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October 24, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Dear Acting Administrator Slavitt:

The American Medical Association (AMA) is writing to express our pressing concern that the Centers for Medicare & Medicaid Services' (CMS) process for vetting qualified clinical data registries (QCDR) is putting the Merit-based Incentive Payment System (MIPS) in jeopardy.

Since the passage of Medicare Access and CHIP Reauthorization Act (MACRA), CMS has routinely stated whether through rulemaking or public statements that it has a great desire to incent and encourage reporting through QCDRs given their robust nature and the great potential for advancing the art of medicine. We strongly support this view and appreciate CMS' growing acceptance of QCDRs in clinical care, not only to meet the maximum allowable points in the quality component of MIPS, but also to help physicians and groups meet other components, such as Advancing Care Information and Clinical Practice Improvement Activities. To achieve this shared goal of greater QCDR participation, QCDRs need the flexibility to incorporate measures that are tailored to their participating specialties and registry participants. We are therefore alarmed at recent actions by CMS' contractor, Signature Consulting Group (SCG), which would severely limit QCDR's flexibility and threaten their viability.

Specialties are spending millions of dollars to improve the quality of care Medicare beneficiaries receive given the promise QCDRs have and the positive interaction physicians have had with them. QCDRs allow physicians to receive more timely and relevant feedback and benchmark information, as well as report on quality measures that are much more robust, often outcomes oriented and more applicable to a physician's patient population compared to traditional Physician Quality Reporting System (PQRS) measures. The current direction and signal from SCG sets QCDRs and the MIPS program back and turns a positive quality improvement exercise into a negative check-box compliance program.

Specifically, we are troubled that as part of its review and approval of QCDR measures for 2017, SCG is requiring any QCDRs that have similar measures to existing PQRS measures to drop the similar QCDR measure and adopt the PQRS measure(s). In the process, the contractor is essentially reducing the more sophisticated QCDR reporting systems and measures and moving QCDRs to a more basic and less meaningful traditional PQRS system.

QCDRs have experienced tremendous growth and success in improving quality because physicians recognize that QCDR measures are meaningful to their profession and patient care even though participation may cost in the hundreds to thousands of dollars. In contrast, SCG is requiring QCDRs to report on measures that may not be relevant or applicable to the data that they were designed to collect. Accordingly, **we urge CMS to direct its contractors to provide flexibility to QCDRs on the measures they can maintain and report, which was the intent of Congress when they created and expanded the QCDR pathway.** Without such flexibility, many QCDRs will struggle with finding relevant measures and maintaining their status, and a promising tool will have been turned into something that is burdensome and meaningless to physicians and does not truly advance care. The house of medicine is actively encouraging participation in QCDRs and investing millions of dollars in the advancement and maintenance of QCDRs, but these demands that QCDRs drop measures that are relevant to each specialty and adopt PQRS measures are dis-incentivizing active engagement and future promotion of QCDRs.

Based on statute, QCDRs are not subject to certain requirements, such as inclusion of measures on the annual final list of quality measures, publication in peer-reviewed journals, or endorsement by a consensus based entity. Therefore, **we believe CMS is not following the statutory intent of section 1848(q)(2)(D)(vi) of MACRA that allows flexibility with the measures QCDRs report.**

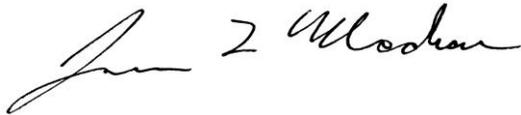
We are extremely concerned with the recent action by SCG given the lack of advance notice and recognition of the potential need for variations with measure specifications and the more advanced capabilities of QCDRs compared to traditional PQRS-specified measures. Many QCDRs do not incorporate billing codes in their data collection process, and we remind CMS that QCDRs are different from traditional registries and are not complete EHR systems. This was the intended purpose of the QCDR—to allow physicians and certain CMS-approved quality improvement registries to select measures from the registry to focus on quality reporting purposes. Furthermore, a specialized registry collects data addressing specific aspects of care (a condition or a specific procedure). Accordingly, there will be Medicare patients eligible for the denominator of for instance, a PQRS measure, but the data would not necessarily be captured in the registry because it may be outside the registry's scope of the condition or procedure (unrelated office visit for example). One problem with CMS' current file format is that the standardized, one-form-fits-all does not always translate seamlessly for each QCDR. Therefore, when developing formats for data submission, it is also critical that CMS work with registries to ensure that CMS can accept formats that allow each registry to utilize the unique features of its data, such as embedded risk adjustment.

In some instances, SCG is also misinformed on the status of the “similar” QCDR measure and/or existing measure within the PQRS program. For example, SCG informed one QCDR that its bowel prep measure must be removed because it is similar to a PQRS measure, but the PQRS measure was actually never finalized for PQRS and lack of acceptance of the QCDR measure by CMS ignores the evidence gap and necessity for incorporating the measure into the QCDR. Another QCDR was told that one of its measures was duplicative, but in fact the QCDR measure reflects an update to the evidence base and change in guideline recommendations, while the PQRS measure is still relying on the old guideline recommendation and is out of date. Thus, **we urge CMS to work with SCG to ensure flexibility with the measures QCDRs report on.** CMS should maintain flexibility by not requiring the use of any specific type of measures in the initial years of the program. Our recommendation maintains flexibility in the design of the category and ensures success by all physician specialties regardless of practice size or patient population.

Andrew M. Slavitt
October 24, 2016
Page 3

We appreciate the agency's attention to these concerns and strongly urge CMS to follow our recommendations for a successful MIPS program. We welcome the opportunity to discuss these ideas with your staff in more depth. Please feel free to contact Koryn Rubin, Assistant Director of Federal Affairs, at koryn.rubin@ama-assn.org or 202-789-7408 for more information.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and a stylized "M".

James L. Madara, MD