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PHYSICIAN CLINICAL REGISTRY COALITION

September 10, 2018

Ms. Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1694-P
P.O. Box 8011
Baltimore, MD 21244-1850

[Submitted online at: https://www.regulations.gov/document?D=CMS-2018-0076-0621]

Re: CMS-1693-P – Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Ms. Verma:

The undersigned members of the Physician Clinical Registry Coalition (the Coalition) appreciate the opportunity to comment on the proposed rule on calendar year (CY) 2019 updates to the Physician Fee Schedule, Medicare Shared Savings Program, Quality Payment Program (QPP), and Medicaid Promoting Interoperability Program (the Proposed Rule).[1] The Coalition is a group of medical society-sponsored clinical data registries that collect and analyze clinical outcomes data to identify best practices and improve patient care. We are committed to advocating for policies that encourage and enable the development of clinical data registries and enhance their ability to improve quality of care through the analysis and reporting of clinical outcomes. Most of the members of the Coalition have been approved as qualified clinical data registries (QCDRs) or are working towards achieving QCDR status.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. No. 114-10) requires the Secretary of the Department of Health and Human Services to encourage the use of QCDRs and certified electronic health record (EHR) technology (CEHRT) for reporting measures under the Quality performance category of the Merit-based Incentive Payment System (MIPS).[2] The Coalition greatly appreciates the Centers for Medicare & Medicaid Services' (CMS) efforts to encourage the use of QCDRs for reporting MIPS data under MACRA. In terms

[1] CY 2019 Physician Fee Schedule, Medicare Shared Savings Program Requirements, QPP, and Medicaid Promoting Interoperability Program Proposed Rule, 83 Fed. Reg. 35,704 (July 27, 2018) (CY 2019 PFS Proposed Rule).
[2] Social Security Act (SSA) § 1848(q)(1)(E); SSA § 1848(q)(5)(B)(ii)(l).

of this Proposed Rule, the Coalition supports CMS's proposal to revise the definition of a QCDR to require clinical expertise in medicine and quality measure development. However, the Coalition has significant concerns about several other proposals related to QCDRs and the use of QCDR measures in MIPS in the Proposed Rule.

As discussed more fully in Section 2 below, we are particularly concerned about the CMS's proposal to radically reverse its current policy of protecting the property rights of QCDR measure owners and instead force these QCDRs to enter into license agreements with CMS as a condition of measure approval. Such licenses would permit the agency to allow any other QCDRs to submit data on those measures outside the measure owners' control and without reasonable compensation to measure owners where appropriate. This blatant taking of QCDR measure owners' property rights is bad policy and patently unlawful.

1. CMS Should Adopt Its Proposal to Require Registries to Have Clinical Expertise in Medicine and Quality Measure Development

The Proposed Rule would modify the definition of a QCDR at 42 C.F.R. § 414.1305 to require that an approved QCDR have clinical expertise in medicine and quality measure development beginning with the 2022 MIPS payment year.[3] Under this proposal, entities may also meet this definition through a signed, written agreement with an external organization with expertise in medicine and quality measure development.

The Coalition supports this modification to the definition of QCDRs. We agree with CMS that entities without expertise in medicine and experience in quality measure development do not satisfy the intent of QCDRs. As a result, we encourage CMS to adopt this modification to the definition as soon as possible, ideally beginning with the 2021 MIPS payment year.

In our comments on the proposed and final rules on the implementation of the MACRA provisions related to MIPS, as well as the CY 2018 QPP proposed rule, the Coalition raised its concerns about EHR vendors and other commercial entities qualifying as QCDRs without the participation of clinician-led professional organizations focused on quality improvement. These vendor-led registries do not have quality improvement or population health management as their primary purpose and do not have clinical expertise or in-depth understanding about quality measurement. Instead, they are created only for commercial purposes. For-profit companies, such as EHR vendors, do not appear to have any population health impact, as measured by published articles in the scientific peer-reviewed literature and practice guidelines for clinicians. As a result, we agree with CMS that approval of commercial QCDRs does not fulfill CMS' intent for the broad population health and public health use of QCDRs.

There are currently no assurances to practices participating in MIPS, or to the Medicare program, that EHR companies and other commercial organizations are able to interpret, extract and calculate the quality measures accurately. Commercial QCDRs without quality measurement expertise threaten the integrity of quality measure performance data, and may inappropriately

[3] CY 2019 PFS Proposed Rule, 83 Fed. Reg. at 35,982.

impact the CMS benchmarks used to calculate MIPS Quality scores. Coalition members have observed EHR vendors incorrectly implementing measures, resulting in inaccurate quality measurement and comparisons. For example, in one vendor's promotional video, a template is offered for quality measure qualification at the time of the patient visit that allows clinicians to attest to meeting the measure, but it is not clear that this template is capturing exactly what the physician does or does not do in the patient encounter to satisfy the electronic CQM specifications. In addition, a Coalition member stated that in one case where an EHR vendor misinterpreted a MIPS measure's intent, the vendor's performance rate for the measure was completely different from the registry's rate, even though the registry's rate was calculated using the same EHR data.

Commercial entities operating qualified registries and/or QCDRs are also at a greater risk of producing inaccurate results due to their lack of operational experience with measure science, including measure development. For example, one Coalition member reports that a MIPS measure included a risk adjustment within the specifications, but no EHR vendors applied the risk adjustment. Failing to do so resulted in the submission of crude measure performance rates, and it was not possible to create benchmarks from the data they collected. If measures are not used or developed properly, CMS is 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 a particular QCDR to interpret the data. Coalition members also report that EHR vendors routinely contact the medical societies to ask basic questions about MIPS measures, demonstrating that they do not have the background to understand, implement, or develop MIPS measures.

We are also concerned that the problems of inaccurate use of measures by commercial QCDRs would be exacerbated by CMS's prior requests for 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 avoid redundant measures and facilitate cross-cutting comparisons, the real-world implementation of harmonized measures often yields incomparable results. There is no accountability for how commercial QCDRs report on the same measures and no standardization for how they use data. Registries with less expertise on how to accurately implement measures may employ different methods for obtaining, risk adjusting, 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. We urge CMS to review this misuse of measures by some vendors to ensure the integrity of the data and the quality of feedback to physicians as well as performance comparison.

For all these reasons, the Coalition recommends that CMS adopt its proposal to require an entity to have clinical expertise in medicine and actual experience in quality measure development in order to become a QCDR.

While this modification to the definition of QCDRs is an important step in the right direction for fulfilling the purpose of QCDRs, we also urge CMS to apply parts or all of the definition of a "clinician-led clinical data registry" included in the 21st Century Cures Act, to the extent possible, for QCDRs.[4] The Coalition was very involved in developing this definition and believes it would help ensure that QCDRs are focused on quality improvement rather than commercial interests.

2. CMS Should Support Measure Development by Respecting and Supporting the Ownership Rights of QCDR Measure Developers Consistent with Intellectual Property Law

CMS proposes that, as a condition of a QCDR measure's approval for purposes of MIPS, QCDR measure owners be required to enter into a license agreement with CMS permitting any approved QCDR to submit data on the QCDR measure (without modification)[5] for purposes of MIPS, beginning with the 2021 MIPS payment year.[6] Our understanding is that, should this proposal be adopted, once a QCDR measure is approved for reporting in MIPS, it would be generally available for other QCDRs to report on for purposes of MIPS without a fee for use and without a direct license with the measure owner.

The Coalition strongly opposes this proposal because it undermines QCDR measure ownership and development and violates the intellectual property rights of QCDR measure owners. We also believe this proposal is an arbitrary and capricious reversal of the current policy that CMS adopted just last year to protect the intellectual property rights of QCDR measure owners; this reversal is in violation of the Administrative Procedure Act and the U.S. Constitution.

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[4] Under the 21st Century Cures Act, a "clinician-led clinical data registry" means a clinical data repository:

1) That is established and operated by a clinician-led or controlled, tax-exempt (pursuant to section 501(c) of the Internal Revenue Code of 1986), professional society or other similar clinician-led or -controlled organization, or such organization's controlled affiliate, devoted to the care of a population defined by a particular disease, condition, exposure, or therapy;
2) That is designed to collect detailed, standardized data on an ongoing basis for medical procedures, services, or therapies for particular diseases, conditions, or exposures;
3) That provides feedback to participants who submit reports to the repository;
4) That meets standards for data quality including—
    A. Systematically collecting clinical and other health care data, using standardized data elements and having procedures in place to verify the completeness and validity of those data; and
    B. Being subject to regular data checks or audits to verify completeness and validity; and
5) That provides ongoing participant training and support.

21st Century Cures Act, Pub. L. No. 114-255, § 4005, 130 Stat. 1033, 1180-81 (2016).

[5] In the event that CMS does implement this proposal, we request that CMS clarify the meaning of "without modification" to include common data elements and consistent statistical methodologies (including data normalization, risk adjustment, etc.).

[6] CY 2019 PFS Proposed Rule, 83 Fed. Reg. at 35,984.

QCDR measures clearly constitute works of authorship that are subject to copyright protection. CMS has already acknowledged this fact in its decision just last year requiring that QCDRs seeking to use the QCDR measures of another QCDR must first obtain permission from that measure owner.[7] Even the Proposed Rule recognizes that CMS must have a license from QCDRs to sublicense those measures to other QCDRs. The problem is the proposal requires QCDRs to give CMS a mandatory, exclusive, and unfettered right to sublicense their QCDR measures for MIPS purposes as a condition of measure approval. This radical reversal of CMS's existing policy violates both agency and judicial precedent.

QCDR measures are subject to the same copyright protection as the American Medical Association's (AMA) Current Procedural Terminology (CPT) code. The AMA owns and collects royalties on the use of its CPT code set. This right was strongly affirmed by the United States Court of Appeals for the Ninth Circuit in *Practice Management Information Corporation v. American Medical Association (PMIC)*.[8] From an intellectual property perspective, there is no meaningful distinction between the AMA's ownership of the CPT and QCDRs' ownership of their measures. Both require substantial time and resources to develop and qualify as original works of authorship equally subject to copyright and other intellectual property protections. CMS has always honored and supported the AMA's right to license and charge royalties for the use of the CPT Code even though it has been incorporated by the agency as an integral part of the Medicare reimbursement system. It should continue to do the same with QCDR performance measures.

In fact, the *PMIC* court specifically held that the AMA's right to license the CPT code to other parties that needed access to the code was not nullified by the fact that the Medicare program had adopted the code as a significant part of its physician payment system. In doing so, it stated:

> . . . copyrightability of the CPT provides the economic incentive for the AMA to produce and maintain the CPT. "To vitiate copyright, in such circumstances, could, without adequate justification, prove destructive of the copyright interest, in encouraging creativity," a matter of particular significance in this context because of "the increasing trend toward state and federal adoptions of model codes." As the AMA points out, invalidating its copyright on the ground that the CPT entered the public domain when HCFA [now CMS] required its use would expose copyrights on a wide range of privately authored model codes, standards, and reference works to invalidation. Non-profit organizations that develop these model codes and standards warn they will be unable to continue to do so if the codes and standards enter the public domain when adopted by a public agency.[9]

The same principles apply to QCDR measures. The ability of QCDRs to license measures (and charge reasonable licensee fees or royalties) allows QCDRs to ensure the appropriate use of their measures and incentivizes organizations to invest in developing new and improved measures, and is crucial to ensuring users respect the intellectual property rights of measure developers.

[7] CY 2018 QPP Final Rule, 82 Fed. Reg. 53,568, 58,813-14 (Nov. 16, 2017).
[8] 121 F.3d 516 (9th Cir. 1997).
[9] *Id.* at 518-19 (citations and footnotes omitted).

Medical societies put in a tremendous and costly effort to develop valid measures—a single measure takes a minimum of one year to develop requiring significant effort and time from physicians and society staff, and additional time to test, maintain, and implement. Testing new measures is also extremely expensive. Without the ability to license measures and collect reasonable royalties to offset the cost of developing measures, QCDR measure owners would have no way to control the appropriate use of their measures and could not responsibly invest in measure development.

If third parties can routinely use these measures and, in the case of commercial QCDRs, profit off of the societies' time and expense, medical societies may no longer be able to dedicate resources to developing QCDR measures and some may choose not to participate in the QCDR program as a result. Without the contribution of medical societies, the QCDR measures available to eligible clinicians may be poorly refined and inaccurately capture quality performance.

The *PMIC* court upheld the AMA's right to assert copyright protection in the CPT Code in part because there was no evidence that the AMA was limiting access to the code. The court reached this conclusion knowing full well that the AMA charged royalties for the use of the CPT code. Similarly here, many societies justifiably assert copyright protection over the QCDR and QPP measures they develop. The copyright statements they affix to their measures usually prohibit commercial use of the measures. But, the goal is not to limit physicians' ability to report on the measures, but rather to protect the integrity of the measures by limiting inappropriate use and preventing commercial entities from profiting off of the societies' intellectual property. There is no evidence that QCDRs are withholding access to their measures to qualified QCDRs—i.e., those who have clinical expertise and experience in measure development.

Thus, CMS's proposal to force QCDRs to license their measures to the agency without a fee, as a condition of approving such measures, effectively nullifies the right of QCDRs to enforce their copyright in such measures and to collect a reasonable royalty from other qualified QCDRs that wish to use them. This policy conflicts with the agency's treatment of the CPT code and the *PMIC* court's clear affirmation of the AMA's rights to enforce its copyright in that code.

CMS's proposal also unjustifiably reverses the agency's decision just last year requiring that QCDRs seeking to use the QCDR measures of another QCDR must first obtain permission from that measure owner. The Coalition previously submitted comments on the CY 2018 QPP proposed rule supporting CMS's proposal that QCDR vendors must 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.[10] In our comments, we also recommended that CMS record the ownership of <u>all</u> 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, requiring assignment of QCDR measure IDs for all approved QCDR measures and required QCDRs that have received permission to report the

[10] CY 2018 QPP Proposed Rule, 82 Fed. Reg. 30,010, 30,160 (June 30, 2017).

measure to use the same QCDR measure ID.[11] CMS stated that it may request that a borrowing QCDR provide proof that it had 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.[12] CMS is now backtracking on this prior rule to protect the intellectual property rights of measure owners—as discussed above, this action would threaten quality measure development; it is also unlawful.

CMS has utterly failed to provide a rational explanation or evidence for this sudden reversal in its existing policy to protect the intellectual property rights of QCDR measure owners. The general conclusion in the Proposed Rule that the existing policy is creating unintended burdens on QCDRs seeking to use the measures of other QCDRs is completely unsubstantiated. Indeed, the agency says only that "some QCDRs charge a fee for the use of their QCDR measures."[13] CMS provides no evidence that qualified QCDRs are being deprived access to approved QCDR measures. Nor does the agency make any attempt to consider the negative effects of reversing its existing policy. CMS also fails to consider any alternatives to the proposed policy change, such as requiring QCDRs to make their measures available to other qualified QCDRs intending to use the measures through license agreements that contain commercially reasonable terms, including reasonable royalties.

Based on the agency's failure to (a) provide any evidence to support its decision to adopt a radical policy change that violates the intellectual property rights of QCDR measure owners, (b) consider the negative effects of this policy reversal on the development of QCDR measures, and (c) consider reasonable alternatives, the proposed new policy is "arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law" in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A).[14]

CMS's sudden and extreme reversal of its current policy protecting the rights of QCDR measure stewards would also constitute an unconstitutional taking of private property without justification or reasonable compensation. QCDRs have made substantial investments in their measures based on the reasonable assumption that, where appropriate, they would be able license their measures to other QCDRs for reasonable compensation. This assumption was confirmed by the policy CMS adopted last year that required other QCDRs to seek the permission of QCDR measure owners before they can use their measures. The proposed reversal in this policy is therefore a blatant and unconstitutional taking of QCDRs' property.[15]

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[11] CY 2018 QPP Final Rule, 82 Fed. Reg. 53,568, 58,813-14 (Nov. 16, 2017).
[12] *Id.*
[13] CY 2019 PFS Proposed Rule, 83 Fed. Reg. at 35,984.
[14] *See Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (agency action is arbitrary and capricious if the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise").
[15] *Ruckelshaus v. Monsanto*, 467 U.S. 986, 1011 (1984) (the Environmental Protection Agency's intended disclosure of Monsanto's pesticide registration trade secret data (a form of intellectual property) submitted during a period when the applicable federal pesticide statutes guaranteed confidentiality of such data would frustrate Monsanto's reasonable investment-backed expectation with respect to such data and could constitute an unconstitutional taking unless just compensation was provided for loss of market value of trade secret data caused by such disclosure).

As noted above, there are much less intrusive options for ensuring that QCDR measures are widely available to all qualified QCDRs, especially if CMS finalizes its proposal to modify the QCDR criteria to ensure that all QCDRs have clinical expertise and experience in quality measures. However, if adopted as proposed, requiring QCDRs to license their QCDR measures to CMS without fee as a condition of approval of such measures for MIPS purposes would be patently unlawful.

We urge CMS to instead to continue to allow QCDRs to enforce their ownership rights in the QCDR measures they develop, and require other qualified QCDRs to enter into licensing agreements with measure owners (not CMS) before they can properly use QCDR measures. QCDRs must also be able to charge a reasonable fee for licenses to use their measures. We would like to work with CMS to create safeguards to protect the proper implementation of these measures and ensure that QCDRs can enforce their intellectual property rights in the measures they develop, while also ensuring that the measures are readily available to other QCDRs with clinical expertise and experience in quality measure development. We would appreciate the opportunity to meet with CMS on this issue.

In the meantime, we strongly object to CMS's decision to require QCDRs, in their self-nomination applications, to attest to their willingness to license their QCDR measures to CMS ***while this rulemaking is pending***. That puts QCDRs in the position of having to agree to what we believe to be an unlawful policy reversal and an unjustified taking of their intellectual property before the agency has finalized its proposal. It also exposes the irrationality of proposing to make the new policy effective for the 2021 MIPS payment year, which essentially requires the unlawful policy to be implemented in 2019. At a minimum, QCDRs should only be required to make the licensure attestation if and when the Proposed Rule is finalized. To that end, if CMS still thinks it needs to change its current policy, we strongly urge the agency to delay the effective date of the proposal at least one year to allow a fuller discussion of the concerns we have expressed about the new policy and to give QCDRs a meaningful opportunity to decide whether they want to participate in a program that forces them to give up their rights and effective control over their QCDR measures.

3. CMS Should Retain its Current Requirement that QCDRs Have At Least 25 Participants as of January 1 of the Performance Period

In the CY 2017 QPP final rule, CMS required that a QCDR must have at least 25 participants as of January 1 of the performance period.[16] CMS now proposes that, starting with the 2022 MIPS payment year, QCDRs must have at least 25 participants by January 1 of the year prior to the performance period.[17] These participants do not need to use the QCDR to report MIPS data; rather, they need to submit data to the QCDR for quality improvement. The Coalition opposes this proposed change, as such a requirement would be exceedingly difficult for entities attempting to establish new registries. Under MACRA, CMS is required to encourage the use of

[16] MIPS Final Rule, 81 Fed. Reg. 77,008, 77,364 (Nov. 4, 2016).
[17] CY 2019 PFS Proposed Rule, 83 Fed. Reg. at 35,983.

QCDRs for reporting MIPS data. Such a requirement would inhibit the ability of new registries to qualify as QCDRs. The Coalition believes that the existing requirement is sufficient to ensure QCDR preparedness.

CMS expressed concern in the Proposed Rule that a QCDR's lack of preparedness to accept data from MIPS eligible clinicians and groups beginning on January 1 of the performance period may negatively impact a clinician's ability to use a QCDR to report and monitor the quality of care they provide to their patients and may inadvertently increase clinician burden. CMS also recently announced to QCDRs by e-mail dated June 18, 2018 that all QCDRs must be "up and running (able to support data collection and submission) on January 1, 2018 for the 2018 performance period."

The Coalition emphasizes that it is not feasible for a QCDR to be fully "up and running" on January 1 of each performance period. CMS does not publish QPP quality measure specifications until the end of December of the year prior to the performance period—for example, 2019 QPP measure specifications are not scheduled to be published until December 27. This provides only two business days to implement the measures based on the new specifications—which is simply not feasible. While most specifications do not change, even minor revisions take significantly longer than two days to enter and test. Additionally, few providers are prepared to begin reporting and monitoring quality on January 1, as submissions for the prior year are just commencing at that time. We hope to work with CMS on a timeline that is feasible and leads to properly functioning QCDRs that can meet the goals of the MIPS program.

4. CMS Should Retain the Current Self-Nomination Period

CMS proposes to revise the self-nomination period from September 1 of the year prior to the applicable performance period until November 1 to July 1 of the calendar year prior to the applicable performance period until September 1.[18]

The majority of Coalition members oppose this change as proposed by CMS because it would negatively impact the life cycle of QCDRs and the maintenance process for QCDR measures. QCDRs dedicate a significant portion of their time during each performance period to reporting for the previous year's MIPS program and validating the data and submitting the Data Validation Execution Report by May 31 of a calendar year. Often, it is not until May or June that QCDRs can review performance on measures and convene groups of expert clinicians to discuss updates to existing measures or develop new measures. By moving the self-nomination period deadline to September 1, CMS would provide QCDRs with a limited time frame to update existing measures and develop new measures.

Some Coalition members would support this change to the self-nomination period for QCDRs if CMS would adopt a multi-year approval cycle for QCDRs. As proposed in the context of the current approval cycle, however, the Coalition opposes these changes to the self-nomination

[18] *Id.*

period for QCDRs. If CMS does adopt these proposed changes to the self-nomination period, it is essential that the agency change its expectations for providing data for measures accordingly, as it is not feasible to have data to support a measure so early in the calendar year.

5. CMS Should Treat Topped Out QCDR Measures Consistently with Topped Out MIPS Measures

In the CY 2018 QPP Final Rule, CMS finalized a 4-year timeline to identify topped out measures, after which CMS may seek to remove such measures through rulemaking.[19] Since QCDR measures (as opposed to MIPS measures) are not approved or removed from MIPS through rulemaking, CMS proposes to exclude QCDR measures from the 4-year timeline for topped out measures.[20] Under the proposal, once a QCDR measure reaches topped-out status under the QCDR measure approval process, it may not be approved as a QCDR measure for the applicable performance period.

The Coalition supports greater consistency between the standards for reviewing and determining topped-out QCDR measures and MIPS measures.[21] CMS's proposal is inconsistent with their other proposals to align the process for QCDR and other MIPS quality measures and is a barrier to the success of QCDRs, as it places a stricter set of criteria on QCDR measures. Furthermore, time should be provided before measure elimination to ensure the benchmark is valid based on a sufficient number of clinicians reporting the measure and for the QCDR to make updates and adjustments based on performance data collected. This would take no less than two years.

In addition, it is critical that CMS create separate benchmarks for QCDR measures just as CMS does for QPP measures that are reported via different mechanisms. Many QCDRs offer two methods of reporting—web portal entry for users that do not have an EHR system, and electronic data extraction and measure calculation for users that do have an EHR system. If a QCDR measure is reported both manually and electronically, two separate benchmarks should be established for the measure. This is done already for QPP measures that are reportable via multiple mechanisms, such as claims, qualified registry or eCQMs. QCDRs are electronically specifying quality measures using the Measure Authoring Tool, and for QCDR measures that are collected, calculated and reported electronically, a separate benchmark should be established to ensure fair comparisons and to encourage electronic reporting. If CMS does not do so, measures may appear to be prematurely topped out, as is apparent from QPP measures for which manual

[19] CY 2018 QPP Final Rule, 82 Fed. Reg. at 53,637-40.
[20] CY 2019 PFS Proposed Rule, 83 Fed Reg. at 35,899-35,900.
[21] The Coalition wishes to note as a threshold issue that we do not believe topped-out status is a valid criterion for measure removal. We believe that the current structure of the MIPS program and Physician Compare provide clear incentives for participants to only report measures where they perform the highest relative to their peers. As a result, the benchmarks for these measures are artificially inflated, leading to the measures being inappropriately topped out. Many "topped out" measures are high-value process measures that are included in QCDRs because they are clinically meaningful to measure quality improvement in that clinical domain. Measures should not be removed if they are meaningful to the patient and provider. It is in CMS' interest for the health of patients to encourage physicians to continue to improve in these areas, rather than drop the measure for reporting. Dropping measures unnecessarily also increases physician burden (having to retrain physicians and retool reporting systems) and increases costs to CMS (having to both develop and review new measures) as well as to measure stewards.

measure benchmarks (QR and claims) are typically topped out before electronically reported measure benchmarks are (eCQMs).

The Coalition urges CMS not to move forward with this proposal. CMS should not exclude QCDR measures from the 4-year timeline for topped out measures and, instead, QCDR measures should only be rejected for the applicable performance year when the measure has been identified as topped out for the prior three consecutive years.

6. CMS Should Delay Adopting QCDR Benchmarks and Seek Input from QCDRs

CMS has received feedback from QCDRs that MIPS-eligible clinicians are hesitant to report QCDR measures without established benchmarks because they are assigned only three measure achievement points. In order to encourage reporting of QCDR measures, CMS seeks comment on an approach to develop QCDR measure benchmarks based off historical measure data.[22] This proposal may require QCDRs to submit historical data in a form and manner that meets benchmarking needs as required by CMS.

The Coalition supports CMS's efforts to encourage reporting of QCDR measures; however, we urge CMS to delay adoption of this proposal pending additional information and discussion with QCDRs. It is imperative that CMS give QCDRs the ability to provide data for CMS to create benchmarks of QCDR measures and also provide opportunities for any interested and capable QCDRs to develop benchmarks themselves. QCDRs may also be able to provide benchmark data using data collected across its registry participants, including participants that are not reporting the measure to CMS for purposes of MIPS. This data could be used to establish CMS benchmarks that would enable QCDR measures to be scored. That said, many QCDRs may run into operational issues in supplying data in the form and manner CMS would require, especially in terms of only submitting data that includes MIPS eligible clinicians. In addition, when establishing historical benchmarks, it is only appropriate to use measure data from a previous year if the measure specification is the same as the year for which the benchmark is being established. If CMS establishes benchmarks for QCDR measures, they must be done prior to the submission window in order to give practices a sense of how they are performing compared to their peers. We look forward to working with CMS on this issue.

7. CMS Should Retain a Separate Process for QCDR Measure Approval

CMS proposes to consolidate their previously finalized standards and criteria used for selecting and approving QCDR measures.[23] Specifically, CMS proposes to apply certain criteria used under the Call for Quality Measures Process when considering QCDR measures for possible inclusion in MIPS beginning with the MIPS 2021 payment year.

Many of the criteria used under the Call for Quality Measures Process are problematic. For example, one criterion CMS proposes is prioritizing outcome measures over process measures.

[22] *Id.* at 35,955.
[23] *Id.* at 35,984.

The Coalition agrees that outcome measures are valuable to the clinical process and to patients and caregivers. However, there are specialties such as neurology where meaningful outcomes in a calendar year are difficult to measure when the disease status is degenerative, results in increased co-morbidities, and is terminal with limited treatment options such as disease-modifying therapies. Given the long time frames for improvement in neurologic diseases, CMS should continue to support the use of process measures until they can feasibly be converted to meaningful outcome measures. In addition to the challenges faced by neurology, it is also often not feasible to measure rare surgical outcome events during the course of one year in a way that is statistically appropriate or reliable. Some outcome measures that evaluate rare incidences require measurement over the course of multiple years to have sufficient statistical power. Given the one year time-frame of the program, it can be inappropriate to use outcome measures for rare events.

We urge CMS to withdraw this proposal. The QCDR measure approval process should remain separate from the standards used for the Call for Quality Measures process. The Call for Measures process is cumbersome and does not recognize the unique nature of QCDRs. The creation of more stringent standards for QCDR measures would place additional burden on QCDRs and run counter to CMS's intention to encourage the use of QCDRs and other clinical outcomes registries.

8. CMS Should Retain the Public Health and Clinical Data Exchange Objective in the Promoting Interoperability Performance Category

CMS proposes to remove in future rulemaking the Public Health and Clinical Data Exchange objective from the Promoting Interoperability performance category no later than CY 2022 and seeks public comment on whether MIPS eligible clinicians will continue to share such data with public health entities once the Public Health and Clinical Data Exchange objective is removed.[24]

The Coalition previously submitted comments on CMS's proposal to remove the Public Health and Clinical Data Exchange objective and measures from the Promoting Interoperability Program no later than CY 2022 in the proposed rule on changes to the Medicare Hospital Inpatient Prospective Payment System (IPPS) for FY 2019.[25] The concerns that we raised in our comments on the FY 2019 IPPS proposed rule are equally applicable here. These comments are attached in full to this comment letter. Further, the Coalition continues to encourage CMS to provide full credit under the Promoting Interoperability category to eligible clinicians and groups using an EHR to participate in a QCDR.

Finally, the Coalition asks CMS to define specialized registry for purpose of the Public Health and Clinical Data Exchange Objective. Similar to the development of commercial QCDRs, many EHR vendors are establishing "specialized registries" in order to help their customers fulfill this Promoting Interoperability objective. These "specialized registries" have no public health benefit and are not created to address a legitimate public health need, but rather are

[24] *Id.* at 35,930.
[25] FY 2019 IPPS Proposed Rule, 83 Fed. Reg. 20,164, 20,520 (May 7, 2018).

created as a way to enable their customers to receive additional MIPS credit. To ensure the specialized registries are advancing the goals of the Public Health and Clinical Data Exchange objective, the Coalition recommends that CMS apply meaningful criteria to specialized registries to ensure they are not created for a commercial purpose and that they are aimed toward achieving a public health objective.

9. CMS Should Amend its Facility-Based Measurement Scoring Option to Encourage Specialists to Report Specialty-Specific Quality Data

CMS proposes to give facility-based clinicians and groups the option to be scored under the MIPS Quality and Cost categories based on their facility's Hospital Value-Based Purchasing (VBP) Program score.[26] This proposal recognizes the challenges that facility-based clinicians currently face with MIPS reporting, but CMS ultimately fails to address the core need to accurately evaluate specialists' quality and value and to incentivize specialists to more fully engage in MIPS.

The challenges that facility-based clinicians face are often due to the limited MIPS reporting options that fail to incentivize the reporting of specialty-specific measures. While CMS's proposal provides an alternative reporting option, it still does not allow specialists to demonstrate their unique value. This is especially true as the Hospital VBP Program moves away from episode-specific measures and towards the use of broader, hospital-wide measures. In addition, while the group reporting option is intended to ease reporting burden, individual specialists within multi-specialty group practices often have little to no control over their groups' measure selections, reporting mechanisms, and overall participation decisions and thus, no way to demonstrate the value of their own care.

We urge CMS to educate physicians about all of their reporting options and encourage and incentivize QCDR participation, which we believe is an important and effective alternative to facility-based reporting. QCDRs provide a valuable and unique source of specialty-specific quality data that is not collected elsewhere and is critical to understanding the entire value equation. Without incentives for specialists to report specialty-specific quality metrics, CMS is setting its quality improvement efforts back and undermining efforts to encourage specialists to meaningfully engage in MIPS.

* * * * *

The Coalition appreciates CMS's attention to these important issues. We urge the agency to adopt the Coalition's suggestions to facilitate and promote the use of QCDRs and other clinical outcomes data registries. The goal is to allow the use of registries to grow and ultimately result in even greater improvements in the quality of patient care. We encourage CMS to adopt policies across the board to further incentivize the development of high quality measures and facilitate the electronic exchange of data between providers and clinical data registries, in light of the critical role that registries play in improving patient outcomes and quality of care.

[26] CY 2019 PFS Proposed Rule, 83 Fed. Reg. at 35,956-63.

Thank you for the opportunity to submit these comments. If you have any questions, please contact Rob Portman at Powers Pyles Sutter & Verville PC (rob.portman@powerslaw.com or 202-872-6756).

Respectfully submitted,

AMERICAN ACADEMY OF DERMATOLOGY ASSOCIATION
AMERICAN ACADEMY OF NEUROLOGY
AMERICAN ACADEMY OF OPHTHALMOLOGY
AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ACADEMY OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY
AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION
AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS
AMERICAN COLLEGE OF EMERGENCY PHYSICIANS
AMERICAN COLLEGE OF GASTROENTEROLOGY
AMERICAN COLLEGE OF RHEUMATOLOGY
AMERICAN COLLEGE OF SURGEONS
AMERICAN GASTROENTEROLOGICAL ASSOCIATION
AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY
AMERICAN SOCIETY FOR RADIATION ONCOLOGY
AMERICAN SOCIETY OF CLINICAL ONCOLOGY
AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY
AMERICAN SOCIETY OF PLASTIC SURGEONS
AMERICAN UROLOGICAL ASSOCIATION
COLLEGE OF AMERICAN PATHOLOGISTS
SOCIETY OF INTERVENTIONAL RADIOLOGY
SOCIETY OF NEUROINTERVENTIONAL SURGERY
THE SOCIETY OF THORACIC SURGEONS

P•C•R•C

PHYSICIAN CLINICAL REGISTRY COALITION

June 25, 2018

Ms. Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1694-P
P.O. Box 8011
Baltimore, MD 21244-1850

[Submitted online at: https://www.regulations.gov/docket?D=CMS-2018-0046]

Re: CMS-1694-P – Medicare Programs: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims

Dear Ms. Verma:

The undersigned members of the Physician Clinical Registry Coalition (the Coalition) appreciate the opportunity to comment on the proposed rule on changes to the Medicare Hospital Inpatient Prospective Payment System (IPPS) for FY 2019, specifically the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) (the Proposed Rule).[1] The Coalition is a group of medical society-sponsored clinical data registries that collect and analyze clinical outcomes data to identify best practices and improve patient care. We are committed to advocating for policies that encourage and enable the development of clinical data registries and enhance their ability to improve quality of care through the analysis and reporting of clinical outcomes. Most of the members of the Coalition have been approved as qualified clinical data registries (QCDRs) or are working towards achieving QCDR status.

Clinical data registries play an essential role in promoting quality of care. QCDRs and other clinical outcomes data registries provide timely and actionable feedback to providers on their performance, speeding and enhancing quality improvement opportunities. In addition, QCDRs and other clinical outcomes data registries allow for patient-centered, statistically valid and timely inter-practice and national benchmarking and comparisons. The measures developed by

[1] 83 Fed. Reg. 20,164 (May 7, 2018).

QCDRs and other clinical outcomes data registries are meaningful and relevant to participating providers and their patient populations.

The Coalition appreciates CMS's previous efforts to encourage the use of QCDRs for electronically reporting data across quality improvement activities. The Coalition is concerned, however, about CMS's proposal to remove the Public Health and Clinical Data Exchange objective and measures from the Promoting Interoperability Program no later than CY 2022. We strongly urge CMS to retain this objective and these measures as a necessary incentive for hospitals and, perhaps more urgently, EHR vendors, to share data electronically with public health entities and clinical data registries. While many hospitals may continue to share data with clinical data registries even if this objective were removed from the Promoting Interoperability Program, this program provides a necessary incentive for EHR vendors to communicate data seamlessly with registries.

As CMS explained in the Proposed Rule, "the Public Health and Clinical Data Exchange objective supports the ongoing systematic collection, analysis, and interpretation of data that may be used in the prevention and controlling of disease through the estimation of health status and behavior."[2] We agree with CMS's recognition of the essential role that electronic data reporting to public health entities and clinical data registries plays in improving "the efficiency, timeliness, and effectiveness of public health surveillance," as well as "safer" and "more coordinated care."[3] Particularly in light of continued electronic reporting issues, this incentive is necessary to, in CMS's own words, "extend the use of electronic reporting solutions to additional events and care processes, increase timeliness and efficiency of reporting and replace manual data entry." CMS should retain this measure to achieve these important goals, particularly given the lack of evidence that this measure imposes any substantial burden on hospitals. At the very least, it would be premature to remove this measure without evidence of such a burden.

The Coalition also wishes to express its support for comments submitted by the Society of Thoracic Surgeons (STS) regarding how CMS can further facilitate price transparency. We agree with STS that clinical data registries could play an even greater role in price and value transparency if CMS provided QCDRs with the access to Medicare claims data required by Section 105(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10).[4] The Coalition has raised its concerns about CMS' failure to properly implement Section 105(b) on several occasions, including in our attached August 31, 2016 letter to CMS regarding the Final Qualified Entity Rule and our attached December 19, 2016 comment letter on the final rule on the implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10) provisions related to MIPS and APMs. We reiterate and incorporate those strong concerns by reference here.

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[2] *Id.* at 20,520.
[3] *Id.*
[4] Section 105(b) explicitly directs CMS to provide QCDRs access to Medicare claims data "for purposes of linking such data with clinical outcomes data and performing risk-adjusted, scientifically valid analyses and research to support quality improvement or patient safety." MACRA, Pub. L. No. 114-10, § 105(b)(1)(A), 129 Stat. 136 (2015).

The Coalition appreciates the opportunity to comment on the Proposed Rule. We urge CMS to adopt the Coalition's suggestions to facilitate and promote the use of QCDRs and other clinical outcomes data registries. The goal is to allow the use of registries to grow and ultimately result in even greater improvements in the quality of patient care. We encourage CMS to adopt policies across the board to further incentivize electronic exchange of data between providers and clinical data registries, in light of the critical role that registries play in improving patient outcomes and quality of care.

Thank you for the opportunity to submit these comments. If you have any questions, please contact Rob Portman at Powers Pyles Sutter & Verville PC (rob.portman@powerslaw.com or 202-872-6756).

Respectfully submitted,

AMERICAN ACADEMY OF OPHTHALMOLOGY
AMERICAN ACADEMY OF OTOLARYNGOLOGY–HEAD AND NECK SURGERY
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AMERICAN SOCIETY OF PLASTIC SURGEONS
AMERICAN UROLOGICAL ASSOCIATION
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THE SOCIETY OF THORACIC SURGEONS

Attachments