



September 21, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Washington, DC 20201

RE: CMS 1743-P

Submitted Electronically via Regulations.gov

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 in response to the [Medicare Program; CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies and Quality Payment Program](#) published in the Federal Register August 17, 2020. HIMSS and PCHAlliance have long envisioned a healthcare system that seamlessly incorporates the use of connected care to enable resilient healthcare delivery that continuously improves quality and access to healthcare for consumers while reducing complexity and costs.

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 more than 80,000 individuals, 480 provider organizations, 470 non-profit partners, 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.

HIMSS and PCHalliance offer comments on the two sections of this Proposed Regulation, the Physician Fee Schedule and the Quality Payment Program.

The Medicare Physician Fee Schedule Proposed Rule (MPFS)

When our nation's COVID-19 Public Health Emergency (PHE) declaration ends, the waivers and temporary healthcare standards and policies that have been adopted for Medicare, Medicaid, private payers, and professional licensure will require a transition, rather than a sudden termination, to ensure stability, embed resilience, and develop a modern, value-based, health delivery system. We believe a framework focused on advancing value-based, patient-centered healthcare should guide the phasing down of some waivers and the transition to permanence of others. The MPFS and other annual payment rules are an excellent means for communicating policy to transition from these valuable and important waivers to an evidence driven, value-based system of coverage that embraces connected care whenever appropriate.

Our specific comments are guided by the following principles that we believe are vital to advancing connected care in a responsible, value-based manner, and that we believe are largely followed in the Calendar Year (CY) 2021 Proposed Physician Fee Schedule:

- ✓ Policies adopted must protect or improve quality, safety, and outcomes of care based on available evidence
- ✓ Connected care offers different value than in-person care, and as such it should:
 - Not be adopted and used exactly as in-person care would be delivered, unless evidence supports adoption and use in such a manner
 - Be valued/paid/priced based on the overall value it brings to care delivery
- ✓ Policies on connected care should enable and improve safe, reliable access to healthcare regardless of race, ethnicity, age, income, geography, gender, religion, sexual orientation, physical or mental ability, or other socio-economic factors
- ✓ Policies should improve access to value-based care for at risk communities, advancing health equity
- ✓ Policies must enable coverage of information-driven and evidence-based connected care, which means:
 - The best available research evidence shows the service works and leads to appropriate clinical outcomes
 - Clinical expertise can be used to evaluate the risks and benefits of use of the connected care service/tool to deliver care
 - Patient and client preferences support use of the communication technology-based tool

- ✓ Policies must be technology agnostic to allow for incorporation of innovation and new evidence-based digital tools
- ✓ Policies must be forward-looking and flexible/adaptable to evolving and future applications of connected care, which would prevent or diminish innovation
- ✓ Connected care coverage must be designed to deliver care according to patients and providers' preferences and in a manner that is most comfortable to them. This includes:
 - In some cases, a patient may wish to choose a technology-based tool with less privacy protection. Privacy and security cannot be used as excuses to drive market share or limit access to only one connected health tool
 - A patient should have the choice to communicate and interact with their provider in their most preferred method, either a telehealth service or an in-person visit

We offer the following comments on Telehealth and Communications Technology-Based Services Sections of the Proposed Rule:

D. Telehealth and Other Services Involving Communications Technology

Comments on Adding Services to the Medicare Telehealth Services List:

- ✓ We support CMS's proposal to add the list of services in Table 8 of the Proposed Rule as Medicare Telehealth Category 1 Services
- ✓ We support establishment of a third category of Medicare Telehealth Services that may be covered on a temporary basis through the end of the calendar year in which the PHE ends, to allow healthcare providers to collect evidence to support adding these services on a permanent basis as Category 1 or Category 2 services. Moreover, we appreciate CMS's articulation of the type of information the agency seeks to inform decisions to cover these as Medicare telehealth services on a permanent basis
- ✓ We urge CMS to add the physical therapy, occupational therapy, and speech-language pathology services to the telehealth services list. As noted by CMS, these services may be provided by a provider eligible to bill for telehealth or on an incident-to basis by physical therapists (PTs), occupational therapists (OTs), and speech-language pathologists (SLPs). These services can effectively be provided via two-way audio-video telecommunications technology, and, are often provided through this means for those who are privately insured

In response to CMS's questions on: 1) How to provide payment only for monitoring and interventions furnished to Medicare beneficiaries when the remote intensivist is monitoring multiple patients, some of which may not be Medicare beneficiaries, and, 2) how this service intersects with both the critical care consult G codes and the in-person critical care services,

- ✓ We suggest ~~that~~ CMS consider the creation of acute care remote monitoring codes that would account for clinical staff time spent monitoring and engaging with each patient if the current remote physiologic monitoring codes do not adequately account for the type of monitoring associated with a shorter term, infectious disease like the flu or other viruses
- ✓ In addition, we note that Tele-ICU is a complex patient management service provided by remote facilities with extensive nursing and intensivist staff who monitor Tele-ICU patients. The Tele-ICU service provides proactive service based on more extensive data and monitoring than typically provided by in-person ICU care. This additional monitoring, surveillance, and coaching of bedside/onsite nursing staff and intervention staff is not currently reimbursed. Remote critical care represents a gap in coding and reimbursement, and we understand that codes 99XX7, 99XX8, 99XX9, and 99X10 are under consideration by the American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel. We urge CMS to address the coverage and payment gaps in concert with the CPT Editorial Panel decisions and approval of new CPT Codes

Comments on Furnishing Telehealth Visits in Inpatient and Nursing Facility Settings, and Critical Care Consultations:

It is heartening that CMS is considering permanently permitting provider visits as required under Section 483.30 (c) to be conducted via telehealth. We support waiving the requirement that these visits be performed personally by the provider. In addition, we firmly believe that two-way audio-video telecommunications permit and support the full array of information a provider would need for a regular monthly visit. We note that the presence of nursing staff allows for collection of additional information that may be needed.

Comments on Proposed Technical Amendment to Remove References to Specific Technology:

We support CMS's proposal to delete the confusing reference to "telephones, facsimile machines, and electronic mail systems" as impermissible technology in the definition of an interactive telecommunications system. We agree that this reference creates confusion about use of eligible devices such as a smart phone or even an interactive telehealth platform operating within an electronic health information system.

Comments on Communications Technology Based Services (CTBS) [in Section D of the proposed rule]:

We support CMS's proposal to:

- ✓ Allow billing of G20X0 and G20X2 by practitioners who cannot bill for evaluation and management services

- ✓ Designate G20X0, G20X2, G2061 and G2063 as “sometimes therapy,” allowing them to be billed by PT, OT, and SLP private practitioners, using the modifier codes

Comments in Response to Comment Solicitation on Payment for Audio-only Visits

We support CMS’s development of coding and payment for telephone-only services, like the virtual check-in, but for a longer period of time. We believe that the provision of audio-only services may, in certain circumstances, be both effective and an important means of care delivery, particularly when factors outside of a beneficiary’s control make the audio-video requirements for a telehealth interaction difficult or impossible. We note that our policy position on use of audio-only connected care is the following:

Use of audio-only in the following cases:

- ✓ When accompanied by Remote Patient Monitoring (RPM) or sharing of patient-generated health data (e.g., home blood pressure readings or glucose meter readings), or
- ✓ When patients face connectivity challenges such as vision impairment or other limiting health conditions that inhibit their use of video, or
- ✓ When patients face technology or connectivity issues, such as lack of broadband access, or video-enabled communication technology, or
- ✓ For services with an evidence base showing equal efficacy to audio-video visits (counseling or medication adjustment to treat mental health conditions)

Comments in Response to Comment Solicitation on Coding and Payment for Virtual Services:

We appreciate CMS’s clear description of Medicare telehealth services versus the communication technology-based services (CTBS) that patients may refer to as telehealth, but may be covered by the MPFS on a routine basis. Regarding additional CTBS or digital health services that CMS should consider covering, we recommend CMS closely examine the agenda for the AMA’s CPT Editorial Panel meeting, and call CMS’s attention to the upcoming consideration for adoption of evidence-based codes for:

- ✓ Remote Patient Education
- ✓ Remote Critical Care Services
- ✓ Remote Patient Status Monitoring
- ✓ Remote Respiratory Status Monitoring Services
- ✓ Remote Physiologic and Clinical Data Monitoring (revision of CPT Code 99091)
- ✓ Remote Metabolism Measurement
- ✓ Sleep Study-Sleep Architecture and Body Position Measurement
- ✓ Digital Cognitive Therapy (for substance abuse)
- ✓ Remote Physical Therapy Services
- ✓ Tele-ICU

We support incorporation of the digital medicine services or CTBS that meet the evidence review standards allowing for the creation of a CPT Code. In addition, we recommend that CMS explicitly permit the provision of services under general supervision for the CPT Codes in the PFS that comprise remote monitoring and patient education.

E. Care Management Services and Remote Physiologic Monitoring Service

Comments on Digitally Stored Data Services/Remote Physiologic Monitoring/Treatment Management Services (RPM):

CMS proposes several clarifications for CPT Code 99454, we provide comments on each of the proposed clarifications.

- ✓ We appreciate CMS's clarification that the device provided to the beneficiary for RPM align with the CPT Codebook description of a medical device as described in section 201(h) of the Federal Food, Drug, and Cosmetic Act. Clarifying that CMS is aligned with the CPT Codebook allows for medically-appropriate and evidence-based RPM, including those devices with product codes placed under enforcement discretion
- ✓ While we support ~~the~~ CMS's clarification that medical devices billed under CPT Code 99454 digitally collect and transmit patient data, we note that some devices digitally collect and transmit non-physiologic data for evidence-based services like pain and side effect monitoring. Such a factor means that limiting use of CPT Code 99454 to devices that collect and transmit physiologic data may create a gap between physiologic and non-physiologic medical device monitoring. CMS may want to encourage the CPT Editorial Panel to consider establishment of new codes for non-physiologic status monitoring
- ✓ We request CMS clarify that CPT Code 99454 may be billed once per month per provider eligible to bill for the practice expense only technical component of an Evaluation and Management service. For example, beneficiaries with multiple chronic conditions may require RPM be conducted for heart failure by their cardiologist and for another condition such as chronic obstructive pulmonary disease by their pulmonologist or diabetes by their endocrinologist. Without such clarification, we believe that costs incurred by providers to provision the supply of equipment to beneficiaries for whom they provide RPM treatment management services would exceed reimbursement, making the provision of evidence-based RPM and treatment management based on physiologic data cost prohibitive
- ✓ We support CMS's clarification that RPM may be provided and billed for both acute and chronic conditions. The COVID-19 PHE dramatically illustrates the broad need for such flexibility and the use case for monitoring the health for those who have communicable or infectious diseases, and this application will continue even after the COVID-19 PHE ends
- ✓ We ask that CMS retain two important COVID-19 PHE policies for RPM:

- The policy to permit billing of RPM if there is a minimum of 2 days of data collection over a 30-day period rather than the 16 days in the CPT Code Descriptor
- The policy to permit RPM to be provided to any beneficiary, not just those with whom the provider has an established relationship

Both policies are fundamental to the safe, effective treatment of patients with infectious or communicable diseases. We now know that monitoring for some patients with acute diseases, particularly communicable or infectious diseases, allows for early interventions that can prevent hospitalization, and such monitoring may not always include 16 days of data collection. Providing this flexibility in RPM billing allows the healthcare system to more safely respond to the flu season and to the next pandemic, as it is a core resiliency policy.

- ✓ We support making permanent the policy that allows for consent to RPM to be obtained at the time services are furnished and that auxiliary personnel may collect the consent

CMS proposes several clarifications for CPT Codes 99457 and 99458, we provide comments on each of the proposed clarifications:

- ✓ We are troubled by the overview of the remote physiologic monitoring approach to coverage and billing as it seems to misunderstand the intent of the CPT Codes, and would exclude any billing for review of physiologic data or care management, and proposes impermissible billing

First, we believe that the proposed definition of interactive communications does not align with the intent of CPT Codes 99457 and 99458.

- The CPT "Description of Procedure" for CPT Code 99457 is "Based on interpreted data, the physician or other qualified healthcare professional uses medical decision making to assess the patient's clinical stability, communicates the results to the patient, and oversees the management and/or coordination of services as needed, for all medical conditions." This CPT Code description includes time spent conducting care management, review of physiologic data, medication management, education on self-management, care coordination, and communication between clinical staff and the patient associated with RPM
- CMS proposes to define "interactive communications" in a manner contrary to the CPT Code Description of Procedure, in a way that would only permit billing of CPT Codes 99457 and 99458 for real-time communications between clinical staff and the patient that totals 20 minutes. This excludes the time spent for clinical management services such as review of digitally delivered physiologic data, medication history, or care coordination, yet, these very services are at the heart of care management

Second, CMS suggests that CPT Code 99457 services (remote, non-face-to-face exchange) are similar to services described in HCPCS code G2012 “real-time audio-only telephone interactions; synchronous, two-way audio interactions enhanced with video or other data.” Yet, these are two very separate services with vastly dissimilar time increments, as noted by the CPT Code Description of Procedure above, CPT Code 99457 is about assessing a patient’s clinical status, communicating as needed with the patient, and conducting care management and care coordination. G2012 is a patient-initiated brief check-in with a provider.

Third, CMS seems to propose that clinicians bill for time spent reviewing physiologic data using CPT Code 99091. Yet, CPT Code 99091¹, not 99457, calls for communication to be a component of intraservice work. In addition, CPT Code guidance to clinicians is that Code 99091 may not be used within the same month or in conjunction with CPT Code 99457.

We recommend that CMS permit the billing of CPT Codes 99457 and 99458 for 20 minutes of clinical care management based on the interactive delivery of digital physiologic data AND interactive communications, which would be aligned with the CPT Code description of procedure for both codes.

- ✓ We ask that CMS retain two important COVID-19 PHE policies for RPM:
 - The policy to permit billing of RPM if there is a minimum of 2 days of data collection over a 30-day period rather than the 16 days in the CPT Code Descriptor
 - The policy to permit RPM to be provided to any beneficiary, not just those with whom the provider has an established relationship

Both policies are fundamental to the safe, effective treatment of those with infectious or communicable diseases. We now know that monitoring for some patients with acute diseases, particularly communicable or infectious diseases, allows for early interventions that can prevent hospitalization, and such monitoring may not always include 16 days of data collection. Providing this flexibility in the RPM billing allows the healthcare system to more safely respond to the flu season and to the next pandemic, it is a core resiliency policy.

- ✓ We support making permanent the policy that allows for consent to RPM to be obtained at the time services are furnished and that auxiliary personnel may collect the consent

¹ CPT Code 99091 – CPT Description of Procedure: “The intraservice period includes your review, interpretation, and report of the data that is digitally stored and/or transmitted by the patient. The intraservice period **involves at least one communication** (e.g. phone call or e-mail exchange) with the patient to provide medical management and monitoring recommendations.”

CMS seeks input on whether current RPM Coding is accurate and adequately includes the full range of clinical scenarios where RPM is beneficial to patients. We urge CMS to:

- ✓ Provide the flexibilities that support RPM for those with communicable or infectious diseases by allowing for 2 days of data collection out of 30 and provision of RPM to any beneficiary
- ✓ Take note of the ten CPT Codes under consideration by the CPT Editorial panel. As noted above, they include:
 - Remote Patient Education
 - Remote Critical Care Services
 - Remote Patient Status Monitoring
 - Remote Respiratory Status Monitoring Services
 - Remote Physiologic and Clinical Data Monitoring (revision of CPT Code 99091)
 - Remote Metabolism Measurement
 - Sleep Study-Sleep Architecture and Body Position Measurement
 - Digital Cognitive Therapy (for substance abuse)
 - Remote Physical Therapy Services
 - Tele-ICU

Valuation and Coverage for Artificial Intelligence (AI) Powered Retina Detection and Monitoring, CPT Code 9225X

As noted in the introduction, HIMSS and PCHAlliance have long supported coupling and using software to improve care and create value for patients. CPT Code 9225X is a first of its kind code, with a strong evidence base, and has potential to improve care and reduce costs. The service would use AI software to provide point of care retinal disease detection and monitoring when a patient is already in the office to receive care. If used, it has the potential to improve efficiency and promote an important preventive service.

A compelling case that supports use of technology and software-enabled retinal screening to improve care delivery is the El Rio Community Health Center, a HIMSS Davies Award winner². The El Rio Community Health Center implemented a digital retinal scan technology to improve diabetic retinopathy screening. This new AI-enabled analysis is the type of service needed in primary care clinics to improve care.

² The [HIMSS Nicholas E. Davies Award of Excellence](#) recognizes the thoughtful application of health information and technology to substantially improve clinical care delivery, patient outcomes, and population health around the world. The Davies Awards program promotes HIMSS's vision and mission by recognizing and sharing use cases, model practices, and lessons learned on how to improve health and wellness through the power of information and technology. Organizations eligible to apply for the Davies Award encompass the entire spectrum of care delivery, including: hospitals and specialty hospitals, integrated care delivery networks, academic medical centers; independent ambulatory practices; community health organizations; enterprise clinics; and state or local public health organizations.

However, such a service can only be used if providers who deploy the service are reimbursed for the associated practice expense. The RUC valuation covers the practice expense associated with the conduct of each (e.g., patient specific) use of the technology. The analysis is conducted by AI software, and there would be no service if the software is not used on a per patient basis. The creator and operator of the software provide a service and value on a per person basis, including continual updates, maintenance, and evidence development. To assume and classify software that must be used on a per patient basis as an administrative expense simply stymies innovative clinical practice and will stifle the improved value that artificial intelligence offers clinicians in improving care value. We urge CMS to approve the RUC valuation of CPT Code 9225X of \$25 as a practice expense-only code.

The Quality Payment Program (QPP) Proposed Rule

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) Program.

QPP will remain an essential component to incenting interoperability to ensure provider and patient access to the information needed for healthcare delivery, healthcare improvement, and healthcare decisions. QPP is generally advancing initial, baseline, functions for the patient-centered connected health at the heart of personal connected health. While we support these initial baseline functions, we feel it is important to note that QPP is almost entirely silent on and does little to advance the two-way system of interoperability essential to the consumer-provider communications of personal connected healthcare.

While there is nothing in QPP that prevents two-way interoperable information exchange, it does little to advance this functionality that is at the core of a patient-centered interoperable healthcare system. We ask CMS to develop Promoting Interoperability Program measures for QPP that incorporate the two-way system of interoperability as well as explore how these functionalities can be fully integrated into the MVP Program, to build on the important advances in Medicare coverage of virtual care and the digital tools that facilitate the delivery of care.

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

- ✓ Alignment of evidence-based model practices for care delivery with improved patient outcomes and cost measures through the MVP Program
- ✓ Reducing complexity in identifying and selecting quality measures that 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

Our specific comments include:

Comments on the MIPS Value Pathway Delayed Implementation Timeline

HIMSS and PCHAlliance support a delay in the timeline for starting the implementation of the MVP Program to at least the 2022 Performance Period. Fundamentally, we support the MVP Program 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.

HIMSS and PCHAlliance encourage the change primarily due to the lack of information currently available about the development of the MVP Program. HIMSS has consistently recommended that any measures reported to CMS should be fully-tested (including field testing) with actual patient data to produce meaningful, clinically-appropriate measures of care quality, which can be reported with minimal burden. Without a clear understanding of the current status of the available MVP Program, it is challenging for the industry to provide guidance on which MVP measures meet those guidelines.

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 eligible clinicians (ECs), particularly specialists. The data completeness requirements finalized in the 2020 QPP rulemaking create additional provider burden for ECs working in specialties where a lack of available eCQMs limits their reporting options to chart-abstracted MIPS clinical quality measures.

HIMSS and PCHAlliance encourage the use of eCQMs and digital measures for the MVP Program, provided those eCQMs 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. The absence of available eCQMs for specialties creates inequity of burden and actionable quality improvement resources between ECs with access to meaningful and actionable eCQMs, and those forced to utilize MIPS chart abstraction measures.

Absent from the rulemaking are details about the current progress of the development of the MVP Program which will be implemented in 2022. HIMSS and PCHAlliance

recommend CMS publish updates on the progress of the development of MVP, including indications of which MVP Program provisions are closest to maturity. HIMSS and PCHalliance also recommend that CMS publish guidance on how specialty organizations can work within the framework of CMS guidance to develop MVP, which meet the proposed MVP development criteria, particularly the Meaningful Measures Framework.

Furthermore, we recommend CMS provide substantive feedback to the industry on how collaborative efforts to develop clinically-driven measures similar to MVP (like the work currently being undertaken by the [National Quality Forum \(NQF\) Core Quality Measures Collaborative](#)) and other specialty organizations can be incorporated into the MVP framework. To effectively reduce burden, it is critical that MVP reporting align as closely as possible with the reporting requirements for states, private payers, and accreditation bodies. Efforts like the NQF Collaborative aim to align the current disparate reporting requirements and should be built upon in the development of the MVP Program.

Comments on Changes to Accountable Care Organization (ACO) Scoring and Policies

We support the Proposed Rule's changes to ensure greater alignment and integration between QPP and the Shared Savings Program, including revising the Shared Savings Program's Performance Year 2021 quality performance standard. This proposed revision would align the Shared Savings Program's quality performance standard with the QPP's proposed Alternative Payment Model (APM) Performance Pathway (APP), as participants in the Shared Savings Program would be required to report quality for purposes of the Shared Savings Program via APP. The idea of APP replacing the current Shared Savings Program quality measure set to streamline reporting requirements for Shared Savings Program ACOs would reduce reporting burden, create new scoring opportunities for participants in MIPS APMs, encourage more participation in APMs, and serve as a suitable complementary path to the MVP Program.

Overall, streamlining quality reporting requirements under the Shared Savings Program—while maintaining alignment with QPP—will help ACOs, as well as their participating providers and suppliers, dedicate limited resources toward improving quality and reducing costs for their assigned beneficiary population. Such efforts allow ACOs to better focus on increasing the value of healthcare and improving care, all while reducing burden, since ACOs would be able to track a smaller set of measures under a unified scoring methodology.

Comments on Qualified Clinical Data Registry (QCDR) Alignment and Data Completeness Requirements for Quality Performance Category of MIPS

In the Proposed Rule, CMS proposes to allow QCDRs and Qualified Registries to support the MVP Program, provided the third parties in question meet the same data validation

requirements as required for eCQM and MIPS measures. Many 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 and continue to recommend that CMS require measure testing and harmonization before QCDR quality measures are the allowed format for measuring quality for MVP. 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 alignment presents significant challenges to the viability of CMS's 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.

HIMSS and PCHalliance recommend that for use in future iterations of QPP, CMS promote the development of a robust de-novo measure set of eCQMs for use by specialty clinicians that are designed specifically to use data captured as part of EHR-enabled care delivery.

These new measures 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 MIPS, the Program should 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.

Comments on the Transition to the Latest Edition of 2015 CEHRT and the Impact on QPP

CMS has proposed that ECs must adopt and use 2015 Cures Edition Update CEHRT criteria after August 2, 2022, to meet Promoting Interoperability and Quality performance category requirements of the MIPS program as well as other QPP components. The 2015 Cures Edition Update was finalized in the Office of the National

Coordinator for Health IT (ONC) Interoperability and Information Blocking Rule, and the compliance date specified in ONC's [enforcement discretion announcement](#) from April 2020.

HIMSS and PCHAlliance Members have been working closely with ONC on implementing these certification program changes. ONC advised that the newly certified 2015 Cures Edition Update technologies must be made available to the community by the August 2022 date, versus what CMS has proposed as the date by which healthcare providers must have adopted and be using the updated certified technologies.

Accordingly, many HIMSS and PCHAlliance Members have been working under ONC's Guidance toward its required target date and creating product roadmaps as well as development plans based on that direction. For health IT developers, the difference in dates between ONC and CMS's Guidance is extremely significant. Under CMS's Guidance, developers would have to finalize all development and certification efforts by the summer of 2021 to meet its summer of 2022 requirement around the Cures Update. That extra year would be required by developers to allow sufficient time for implementation, testing, and training so that ECs could have adopted and be using certified technologies by the summer of 2022, according to CMS's Guidance.

This change requires a significant difference in development schedules, and given the magnitude of changes included in the 2015 Cures Edition Update, would require additional development planning and implementation time in order to meet the date CMS specifies for adoption and use.

HIMSS and PCHAlliance recommend that CMS align with the previous ONC Guidance and clarify that developers have until August 2, 2022, to make the 2015 Cures Edition Update CEHRT available to their healthcare provider clients.

Comments on the Proposed New Measure Related to Bi-Directional Exchange through a Health Information Exchange (HIE)

We support the importance of HIEs in the broader healthcare exchange ecosystem, and believe that incentivizing participation in HIEs that support bi-directional exchange will contribute to a longitudinal care record for the patient and facilitate enhanced care coordination across settings.

HIMSS and PCHAlliance endorse the development of this new measure to incentivize MIPS ECs to engage in bi-directional exchange through an HIE, under the HIE objective beginning with the 2021 Performance Period. Adding this proposed measure would be an optional alternative to the two existing measures: the Support Electronic Referral

Loops by Sending Health Information measure, and the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure.

This step from CMS would help ECs meet an overall standard of performance on health information exchange that is broader than the numerators and denominators of the current measures. To successfully attest to the new measure, ECs or groups would need to establish the technical capacity and workflows to engage in bi-directional exchange via an HIE for all patients seen and for any patient record stored or maintained in their EHR.

HIMSS and PCHalliance are committed to assisting CMS in supporting the shift to value-based care delivery and facilitating greater data exchange across the healthcare community through MPFS and QPP. In addition, we 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.

We look forward to the opportunity to discuss these issues in more depth. Please feel free to contact David Gray, HIMSS Senior Manager, Government Relations & Connected Health Policy, at dgray@himss.org, or, Robert Havasy, Managing Director of PCHalliance, at rhavasy@pchalliance.org, with questions or for more information.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Harold F. Wolf III". The signature is written in a cursive style with a long horizontal stroke extending to the right.

Harold F. Wolf III, FHIMSS
President & CEO