September 26, 2019
Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1715-P

Submitted via electronic submission to http://www.regulations.gov

RE: Medicare Program; CY 2020 Updates to the Quality Payment Program

Dear Ms. Verma:

The PCPI Foundation (PCPI) appreciates the opportunity to submit comments regarding the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2020; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations published in the Federal Register on August 14, 2019.

PCPI is a membership organization uniquely focused on improving health outcomes through the advancement of performance measurement, clinical registries, data standardization, and quality improvement initiatives. Our membership includes medical and clinical specialty societies, patient advocacy and consumer organizations, care delivery organizations, health information technology organizations, and quality improvement organizations.

Outlined below are specific provisions of the proposed rule and PCPI’s comments.
Selection of MIPS Quality Measures for Individual MIPS Eligible Clinicians and Groups Under the Annual List of Quality Measures Available for MIPS Assessment

Topped-Out Measures
Last year, CMS finalized their proposal in the 2019 PFS final rule to recommend measures that have reached “extremely topped out status” (a measure with an average mean performance within the 98th to 100th percentile range) be removed in the next rule-making cycle, regardless of where the measure is in the midst of the topped-out measure lifecycle. However, CMS may retain these measures in the program if the resulting removal of the measure(s) would impact the number of measures available for a specialist type for reporting purposes or if the measure addressed an area of importance to CMS.

This year, CMS is seeking comment on increasing the data completeness threshold for measures retained in the program that meet “extremely topped out status”. While a specific threshold percentage is not mentioned, PCPI agrees with that approach if the specialty that reports the measure is also in agreement. As measures that reach this “extremely topped out status” tend to be in smaller specialties that can have either fewer providers reporting or experience challenges with accessing hospital-based data across multiple sites, the specialty should be part of the decision as to whether they would like the measures to remain in the program with a higher data completeness threshold.

It is noted that CMS is seeking comment on other potential solutions to “topped out/extremely topped out” measures. It has been documented that once measures that have consistently high performance rates are no longer used for measurement, performance rates decrease, therefore we are supportive of solutions that retain measures in the program.1 PCPI would like to reiterate the recommendation made last year that rather than removing measure(s), CMS restrict clinicians from reporting on measure(s) in future years when they reported on a measure in the 98-100% range consistently for three consecutive years. This recommendation supports the concept that topped out measures may not be topped out by all clinicians, but rather solely by the clinicians that self-selected to report on the measure. The potential for variation in performance at sub-group levels remains a concern. As such, this approach leaves opportunity for improvement amongst other clinicians.

Increasing the Data Completeness Threshold
CMS is proposing to increase the data completeness threshold for quality measure reporting from 60% to 70% for the 2020 MIPS performance period. While we appreciate the higher data completeness rates that CMS is seeing in reported data, we caution that there are instances where meeting a 70% threshold may be difficult. Some clinician specialties have issues

accessing hospital-based data (most commonly seen in the diagnostic and procedural specialties), which affects their ability to fully assess their data accurately. Additionally, providers that report at multiple sites under the same TIN may encounter reporting issues when these sites use different electronic health records. Lastly, some measures are shared among multiple disciplines at the same site (e.g., physical therapy, occupational therapy, speech therapy, physicians, and advanced practice nurses) and only one gets an opportunity to report on the measure. Increasing the data completeness threshold will make it even more challenging to meet reporting requirements. **PCPI recommends keeping the data completeness threshold at 60% until these issues can be addressed.**

**Aligning Measure Update Cycles**

PCPI stewards many measures that are implemented via multiple reporting modalities; some have specifications for all four modalities: claims, registry (CQM), EHR (eCQM), and web interface. While we appreciate CMS considering methods to improve the measure update processes and create efficiencies, PCPI believes overlapping the eCQM and quality measures annual update timelines would present significant logistical burdens. Typically, PCPI convenes technical expert panels in the fall in advance of the eCQM annual update process. These conversations determine relevant changes that will be made initially within the eCQMs and will eventually be incorporated into other applicable specifications for use in CMS’s Quality Payment Program. Throughout the eCQM annual update process, numerous external stakeholders are involved, whose feedback occurs at various stages, and can result in additional modifications to what has been previously proposed as an update. If the timelines were aligned and each version of a measure’s specification were to be updated at the same time, it could result in many more steps in the process to make further revisions, as each of the measure’s specifications would need to be updated to reflect the new changes.

In consideration of clinical burden, aligning measure update cycles would create significant rework on the part of not only the measure owner, but also CMS and its contractors. In addition, given that eCQM annual updates and QPP program updates are managed by different contracted teams, there is the risk that feedback on the same measure may vary by contractor which would need to be evaluated and a resolution determined, and careful coordination between the contractors would be of the utmost importance, though challenging to accomplish. Additionally, CMS evaluates and approves each proposed change for an eCQM, which typically occurs in December and January; and again, evaluates the substantive change log submitted for the quality measures, typically in February. Requiring both change logs to be developed and submitted separately, but at the same time would entail significant time spent by various teams and be redundant. **It is for these reasons that PCPI does not support aligning measure update cycles at the present time.**

However, PCPI supports CMS providing guidance to its contractors regarding the nuances across modalities. This guidance will allow contractors to provide feedback to measure owners and stewards that reflects accurate interpretation of verbiage, acceptable specification variation, and also ensures that any changes approved during the eCQM annual update process are accepted without issue by the contractor managing the updates to the quality measures.
Quality Measures Proposed for Removal in the 2021 MIPS Payment Year and Future Years

CMS proposes to remove 55 previously finalized quality measures from the MIPS Program for the 2022 MIPS payment year and future years. This includes two PCPI-stewarded measures:

- Quality ID #110 – *Preventive Care & Screening: Influenza Immunization*, specified for all reporting modalities
- Quality ID #192 – *Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures*, specified for registry and EHR submission.

As the measure steward, PCPI reaffirms its commitment to continue the maintenance of these measures and supports their continued inclusion in the MIPS.

In the rationale for removal of the measure, the rule states that PCPI *Preventive Care & Screening: Influenza Immunization* measure is duplicative of a new measure (Adult Immunization Status) that is proposed for inclusion in MIPS within this rule. In reviewing the proposed Adult Immunization Status measure, it is noted that this measure is not yet tested at the individual clinician or group level. PCPI cautions CMS against introducing a composite measure which has not been tested, but also for which the specifications are not readily available. Without the specifications of this newly proposed measure, implementers and developers cannot compare the proposed specification to those of the measures which it is intended to replace, including the currently implemented Influenza Immunization measure (QI#110/CMS147). As it relates to terminology coding and data element development, consistency is vital to ensuring there would be a seamless transition from reporting the individual measure to the composite. While CMS states that the Adult Immunization Status measure is “more robust,” it is unclear as to how an untested measure is more robust than a measure that is already included in the program for which results are available. In our experience, a measure should not be described as robust simply because it is a composite measure.

It should also be noted that the Adult Immunization Status measure was not recommended with potential for mitigation by the Measure Application Partnership (MAP) for inclusion in MIPS in its 2019 report, citing that the measure should be specified and tested at the clinician level of analysis and that the measure should be submitted to the National Quality Forum for endorsement review. The MAP also “cautioned there is a need for a review with more detailed specifications while considering variability of benefits (i.e., reimbursement for vaccinations), vaccine shortages, data availability/feasibility, and more clarity into the timeframe of reporting, and MAP noted that the composite measure required internal harmonization of its component parts.”  

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Adult influenza immunization is an important population health priority as it is the best way to prevent illness from influenza and associated complications. The Centers for Disease Control estimates that during the 2017-18 influenza season, influenza vaccination prevented 7.1 million illnesses, 3.7 million medical visits, and 8,000 deaths\(^3\). Through available performance data in the MIPS 2019 Benchmark Report, we have seen that variation in performance and the opportunity for improvement remain issues as evidenced by the average performance of 42% among providers reporting the eCQM version of the measure, 64.2% among providers reporting the claims version of the measure, and 61.8% among providers reporting the MIPS CQM.

While PCPI can appreciate that a complex composite measure can appear to be more robust, from a quality improvement perspective, in our experience it is not. The Adult Immunization Status measure appears to have five reporting rates and it is unclear as to which rate(s) will be used to evaluate performance. While composites do present the ease of having a single rate representing performance on multiple measures, from our perspective, providers lose the ability to determine where improvement is needed if their overall rate is low.

Quality ID#192 is proposed for removal, as CMS considers this measure a standard of care and to be extremely topped out. For the reasons stated above, which highlight our concerns over the classification of measures as topped out and subsequent removal from the program, we believe this measure should be retained and not removed. Additionally, this measure is an outcome measure which has been part of the CMS program and one that speaks to the careful attention of the surgeon performing the cataract procedure. With well over 3 million cataract surgeries performed each year, there is likely a portion of ophthalmologists who do not submit this measure under the QPP.

CMS states in the proposed rule that measure removal criteria consider varying performance where meaningful distinctions and improvement in performance can be made, and whether the removal of a measure would impact the number of measures available to a specialist type. Furthermore, CMS states that incrementally removing topped out or non-high priority process measures, through notice and comment rulemaking is appropriate.

**PCPI strongly recommends that CMS retain these measures in the MIPS program for the 2020 reporting year.** Additionally, as we have shared in our previous comments, when removal for any measure is warranted, we recommend CMS consider an incremental phased approach according to a specified timeline that is similar to the four year timeline currently in place for removing topped out measures from the program. This approach will ensure that the removal of the measures is truly warranted and will allow providers time to begin implementing other measures for reporting purposes.

CMS also proposes to remove Quality ID #131 *Pain Assessment and Follow Up* as a quality measure from the MIPS program stating concern with the potential overprescribing of opioid

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medications. While we understand this concern, we believe that removing the measure for this reason is misguided. Regardless of the opioid epidemic, there are patients who require evaluation and management of pain. This measure does not require the prescription of any medication to meet the measure, as evidenced by the definition within the measure specifications of what is considered a follow-up plan: “A documented outline of care for a positive pain assessment is required. This approach must include a planned follow-up appointment or a referral, a notification to other care providers as applicable OR indicate the initial treatment plan is still in effect. These plans may include pharmacologic, interventional therapies, behavioral, physical medicine and/or educational interventions.” A follow up plan is likely to be multi-faceted and includes non-pharmacologic interventions.

Additionally, this measure is valuable because it can be utilized by numerous specialties and clinicians and it crosses various care settings. **For these reasons, CMS should not remove measure Quality ID #131 from the MIPS program.**

CMS has proposed to remove four nephrology measures from the MIPS program, which would result in the absence of nephrology specific measures in the program.

Quality ID #328: Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level <10g/dL is proposed for removal because it is applicable to a limited patient population, is not aligned with the Meaningful Measures Initiative, and the rationale that limited adoption of the measure indicates that it is not an important clinical concept to MIPS eligible clinicians. However, while the number of pediatric patients with end-stage renal disease is small, management of anemia in pediatric patients with kidney disease is important to avoiding multiple adverse events including increased morbidity/mortality and increased risk of heart disease. This outcome measure is aligned with the Meaningful Measure area of Management of Chronic Conditions.

Also proposed for removal are Quality ID #329: Adult Kidney Disease: Catheter Use at Initiation of Hemodialysis and Quality ID #330: Adult Kidney Disease: Catheter Use for Greater Than or Equal to 90 Days. CMS states that these paired measures do not align with the Meaningful Measures Initiative. It should be noted that these measures can be linked to three Meaningful Measure areas including Healthcare-Associated Infections, Admissions and Readmissions to Hospitals, and Management of Chronic Conditions. Catheter use for dialysis is meant to be a short-term solution until more permanent access can be established. It is well documented that the long-term catheter use increases the risk for infection and other complications. As there are also measures that address vascular access for dialysis patients in the ESRD Quality Incentive Program, removing these measures from MIPS seems to be counterintuitive to the CMS goal to harmonize measures across programs.

Lastly, Quality ID #403: Adult Kidney Disease: Referral to Hospice is also proposed for removal from the MIPS program. The rule states that this measure does not align with the Meaningful Measures Initiative and that limited adoption over the years suggests this is not an important topic for MIPS eligible clinicians. Furthermore, the rule states that this measure could potentially be improved if the denominator included multiple chronic conditions. This measure is linked to the End of Life Care According to Preferences Meaningful Measure Area. The nephrology team is an integral part of working with the patient and family to develop an advance care plan, which includes hospice care. The goal of this measure is to increase the utilization of hospice care services for the ESRD patient population specifically, given that after withdrawal of dialysis, life expectancy is limited.
PCPI supports the continued inclusion of these measures in the MIPS program.

It is also noted that there are four pathology measures proposed for removal from the program. Quality ID #249: Barrett’s Esophagus, Quality ID# 250: Radical Prostatectomy Pathology Reporting, Quality ID #395: Lung Cancer Reporting (Biopsy/Cytology Specimens), and Quality ID #396: Lung Cancer Reporting (Resection Specimens) are all proposed for removal, which would leave pathologists with only two measures left to report on in the program. Additionally, conflicting information exists within different sections of the rule. In the text on page 775 includes the following;

*Four of the five quality measures within the pathology specialty set have been identified as extremely topped out in the 2019 benchmarking file. However, we believe that it is important to retain these pathology specific measures in the MIPS quality measure set to ensure that pathologists have a sufficient number of quality measures to report.*

*The following specialty measure sets have been excluded from this proposed rule because we did not propose any changes to these specialty measure sets: Pathology…*

However, in review of the measure specialty sets in the appendix, the measures listed above are proposed for removal. The rule also uses pathology as an example in the proposal for increasing the data completeness threshold for measures retained in the program that meet “extremely topped out status”. This language leads us to conclude that maintaining these measures in the program so that they are available for reporting by pathologists is a viable option and that CMS should pursue additional discussions with the College of American Pathologists to pursue options for keeping these measures in the program.

Qualified Clinical Data Registries

PCPI supports the QCDR program and historically has supported organizations that participate in the QCDR program through measure creation, advocacy, and education. As champions of physician-level measurement, we understand and support CMS’s stance in maintaining a program that is streamlined, useful and not burdensome to clinicians. We applaud CMS for recognizing the need to further integrate the elements of the Quality Payment Program by proposing that QCDRs support the quality, improvement activity, and promoting interoperability categories.

However, we strongly believe that these streamlining efforts should be performed with the goal of encouraging QCDRs and Qualified Registries to develop quality improvement-oriented programs that complement the registry. Registries that participate in the Qualified Clinical Data Registry program are an important source of clinical data expertise and serve a vital quality improvement function beyond public reporting. Overregulation of the QCDR program as a tool to reduce the volume of quality measures could potentially lessen the value of clinician participation and therefore decrease the quality of data.
Strengthening Measure Standards and the QCDR Program

Requirements at Self-Nomination
Overall, PCPI supports rigorous requirements for the QCDR program, as we believe that adherence to standard, tested practices lead to overall successful implementation of the program and the collection and application of high-quality data. However, as a convener of the community of registries in the QCDR program, we caution CMS against implementing policies that undermine the general workflow and function of QCDRs. The comprehensive activities of measure specification, development, and testing are vital to the creation and maintenance of viable measures. As evidenced by previous conversations between CMS and the QCDR community, we believe that developing policies in a collaborative fashion is crucial to the success of both the QCDR program, and the Quality Payment Program at large.

Linkages to CMS Quality Payment Program Areas
We applaud CMS in creating a more cohesive program by linking QCDR measures to cost measures, improvement activities, and/or CMS-developed MIPS Value Pathways. We believe that this approach is integral in creating actual quality improvement projects that can lead to improved patient care and ultimately leads to participation in advanced payment models. However, we have concerns surrounding linkages to cost data and to untested CMS-developed Value Pathways. Cost data is largely held by CMS and many QCDRs do not have access to this information; unless there is a systematic approach to release this data and incorporate it across QCDRs, we believe this could be a hindrance to the program.

Requirements for Measure Approval
We understand CMS’s need to minimize the number of extraneous measures in the QCDR program. PCPI supports adherence to a clearly stated rubric that allows for the systematic review of measures. Furthermore, we support alignment of similar measures in the QCDR program to promote fewer and more meaningful measures in the QCDR program.

Requirement of Pre-Program Data Collection and Measure Testing
PCPI generally supports the requirement that QCDR measures are fully specified and undergo full testing before inclusion in MIPS. We support the inclusion of measures that are beyond the measure concept phase and agree that measurement should address persistent issues including outcomes, patient safety/adverse events, care coordination, patient/caregiver experience, cost/resource use and other considerations. However, from our extensive measure development experience we have learned that process measures are an important component of measurement. As such, we do not support exclusion of clinical process measures from the program. Process measures play a very important role in improving care as they provide insight into the process changes that need to occur to support improvement in outcomes.

We recognize the need to fully develop and test measures at the clinician level for robust quality reporting data, however measure development and implementation is time and resource intensive. Requiring data collection on measures prior to inclusion in the Quality Payment
Program and measure testing would create undue burden for QCDR stewards as procuring data for testing is difficult and this does not currently fit into the already-crammed QCDR workflow. Many Qualified Clinical Data Registries sought to participate in the program as an alternative to National Quality Forum (NQF) submission and this requirement essentially duplicates the NQF process. PCPI instead proposes fit-for-purpose testing after the measure(s) have been deployed as well as utilizing the data from implementation rather than a specialized testing requirement. **We believe that promoting measure testing through provisional implementation in real-world conditions is the most practical way to ensure that measures are fit for inclusion in the program.**

Additionally, we caution CMS against requiring data collection on measures prior to inclusion in the Quality Payment Program. Clinicians are unlikely to attest to additional measures that are not actively being used for quality reporting.

**QCDR Measure Availability and Measure Harmonization**

We applaud CMS for taking a systematic approach to allow measure licensing from one QCDR to another. We believe that measure alignment and coordination across QCDRs prior to measure submission will encourage harmonization when possible. We also support the discouragement of limiting measure availability by provisioning that measures may be rejected if not made available to MIPS eligible clinicians, groups, and virtual groups.

We understand CMS’s desire to address measurement gaps and promote measure harmonization and to this end, we encourage CMS to consider supporting a systematic clearinghouse and sandbox for measures and measure concepts to encourage registry stewards to align early in the measure conceptualization process. We would like to reiterate our recommendation that CMS utilize standardized definitions for related or competing measures as described by NQF and emphasize that **harmonization** of measures is not always appropriate, but alignment along similar concepts is, and that some seemingly duplicative measures are created separately by design.

**Benchmarking Threshold**

Fundamentally, PCPI believes that reducing measures by eliminating those that do not meet reporting thresholds is good practice. However, since the inception of the Quality Payment Program, measures that have the highest reporting rates are those that are the least difficult to meet as this is the least burdensome path for clinicians to follow. This notion of less burden is at odds with the concept of more robust measures for quality improvement. We applaud CMS for taking specialties with small numbers of measures into consideration and believe that a measure participation plan is a viable means of ensuring that specialties with low numbers of measures can participate in the program. Considering that developing a communication and education program to encourage participation is itself labor intensive, we would suggest a longer timeframe than two years for meeting benchmarking thresholds to encourage socialization of measures, data collection, field testing, and a collaborative process for retiring measures. We are concerned that specialties that have few measures in the program will have their measures removed with no recourse.
Duplicative Measures and Measure Removal
In theory, the proposal to provisionally accept seemingly duplicative measures into the program with the intent of forcing harmonization is an acceptable solution to the problem of measure proliferation. **We applaud CMS for amending measure rejection/removal criteria to be more specific and for taking the number of measures available for a specific specialty into consideration,** however some stipulations will adversely affect clinicians in the QCDR program.

QCDR and Quality Registry Performance Feedback Requirement
**PCPI supports more frequent reporting on clinician performance as this feedback will be timelier to incorporate into the patient care process.** We are concerned with the standardization of the data reported for clinician feedback and encourage CMS to continue to work collaboratively with the QCDR community to develop a timeline and standard template for reporting that allows for prompt data collection and feedback.

Multi-Year Approval Process for QCDR Measures
**PCPI applauds CMS for working collaboratively with QCDR stewards to develop a program for multi-year QCDR measure approvals for QCDRs in good standing.** This will mitigate some burden of self-nomination and will hopefully divert resources spent on self-nomination to focus on improvement.

Incorporating QCDR Measures into MVPs
**PCPI does not support decisions by CMS that effectively limit QCDR participation in the future of the Quality Payment Program.** We understand CMS’s perspective of curating a smaller and more focused set of quality measures and the desire to assemble these into an MVP, integrated with cost measures and improvement activities. However, we must reiterate that registries, and specifically registries that address clinical specialties that participate in the QCDR program are bastions of clinical expertise. While developing a program that utilizes administrative claims data as the basis of quality measurement may decrease clinician burden, it will also likely limit the value of the measure which is contrary to the goal of the Quality Payment Program.

Improvement Activities

**PCPI generally supports CMS’s modifications, deletions, and expansions to the Improvement Activities Inventory for 2020.** While PCPI supports the clarification of factors for removing improvement activities, we believe it is important to continue to allow adequate opportunities for stakeholders to provide feedback on proposals to remove specific improvement activities. **However, we must reiterate that improvement activities do not fully address the work of specialties, including surgery.**

Where CMS has “merged” existing separate improvement activities into other improvement activities, we suggest that CMS analyze current reporting patterns for the “merged” activities to
determine if providers would be required to make significant and possibly burdensome changes in their practices to support participating in improvement activities.

Promoting Interoperability

PCPI generally supports the proposed changes to the interoperability measures. For the proposed modification of the Support Electronic Referral Loops measure we recommend that the change be applied to reporting for the 2020 performance period and 2022 MIPS payment year to avoid impact to providers who are capturing data on this measure in the current year. For the Query of Prescription Drug Monitoring Program (PDMP) measure, PCPI supports CMS’s intention to advance access to and use of PDMPs. We also agree that this measure should be optional and encourage CMS to undertake research to assess the changing PDMP landscape including the capabilities of EHRs and PDMPs to support integration. For many providers query of the PDMP requires a separate and sometimes slow PDMP sign-on process and PDMP data cannot be viewed within the EHR. In these circumstances making query of the PDMP a mandated measure would place additional burden on providers.

Request for Information: Potential Opioid Measure for Future Inclusion in the Promoting Interoperability Category

PCPI supports CMS’s consideration of opportunities to adopt measures associated with the use of CEHRT to enable providers to better assess their patient’s need for use of opioids. In the current environment there are several barriers to implementing these measures. The barriers include the lack of integration between PDMPs and EHRs, limited availability of PDMP data across state lines, the early stage of clinical decision support tools related to opioids, and lack of defined clinical concepts that are fully semantically interoperable. We also encourage CMS to carefully consider unintended consequences that can emerge with the adoption of measures that have not been fully assessed in a broad range of care settings. Should CMS choose to adopt measures in this area PCPI recommends that these measures exclude providers in practices in which opioids are not a consideration. PCPI encourages CMS to continue to research and assess opioid-related measures and the requirements to advance CEHRT and PDMP capabilities that need to mature to support the vision of the opioid measurement implied in the RFI.

Request for Information: Provider to Patient Exchange Objective

PCPI is in support of the export of electronic health information to support provider to patient data exchange. PCPI suggests that this requirement include that the data adhere to a consistent standard certified technology for export to reduce the need for intermediaries to format data to be compatible between systems. We believe that making data export available without regulating its format is useful in theory but in practice will result in data loss, poor data quality, and increased costs.

As patients become increasingly empowered to self-advocate in their care, they are using self-managed technologies to access their health information. Patient empowerment should be promoted by giving patients more direct access to their full record in a manner that is readable by other systems. This is where the use of a standard is critical, and we understand that HL7 Fast Healthcare Interoperability Resources (FHIR) is the proposed standard. As we have stated
in previous responses to proposed rulemaking from both ONC and CMS, since FHIR is still a nascent standard, we are concerned with the need for additional testing before it is able to promote seamless data transfer and be implemented for patient to provider exchange.

Request for Information: Integration of Patient Generated Health Data (PGHD) into EHRs Using CEHRT

PCPI supports CMS’s vision for integrating PGHD into EHRs and clinical workflow. **We do not believe that experience and capabilities in this area are sufficient to make it likely that many providers would be able to report on high value PGHD-related metrics.** We would encourage CMS to build on the PGHD research and recommendations put forth by ONC in their report on “Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024” by examining and sponsoring pilot implementations of the use of PGHD and its integration into EHRs.

PCPI believes that the integration of PGHD into EHRs could enable integration of such data into performance measures and support ongoing advances and innovations in performance measure development. There are certain fields in which PGHD data has significant utility in the management of conditions and may be as accurate or better than data collected in the office setting, if done correctly. For example, research has shown that self-measured blood pressure predicts cardiovascular morbidity and mortality better than office BP measurements. As a result, a performance measure that is able to rely on this data as integrated into EHRs would be more accurate and reliable than one based solely on office BP measurements.

PCPI recommends that CMS partner with ONC to establish standards for the exchange of PGHD to ensure that PGHD can be integrated into EHRs and other tools with the least cost and burden. Current methods for the exchange of PGHD rely on proprietary data exchange specifications and in many instances require the use of an intermediary to “translate” the data from the sending to receiving party.

MIPS Value Pathways

Overall Comments

PCPI supports the underlying concept of a MIPS Value Pathway (MVP), especially if it aligns well and is meaningful to a clinician. PCPI appreciates the concept of aligning multiple measures and activities from multiple categories to one pathway where measures and activities can speak to all four categories, thus reducing the performance and reporting burdens on clinicians and creating an integrated approach to quality measurement. **PCPI is concerned that the proposed timeframe for development and implementation of MVPs is too short and does not provide for adequate planning, piloting, and review prior to implementation.** The complexity of the development and transition to MVPs is illustrated by the over 80 questions posed by CMS in this section of the NPRM. Answers to many of these questions may not even be feasible without piloting MVPs and comparing the outcomes of an MVP approach with the current approach. Decisions related to these questions are interlocking and these interrelated impacts will need to be carefully assessed. Allowing adequate time for planning and
preparation for MVPs is essential to successful implementation and achieving the program’s goals. Ultimately, we believe that if CMS chooses to move forward with the program in its current iteration, it should be opt-in only.

Selection of Measures and Activities for MVPs
CMS’s proposed approach to MVPs is anticipated to establish MVPs aligned to diseases and specialties. PCPI recommends that there be strong engagement of clinical societies to ensure alignment and meaningful pathways.

For specialists, it will be important to have an MVP(s) related to a common pathology or disease state/condition being treated so the largest number of clinicians within said specialty can participate, meaningfully. Currently, specialists often do not have six specialty specific quality measures that are meaningful to their specialty. Specialties should be able to suggest multiple MVPs as there may be clinicians within a specialty who do not treat the one condition/pathology addressed by a single MVP per specialty. PCPI recommends that multiple MVPs be defined for each specialty to ensure coverage of the broadest range of practice patterns.

MVP Assignment
PCPI recommends that clinicians be able to choose the MVPs that are applicable to their practice. We do not believe the MVPs should be limited to a single specialty or specialty as identified in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) or the specialty reported on claims as, for example, there may be podiatrists who participate in a practice that is highly dermatology or orthopaedic focused and an MVP regarding dermatology or orthopaedics may be a more applicable and meaningful pathway. We support clinicians being able to select or choose the MVP that is most applicable to their practice and would provide the most meaningful participation in the program.

Adjusting MVPs for Different Practice Characteristics
PCPI supports MVP adjustments to address the special characteristics of small and rural practices. Examples of these adjustments include continuation of EHR related forgiveness for those who have limited internet access, lower performance thresholds and fewer measures and activities to fully participate.

PCPI recommends that multi-specialty groups should be able to allow specialties within the group to report their preferred MVP and/or the group should be able to pick which MVP certain clinicians report. There should not be a limit on the number of MVPs being reported by a multi-specialty group because there are groups that have many different specialty types and in order to engage the largest number of clinicians, there should be meaningful MVPs for any specialty that is part of the group. The multi-specialty group should be able to decide which MVP(s) they wish to report, and that decision should be at the time of reporting.

Population Health Quality Measures Set
PCPI supports CMS’s goal of reducing the reporting burden on clinicians. We are concerned that claims data may not be sufficiently accurate or precise to produce reliable measures of clinician performance. We recommend that CMS undertake studies to
compare the results of using claim data alongside data from other sources for the specific measures that are proposed to draw on claims data.

Enhanced Information for Patients

**PCPI supports CMS plans to make MIPS and MVP data available to patients.** We encourage CMS to obtain input from patients on the types and presentations of data that they would find useful. This may require methods such as focus groups and market research since patients are unlikely to be engaged in the rulemaking comment process. Piloting of alternative approaches and obtaining patient feedback should be undertaken to ensure that the data provides high value to patients and is well understood.

PCPI appreciates the opportunity to provide comments on this proposed rule and looks forward to continuing to work with CMS on implementation of this program. Should you have questions or require additional information, please contact Kerri Fei, at kerri.fe@thepcpi.org.

Regards,

John S. McIntyre, MD
Board Chair
The PCPI Foundation

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