January 29, 2016

Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave., SW
Washington, DC 20201

Dear Acting Administrator Slavitt:

On behalf of the American Academy of Family Physicians (AAFP), which represents 120,900 family physicians and medical students across the country, I write in response to the "Certification Frequency and Requirements for the Reporting of Quality Measures Under CMS Programs" request for information as published in the December 31, 2015 *Federal Register*.

This regulation seeks comment regarding the certification of health information technology used for reporting to certain CMS quality reporting programs and seeks feedback on how often to require recertification, how many clinical quality measures (CQMs) a certified Health IT Module should be required to certify to, and the process for testing certified Health IT Module(s). The AAFP continues to support efforts to improve quality measure reporting programs and the use of EHRs and we offer the following comments to sections of this request for information that impact family physicians and other primary care physicians.

A. Frequency of Certification
5. What are the benefits and challenges of establishing a predictable cycle from measure development to provider data submission?
The biggest benefit is the ability for parties in the clinical quality measurement space, including vendors and eligible professionals, to plan for the future. Certification is only one step in the clinical quality measurement life cycle. To create a predictable cycle of measure development, the entire life cycle needs to be addressed. If it is not addressed, the certification process will artificially dictate the entire life cycle of quality measurement which we find unacceptable.

B. Changes to Minimum CQM Certification Requirements
6. Consider feasibility of health IT developers complying with the requirements of each option in the first year; the impact of each option on EPs; and what CMS would need to consider when assessing each of these options.
The AAFP is very concerned that the three options presented by CMS will likely produce bloated products in the arena of clinical quality measurement. Developers will be required to develop components that their users do not want or need. This diverts valuable development

resources away from other improvements in the products and increases costs without increasing value. Options 2 and 3 would limit the eligible professional's ability to evaluate products if their clinical quality measures are not in the subset of measures tested. We believe a better option is measure level testing. The results from single measure testing can be aggregated into collections to support customer's evaluation of products. This allows all measures to be tested but allows the developer to select the measures that their market segment is demanding.

Because we see flaws with all three options proposed by CMS, the AAFP strongly urges CMS to consider an alternative approach to certification frequency and requirements. First we recommend that CMS provide testing for all measures supported by CMS programs and publicly provide testing reports at the measure level. This is so end-users can easily determine which measures the certified technology supports and which were not tested. Secondly, we believe that certification should be based on the core measure sets developed by the Core Measures Collaborative such as the PCMH/ACO/Primary Care Core Set. A developer must certify against each core measure set; yet there would be an exclusion for each core measure set. The exclusion would be that the developer does not currently have, nor plans to market to, providers in the medical specialties that the core measure covers. We do not believe that a developer would be able to be excluded from the PCMH/ACO/Primary Care Core Set.

The AAFP urges CMS to consider the quality measurement process including measure development, specification updating, testing and electronic testing, and certification as a comprehensive cycle. Currently, many of these factors operate on siloed cycles that do not take into account how each impacts another. While not all measures are electronically specified, the AAFP encourages that the eCQM process aligns and integrates with other well-developed quality measurement life cycles. This will ease the burden on eligible providers, as they will better know when updated and tested measures will be available in their systems. Vendors will benefit from a well-planned and predictable measurement cycle that can be incorporated into their current business practices.

C. CQM Testing and Certification

7. What changes to testing are recommended (or not recommended) to increase testing robustness?

The complexity of measures can vary widely from measure to measure. We are concerned that testing every piece of logic in an implementation for a clinical quality measure may not always be feasible. For the market to adequately determine the reliability of a certified product to accurately calculate a quality measure, we need to know what parts of a measure were tested. The market would likely be able to trust a measure where the majority of the logic and controlled vocabularies used are tested. We would recommend that the testing results include the percentage of the measure logic and codes (i.e. code coverage) that was tested during certification process for each measure test.

8. How could CMS and ONC determine how many test cases are needed for adequate test coverage?

The number of test cases for a measure depends on its complexity and the extensiveness of the controlled vocabularies included in the measure. It is not feasible to set a specific number of test cases. Rather a determination of "code coverage", which is the percentage of logic and controlled vocabulary codes, is important. A minimum coverage percentage could be set. CMS should determine the code coverage of current testing to inform its decision on a minimum

percentage. A stratification of measures by risk of error or other characteristic may be valuable moving forward to have a higher bar for some types of measures.

11. Are there recommendations for or against single measure testing?
The AAFP is very supportive of single measure testing to allow health IT purchasers to understand which CMS measures the technology supports. That said, we believe that **certification** should be based on the core measure sets developed by the Core Measures Collaborative such as the PCMH/ACO/Primary Care Core Set. A developer must certify against each core measure set; yet there would be an exclusion for each core measure set. The exclusion would be that the developer does not currently have, nor plans to market to, providers in the medical specialties that the core measure covers. We do not believe that a developer would be able to be excluded from the PCMH/ACO/Primary Care Core Set.

CMS should report, as part of a product's certification status, the results of testing for each CMS supported measure.

14. What, if any, adverse implications could the increased certification standards have on providers?
By requiring that developers test against measures that are not needed nor wanted by its customers, CMS would be increasing the cost of products and diverting developer resources away from improvements in the health IT.

15. 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?
Transparency of testing should be apparent so the end users and purchasers understand the both the rigor of the testing for the measure and which parts of the measure processing was tested (i.e. code coverage percentage).

16. Would flexibility on the vocabulary codes allowed for the test files reduce burden on health IT developers?
The more complex the testing, the more resources (i.e. money) is needed to complete testing. Without flexibility of vocabulary codes, there is a potential to miss issues in measure processing. These issues would stem from mapping issues between the vocabulary used internally in the health IT product and the vocabulary used to test the measure. We would recommend flexibility wherever feasible.

18. 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?
In a recent study conducted by the AAFP, we found that quality measurement was a burden on eligible professionals. The level of burden was higher than needed due to the lack of automation in the area of clinical quality measure reporting. Quality measurement and data extraction should be automated, should be required as part of the certification process, and should be no burden on the provider to perform this functionality. Current technology is burdensome to physicians to do this work. This is not surprising given the technology's outdated focus on fee-for-service and current documentation requirements. Until the focus is diverted to automating care delivery and value-based payment, the burdens will remain. To truly answer this question and make a significant impact in the market requires a lot of thought and investigation by CMS and ONC.

19. 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?
The filtering criteria are very useful for eligible providers, as it helps with population health management efforts. It allows them to better understand the population they serve, identify care gaps, and stratify patients by risks to better manage care and engage patients.

20. Are there additional filters/data would be helpful to stratify CQM-Filters data by?

The Department of Health and Human Services, along with other stakeholders in the measurement space such as the National Quality Forum, are pushing to better understand the sociodemographic factors of a physician's patient panel for quality measurement and performance purposes. For these reasons, the AAFP suggests including ZIP+4 so social determinates of health can be taken into consideration. The additional four digits allows for the granularity needed for geolocation data to consider social determinates of health at the practice level.

21. What, if anything additional, regarding this testing/certification should be published via the Certified Health IT Product List?
The AAFP would like the list to provide measures that are certified, tested, and can calculate for reporting requirements for each specific vendor.

The AAFP urges HHS to follow these recommendations in order to improve the reporting of quality measures in CMS programs. Should you have questions, please contact Erin Solis, Regulatory Compliance Strategist, at (913) 906-6000, Ext. 4121 or esolis@aafp.org.

Sincerely,

Robert L. Wergin, MD, FAAFP
Board Chair