September 27, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Dear Administrator Verma:

On behalf of the Healthcare Information and Management Systems Society (HIMSS) and the Personal Connected Health Alliance (PCHAlliance), we are pleased to provide written comments to the Notice of Proposed Rule Making (NPRM) regarding Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; 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 (CMS-1715-P). HIMSS and PCHAlliance appreciate the opportunity to leverage our expertise in offering feedback on the Physician Fee Schedule (PFS), as well as the Quality Payment Program (QPP) and telehealth services, and we look forward to continued dialogue with CMS on these and other relevant policy topics.

HIMSS is a global advisor and thought leader supporting the transformation of the health ecosystem through information and technology. As a mission driven non-profit, HIMSS offers a unique depth and breadth of expertise in health innovation, public policy, workforce development, research and analytics to advise global leaders, stakeholders and influencers on best practices in health information and technology. Through our innovation engine, HIMSS delivers key insights, education and engaging events to healthcare providers, governments and market suppliers, ensuring they have the right information at the point of decision. Headquartered in Chicago, Illinois, HIMSS serves the global health information and technology communities with focused operations across North America, Europe, the United Kingdom, the Middle East, and Asia Pacific. Our members include nearly 80,000 individuals, 475 provider organizations and 650 health services organizations.

PCHAlliance, a membership-based HIMSS Innovation Company, accelerates technical, business and social strategies necessary to advance personal connected health and is committed to improving health behaviors and chronic disease management via connected health technologies. PCHAlliance is working to advance patient/consumer-centered health, wellness and disease prevention. The Alliance mobilizes a coalition of stakeholders to realize the full potential of personal connected health. PCHAlliance members are a vibrant ecosystem of technology and life sciences industry icons and innovative, early stage companies along with governments, academic institutions, and associations from around the world.

Interoperable, connected health requires a broad ecosystem of shared digital health information. It is particularly noteworthy that this proposed rule continues to build upon and advance patient-centered digital, interoperable, connected healthcare in several areas, including: care management service coverage, virtual substance use disorder treatment provisions, and, the merit-based incentive payment system (MIPS) Value Pathways (MVP). HIMSS and PCHAlliance members support the advancement of evidence-based connected health. CMS' work to develop and ensure appropriate use of care management services is particularly noteworthy as one of the key enablers of modernizing Medicare and imperative in improving patient outcomes.

Overall, HIMSS and PCHAlliance support the goals of the proposed changes within this NPRM, including:

- Alignment of evidence-based model practices for care delivery with improved patient outcomes and cost measures through MVP.
- Continued development of robust care management tools that leverage evidence-based connected health.
- Reducing complexity in identifying and selecting quality measures which are meaningful and actionable in driving care delivery improvement.
- Increasing transparency on individual eligible clinician performance to put the patient at the center of care delivery.

HIMSS and PCHAlliance will focus our comments primarily on the proposed changes to QPP that include the proposal to adopt the new MVP as the scoring mechanism for the MIPS program and the provisions of the proposed rule that incorporate patient- centered connected care and recognize communications technology-based services for enabling and improving care management. Our comments include:

MIPS Value Pathway Implementation Timeline

HIMSS and PCHAlliance recommend that CMS extend the timeline for implementing the MVP initiative. In previous federal regulatory public comment letters, we have specifically asked for 18 months as the minimum length of time needed between the release of final rules and the start of a new program reporting period, including on various Meaningful Use stages (now the Promoting Interoperability Program), certification criteria, or standards implementation. This minimum 18-month timeframe allows stakeholders greater opportunity to educate and prepare their staffs and front-line providers on the requirements of the upcoming reporting period. Assuming new MVP requirements are finalized in the CY2020 PFS Final Rule, we would ask that these changes not be fully required until at least July 1, 2021, to allow adequate time for new software development and deployment, as well as stakeholder education. We realize that this change would be out of cycle with CMS' typical reporting period sequences, so if it would be challenging from an administrative perspective, we would advocate for a start date of January 1, 2022, to be in alignment with the beginning of the next calendar year's payment cycle.

We also urge consideration of this recommendation in an effort to ensure that the electronic clinical quality measures (eCQMs) assigned to each MVP are meaningful, actionable, and have been fully tested to ensure they produce an accurate reflection of the quality of care being delivered and are available to populate MVP for specialists. Currently, eCQMs are not available for many ECs, particularly specialists. Moreover, the proposed data completeness requirements create additional provider burden for eligible clinicians (ECs) and are limited to chart-abstracted MIPS clinical quality measures. Furthermore, by extending the timeline for implementation, additional data from

CMS innovation programs and new care delivery models should become available to demonstrate which clinical care interventions and practice improvements correlate most significantly to improved outcomes. Overall, with more time to implement MVP comes more available data to help providers identify important trends as well as incorporate into their change management processes. Adoption of MVP by Performance Year 2021 will not allow for a thoughtful consideration of available data to identify which evidence-based model practices and improvement activities best support MVP.

The lack of available eCQMs for specialists, coupled with the increased data completeness requirements will lead to significantly higher administrative burden for specialists and multi-specialty practices. We encourage the use of eCQMs when they have been fully tested (including field testing) to the extent that they generate comparable and consistent results across care settings and meaningful and actionable measurement of the quality of care delivered to patients. We find that the industry currently is not prepared to support only one method of quality reporting, like eCQMs, due to the significant gaps in available eCQMs for many specialties.

It is critical that the extra time prior to implementation of MVP be used to evaluate the measures used for the Program and the alignment with other reporting requirements. HIMSS and PCHAlliance emphasize that the adoption of a more constrained set of measures for MVP will not significantly reduce provider burden unless eCQMs, MIPS clinical quality measures, Qualified Clinical Data Registry (QCDR) measures, and qualified registry quality measures are more effectively aligned with measure reporting requirements for state agencies, accreditation bodies, and private payers.

Care Management Services Section of Proposed CY2020 PFS

HIMSS and PCHAlliance extend our appreciation for CMS' work to provide clarity and information to guide the provision of the full range of appropriate care management services**.** The coverage of evidence-based care management allows for better patient-centered care delivery. As care management services have been added over time, it is helpful that CMS has created the overview and tables in the CY2020 PFS to clarify when each code can be used, for what, and how the codes may be billed together. We appreciate all the work CMS has done to bring appropriate care management into medical care delivery through coverage for and attention to care management.

We do have several specific comments on care management services provisions of the CY2020 PFS, which include:

Table 16. Summary of Special Care Management Codes:

- **Please include chronic care remote physiologic monitoring services, CPT 99457 and 994X0 in the table**. Currently the table includes CPT 99091, clinician review of physiologic data of 30 minutes or more. CPT code 99091 may be used for remotely monitored physiologic data, however it's for the collection and interpretation of physiologic data collected through a variety of means. We note that "Chronic Care Remote Physiologic Monitoring Services" is a specified service covered as of CY2019, and it is listed as a service in the Care Management section of this proposed PFS. We urge CMS to include each of the care management services detailed in "Care Management Services" in Table 16.

Chronic Care Remote Physiologic Monitoring Services:

- We applaud and thank CMS for the clarification that remote physiologic monitoring (CPT code 99457 and CPT code 994X0), can be provided under general supervision when they meet all criteria and clinical service time requirements. This service is similar to chronic care management which may be delivered under general supervision, allowing providers to make arrangements for 24-hour, 7 day a week coverage of monitoring that may be delivered by an offsite center/provider.
- We support the adoption and coverage for each additional 20 minutes time increment, CPT code 994X0, for remote physiologic monitoring.
- We urge CMS to value CPT code 994X0 with the same valuation as CPT 99457. The first 20 minutes of this service is the same as the second 20 minutes, and the lower value for the second 20 minutes is inaccurate. To justify a lower valuation, CMS analogizes CPT code 88381 "Microdissection" (i.e., sample preparation of microscopically identified target); which as a professional service is not similar in service or scope to remote monitoring treatment management services.

Transitional Care Management (TCM):

- We appreciate the proposal to allow care management services to be provided and billed in the same month as remote physiologic monitoring. These non-face-to-face services—such as TCM—are complementary and may need to be utilized on some beneficiaries within the same month.
- Care management codes, in the instance when the care management time is provided in addition to other care management services (such as TCM services), should be covered in the same month. For example, Medicare beneficiaries receiving care management, whether chronic condition remote physiologic monitoring (CPT 99457 and CPT 994X0), Principal Care Management, or Chronic Care Management (CCM)/Complex CCM (CCCM), may have a required transition (hospitalization, need for skilled nursing services, etc) and both services may be provided in a single month.
- We urge, however, that CMS correct Table 17. The table incorrectly lists CPT code 99091 as a code that currently cannot be billed concurrently with TCM. In the 2018 Physician Fee Schedule, CMS states this affirmatively in the discussion about CPT Code 99091: "*Finally, because we believe the kind of analysis involved in furnishing this service is complementary to CCM and other care management services, for the purposes of Medicare billing, we are allowing that CPT code 99091 can be billed once per patient during the same service period as CCM (CPT codes 99487, 99489, and 99490), TCM (CPT codes 99495 and 99496), and behavioral health integration (BHI) (CPT codes 99492, 99493, 99494, and 99484). We note that under current billing rules, time counted toward the CCM codes generally refers to time spent by clinical staff furnishing care management services; while CPT code 99091 refers to practitioner time. We note that time spent furnishing these services could not be counted towards the required time for both codes for a single month.*"

CCM and CCCM:

- We appreciate that CMS provides a pathway that allows clinicians to continue to provide for CCM and CCCM services while the CPT editorial panel reviews the original codes. We concur with the CMS analysis that these services are being underutilized. The CPT editorial panel review will be helpful and very valuable for patient care.

Principal Care Management (PCM):

- We applaud CMS for establishing coverage for care management that focuses on one, usually serious, chronic condition and support coverage for PCM. We think this will allow for care management by providers who specialize in conditions like diabetes, heart disease, or cancer that focus on the chronic condition associated with a patient's most serious health issue, and provides a pathway for providers to manage the chronic condition that underlies acute care episodes.
- The CMS proposal to apply CCM requirements to PCM is a step in the right direction and makes sense. However, if policy modifications to simplify the administration and provision of CCM are made, they should be applied to PCM. We remain concerned that the administrative requirements for CCM and CCCM are extensive and pose barriers to delivery of this important care management service.

Virtual Visit Documentation:

HIMSS and PCHAlliance appreciate CMS raising the questions about virtual visit consent documentation. On an annual basis, we recommend that (verbal or written) consent be documented by the physician who was contacted by the patient, and the consulting physician should simply confirm that the patient contacted the physician and verbally confirmed his/her consent. It is nearly impossible for a consulting physician to obtain consent from a patient with whom they do not have a direct relationship.

We encourage CMS to ensure that technology and electronic health records (EHRs) are being appropriately utilized to address these documentation challenges, so that all parties have access to this information, and can easily confirm that the verbal confirmation as well as the notification back to the physician has occurred. HIMSS and PCHAlliance would welcome a broader discussion with CMS to discuss how best to leverage technology to ensure that the hand-off is completed between the clinicians and the documentation is accessible to all participants.

Bundled Payments Under the PFS for Substance Use Disorders:

As noted in our comments on the proposed 2019 PFS, HIMSS and PCHAlliance support the creation of a reimbursement bundle for substance use disorder treatment which includes both face-to-face (including telehealth delivery) and non-face to face services. We believe that this approach encourages the provision of the most effective services, and incorporates tools as well as contracted specialty providers on an evidentiary basis. Like CCM and CCCM, efficacious delivery of this service bundle demands that they be delivered by a responsible provider under general supervision, as this allows the provider to identify evidence-based tools and services to wrap around the substance use disorder treatment delivered. We believe this bundled payment could provide a model for other care management services and the development of additional bundled payment approaches, which is a core component to delivery of evidence-based connected care.

Opioid-Related Measures Should be More Outcomes-Focused:

In the Promoting Interoperability Performance Category, HIMSS and PCHAlliance are supportive of the inclusion of opioid-related measures in the e-Prescribing Objective and leveraging Medicare and Medicaid payment policy to address our nation's opioid crisis.

We encourage CMS to move forward with finalizing the *Query of Prescription Drug Monitoring Program (PDMP) measure* as optional in 2020, as well as removing the numerator and denominator for the measure and instead requiring a ''yes/no'' response. HIMSS and PCHAlliance also support removing the *Verify Opioid Treatment Agreement* measure.

More broadly, HIMSS recommends CMS consider utilizing opioid measures that have a stronger focus on outcomes, as these measures would help drive treatment decisions and improve patient safety. Ultimately, we want to support efforts to have PDMP information fully integrated or embedded in EHRs to allow for optimal provider workflows and reduced clinician burden. Over the long term, HIMSS and PCHAlliance pledge to work with CMS and other stakeholder organizations to find the appropriate clinically-focused outcomes measures for use as soon as possible beyond 2020.

Medical Record Documentation Changes to Help Address Clinician Burden:
HIMSS and PCHAlliance support the idea that much of the work that clinicians face today is unnecessarily burdensome, where burden is defined as clinician activity that does not serve patient interests, does not improve quality or safety, or regardless of intent, is a barrier to clinical workflow and limits the ability of clinicians to appropriately engage with patients.

HIMSS has collaborated with the Association of Medical Directors of Information Systems on two recent comment letters related to prioritizing the use of health IT in resolving clinician burden. We were pleased to see CMS continue to take steps to reduce documentation requirements in this Proposed Rule. HIMSS and PCHAlliance are supportive of allowing clinicians—including, physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse-midwives and others who document and are paid under PFS—to review and verify (sign and date) a clinical note rather than re-document the note in another part of an EHR. Such a change will have a major impact on reducing a significant source of clinician burden.

Proposed Changes for Performance Year 2020: QCDR Alignment and Data Completeness Requirements for Quality Performance Category of MIPS

In the Proposed Rule, CMS proposes several major changes for ECs to report Quality Performance Category data to MIPS via QCDRs. CMS acknowledges that QCDR measures do not currently meet the same requirements nor the rigorous evaluation of MIPS eCQMs and MIPS clinical quality measures. QCDR measures are not endorsed by a credible consensus entity, such as the National Quality Forum, and hence do not create comparable and consistent results which allow patients to make accurate decisions about where they receive care.

HIMSS and PCHAlliance support the proposed changes to require measure testing and harmonization before QCDR quality measures are the allowed format for measuring quality for the MIPS program. When presenting performance indicators to stakeholders, it is critical that all methods of measurement generate comparable, accurate, and consistent results against the measure's intent in all care settings in order to remain transparent with regard to determining material factors that influence reimbursement.

Clinical registries have deep penetration in many specialties; at the same time, many registries often use heavily chart-abstracted information that may not be interoperable to certified electronic health record technology (CEHRT) because the chart-abstracted data may be in an unstructured format. This lack of interoperability presents a significant challenge to the viability of CMS interoperability goals, and raises concerns that measurement via registries are not directly comparable to structured CEHRT data. In the short term, encouraging ongoing adoption of standards as well as increasing the interoperability of clinical registry data will help enable data exchange with structured EHR clinical data. We would like to note that the Immunization

Integration Program (IIP) represents an example of quality data capture within EHRs that ensures better workflow and usability to enhance the content within conformance testing. Given our involvement with this project, we are available to work with you and your team to provide additional details on the IIP program and progress in this critical area.

HIMSS and PCHAlliance recommend that for use in future iterations of QPP, CMS promote the development of a robust de-novo measure set of CQMs for use by specialty clinicians that are designed specifically to capture CQM data as part of EHR-enabled care delivery. These new CQMs should support meaningful measurement of care delivery, be actionable for ECs, and feature data elements that measure both process improvement and improved care outcomes. In order for specialists to realize value from the MIPS program, the program will require development of eCQMs specifically designed to measure process improvement and improved outcomes relevant to particular specialties. Some specialties may face inherent problems in capturing measure-specific data because these data were not available in a standardized format, not codified to the national standard, and unable to be utilized except with manual abstraction and correction.

We support CMS's proposal requiring QCDR measures be linked to other MIPS performance categories such as "Cost" and "Improvement Activities." This connection helps to ensure that high performance on QCDR measures correlates to improved overall performance on all MIPS performance categories.

HIMSS and PCHAlliance support CMS' proposal requiring improved clinician feedback on QCDR measures. CMS' proposal to require QCDRs to provide reports on individual EC performance and benchmark EC performance against all other ECs, at least quarterly in that QCDR, creates a much needed tool which will allow ECs to identify gaps in care and address those gaps during the performance year.

Access to accurate, clinically relevant, and as close to real-time trended data is critical to ensure that quality measurement reporting can be a tool to identify gaps in care and opportunities for improvement.

CMS has also proposed that, in order for an EC or group to meet the quality reporting performance category data completeness requirements for each quality measure in the MIPS program in performance year 2020, ECs or groups must report on at least 70% of an EC or a group's patients across all payers for that performance period. Despite the fact that this requirement should be relatively easy to facilitate for ECs and groups reporting via eCQMs, it does place additional burden on ECs who report using chart-abstracted MIPS quality measures, as more time and resources will need to be devoted to enable more robust chart abstraction.

The Future State: MVP replacing MIPS Performance Categories

CMS is proposing to eliminate the four performance scoring categories (Quality, Cost Savings, Promoting Interoperability, and Improvement Activities) for the Merit Based Payment System (MIPS) starting in performance year 2021. To replace the four MIPS categories, CMS is proposing the launch of MVP. If finalized, ECs will be asked to report on a smaller set of measures (MVP) that would be based on specialty as well as outcomes and are more aligned with new Alternative Payment Models and the Medicare Shared Savings Program.

Fundamentally, HIMSS and PCHAlliance supports the MVP concept connecting quality, cost, and improvement activity measures around specific chronic conditions or specialty cohorts. More constrained measurement for each specialty and chronic care condition would reduce variability and reliability of measures and create more effective benchmarking mechanisms for driving care quality and performance transparency for patients.

We also support the inclusion of consistent Promoting Interoperability requirements and administrative claims-based population health measures across MVP. Access to timely performance data feedback on administrative claims-based quality and cost measures would be a significant contribution to ECs toward understanding their performance and preparing to take on risk as required in Advanced APMs.

Despite these positive elements, HIMSS and PCHAlliance members have detailed several significant concerns with aspects of the shift of the MIPS program to MVP as proposed in the rulemaking. We include the following example to illustrate many of our concerns:

- By Performance Year 2021, there will be several specialty ECs which will meet the MIPS minimum threshold criteria, but not have the end-to-end electronic solutions to EHR integration and solution workflow required to support reporting. For example, a large percentage of Emergency Physicians are contractors to hospitals. As contractors, most Emergency Physicians are not provided access to data rights as employed physicians. These clinicians still need to participate in MIPS/QPP and report on their quality measures. Further, most of the QPP Quality Measures are either primary care-centric, disease-condition specific, or hospital facility-centric. There are few valid measures available to specialties that are not on the topped-out candidate list and there are zero CQMs available to Emergency Physicians. Organizations such as the American College of Emergency Physicians are developing Emergency Physician-specific eCQMs. Those new Emergency Physician eCQMs will require clinical data, which is not always made available by health systems to their contracted physicians.

CMS should seek additional feedback on how to best measure care delivered in health systems that coordinate team-based care. Clinical research organizations and professional medical societies will require more than a year to make thoughtful recommendations about which measures and activities should be captured as part of MVP. In addition, we encourage CMS to explore the development of eCQMs using potentially new frameworks that could leverage patient-generated health data (PGHD) sources captured by digital devices including patient wearables.

Most of the challenges raised in relation to this NPRM cannot be addressed before a January 1, 2021 deadline. Haphazard implementation will create confusion, additional clinician burden, and exacerbate inequity and variation in reporting and performance. HIMSS and PCHAlliance strongly recommend CMS adopt a timeline that is data-driven as well as based on voluntary adoption prior to being mandated for MVP adoption.

We recommend that the current MIPS Performance Categories remain in place until:

1. Appropriate options for eCQM-based reporting are developed for all potential EC specialties and multi-specialty practices.
2. Quality measures and Improvement Activities within each MVP have been thoroughly vetted, tested, and field tested. This approach would ensure all such measures could be captured within a health and information-technology enabled care delivery workflow in all EC care settings as well as represent a meaningful measurement of the quality of care

delivered that can be directly correlated with improved patient outcomes. In addition, these measures should be able to be leveraged in as close to real time as possible by ECs to identify care gaps and opportunities for care improvement.

3. De-novo eCQMs are accurate reflections of the quality of care delivered, specifications work properly in all care settings, and are actionable by ECs to identify gaps in care and take action to improve quality in real time. Required data elements for selected eCQMs must be accurately and efficiently gathered in the healthcare provider's workflow, using data elements already collected as part of the care process and stored in EHR or other interoperable clinical and financial health IT. Reusing these data elements for eCQMs as a byproduct would significantly reduce provider burden. For additional detail, please refer to the May 2018 letter - HIMSS eCQM Policy Recommendations to CMS.
4. Data collected from MVP, particularly for MVP eCQMs, can be easily extractable for reporting purposes. As we move into a more interconnected healthcare environment, we need to be thoughtful about assuring data quality as it is gathered and reported from multiple data sources outside of the typical clinical workflow.

HIMSS and PCHAlliance recommend that CMS focus on building an MVP Program that features measures of adherence to clinical model, evidence-based practices that demonstrate impact on improving outcomes, as well as outcomes directly impactful to patients, including reducing mortality and morbidity, improving quality of life, and reducing avoidable hospitalizations.

CMS sought comments on the best ways to identify which MVP measures should be reported by multispecialty groups. We recommend CMS explore ways to allow "sub-taxpayer identification number (TIN)" level reporting for "sub-groups" within the TIN based on specialty, according to their patient populations within the parent TIN.

Comments on Requests for Information

Within the NPRM, CMS also solicited a Request for Information on the Promoting Interoperability Program category and how to advance the best use of CEHRT functionalities, modernize existing processes, and empower individual beneficiaries to manage their health goals through approaches like PGHD. On this particular topic, we urge CMS to revisit and incorporate the substantive requirements for Meaningful Use, Stage 3 related to PGHD rather than create another measure. This measure has been in the public domain as it was part of Meaningful Use Stage 3.

In response to the request for feedback on physician self-referral advisory opinions, we support CMS' cautious exploration of process improvements. In a hyperconnected world, with health care driving to full interoperability and incorporation of evidence-based, connected technology as a tool for delivery of care, an advisory opinion process established in the prior century may not serve the program or Medicare beneficiaries appropriately. We urge CMS to update the advisory opinion process on a continuing and continual basis so that it balances evidence-based advances in models of care delivery and technology with its important responsibility to protect the Medicare Trust Funds.

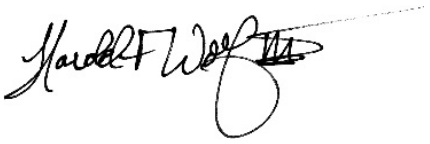
We are committed to assisting CMS in supporting the shift to value-based care delivery and facilitating greater data exchange across the healthcare community through the Physician Fee Schedule and Promoting Interoperability Program. In addition, HIMSS and PCHAlliance want to continue to help CMS leverage information and technology to support the demonstration of

innovative care delivery models for coordinating smarter, safer, and more efficient high-quality care, while ensuring that individuals remain at the center of all our efforts.

HIMSS and PCHAlliance remain committed to fostering a culture where health information and technology are optimally harnessed to transform health and healthcare by improving quality of care, enhancing the patient experience, containing cost, improving access to care, and optimizing the effectiveness of public payment. We look forward to the opportunity to further discuss these issues in more depth. Please feel free to contact Jeff Coughlin, Senior Director of Federal & State Affairs, at 703.562.8824, or Eli Fleet, Director of Federal Affairs, at 703.562.8834, with questions or for more information.

Thank you for your consideration.

Sincerely,



Harold F. Wolf III, FHIMSS
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HIMSS and PCHAlliance