November 20, 2017

VIA ELECTRONIC MAIL
Pierre Yong, MD, MPH, MS
Director
Quality Measurement and Value-Based Incentives Group
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8013
Room S3-07-17
Pierre.Yong@cms.hhs.gov

Re: Concerns Regarding the Commercial Use of MIPS Measures

Dear Dr. Yong:

The undersigned members of the Physician Clinical Registry Coalition (the Coalition)[1] are writing to express our ongoing concerns about the commercial misuse of quality measures developed for the Merit-based Incentive Payment System (MIPS), which was established by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). While we appreciate the responsiveness of your office to our previously-stated concerns regarding the ownership and licensing of Qualified Clinical Data Registry (QCDR) measures, we have become increasingly aware of inappropriate and opportunistic commercial misuses of copyrighted MIPS measures developed by medical societies that operate qualified registries or QCDRs. We respectfully request that your office issue similar sub-regulatory guidance about the ownership and licensing of MIPS measures as it has issued for QCDR measures.

We previously sent a letter to you dated July 11, 2017 that discussed our concerns regarding the ownership and licensing of QCDR measures. We requested that CMS properly record ownership of all approved QCDR measures to protect the intellectual property rights of the owner of the measure, because these protections incentivize organizations to develop new and improved measures, and to maintain and update existing measures. We also submitted comments on the CY 2018 QPP proposed rule that reiterated our support of the proposal that QCDR vendors must

[1] The Coalition is a group of 25 medical societies and other physician-led organizations that sponsor clinical data registries that collect identifiable patient information for quality improvement and patient safety purposes to help participating providers monitor clinical outcomes among their patients. We are committed to advocating for policies that enable the development of clinical data registries and enhance their ability to improve quality of care through the analysis and reporting of these outcomes. Over half the members of the Coalition have been approved as qualified clinical data registries and most of the others are working toward that goal.

seek permission from the owner of a QCDR measure before using that measure during the performance period, and that such permission should be obtained at the time of self-nomination.[2] In our comments, we also recommended that CMS record the ownership of all approved measures to protect the intellectual property rights of the owner and ensure that the measures are used appropriately. In the CY 2018 final rule, CMS finalized its proposal, required assignment of QCDR measure IDs for all approved QCDR measures, and required QCDRs that have received permission to report the measure to use the same QCDR measure ID.[3] CMS stated that it may request that a borrowing QCDR provide proof that it has received permission to use a QCDR measure owned by another QCDR. CMS also clarified that the borrowing QCDR must use the exact measure specification provided by the QCDR measure owner. [4]

As electronic health record (EHR) vendors and other commercial entities are increasingly using MIPS measures (developed by medical societies) for purposes other than quality improvement, the Coalition has similar concerns about the need for licensing of MIPS measures. We detail our concerns below and wish to work with CMS to create safeguards to protect the proper implementation of these measures and enforce the intellectual property rights medical society developers of MIPS measures.

Concerns Regarding Commercial Entity Misuse of MIPS Measures

Coalition members have several concerns regarding the commercial misuse of MIPS measures developed by their societies. First, EHR companies and other commercial organizations are using measures for profit and not for the purpose of quality improvement. Many of these commercial organizations lack the clinical expertise to appropriately and accurately implement and report quality measures.

Coalition members have witnessed EHR vendors incorrectly implementing measures with clear guidelines, resulting in inaccurate quality measurement and comparisons. For example, a Coalition member stated that in one case where an EHR vendor misinterpreted a MIPS measure's intent, the vendor's performance rate for a MIPS measure was completely different from the registry's rate, even though the registry's rate was calculated using the same EHR data. In addition, Coalition members report that EHR vendors routinely contact the medical societies to ask basic questions about MIPS measures, which highlights that they do not have the background to understand or implement MIPS measures.

Second, we are concerned the problems of inaccurate commercial use of measures will be exacerbated by CMS's request for the harmonization of similar MIPS measures to allow for the broader use of measures developed by clinician-led QCDRs by other qualified registries and other non-clinician-led QCDRs, including commercial entities. While we understand that CMS's goal for this policy is to facilitate cross-cutting comparisons, the real-world implementation of harmonized measures often yields incomparable results. Registries with less

[2] 82 Fed. Reg. 30,010, 30,160 (June 30, 2017).
[3] 82 Fed. Reg. 53,568, 58,813-14 (Nov. 16, 2017).
[4] *Id.*

expertise on how to accurately implement measures may employ different methods for risk adjusting data, obtaining data, and aggregating data, which creates variation in how providers are measured and how their care is classified. Often, clinician-led registries will develop clinical quality measures for use in MIPS and other commercial-led registries will report these measures but employ their own methodology for analyzing and interpreting the data. Therefore, given the inconsistencies in implementation and methods, harmonizing measures across registries does not ensure accurate benchmarking and is not always ideal.

Commercial entities operating qualified registries and/or QCDR are at greater risk for having increased inaccuracy due to their lack of operational experience with measure science. When measuring providers "en masse," the results from qualified registries and QCDRs will not be able to account for the differences across and within specialties. For example, one Coalition member reports that a MIPS measure included a risk adjustment within the specifications, but no users applied the specification. The lack of utilization of the risk adjustment resulted in the submission of crude rates to measure performance and it was not possible to create benchmarks. In addition, CMS will not able to accurately assess the performance of physicians and reward those with superior performance. As a result, provider payment may be based on the random process used by particular qualified registry or QCDR, including those operated by commercial entities, to interpret the data. Overall, the lack of mandated consistent methods for measure implementation and data interpretation, which will especially impact the results from commercial entities, harms the validity and reliability of MIPS measures.

The improper implementation of measures threatens the success of the QPP program because it could lead to inaccurate statistics and reimbursement. If payments to physicians are not based on actual performance on quality measures, improvements in quality of care will not be achieved and the clinicians that have the best quality of care performance may not be compensated appropriately.

Enforcement of Ownership/Copyrights of MIPS Measures

Medical societies that develop MIPS measures can and do assert copyright ownership of such measures and should be able to control their use by third parties. The copyright notice for MIPS measures typically states that the measures can be reproduced and distributed for noncommercial purposes, but commercial uses require a license agreement. Commercial uses include the direct sale, license, or distribution of the measures for financial gain, or incorporation of the measures into a product or service that is sold, licensed, or distributed for profit. Medical societies may also elect to charge a licensing fee for the use of MIPS measures. Coalition members have learned that EHR vendors and other third party entities are incorporating MIPS measures developed by medical societies into their products and charging their physician-customers to use such measures without entering into licensing agreements to the measure owner.

The MIPS final rule states that MIPS and QCDR measures are owned by the entities/stewards that develop and submit them to CMS for use in the QPP program.[5] Specifically, the final rule states that QPP must submit new MIPS measures to peer-reviewed publications, as required by MACRA, "in accordance with applicable ownership or copyright restrictions and cite the measure developer's contribution in the submission."[6] However, while the MIPS final rule specifically requires QCDRs to license QCDR measures from the QCDR measure owner,[7] there is no regulatory language, discussion, or guidance on the licensing of MIPS measures from their measure owners.

The requirement that entities that use QCDR measures developed by QCDRs must enter into a licensing agreement with the measure owner should apply equally to the uses of MIPS measures. From an intellectual property perspective, there is no meaningful distinction between the MIPS and QCDR measures that are created by medical societies and/or QCDRs. Both require substantial time and resources to develop and should qualify as original works of authorship equally subject to copyright and other intellectual property protections. While we understand the importance for eligible clinicians to use MIPS measures without a license agreement for reporting purposes, we ask CMS to clarify that MIPS measure developers/owners, including medical societies and clinical data registries, can enforce copyrights, and that third parties wishing to use such measures must enter into licensing agreements with measure owners before they can properly use MIPS measures.

Medical societies invest significant amounts of time and money to develop new MIPS measures. A single measure takes a minimum of one year to develop and additional time to test. Testing new measures is also extremely expensive. However, if commercial parties can routinely use these measures and profit off of the society's time and expense, medical societies may no longer be able to dedicate resources to developing MIPS measures. Without the contribution of medical societies, the MIPS measures available to eligible clinicians may be poorly refined and inaccurately capture quality performance.

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As noted above, we applaud your flexibility and willingness to discuss the Coalition's concerns regarding licensing QCDR measures. In that same vein, we would appreciate the opportunity to meet with you and other appropriate CMS representatives to discuss our concerns regarding the commercial use of MIPS measures. Please contact Rob Portman at 202-872-6756 or rob.portman@powerslaw.com to let us know if you are able to meet with representatives of the Coalition and, if so, what time would be best for you.

Respectfully submitted,

AMERICAN ACADEMY OF DERMATOLOGY ASSOCIATION

[5] 81 Fed. Reg. 77,008, 77,154; 77,155 (Nov. 4, 2016).
[6] *Id*. at 77,154.
[7] *Id*. at 77,370.

AMERICAN ACADEMY OF NEUROLOGY

AMERICAN ACADEMY OF OPHTHALMOLOGY

AMERICAN ACADEMY OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY

AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION

AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS/NEUROPOINT ALLIANCE

AMERICAN COLLEGE OF EMERGENCY PHYSICIANS

AMERICAN COLLEGE OF GASTROENTEROLOGY/GIQUIC

AMERICAN COLLEGE OF RHEUMATOLOGY

AMERICAN COLLEGE OF SURGEONS

AMERICAN GASTROENTEROLOGICAL ASSOCIATION

AMERICAN JOINT REPLACEMENT REGISTRY

AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY/ GIQUIC

AMERICAN SOCIETY FOR RADIATION ONCOLOGY

AMERICAN SOCIETY OF CLINICAL ONCOLOGY

AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY

AMERICAN SOCIETY OF PLASTIC SURGEONS

AMERICAN UROLOGICAL ASSOCIATION

NORTH AMERICAN SPINE SOCIETY

SOCIETY OF INTERVENTIONAL RADIOLOGY

SOCIETY OF NEUROINTERVENTIONAL SURGERY

THE SOCIETY OF THORACIC SURGEONS