHRs. We would rather spend our resources on features that our customers are requesting and on usability improvements that the market is demanding.
- *CQM Testing and Certification:* We continue to be concerned that the quality of the measure specifications and testing tools is not what it needs to be in order for EHR developers and their customers to be confident that submissions will not be erroneously rejected. As software developers, we understand very well that thorough testing and validation of documentation is essential before requiring the use of any application or tool. The Association sees great opportunity for improvement in this area.
- We believe that establishing a predictable cycle with stabilized requirements, tools, and documentation delivered in a timely manner would be beneficial to ensure accurate CQM development, calculation, and submission. We are concerned that the current rulemaking cycle does not support this, as we look toward the implementation of MACRA as well as the addition of new eCQMs for reporting.

We appreciate the opportunity to provide feedback to CMS on proposed changes to the eCQM certification requirements. The EHR Association strives to represent not only our member companies, but also our collective customers to ensure that regulations do not impose additional and unnecessary burden to busy clinicians. We look forward to our ongoing collaboration to make these programs more efficient and effective as we move forward to implement value-based reimbursement models.

Sincerely,



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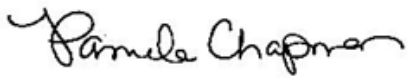

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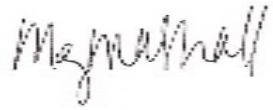

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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of over 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehrassociation.org.

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

A. Frequency of Certification		Comments
Annual CQM Updates: CMS currently requires the most recent version of the CQM specifications to be used for electronic reporting methods, and understands 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, **CMS has considered requiring recertification of already certified EHR products with these annual updates**. CMS states also that standards for electronically representing CQMs continue to evolve, and believes 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. They have not required this recertification to date.		
Frequency of Certification – Testing and Recertification **Q1**	Requesting feedback on requiring CEHRT products to be recertified when a new version of the CEHRT is available in order to ensure the accuracy of implementation	The Association asks for clarification around this question. We believe that it is intending to ask about requiring EHRs to be recertified if a new or updated version of a standard is required for CQMs, such as a new version of one of the QRDA standards. If this is the intent, although we generally feel it would be reasonable to expect recertification in this instance, we have several concerns regarding this. First, we are concerned that the timing as it stands today may not lend itself to a successful process. We urge CMS and ONC to ensure that adequate time is allowed for this process, including an 18 month timeframe between the release of a final rule with new certification requirements, and use by our customers. This timeframe must include any associated tools and documentation, such as the version of Cypress needed for certification. We are also concerned that requiring recertification would not ensure that the CQM submission could be accepted by CMS without error. ONC has repeatedly clarified that certification is not meant to test for this level of accuracy. We have commented previously regarding our concern that certification today does not ensure providers that their CQM submission will be accepted by CMS. We urge CMS and ONC to align these processes. With the addition of the recommendations given above, the Association generally supports the requirement for CEHRT products to be recertified when a new edition of CEHRT is available. Most vendors include a plan to recertify those products to the most recent CEHRT version available to ensure that CEHRT is available to providers when required for use by the meaningful use program or other regulations and programs. However, we caution that this must also take into account the appropriate timeframe, considering the following:

		● Recertification should **not** be required just because a new CEHRT edition is available, if the CEHRT functionality is not yet required for use by an EP or EH by some program. Otherwise, this would divert resources from other customer-driven development priorities, as well as create a potential conflict with mismatched requirements between a new version of CEHRT and the current functions and capabilities required and/or supported by CMS (and other organizations). ● For example, the 2015 CEHRT edition requires the use of QRDA 1, Release 3, but this is not yet supported by CMS for submission of the measures. If vendors implemented this in their products today just to certify to a new version of CEHRT, it would be wasted work AND would have to be "undone" in order to ensure that CQMs could be submitted using the current version of QRDA 1 supported by CMS today. This results in wasteful development that prevents us from focusing on customer priorities and enhancements to usability, among other development priorities.
Frequency of Certification – Testing and Recertification **Q2**	Requesting feedback on requiring Health IT Modules to undergo annual CQM testing through CMS approved testing tools and the ONC Health IT Certification Program	The Association has provided recommendations on the topic of the annual CQM updates in many of our prior comments. We also initiated an all-day meeting with CMS, ONC, and other stakeholders on June 16, 2014 to discuss the unintended consequences of the 2014 annual updates to both providers and vendors. We are very concerned about requiring annual CQM certification, primarily because of the scope of the annual measure updates and the implementation burden this imposes on both vendors and providers. In addition, as mentioned in Q1, requiring recertification would not ensure that the CQM submission could be accepted by CMS without error. We provided the following recommendations in the 2016 Physician Fee Schedule proposed rule, as well as in past comments, and we reiterate them here: ● If certification of the annual measure updates is required, it would add on to existing issues around the already compressed timeframe for software development and implementation. Two additional challenges that are likely to arise are the availability of a Cypress version for certification that will accommodate testing of these updated measures, as well as the availability of certification "slots" with each authorized testing lab (ATL) in order for them to accommodate all vendors. Currently, there is no version of Cypress available to test the 2015 annual measure update, and a

		version will not be available until July 28, 2016. If certification were required for the 2015 annual updates, this obviously would not be feasible given this Cypress schedule. ● As we have commented on previously, the extensive changes to every measure contributes to the burden on both vendors and providers to implement the annual updates. We reiterate our past recommendation that the annual updates be limited to changes that do not have a significant impact on clinician workflow or provider implementation time, or require extensive software code changes or recertification. ● If a CQM requires more extensive modification, and for any new CQMs introduced, a minimum of 18 months must be allowed. This would accommodate the need to include certification (or recertification) for these types of major changes impacting the CQMs. The Association recommends that only these types of updates and any new measures be subject to certification and given adequate time to accomplish the full cycle of software development, testing, and implementation.
Frequency of Certification – Testing and Recertification **Q3**	What is the burden (both time and money) of additional testing and recertification?	We are concerned that the compressed timeline already in place to safely and accurately implement the annual updates by January 1, the beginning of most reporting years, does not provide enough time, given the breadth of changes to the CQMs that we have experienced so far. It takes a large number of resource hours from both the vendor and provider to implement the annual updates. Adding the burden of preparation and execution of additional testing and certification further compresses an already inadequate timeline. ● The timing of the annual eCQM measure updates as well as the release of any new eCQMs should be tightly correlated with the release of updates to the CMS Implementation Guide (which we assume will cover multiple CMS quality and incentive programs), as well as revisions to the validation tools used for electronic submission. This linkage should include adequate time for implementing any changes. ● One of our members provided an estimate of the burden, communicating that prepping for certifying a single measure takes about 20 hours. For developers new to the process of certification, certification can take much longer. ● If measures (new or changed) require the addition of fields or content to the EHR, it results in both added development time as well as a burden on end-users who have to upgrade their software and perform implementation of the new requirements.

Frequency of Certification – Testing and Recertification **Q4**	What are the benefits of requiring additional testing and recertification?	Given the fact that the certification process does **not** ensure that the CQM submission can be successfully accepted by the CMS program it's intended for, as well as the additional development effort required to ensure that CQM submission is successful for **EACH** CMS program (as they each have different requirements), we see no benefit in requiring recertification based on the annual measure updates and the ONC certification process.
Frequency of Certification – Testing and Recertification **Q5**	How will it affect the timeline for CQM and standard updates?	We have provided information in the responses above regarding Issues around compressed timelines, and reiterate that recertification is not feasible within the timelines required today.
Frequency of Certification – Testing and Recertification **Q6**	What are the benefits and challenges of establishing a predictable cycle from measure development to provider data submission?	The Association believes that establishing a predictable cycle with stabilized requirements, tools, and documentation delivered in a timely manner would be beneficial to ensure accurate CQM development, calculation, and submission. However, In our response to the Medicare Reform Law and CHIP Reauthorization Act of 2015 (MACRA) RFI, we noted that there have been frequent revisions to the requirements for eCQM submission, including changes to the Cypress certification tool, updates to the version of QRDA expected to be utilized, and updates to the CMS implementation guide. In CY 2015 alone, revisions were made in January, April, and June. It is difficult for a vendor or provider to identify all the relevant documents and information to ensure that they are utilizing the most recent requirements. We strongly urge CMS to reduce the number of revisions to the requirements, tools, and documentation for eCQM certification, validation, and submission in a given calendar year in order to provide a stable environment for implementation, certification, and delivery to our customers. In addition, we have provided numerous recommendations in the past regarding the need for more testing and piloting of the eCQMs, the standards utilized, and the submission process. We reiterate the importance of this testing and validation process prior to requiring the use of new and revised eCQM specifications, along with the associated standards and tools.

B. Changes to Minimum CQM Certification Requirements		Comments
CMS states that they believe EHRs should be certified to more than the minimum number of CQMs (9 for EPs, 16 for EHs) and think that EPs and EHs should have a choice of which CQMs to report. They are seeking comment on the following options:		
Option 1: Require EP and EH developers to certify to ALL CQMS **Q1**	What is the feasibility of health IT developers complying with the requirements of this option in the first year in which the requirements would become effective?	Software developers are best able to meet the needs of the market by their own determination of which CQMs to implement and, in turn, best serves their customers. The decision to add measures is just like adding other types of functionality - vendors must take priority and resource burden into consideration. The requirements should not force health IT developers to be divorced from their customer base. We would like to propose an option suited to the needs of providers and also feasible for health IT vendors. This option may vary slightly for EP versus EH settings, but to be valuable would include the following: ● A limited core set of CQMs all health IT would implement that is made up of measures common to a broad range of providers and inclusive of specialty providers ● Supporting CQM sets available to help health IT and customers make wise decisions. For instance, specialists may have a CQM set specific to their practices. ● EH specific sets which may be more focused due to the nature of various settings and the CQMs applicable to those settings. It is not feasible to require vendors to certify to all CQMs. Vendors may market their products and services to a certain specialty or specialties, and there would be no return on investment to add content to support measures that their clients would not report. In addition, a number of the CQMs require use of proprietary scales which are not available without release by the copyright holder. Our members can describe a number of instances where the intellectual property (IP) holder refused to grant permission to include the scale or wanted larger sums of money than would be warranted by the client use of that measure. Under MIPS, there is an expectation that there will be many more measures introduced, including more specialty-specific measures. This makes a requirement to certify all measures too expansive. Implementing a new measure has a different impact and burden than updating an existing CQM. The

		Association has consistently asked that there be 18 months allowed for the implementation of a new CQM once the final rule has been released. Even those 18 months may not be enough time if the standards used in the implementation continue to change as drastically as they have in the past.
Option 1: Require EP and EH developers to certify to ALL CQMS **Q2**	What is the impact of this option on EPs, eligible hospitals/CAHs, and health IT developers?	This option would require HIT developers to devote time and resources to producing measures their customers may never use. This will impact the time and resources available to implement features needed to improve usability and customer satisfaction. The time necessary to optimize workflows of valid measures for a specific EHR would be greatly increased. Providers using the health IT would then be given a number of measures they would never use, in the place of fewer, well-implemented measures. There are also costs to including copyrighted materials required by given measures, which could increase the costs of the products and services to clients.
Option 1: Require EP and EH developers to certify to ALL CQMS **Q3**	What would CMS need to consider when assessing this option?	This is an unnecessary requirement, as many EHRs provide a variety of CQMs pertinent to their users. The burden of this option does not only fall on health IT, but also heavily on providers. This would negatively impact them by taking developers away from customer priorities, and placing more importance on meeting regulations. There is questionable feasibility in the ability of providers from all specialties to be able to capture the data needed for all measures, therefore there is no need to require health IT developers to implement measures which calculate data some providers may never use in their practice. The feasibility of this option is not only dependent upon the abilities of EHR developers, but the combined capabilities of those involved with Cypress, measure update releases (and corrections), values set releases, certification body availability, and QRDA version releases. It will not be possible for every EHR to certify to all CQMs unless each and every party involved in the process has removed all the barriers to the smooth development and certification of a CQM. As we have previously advised in other comments, there should be at least 18 months between the time a final requirement is released and the time it is expected to be implemented. While it may make sense to increase number of CQMs, the process still suffers from defects. If vendors develop what is necessary to support all CQMs, this

		could lead to complexities that make health IT less usable. If, for example, 20 measures for cardiology were required, an EHR would be required to provide functionality and the data to implement those 20. This functionality may make little, if any, sense to a dermatologist. EHRs could reach a point where they do not provide good workflows and functionality to support the measures. Providers would then have a very hard time collecting accurate data, making workflows even more tedious.
Option 2: Incrementally increase the # of CQMs each year until certified for all CQMs. **Q1**	What is the feasibility of health IT developers complying with the requirements of this option in the first year in which the requirements would become effective?	This option is more feasible than Option 1, yet it is still unnecessary for every EHR to use resources to provide measures which their customers are unlikely to use. We would like to reiterate support for a limited set of core CQMs for all health IT to implement with a variety of specialty-specific sets to select from.
Option 2: Incrementally increase the # of CQMs each year until certified for all CQMs. **Q2**	What is the impact of this option on EPs, eligible hospitals/CAHs, and health IT developers?	Depending upon the customer base of an EHR, the impact would be greater on some types of health IT compared to others. Health IT vendors with a large, varied customer base are more likely to have developed a higher number of CQMs in order to satisfy the needs of their customers. Specialty EHRs would be most impacted because they would have to invest more of resources to develop CQMs their customers are not likely to use. Adding content to support measures not relevant to the client base could require additional and unnecessary upgrades, something already proven to be burdensome. Vendors would be forced defer enhancements clients actually want while developing CQMs and functionality to support them, which will not be used.
Option 2: Incrementally increase the # of CQMs each year until certified for all CQMs. **Q3**	What would CMS need to consider when assessing this option?	The burden of this option will not be equal for vendors or their respective customers. Vendor currently provides different sets of CQMs in their systems, depending on their clients' needs. One EHR may already have nearly all CQMs certified and another may need to certify dozens to meet this requirement. This option is less intrusive than requiring all CQMs be developed and certified at once, but it is still not focused on the right objectives. This option would still be both problematic and not targeted to providers actual needs.

Option 2: Incrementally increase the # of CQMs each year until certified for all CQMs. **Q4**	We invite input on the advantages and disadvantages of an incremental increase in the number of CQMs required to be certified each year.	Disadvantages of this option far outweigh any potential advantages. It is important to understand that the initial implementation and certification effort for a CQM is not the end of the effort; maintenance of each CQM is potentially more costly. The more CQMs supported by a health IT application, the more burdensome the annual updates will be.
Option 3: Require EP and EH developers to more than the current minimum # but not to all available CQMs. **Option A Approach**	Option A: Set a minimum # of measures that is greater than today. If so, what is the appropriate # that could be required? In this approach, developers could choose from ANY measures in the CQM list.	This option is most aligned with provider requests which drive health IT business strategies. The appropriate number of CQMs should be determined by marketplace feedback. Vendors are very responsive to the requests of their clients, and the number that they chose to certify to meet client demand will vary widely across vendors depending upon the market segment and specialties that they serve. Health IT vendors conduct a great deal of research to ensure that CQM implementation is appropriate for the customers being served. A balance must be found which considers all of the following: ● the minimum number of CQMs to accomplish goals and be appropriate for the most specialties; ● the priority relative to other regulatory requirements and customer requests; ● and the fewest CQMs to meet client needs so that the benefits to exceed costs. It is better to develop fewer measures and have them actually mean something. The focus should be more on quality than quantity.
Option 3: Require EP and EH developers to more than the current minimum # but not to all available CQMs.	Option B: For EPs, certify to all measures in a core/required set (segmented by adult/pediatric) and all measures in a least one specialty measure set relevant to product scope of practice. Provide general feedback on requiring developers to ensure they are certified to the measures most relevant to their clients.	The market already requires that health IT vendors certify to the most relevant set of CQMs for their clients.

Option B approach	CMS is considering using an approach for providing specialty measure sets similar to those under PQRS. As these don't address all specialties, what additional specialties would benefit from a measure set and are any efforts underway to define this? Would this approach achieve the desired goal for all specialty types to have certified measures in their CEHRT?	
Option 3: Require EP and EH developers to more than the current minimum # but not to all available CQMs. **Option C approach**	Option C: A developer must choose one of the following: ++ Multispecialty health IT developer -– certifies all CQMs. ++ Primary care health IT developer – certifies a set of primary care CQMs. ++ Specialty provider health IT developer – certifies a minimum number of CQMs on an "a la carte" basis. For this approach, CMS solicits comments on the number of measures to require of a "primary care developer" as well as a "specialty provider developer".	This option would define a health IT application as multispecialty, primary care, or specialty solely based upon the number of certified CQMs it makes available. There is a great deal more (than only CQMs) involved in health IT which should be used to define it. Even if a vendor serves multiple specialties, that does not mean that they support all specialties and it would be unreasonable to require this. Until CMS removes CQMs that require proprietary content, making support for all measures mandatory would increase the documentation burden on users of the software. For example, if a vendor cannot secure rights to electronically reproduce a required scale or assessment, the provider will have to complete the survey on paper or on another website and manually enter the results into the EHR. EHR developers have encountered problems in the past where certain assessments were not licensed for incorporation in commercial products.
Changes to minimum CQM certification requirements	Are there other ways of grouping or classifying measures that we should consider to ensure applicability and selection for providers? Examples given: Invasive, non-invasive and cognitive; or by setting of care/venue	We have no comments on this section.

C. CQM Testing and Certification		Comments
CMS' expectation is that as time progresses and technology improves, EHR systems will have to demonstrate they are able to 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. CQM functionality is tested 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		
Areas to improve the testing. **Q1**	What changes to testing are recommended (or not recommended) to increase testing robustness?	As discussed at the August 2015 CMS vendor summit, we urge that CMS and ONC take more focused care to develop CQM-specific test data sets that are tuned to the specific CQM in question, while also maintaining the current approach of keeping test data sets as small as possible to reduce testing burden. Such more finely tuned test data sets will enhance the ability of certification and validation tools to increase the accuracy of specific CQM calculations. We recommend that CMS take several actions to improve the robustness of the testing process ● Finalize guidance for all specifications and implementation guides before finishing the development of the testing tools. ● Verify that the testing tools validate all of the required elements in the guides before EHR developers begin testing. ● Improve the quality of the testing tools so that the tools do not show inaccurate errors for valid files. ● Provide sufficient time between when testing tools based on final requirements are available and the beginning of the reporting year, so that EHR developers can make updates based on results from the testing tools and providers have time to implement and validate the changes. ● Well-defined, well-clarified error messaging is required. CMS states that JIRA is not well monitored, and the QualityNet help desk tier 1 and 2 support is not able to help when health IT vendors encounter errors. These changes would reduce the burden of the testing process for EHR developers and improve the success rate of submission for providers. Also, providers would have more time to implement changes identified during testing and a better experience with quality measure reporting. CMS could also streamline the testing process by focusing on test cases that test the boundaries of measure specifications or on differences in specifications between years.

		An overarching approach to testing that is focused on creating tools and test data sets that are useful to EHR developers in testing their products, as well as used for CMS or ONC processes, would be advantageous.
Areas to improve the testing. **Q2**	How could CMS and ONC determine how many test cases are needed for adequate test coverage?	CMS should focus on high quality test cases that test the boundaries of measure specifications or on differences in specifications between years. Where there are common pathways in similar measures, testing tools should optimize across all measures being tested at one point and not duplicate test cases unnecessarily.
Areas to improve the testing. **Q3**	Are there recommendations for the format of test cases that could be entered both manually and electronically?	We see both manual and electronic entry of test cases being important options. As more systems are able to import data, electronic entry will provide convenience. However, we note that electronic data import does not simulate the user experience in the same fashion that manual entry does, and therefore does not replace manual entry for all testing purposes. Electronically, we would assume QRDA format. Manual entry of data is challenging and EHR systems vary in requirements, specifically with entering retrospective data. An EHR is designed to support real-time input of data, and manual data entry test cases should be designed for entry of real-time data. Backdating data to support, for example, specific dates in the past defined in the test case, should not be included in test cases for manual input.
Areas to improve the testing. **Q4**	What kind of errors should constitute warnings rather than test failures?	Errors in calculation or errors that would cause a document to be rejected at submission or following submission for the intended use of the quality data should be test failures in a validation test tool. Conversely, errors that do not prevent submission or following submission for the intended use of the quality data should appear as warnings in a validation test tool. EHR developers will be better able to prioritize updates and support providers with successful submission if errors in calculation or that prevents submission are clearly differentiated from non-critical warnings. In addition, if a batch of files is rejected but only contains a few errors on particular files, CMS should accept the files that are valid and flag those that must be re-submitted, including the specific error message.
Areas to improve the testing.	Are there recommendations for or against single measure testing?	In most situations, testing multiple measures at the same time is much more efficient. Single measure testing can be useful in certain limited circumstances, such as to recertify a single measure based on changes in development or

Q5		measure specifications. Both multiple measure and single measure testing should continue to be options so that EHR developers have the flexibility to choose the method that is most efficient for their situation. We also believe that there are clear advantages to defining test cases that encompass multiple measures. Test cases also need to reflect realistic workflows and patient examples. If new measures are introduced, we would want the ability to test/certify the single new measure.
Areas to improve the testing. **Q6**	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?	The quality of the testing tool used in certification (Cypress) has more impact on the testing experience than the test procedure or companion guide. Guides that are written in natural language would improve success.
Increased developer burden **Q1**	How can the CQM certification process be made more efficient and how can the certification tools and resources be augmented or made more useable?	If CMS increases the frequency of certification, the process will need to be streamlined so that certifying bodies can test and validate all products presented for certification before the reporting period begins. One way to improve the efficiency of the certification process is to allow EHR developers to perform validation asynchronously. Because validation is performed by a testing tool, EHR developers can submit successful validation files to the certifier instead of requiring real-time validation. Certifiers could perform additional validation through observation or spot-checks as they deem necessary. Certification would also be more efficient if health IT Modules could test QRDA 1 for multiple measures at once in the Cypress testing tool, instead of having to perform one test for each measure. Additionally, CMS could consider focusing the certification process on measures with significant changes since the previous certification. Vendors need a clear view of which version of each implementation guide is expected to be implemented, as well as the VSAC version, QRDA version, CQM version, SEVT version, etc. We also recommend that MITRE provide added functionality to Cypress to incorporate a method of identifying the source of failures or mismatches, similar to the Joint Commission Rule Engine report.

Increased developer burden **Q2**	What, if any, adverse implications could the increased certification standards have on providers?	• Providers would be adversely affected by increased certification standards because EHR developers would have to dedicate resources to quality measure support at the expense of other development priorities that clients request. • Increased certification could have particular impact on EHR developers serving specialty areas. An EHR focused on a particular specialty might not have users requesting quality measures that are not relevant to their specialty. If those developers are forced to spend more time on quality measures, particularly measures that are not relevant, the users will see that as a detriment. • Also, if increased time must be spent on certification, this could cause EHR developers to implement fewer measures overall. Generally we do not see increased certification as improving provider experience with CQMs or addressing what we hear as provider interests in quality measurement, so we worry that increased certification will distract from their requests. Increased certification standards still do not assure that a provider could successfully submit data for a measure, and yet they increase the time and cost burden on health IT.
Increased developer burden **Q3**	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?	The certification process is not well designed as a method for verifying usability in relation to quality measurement. Usability challenges with quality measures generally originate from provider concerns that capturing data at the level of granularity required by the measure specifications for calculation is not necessarily something they have previously documented or that they feel is useful. Certification should focus on making available objective information on the CQMs that each product supports, and the capability of certified systems to capture required data and generate files in the required format. Testing a pre-defined script does not test realistic workflow or use cases. Currently, certification does not provide anything directly related to usability.
Increased developer burden **Q4**	Would flexibility on the vocabulary codes allowed for test files reduce burden on health IT developers?	We see several areas where flexibility around code sets could facilitate convenient testing: • Flexibility should accommodate when a system being tested has updated to recent versions of a particular code set (updated LOINC, updated SNOMED, etc).

		• When multiple code sets can be used to express a single concept, flexibility should be permitted in testing as to which code set is used. • Testing should permit use of alternate codes where applicable. • Providers and health IT developers would experience less burden with more flexibility of RxNorm values. • Qualitative and qualitative for immunizations – both developers and providers need flexibility here. • Regarding patient refusals, the same codes are being used for multiple measures which makes this value set too flexible.
Increased developer burden **Q5**	What are other ways in which the Cypress testing tool could be improved?	The Cypress testing tool has been historically challenging because it tends to perform slowly, can unexpectedly quit, and does not reliably match the measure specifications. EHR developers could save time in the testing process if the Cypress testing tool functioned as intended, was more reliable and had faster performance. The Cypress testing tool should also be improved to more closely test the measure specifications. In our experience, the testing tool frequently shows inaccurate errors when the submitted files are acceptable based on measure standards. Health IT developers must then spend resources investigating these inaccurate errors, and the cost multiplies across developers as different health IT modules encounter and troubleshoot the same inappropriate errors. These issues have been reported numerous times through JIRA, such as issue ticket Cypress-541 that documents errors that appear for unexpected supplemental data even though the files are consistent with the implementation guides. Cypress validation of time is very specific, making the setup for configuration difficult. This could be improved with flexibility on data entries with associated times associated.
Increased developer burden **Q6**	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?	Conversations with users indicate that quality measures data is exported primarily by IT support staff instead of providers. Technical staff appreciates the ability to export quality measures data in the same location and using the same tools they use to perform other configuration and exports. They also want to be able to export quality measures data efficiently, such as when processing capacity is available overnight. Therefore, we do not hear requests for physician users to be able to generate xml "on demand," but rather that the support staff who performs that role would like the function to be convenient to run based on their needs.

		In response to requests from our user community, we have prioritized the ability for clinical users to view and act on their quality measures results through dashboard tools that are separate from QRDA files. We continue to receive additional requests to expand those options, prioritized above the ability for providers to export their data.
2015 Edition certification criterion for filtering of CQMs (45 CFR 170.315(c)(4))	How useful are the "filtering" criteria to end users of systems for the purpose of safety and quality improvement? To quality improvement staff and organizations? • Are there additional filters/data would be helpful to stratify data by? • What, if anything additional, regarding this testing/certification should be published via the Certified Health IT Product List?	We have received requests for the ability to filter based on TIN, location, and NPI to facilitate reporting and submission that meets program-specific requirements. However, we have not heard of use cases for other filtering capabilities specifically for quality measures or QRDA data. Filtering and analytic capabilities outside of what is needed for submission for a particular CMS program should be left to market differentiation and innovation, and should not be prescriptively set by certification. Certification should identify what successful testing has taken place in relation to CQM filters, but there is not a need for further CHPL publications.