ConnectedHealth

September 16, 2019

Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, District of Columbia 20201

RE: *Medicare Program: CY2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; etc.* (CMS-1715-P)

Dear Administrator Verma:

The Connected Health Initiative (CHI) appreciates the opportunity to respond to the Centers for Medicare and Medicaid Services (CMS) on its proposed changes to the Medicare Physician Fee Schedule (PFS) and other Medicare Part B payment policies to ensure that CMS' payment systems reflect changes in medical practice and the relative value of services, as well as changes in statute and to the Quality Payment Program (QPP).[1] CHI offers its views on a variety of proposed changes to the PFS and QPP related to CMS' proposals affecting the use of digital health technologies, particularly in light of the priority to advance innovative value-based care solutions while protecting the integrity of the Medicare program.

I. Introduction & Statement of Interest

CHI is the leading multistakeholder policy and legal advocacy effort driven by a consensus of stakeholders from across the connected health ecosystem. CHI aims to realize an environment in which Americans can see improvement in their health through policies that allow for the potential of connected health technologies to improve health outcomes and reduce costs. CHI members are developers and users of connected health technologies across a wide range of use cases. We are active advocates before Congress, numerous U.S. federal agencies, and state legislatures and agencies, where we seek to advance responsible pro-digital health policies and laws in areas including

[1] Centers for Medicare and Medicaid Services, *Medicare Program; Medicare Program: CY2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; etc.CY2*, 84 FR 34598 (July 18, 2019) ("Draft CY2020 PFS/QPP").

reimbursement/payment, privacy/security, effectiveness/quality assurance, FDA regulation of digital health, health data interoperability, and the rising role of artificial/augmented intelligence (AI) in care delivery. For more information, see www.connectedhi.com.

CHI is a long-time active advocate for the increased use of telehealth and remote monitoring. We maintain an ongoing dialogue on connected health modalities with the U.S. Department of Health and Human Services (HHS) as well as before other agencies such as the Federal Communications Commission. In addition, CHI engages with a broad and diverse cross-section of industry stakeholders focused on advancing clinically validated digital medicine solution. For example, CHI is an appointed member of the American Medical Association's (AMA) Digital Medicine Payment Advisory Group (DMPAG), an initiative bringing together a diverse cross-section of 15 nationally recognized experts who identify barriers to digital medicine adoption and propose comprehensive solutions revolving around coding, payment, coverage and more.[2] CHI is also a board member of Xcertia, a collaborative effort to develop and disseminate mHealth app guidelines that can drive the value these products bring to the market and the confidence that physicians and consumers can have in these apps and their ability to help people achieve their health and wellness goals.[3]

II. Connected Health's Integral Role in the Future of Medicare

Data and clinical evidence from a variety of use cases continue to demonstrate how the connected health technologies available today – whether called "telehealth," "mHealth," "store and forward," "remote patient monitoring," or other similar terms–improve patient care, prevent hospitalizations, reduce complications, and improve patient engagement, particularly for the chronically ill. Connected health tools, including wireless health products, mobile medical device data systems, telemonitoring-converged medical devices, and cloud-based patient portals, are able to fundamentally improve and transform American healthcare. By securely enabling the exchange of health information and incorporating patient-generated health data (PGHD) into the continuum of care, these tools can render meaningful and actionable outcomes. We urge CMS' review of CHI's aggregation of numerous studies that demonstrate the improved outcomes and reduced costs associated with greater use of connected health innovations.[4]

[2] https://www.ama-assn.org/delivering-care/digital-medicine-payment-advisory-group

[3] http://www.xcertia.org/

[4] This CHI resource is publicly accessible at https://bit.ly/2MblRou.

Despite the proven benefits of connected health technology to the American healthcare system, statutory restrictions and CMS regulatory-level policy decisions, among other constraints, inhibit the use of these solutions. As a result, utilization of digital health innovations is embarrassingly low, despite their ability to drastically improved beneficiary outcomes as well as generate immense cost savings. CMS coverage of remote monitoring was relatively anemic until CY2018 when CPT® Code 99091 was unbundled, and the following year (CY2019) when CMS activated and paid for three new remote physiologic monitoring (RPM) codes. CMS has also ensured that RPM utilization by home health agencies, as well in key alternative payment models such as the Medicare Shared Savings Program (MSSP) and Medicare Advantage.

CMS also took crucial steps in 2017 to promote flexible use of remote monitoring innovations in QPP. For example, as part of the QPP's merit-based incentive payment system (MIPS) rules, CMS adopted an Improvement Activity (IA) that CHI proposed – IA_BE_14 (Engage Patients and Families to Guide Improvement in the System of Care) – which incents providers to leverage digital tools for patient care and assessment outside of the four walls of the doctor's office. The IA incents providers to ensure that any devices they use to collect PGHD do so as part of an active feedback loop. CHI is encouraged that CMS assigned high weight and linkage to an Advancing Care Information bonus to this IA, signaling to providers that CMS acknowledges the important role connected health tools can play in improving health outcomes and controlling costs.

While the progress described above represents important pro-digital health policy changes that are long overdue, the pace of uptake for digital health innovations in the Medicare system continues to lag when compared to the well-established benefits and efficiencies this cutting-edge technology offers. As a community, we continue to support CMS' efforts to utilize advanced technology to augment care for every patient. With the congressionally-mandated shift from fee-for-service to value-based care in Medicare approaching, CMS' efforts in continuing to advance the range of connected health innovations that will help American healthcare the improve outcomes and cost savings are essential.

III. Input of the Connected Health Initiative on the Proposed CY2020 Physician Fee Schedule

CHI offers the following comments on specific proposals in the CMS' proposed CY2020 PFS:

a. CHI's Continued Support for CMS' Approach to Modernizing Medicare Physician Payment through its Approach to Communication Technology-Based Services

CHI continues to agree that many "communication technology-based services" do not meet the statutorily provided definition for telehealth services in Section 1834(m) of the Social Security Act.[5] We have long advocated to CMS that it should waive 1834(m)'s overburdensome and unnecessary restrictions, including its geographic and originating site constraints, in all ways and as widely as possible for Medicare telehealth services. We also ask that such restrictions should not be applied to any other virtual modalities. We acknowledge that 1834(m) must still apply to the narrow set of technologies and services that fall under its definition moving forward until Congress acts to address the statute. However, any sweeping of new modalities into the "Medicare telehealth services" definition by CMS would be disastrous to the development of connected health technology innovations as well as their being made available to countless American Medicare beneficiaries. We support CMS' approach to modernizing Medicare physician payment through recognizing that communication technology-based services (1) provide a much-needed assurance to the public and private healthcare stakeholder communities that CMS agrees that 1834(m) has had a deleterious impact on quality and innovation in the delivery of healthcare, and (2) further solidifies that the wide range of innovative asynchronous technologies that offer much more efficient ways to prevent and treat disease will continue to enjoy relief from Section 1834(m)'s restrictions. In the Draft CY2020 PFS/QPP, CMS makes no proposal to alter this approach that was finalized in the CY2019 PFS/QPP rule, which CHI supports.

[5] Final CY2019 PFS/QPP at 35722-3.

b. CHI Views on CMS' Proposed Approach for Remote Physiologic Monitoring (99453, 99454, 99457, and 994X0)

CHI again notes its strong support for CMS' activation of and payment for the three CPT codes developed by the AMA's CPT Editorial Panel to address remote physiologic monitoring (99453 [Remote monitoring of physiologic parameter(s) (e.g. weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment]; 99454 [Device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days]; and 99457 [Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month]).

CHI also notes strong support for the proposed activation of and payment for CPT code 994X0 (Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; additional 20 minutes) (finalized as CPT code 99458); as well as the related proposal to change the descriptor for 99457 to be "initial."

Across the CPT codes developed to address the technical and professional components of RPM, we urge for CMS to provide as inclusive of a framework as possible so as to maximize the value of remote monitoring to Medicare beneficiaries. We believe that CMS can maximize the value of these new remote monitoring codes by, among other steps, clarifying that:

- Patient-reported data collected via automated remote monitoring medical technology fits within CMS' definition of physiological data.
- An established relationship between a provider and a patient exists after such a relationship is created by a provider in that practice.
- CMS is waiving the copay requirement for 99453, 99454, 99457, and 994X0 using the same legal rationale as was used by CMS to waive copays for annual wellness visits.

CHI urges for CMS to provide a baseline framework, consistent with the above. CHI has continued to work with CMS to inform its sub-regulatory guidance on the use of RPM in Medicare.

i. *CMS Should Provide Payment for RPM Codes Based on the AMA's RVS Update Committee's (RUC) Recommendations*

Each of the RPM codes were developed through concerted and thoughtful deliberations of the DMPAG comprised of experts in digital medicine services as well as coding, valuation, and coverage. The DMPAG, in turn, submitted applications for the creation of these new codes to the independent CPT Editorial Panel which vetted and approved the applications for new codes. The CPT Editorial Panel, among other relevant factors, considered significant supporting clinical documentation. Generally, we urge CMS to cover, price and pay those new CPT codes utilizing the AMA's RVS Update Committee's (RUC) information. There is an existing body of evidence, used in making such recommendations, demonstrating that these services will increase value and improve patient health outcomes, particularly for patients with multiple co-morbidities, chronic conditions, and those facing access barriers due to geography, limited mobility, and/or medical fragility, among others. CHI is concerned with CMS' continued underpayment for 99453, 99454, and 99457, which CMS has elected to value lower than the RVU recommended by the RUC, and we urge CMS to update its payment approach for these codes that were activated and paid for in the CY2019 PFS/QPP Rule to align with RUC recommendations.

Regarding 99454, CHI requests that CMS reconsider its approach to 99454 that excludes the monthly cellular and licensing service fee supply as a form of indirect practice expense. CMS based its decision on a belief that such licensing fees should be understood as "forms of indirect costs similar to office rent or administrative expenses." CHI strongly disagrees with this proposed path forward and the rationale for it. Without dedicated wireless connectivity for the patient's specific device, this excludes the vast majority of the remote monitoring technology needed to achieve remote physiologic monitoring of parameters in treatment of chronic conditions, contrary to the stated intentions of CMS. The monthly cellular and licensing fee is a direct cost that is attributable to a specific patient for a specific service, as the device that each patient uses to facilitate remote monitoring must have the capability to transmit healthcare data either via a cellular network or other wireless network. Therefore, CHI continues to urge CMS to reconsider its approach to the cellular and licensing service fee consistent with the above in doing so.

Similarly, CHI supports the RUC's proposed approach to payment for 994X0. We disagree with CMS' proposed rationale to value an additional 20 minutes of RPM review at an RVU lower than that for the same service for the first 20 minutes (99457). CMS' rationale, using an analogy to CPT code 88381, is inapplicable as Microdissection (i.e., sample preparation of microscopically identified target; manual) as a professional service bears no similarity or resemblance to remote monitoring treatment management services. CMS is insufficient and does not provide an acceptable explanation as to why review of RPM by a physician, qualified health care professional (QHCP), or clinical staff is analogous to CPT Code 88381. CMS should adopt the proposed RUC-recommended RVU of 0.61 direct PE inputs for CPT code 994X0. First, the additional

20 minutes of analysis is likely furnished to patients who need deeper analysis of their RPM data, making the service at least as valuable as the same service for the first 20 minutes that month. Second, with more data points and analysis of such data points providing even greater insight into health trends for a patient, we argue that the analysis done in the additional 20 minutes is at least as valuable as the first 20 minutes (if not, in some cases, more valuable). CMS' rationale for undervaluing 994X0 addresses neither of these points. We, therefore, request that CMS alter this aspect of its coverage of 994X0 and adopt the RUC-recommended RVU of 0.61.

CHI also notes its disagreement with CMS' proposal to reduce the practice expense of code 99453 from 0.54 wRVW in CY2019 to 0.52 wRVW in CY2020, and to reduce the practice expense of code 99454 from 1.77 in CY2019 to 1.71 in CY2020. As CMS has not provided any rationale as to a change in equipment, supplies, or staff which would justify a reduction in practice expense, we strongly encourage CMS to maintain the existing practice expense for these codes in CY2020.

ii. *CHI Strongly Supports CMS' Proposed Clarification that CPT Codes 99457 and 994X0 May Be Furnished Under General Supervision*

In the Draft CY2020 PFS/QPP Rule, CMS puts forward a crucial proposed clarification in proposing that 99457 and 994X0 may be furnished under general supervision rather than the currently required direct supervision. CMS is proposing to include 99457 and 994X0 as designated care management services because such services can be furnished under general supervision under Section 410.26(b)(5). Realizing the full potential of RPM will require clinical staff furnishing the service and the flexibility provided by general supervision.

CHI has been working closely with CMS throughout 2019 to find a path forward for 99457 and 994X0 so that all impacted stakeholders can enjoy certainty that CMS agrees to permit clinical staff to furnish these services under general supervision. We appreciate CMS' technical correction made earlier in 2019 to clarify that auxiliary staff may furnish the 99457 service, and CMS' dialogue with CHI about further steps needed to provide the ability for clinical staff under general supervision to furnish RPM data review services for beneficiaries. CHI fully supports CMS' proposed clarification that 99457 and 994X0 may be furnished under general supervision rather than the currently required direct supervision.

iii. *CHI Requests that CMS Clarify that Remote Patient Monitoring Service Codes are not Chronic Care Management Codes*

CHI continues to experience confusion in the market as to whether the 99457 service may be furnished to beneficiaries that do not experience two or more chronic conditions (and we expect the same question will arise for 994X0 should CMS activate and pay for this code). We have relied on numerous discussions with CMS and public statements made by CMS staff during which it was reinforced that the 99457 service is not a Chronic Care Management (CCM) code, and is therefore available for use to address scenarios such as post-surgical monitoring and others that do not necessarily meet CCM requirements. Restricting the use of the 99457 and 994X0 codes to beneficiaries with two or more chronic conditions would unduly preclude millions of beneficiaries from enjoying RPM tools' benefits and would represent a policy change without a sufficient rationale. We, therefore, request that CMS clarify in the final CY2020 PFS/QPP Rule that the 99457 and 994X0 services can be furnished for any medically necessary use cases and that neither are CCM codes.

iv. *CHI Requests that CMS Embrace the Value of Non-Physiologic Data in Medicare*

CHI supports the numerous steps already taken, and those proposed, that will bring new PGHD into the care continuum. We do note concern that CMS would limit such data sets to those that are "physiologic." Further categories of data, including therapeutic, mental, and behavioral data generated and reported outside of the four walls of the doctor's office, offer immense potential to improve outcomes and reduce costs. We request that, in its final CY2020 PFS/QPP rule, CMS address the role of "non-physiologic" PGHD, its role in the future of value-based Medicare, and provide a vision for the utilization of patient-reported data which is clinically relevant to the physician, outside of what has previously been outlined by CMS as "physiologic data," in the future value-based Medicare.

c. CHI Supports CMS' Proposed Creation of and Payment for Non-Face-to-Face Codes for Patient-Initiated Digital Communications

CMS proposes to adopt new non-face-to face codes, created by the CPT Editorial Panel, for "patient-initiated digital communications" that require a clinical decision typically provided in the office. For those who may independently bill evaluation and management (E/M) services, CMS proposes to activate and pay for CPT Codes 9X0X1/99421 (Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7days; 5-10 minutes), 9X0X2/99424 (Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes), and 9X0X3/99423 (Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes). For non-physician healthcare professionals, CMS proposes to create and pay for Healthcare Common Procedure Coding System (HCPCS) Codes GNPP1 (Qualified non-physician healthcare professional online assessment, for an established patient, for up to seven days, cumulative time during the 7 days; 5-10 minutes), GNPP2 (Qualified non-physician healthcare professional online assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 11-20 minutes), and GNPP3 (Qualified non-physician qualified healthcare professional assessment service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes). CHI supports CMS' proposal to adopt and pay for these new CPT and HCPCS codes.

d. CHI Supports CMS' Proposal to Establish Reimbursement for New Self-Measured Blood Pressure Monitoring and Revised Ambulatory Blood Pressure Monitoring CPT codes

CMS proposes to establish reimbursement for codes 99473 and 99474 (Self-Measured Blood Pressure Monitoring and revised Ambulatory Blood Pressure Monitoring CPT codes) and to accept the RUC recommendations for payment of these codes. CHI commends CMS for taking these actions to promote patient care and supports CMS' support for new Self-Measured Blood Pressure Monitoring and revised Ambulatory Blood Pressure Monitoring CPT codes as proposed.

e. CHI Supports Permitting Single Advanced Beneficiary Consent for Virtual Visits

CHI briefly notes its support for CMS' proposal to permit single advance beneficiary consent for virtual visits (HCPCS G2012), remote evaluation of images (HCPCS G2010), and Interprofessional Internet Consultations (99446-99449, 99451 and 99452). CHI supports a one-year interval of time for obtaining consent for all these services furnished within that period. Any services furnished after would require obtaining new consent.

CMS seeks input on program integrity issues related to its single advanced beneficiary consent proposal. CHI is not aware of specific program integrity issues that CMS' proposal gives rise to. CHI strongly supports measures to avoid waste, fraud, and abuse in the PFS and believes that the use of connected health technology does not inherently mean that it will translate to greater waste, fraud, and abuse. To the contrary, program integrity is more easily ensured through data analytics facilitated by greater use of connected health technologies provide.

f. CHI Views on CMS' Proposed Expansion of the Medicare Telehealth Services List

CMS proposes to add HCPCS code GYYY1 (Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month); HCPCS code GYYY2 (Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month); and HCPCS code GYYY3 (Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure) to the Medicare Telehealth Services List. Noting our support for CMS' rationale in differentiating Medicare telehealth services from remote communications technologies, CHI offers its support for CMS' proposed expansion of the telehealth services list. CHI further notes its support for the SUPPORT Act, which has removed the geographic limitations for telehealth services furnished to individuals diagnosed with a substance use disorder (SUD) for the purpose of treating the SUD or a co-occurring mental health disorder.

g. CHI Supports Modality-Neutral Use of CMS' New HCPCS Codes for Non-Complex CCM

Under non-complex CCM, CMS proposes to replace the single CPT code 99490, in place today, with two new temporary G codes, HCPCS code GCCC1 (covering the initial 20 minutes of clinical staff time) and HCPCS code GCCC2 (covering each additional 20 minutes). CMS' rationale includes that this new approach will enable greater accuracy in its CCM payment policies. CHI supports CMS' proposal.

However, CHI requests that CMS reinforce its previous assurances provided to stakeholders about non-complex CCM codes being modality-neutral, enabling the use of a variety of remote communications technologies. As discussed above, a diversity of digital health tools can improve outcomes and cost savings, and CMS should take steps to ensure that it provides certainty about these tools' ability to help beneficiaries suffering from chronic conditions.

h. CHI Supports Modality-Neutral Use of CMS' New HCPCS Codes for Complex CCM

Under complex CCM, CMS proposes to replace CPT codes 99487 and 99489 with HCPCS codes GCCC3 (Complex chronic care management services, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored; moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month. (Complex chronic care management services of less than 60 minutes duration, in a calendar month, are not reported separately)) and GCCC4 (each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure). (Report GCCC4 in conjunction with GCCC3). (Do not report GCCC4 for care management services of less than 30 minutes additional to the first 60 minutes of complex chronic care management services during a calendar month)). These two new G codes would exclude the "substantial care plan revision" service component. Based on CMS' rationale for this policy shift, CHI supports CMS' proposal.

As stated above, CHI requests that CMS reinforce its previous assurances provided to stakeholders about complex CCM codes being modality-neutral, enabling the use of a variety of remote communications technologies. As discussed above, a diversity of digital health tools can improve outcomes and cost savings, and CMS should take steps to ensure that it provides certainty about these tools' ability to help beneficiaries suffering from chronic conditions.

i. CHI Supports CMS' Proposed Allowance for Concurrent Payment of Transitional Care Management Codes and Certain HCPCS Codes

CMS proposes that 14 HCPCS codes, when medically necessary, may complement Transitional Care Management (TCM) services and no longer present a danger of substantially overlapping with or duplicating such TCM services. CMS also proposes to remove the billing restrictions associated with these 14 codes, reasoning that removing such restrictions may increase utilization of TCM services. Many of these 14 HCPCS codes support the use of digital health innovations, including 99091 and various CCM codes. Consistent with our views elsewhere in this comment, CHI supports CMS' proposed policy changes to how it addresses TCM services, noting that 99091 is already billable with TCM services as of January 1, 2018 (which we request CMS clarify).

j. CHI Supports CMS' Proposed Creation of Principle Care Management Services and Encourages Connected Health Technologies in Supporting Them

CMS seeks to create Principle Care Management (PCM) services to address beneficiaries with a single chronic condition, proposing to put HCPCS codes GPPP1 (at least 30 minutes of physician or other qualified health care professional time per calendar month) and GPPP2 (at least 30 minutes of clinical staff time directed by a physician or other qualified health care professional) into place. CHI supports this CMS proposal.

Again, CHI requests that CMS assure stakeholders that PCM codes are modality-neutral, enabling the use of a variety of remote communications technologies. As discussed above, a diversity of digital health tools can provide both improved outcomes and cost savings, and CMS should take steps to ensure that it provides certainty about these tools' ability to help beneficiaries suffering from a chronic condition. Further, we request that CMS clarify that PCM services may (like CCM and TCM services already can) be billed in the same month as RPM codes 99453, 99454, 99457 and proposed 994X0.

k. CHI Urges CMS to Expand the Medicare Diabetes Prevention Program to Support Virtual Encounters

CHI feels strongly that CMS should maximize virtual Medicare Diabetes Prevention Program (MDPP) services and when applicable, utilize other non-face-to-face services via any available modality that best serves the intended population. CMS has acknowledged that the use of connected health tech products and services will be vital to the success of the MDPP, and a virtual MDPP would reap benefits consistent with the experiences and data of the broad community of stakeholders from across the healthcare and technology sectors that CHI represents.

CMS' continued lack of support for virtual MDPP discards the well-established value of connected health technology to at-risk diabetics, leaving countless Americans in peril, particularly in rural areas of the country as 67 percent of the 65+ population lives further than five miles away from a face-to-face delivery location. Building on the Center for Disease Control's (CDC) recognition of the effectiveness of a virtual MDPP since 2015, we encourage a renewed actuarial analysis of virtual MDPP.

Further, we encourage CMS to permit Medicare Advantage (MA) plans to use virtual MDPP encounters in addition to in-person MDPP encounters, and to permit virtual DPP to register as Medicare Suppliers to enable uptake by MA plans. Without this allowance, in-person MDPP providers will be unable to service MA plans which will leave numerous beneficiaries without access. CMS can alleviate this issue by affirming that MA plans

may use virtual MDPP to meet network adequacy requirements and satisfy the requirement to provide MDPP services; and by allowing virtual MDPP providers to register as Medicare Suppliers for this purpose. We also note that, whether in the Medicare fee-for-service or MA context, a successful MDPP will require the inclusion of a virtual program the MDPP supplier enrollment, preliminary recognition, and supplier standard provisions of the final rule.

IV. Input of the Connected Health Initiative on the Proposed CY2020 Quality Payment Program

With respect to QPP, with the passage of the Medicare and CHIP Reauthorization Act of 2015, Congress has directed CMS to evolve the Medicare program to emphasize care quality over quantity, requiring enhancements to the healthcare system that connected health technologies may facilitate. Through the CY2020 QPP rulemaking, CMS has an excellent opportunity to advance the American healthcare system by leveraging digital medical technologies, both those available today as well as emerging fields like systems medicine, AI, and enhanced data analytics. We encouraged CMS to incentivize the use of connected medical technologies throughout the Merit-based Incentive Payment System (MIPS). Furthermore, CMS should avoid overly burdensome MIPS Promoting Interoperability program compliance and reporting requirements. CMS should explicitly endorse the use of digital medical technologies' in Alternative Payment Models (APMs).

We urge CMS to utilize every opportunity available to move away from legacy technology systems and towards a truly connected continuum of care through its implementation of the QPP.

a. CHI Supports CMS' Acceptance of Connected Health Technology in the Merit-based Incentive Payment System

We continue to support the overall approach by CMS to the QPP MIPS Improvement Activities (IAs), which have taken a more goal-oriented and technology-neutral approach to compliance. This shift is important because it will provide needed flexibility to MIPS practitioners to select the most effective approaches for their patients. Further, we appreciate CMS' focus on incenting the use of health IT, telehealth, and the connection of patients to community-based services.

By specifically calling for an inventory that "shall include activities such as…remote monitoring or telehealth" under the Care Coordination performance subcategory,[6] Congress signaled the importance of these technologies to support providers through the transition from volume- to value-based reimbursement. The IA Inventory should provide a robust menu of activities that, through appropriate use of remote monitoring, telehealth, and consumer-oriented information technology, eligible practitioners may use for care improvement. It is crucial that the IA Inventory, from which all MIPS-eligible clinicians or groups must select activities, reflect both congressional intent and the benefits of connected technologies to the Medicare program.

[6] MACRA Section 101(c)(2)(B)(iii)(II).

In the context of MIPS, CMS has already taken a major step to promote flexible use of remote monitoring innovations in the QPP: as part of the QPP's MIPS rules, CMS adopted an IA that CHI proposed—IA_BE_14 (Engage Patients and Families to Guide Improvement in the System of Care)—which incents providers to leverage digital tools for patient care and assessment outside of the four walls of the doctor's office. The IA incents providers to ensure that any devices they use to collect PGHD do so as part of an active feedback loop. We encourage CMS to build on IA_BE_14 moving forward.

CMS' previous policy of providing bonus points in the Promoting Interoperability (PI) category represented CMS' understanding that health IT plays a role in improving outcomes and incented physicians to incorporate health IT into their practice workflows and clinical activities. CMS should reward practices who embrace technical solutions and approaches that capture PGHD and incorporate it into the certified EHR technology (CEHRT) using a standards-based approach for purposes of the Promoting Interoperability performance category. Over the past decade, the FDA has listed, cleared, and approved a vast array of technologies which allow for the capture and transmission of PGHD on which providers may act. Pilots to further study the role of PGHD in Medicare at this point are unnecessary, wasteful, and redundant; the CHI is more than happy to offer a range of resources and studies which outline the vast evidence on the benefits of remote patient monitoring technologies.[7]

We urge CMS to underscore this understanding by continuing to provide providers with bonus points when using CEHRT to accomplish IAs. Given CMS' proposal to remove the bonus score component of PI, CMS could simply apply bonus points at the composite score level. Doing so would avoid having to "reinvent the wheel" and would provide some consistency to providers who have already adjusted their workflow in the interest of earning the PI bonus. CHI would also support CMS applying high-weighting to any improvement activity employing CEHRT.

With regard to how health IT could better support the feedback related to participation in the QPP and quality improvement in general, we believe that CMS' evaluation must reflect the fact that remote communications technologies and telehealth—across patient conditions—offer key "health IT functionalities," including the automatic collection and transmission of important biometrics for timely caregiver review and analysis. A diversity of application program interfaces (APIs) are emerging to assist in bringing PGHD into the continuum of care, but we stress that not all of these are necessarily well integrated with EHRs. While CEHRT will be required to support APIs, many vendors will enable "read only" access—allowing for data to only flow out of the EHR rather than both in and out. Additionally, we are aware that CEHRT vendors have not implemented a common approach to API development and lack a consistent implementation of API technical standards—creating "special effort" to develop applications and undue burden and costs for our members.

[7] https://bit.ly/2MblRou.

Many CHI members develop innovative and unique applications that benefit both providers and patients. However, CMS' regulation that includes misplaced CEHRT incentives drive EHR development to focus on measurement and reporting, rather than patient and clinician needs. Similarly, providers are not rewarded for health IT use consistently across all MIPS components. For instance, the PI component is solely focused on CEHRT use, while the IA category rewards for the use of both CEHRT and non-CEHRT.

We urge CMS to consider shifting away from rigidly requiring the use of CEHRT to an outcomes-based approach that would permit the use of non-CEHRT across the entire MIPS program. CMS should also seek to minimize administrative burdens (*e.g.*, lengthy documentation reporting requirements) on Medicare caregivers. Such steps must serve as a cornerstone of CMS' effort to provide flexibility for MIPS-eligible clinicians to effectively demonstrate improvement through health IT usage. Changes in MIPS are inherently linked to other important rules CMS is responsible for, including the Physician Fee Schedule which has recently begun to incent the use of asynchronous tools that will bring PGHD into care. Efforts to revise MIPS measure and objectives generally should be made in alignment with non-CEHRT use, *e.g.*, remote monitoring technology, which can greatly improve patients' care and wellness.

Based on the above, we offer the following recommendations for CMS' proposed 2020 MIPS Program:

- CHI supports CMS proposed revisions to Quality Measures that would add in telehealth encounters to be included as eligible encounters, which include:
    - D.4. Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD);
    - D.10. Adult Major Depressive Disorder (MDD): Suicide Risk Assessment;
    - D.31. Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention;
    - D.40. Initiation and Engagement of Alcohol and Other Drug Dependence Treatment; and
    - D.53. Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment.

- CMS solicits a Request for Information regarding Promoting Interoperability category and how best to prioritize the advanced use of CEHRT functionalities by moving away from paper-based processes and empowering individual beneficiaries to manage their health goals. As an example, CMS highlights PGHD as a way to offer providers an opportunity to monitor and track a patient's health-related data from information that is provided by the patient and not the provider. We remind CMS to note the various forms of PGHD, including those that are self-reported and input manually by the patient, and PGHD which are physiological parameters generated by a person's body, captured as signals by remote patient monitoring digital medical devices, and reported/transmitted to other health information systems, portals, EHRs, etc. Health care providers should be encouraged and rewarded for collecting information from their patients outside of scheduled appointments and procedures. When CMS and ONC finalized the now-defunct Meaningful Use Stage 3 objectives and measures, as well as the beneficiary engagement Improvement Activities offered under the Merit-Based Incentive Payment System, it did so with the idea of allowing bi-directional availability of data (meaning that both patients and their health care providers have real-time access to a patient's EHR.

  CMS states that "Increasingly affordable wearable devices, sensors, and other technologies capture PGHD, providing new ways to monitor and track a patient's healthcare experience." By capturing health information through devices and other tools between medical visits, CMS argues that care management and patient outcomes could improve, potentially resulting in increased cost savings. Although the use of PGHD in clinical settings continues to steadily increase, integration of patients' health-data into EHRs remains uncommon and not widely adopted, CMS correctly points out that in the 2015 Edition Health IT Certification Criteria final rule,[8] ONC finalized "Objective # 6: COORDINATION OF CARE THROUGH PATIENT ENGAGEMENT" measure 3 to allow PGHD or data from "a nonclinical setting" to be incorporated into the CEHRT. Adoption of this functionality would have allowed beneficiaries to identify, record, upload, and access information electronically shared by a patient. Although CMS finalized this measure requiring healthcare providers to incorporate PGHD into CEHRT,[9] it was removed in the CY 2019 PFS final rule (83 FR 59813), for reasons which continue to remain unclear. At the time of the removal, CMS stated concerns that the measure was "not fully health IT-based" and could "include paper-based actions, an approach which did not align with program priorities to advance the use of CEHRT;" yet, CMS had the ability to strengthen the measure by requiring only automated digital formats of PGHD to be shared by patients and become part of the CEHRT. Doing so would have eliminated any argument that manual processes to conduct actions would increase health care provider reporting burden or confusion over which types of PGHD health data would be applicable and when. Despite having been able to strengthen the measure, CMS rightly points out that "there was ample support from the public for ONC and CMS to continue to advance certified health IT capabilities to capture PGHD."

Considering how the Promoting Interoperability performance category could advance the use of PGHD, CMS notes that a future element related to PGHD would not necessarily need to be implemented as a traditional measure, and in lieu of a traditional measure, could have providers attest to demonstrating utilization of remote monitoring system predicated on wireless or mobile medical device(s) as defined by FDA that automatically capture PGHD, transmit that data for the physician, QHCP, or clinical staff to act upon it. We offer the following specific use cases for capture of PGHD as part of treatment and care coordination across clinical conditions and care settings to improve patient outcomes.

- Clinical examples where remote patient monitoring services can be provided under clinical supervision include, but are not limited to:
  - Emergency department triage or post-discharge follow-up
  - Follow-up services furnished to beneficiaries in hospitals or SNFs
  - Nursing facility care services
  - Individual and group kidney, chronic kidney disease, and ESRD remote monitoring services
  - Individual and group diabetes self-management services
  - Individual and group health and behavior assessment and intervention
  - Individual psychotherapy
  - Telehealth pharmacologic management
  - Psychiatric diagnostic examinations
  - Neurobehavioral status
  - Intervention services
  - Depression screening
  - Cardiovascular disease and heart failure
  - Obesity
  - Psychoanalysis
  - Family psychotherapy

[8] 80 FR 62661; 45 CFR 170.315(e)(3).

[9] 80 FR 62851.

- Other medical uses and use cases for remote monitoring services include, but are not limited to:
  - Asynchronous exception management remote monitoring
  - Cardiac (general) ECG monitoring
  - COPD
  - Sleep apnea and other sleep disorders
  - Respiratory care
  - Sepsis
  - Infection management
  - Cardiac (general) ECG monitoring
  - Medication adherence
  - Medical device data systems for remote monitoring
  - Clinical event tagging/patient remote alarm monitoring
  - Acoustic gastro-intestinal surveillance
  - Remote pulse oximetry
  - Psychiatric mental health
  - Behavioral medical health
  - Mobile monitoring of peritoneal dialysis
  - Remote chronic pain relief therapy
  - Mental deterioration remote monitoring
  - Remote auscultation
  - Asthma and environmental scanning analysis
  - Respiratory care event detection, compliance, and efficacy
  - Pulmonary pressure monitoring
  - Smart ingestible pills for monitoring and tracking
  - Digital health monitoring for clinical trials
  - Family planning fertility monitoring
  - Infant development tracking/monitoring
  - Remote otolaryngology infection monitoring
  - Diabetes monitoring
  - Continuous blood glucose monitoring
  - Mobile radiology and diagnostic imaging services
  - Tinnitus therapy
  - Remote neurobehavioral cognitive testing
  - Mobile vision degeneration monitoring
  - Physical therapy rehabilitation
  - Brain trauma evaluation and activity tracking
  - ADHD assessment tools for long-term development
  - Surgical planning
  - Spirometry for lung function
  - General diagnostic remote monitoring
  - Spinal cord stimulation trial system

- CHI notes its support for CMS' acknowledgment that the use of health IT past CEHRT offers the ability to improve care and keep patients safe. While CMS has made this statement in its proposed Query of Prescription Drug Monitoring Program (PDMP) measure, we believe that this principle applies across MIPS, and we urge that CMS move away from its reliance on CEHRT (through, for example, permitting health IT that builds on top of CEHRT) in order to provide increased competition in the marketplace as well as greater flexibility and choice to providers and patients. CHI notes its support of 2015 CEHRT requirements in 2019, but we reiterate our concern with, and lack of confidence in, any presumption that the 2015 ONC CEHRT standards will facilitate seamless interoperability.
- In an effort to provide CMS with alternative approaches, flexibilities, and methodologies to consider for scoring the PI component of MIPS, CHI urges CMS to align its PI requirements across CMS beneficiary programs to provide simplicity and certainty for connected healthcare stakeholders. Specifically, CHI strongly recommends CMS apply the same 50-point scoring standard enjoyed by facilities to the PI performance category of MIPS to better reduce provider burden and ease concerns with succeeding in PI. In other words, providers who earn 50 points or higher in PI should be deemed to have satisfied the requirements of PI and should receive a 100 for the category, translating to 25 points towards a provider's final composite score.
- We urge CMS to make compliance burdens for PI participants as low as possible to maximize participation and support CMS' levering the 2018 Bipartisan Budget Act to move away from the Meaningful Use program's "pass/fail" approach.
    - CHI supports scoring measures at the objective level to provide greater flexibility to providers.
    - CHI recommends that CMS move away from numerator/denominator scoring, and instead utilize a yes/no attestation for all measures.
    - CHI recognizes that scoring at the objective level and utilizing a yes/no attestation for all measures may not be practicable for the 2020 reporting year. We, therefore, reiterate our desire for CMS to extend the 50-point scoring standard to the PI performance category in 2020 as a necessary step to align the two PI programs and reduce provider burden. We further recommended CMS establish a plan to transition away from measure-level and numerator/denominator scoring by the 2021 MIPS reporting year.

- CHI specifically supports various proposed PI measures that will, using a light touch, incent the leveraging of remote monitoring and telehealth innovations to address pressing public safety needs, namely the opioid crisis in America. For example, CHI supports measures related to enable the appropriate electronic prescription of controlled substances (ECPS), for which we have also urged the Drug Enforcement Administration to take steps to improve the ability of connected health innovators to provide new efficiencies.[10] These measures, however, should continue to be offered as a bonus through 2020.
- CHI supports efforts to address health data interoperability issues and urges CMS to work in concert with sister agencies that are working to address the same issues now. For example, the Office of the National Coordinator for Health IT (ONC) is currently developing a Trusted Exchange Framework and Common Agreement (TEFCA) to advance interoperability, on which CHI has provided its detailed input;[11] further, an information blocking rulemaking is being advanced by ONC, along with a sister rulemaking by CMS. We urge CMS to ensure its approach aligns with ONC's (as well as other agencies) and to minimize compliance burdens on affected stakeholders. As such, CHI supports CMS' proposal to have participation in the TEFCA qualify as a health IT activity that could count for credit within the Health Information Exchange objective in lieu of reporting on measures for this objective. Furthermore, we recommend that CMS also consider similar trust agreements and not limit potential Health Information Exchange objective options to just the TEFCA.

[10] *See* https://bit.ly/2jHwAXT.

[11] *See* https://bit.ly/2IrvKbI.

- CHI strongly supports incentives to ensure the secure exchange of information. We urge that reporting requirements present as low a burden as possible and that the new CMS rules do not have the effect of incentivizing data dumps that have little practical value.

  Further, CHI supports the use of the strongest technical protection mechanisms (TPMs), including end-to-end encryption and multi-step authentication. We urge CMS to include direct endorsement of the strongest TPMs used for securing data integrity, confidentiality, and access. We do, however, highlight that the use of TPMs must also be balanced with the potential financial, staff, or other resource burdens on small, solo, and rural provider offices in a holistic risk management process.

  Regarding the Health Insurance Portability and Accountability Act of 1996 (HIPAA), CHI notes its appreciation for CMS' work with HHS' Office of Civil Rights to align the PI program with HIPAA. CMS' rules should avoid creating uncertainty as to what can be shared, and how patients would be properly notified of their data's use under HIPAA. We strongly discourage creating a scenario where a party making a query must choose between satisfying the PI program's requirement for disclosing data fields and violating HIPAA's "minimum necessary" requirements.

- CHI urges for CMS to take all practicable steps to align Medicaid policies with changes to the Medicare program that are increasingly enabling physicians to flexibly use telehealth and remote monitoring technologies to improve care and reduce costs.

b. Without Adequate Guidance from CMS, Alternative Payment Models (APMs) Cannot Realize the Benefits of Telehealth and Remote Monitoring Technology Innovations

CHI supports Congress's goal of realizing innovative APMs and continues to work with stakeholders to find eligible alternatives to MIPS. At a minimum, we strongly believe that APMs must affect the utilization of connected health technology in a significantly expanded way. APMs, with their financial and operational incentives, should demonstrate the best uses of remote monitoring or telehealth tools. To date, CMS has not discussed telehealth and remote monitoring's key role in the success of APMs. CHI maintains that this glaring oversight forces eligible clinicians, as well as other key stakeholders and organizations, to conclude that telehealth and remote monitoring do not have a role in APMs. We call on CMS to provide this crucial commentary and insight in the final QPP rule and to advance best practices on how to best utilize digital health innovations in APMs.

Further, the current restrictions of 1834(m) are particularly inappropriate for APMs. We strongly support relieving APMs from the onerous Medicare telehealth restrictions in 1834(m). In a limited set of circumstances, CMS has taken steps to provide relief from section 1834(m)(4)(C) to APMs, demonstration projects, and Innovation Center models. For example, CMS provided this limited relief to Next Generation Accountable Care Organizations (ACOs).[12] In addition, in the Comprehensive Care for Joint Replacement (CJR) Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services, CMS waived the rural geographic requirement and allowed telehealth services to be covered in patients' homes or place of residence.[13]

This rulemaking presents CMS with a golden opportunity to provide APMs with waivered exemptions from all of 1834(m)'s restrictions, to reconcile a policy that caused the Medicare system to utilize a backwards-looking approach to connected health technology. To attract participants to the APM program, less restricted telehealth can be a reward and a competitive advantage. In addition, a waiver would allow APMs to demonstrate the value of connected health technologies in improving access to innovative and efficient care delivery, in rural and urban settings. APM quality and performance measures, alongside other participation requirements, will protect against fraud and Medicare's traditional fee-for-service utilization controls.

Finally, an APM should have the flexibility to use connected health technologies for patients with specific at-risk chronic conditions. In addition to the statutory benefits enjoyed by qualifying APM participants, including the initial 5 percent incentive payment under the PFS, CMS should waive specific payment and program requirements for these participants. In order to help providers utilizing APMs meet statutory requirements to reduce total costs, CMS should exercise its statutory authority under 42 U.S.C. 1315a(d)(1) (in the case of CMMI Models) and 42 U.S.C. 1395jjj(f) (in the case of the Medicare Shared Savings Program) to waive payment and program requirements as appropriate. This would allow for remote monitoring to be used to improve quality while reducing per capita total costs of care. CMS' use of relevant waiver authority to allow payment for remote monitoring services would further enable the participation in and success of APMs.

[12] https://innovation.cms.gov/initiatives/Next-Generation-ACO-Model/.

[13] *Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services*, 80 FR 73273 (Nov. 24, 2015).

V. Conclusion

CHI appreciates the opportunity to submit comments to CMS and urges its thoughtful consideration of the above input. We look forward to the opportunity to further work with CMS and other stakeholders towards realizing the most successful PFS and QPP possible.

Sincerely,

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