ConnectedHealth

September 9, 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: *Comments of the Connected Health Initiative to the Centers for Medicare and Medicaid Services on* Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements *(84 FR 34598)*

Dear Administrator Verma:

The Connected Health Initiative (CHI) appreciates the opportunity to respond to the Centers for Medicare and Medicaid Services (CMS) on its draft payment rates for home health agencies (HHAs) for calendar year (CY) 2020.[1]

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 enhance 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 states, where we seek to advance

[1] Centers for Medicare and Medicaid Services, Medicare and Medicaid Programs, *Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements*, 84 FR 34598 (July 18, 2019) ("Draft CY2020 HHPPS").

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of ACT | The App Association

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responsible pro-digital health policies and laws in areas including reimbursement/payment, privacy/security, effectiveness/quality assurance, U.S. Food and Drug Administration (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 advocate for the increased use of telehealth and remote monitoring across the Department of Health and Human Services (HHS) as well as before other agencies such as the Federal Communications Commission, and the U.S. Congress. CHI is also a current appointed member of the American Medical Association's (AMA) Digital Medicine Payment Advisory Group, an initiative bringing together a diverse cross-section of 15 nationally recognized experts that identifies barriers to digital medicine adoption and proposes 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 mobile health (mHealth) application guidelines that can drive the value these products contribute to healthcare and the confidence that physicians and consumers will have in the quality of these applications 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, can fundamentally improve and transform American healthcare. These tools securely enable the exchange of health information and incorporating patient-generated health data (PGHD) into the continuum of care in a way that is meaningful and actionable results. We urge CMS' review of CHI's aggregation of numerous studies demonstrating the improved outcomes and reduced costs associated with greater use of connected health innovations.[4]

Despite the proven benefits of connected health technology to the American healthcare system, these solutions have traditionally been inhibited by statutory restrictions and CMS regulatory-level policy decisions, among other constraints. As a result, utilization of digital health innovations that could bring both drastically improved beneficiary outcomes as well as immense cost savings have been excruciatingly low. CMS coverage of remote monitoring has been relatively anemic until CY2018, when CPT® Code 99091 was unbundled. The following year (CY2019), CMS took significant steps

[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.

forward in activating and paying for three new RPM codes;[5] further, in the proposed CY2020 Physician Fee Schedule (PFS), a fourth is proposed for activation and payment in CY2020.[6] CMS also ensured that remote patient monitoring (RPM) can be utilized in existing alternative payment models such as Medicare Advantage, confirming RPM's eligibility for inclusion as a basic benefit.

Specific to the Home Health Prospective Payment System (HHPPS), CMS took an important step forward in CY2019 by allowing RPM costs incurred by an HHA for purposes of augmenting the care planning process to be included in allowable administrative costs that are factored into the costs per visit. Such a change ensured that RPM can be utilized on a cost per visit basis when it is used by an HHA to augment the care planning process, and a more realistic HHA Medicare margin calculation. CHI agrees with CMS that RPM will be helpful in (1) augmenting HHA services in the patient's plan of care; (2) enabling HHAs to more rapidly identify changes in a patient's clinical condition and to monitor patient compliance with treatment plans (further enabling more effective and efficient review and appropriate alteration of plans of care); and (3) augmenting home health visits.

CMS also took crucial steps in 2017 to promote flexible use of connected health innovations in the Quality Payment Program (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 incentivizes providers to ensure that any devices they use to collect PGHD do so as part of an active feedback loop. CHI is especially 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

[5] These CPT codes are:

- 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].

[6] For the CY2020 PFS, CMS has proposed to activate and pay 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).

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 approaches, CMS' efforts in continuing to advance a range of connected health innovations that will help American healthcare the improve outcomes and cost savings. It is essential that the wide range of connected health tools and services available today, as well as those in development, be leveraged by HHAs to advance care and lower costs.

III. Input of the Connected Health Initiative on the Proposed CY2019 Home Health Prospective Payment System

CHI offers its views on several provisions in the draft CY2020 HHPPS impacting the use of connected health technologies, particularly remote patient monitoring, considering the priority to advance innovative value-based care solutions while protecting the integrity of the Medicare program:

- CHI strongly urges CMS to align the HHPPS definition of "remote patient monitoring" with that captured in CPT codes that CMS has activated and paid for in the Physician Fee Schedule (e.g., CPT codes 99453, 99454, and 99457). While CMS correctly distinguishes between "remote monitoring" services and "telehealth" in the HHPPS, CMS borrows heavily from CPT code 99091 in defining "remote patient monitoring" as the "collection of physiologic data (for example, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the HHA." CPT code 99091 describes the collection of physiologic data and may not optimally describe remote monitoring as currently furnished as stated by CMS in the 2018 Physician Fee Schedule final rule: "…we believe that activating CPT code 99091 for separate payment under Medicare for 2018 will serve to facilitate appropriate payment for these services in the short term," underscoring how this code and its descriptor do not accurately capture remote patient monitoring elements. Moreover, in the CY2019 PFS, CMS activated and paid for newly created and appropriate remote monitoring codes that provide for the supply of devices; set up and instruction; data collection (attended, unattended with algorithmic alerts, and unattended); transmittal; and report preparation of quantitative results. CHI suggests that CMS, in the HHPPS, contribute to a common definition of "remote patient monitoring" across its beneficiary programs (e.g., consistency with technical CPT codes 99453, 99454, and 99457).

  For example, CMS' insistence on disparate RPM definitions between the HHPPS and the PFS has resulted in HHAs being unable to include RPM as administrative costs associated with visits to a beneficiary's home for the sole purpose of supplying, connecting, or training the patient on the RPM equipment. CMS has not offered any explanation as to why this disparity is in the public interest, and CHI knows of no rationale to justify it.

We therefore urge for CMS to shift away from the definition it adopted in the CY2019 HHPPS, and to align its definition of remote patient monitoring in the CY2019 HHPPS with that utilized in the PFS through CPT codes 99453, 99454, and 99457.

- CHI supports CMS' continued inclusion of RPM expenses incurred by an HHA to augment the care planning process as allowable administrative costs that are factored into the costs per visit. This policy, in place since the beginning of CY2019, ensures that remote patient monitoring is utilized on a cost per visit basis when it is used by an HHA to augment the care planning process, and will result in a more realistic HHA Medicare margin calculation. CHI agrees with CMS that remote patient monitoring will be helpful in (1) augmenting HHA services in the patient's plan of care; (2) enabling HHAs to more rapidly identify changes in a patient's clinical condition and to monitor patient compliance with treatment plans (further enabling more effective and efficient review and appropriate alteration of plans of care); and (3) augmenting home health visits.

  Still, there is a need for CMS to provide key clarifications regarding RPM's use by HHAs which have left HHAs reluctant to undertake RPM for HHPPS beneficiaries. CHI calls on CMS to address these questions and ambiguities in its final CY2020 HHPPS rule by providing more detailed guidance on the use of RPM by HHAs. Further, we call on CMS to explain how uses of RPM technologies by HHAs and Part B eligible caregivers' use of RPM (CPT codes 99453, 99454, 99457, and 994X0) relate. The home health stakeholder community would also benefit immensely from CMS describing its vision for future use of RPM and other connected health technologies for HHPPS beneficiaries.

  And while inclusion of RPM expenses incurred by an HHA to augment the care planning process as allowable administrative costs represents an important step forward for the HHPPS, we urge CMS to acknowledge in its final CY2020 HHPPS rule that the policy change is incremental. The HHPPS must do more to encourage the uptake of RPM by HHAs. We recommend CMS to take any and all steps possible to make further policy changes needed to help HHPPS beneficiaries fully realize improved health outcomes through the responsible use of connected health technologies, which CMS has already acknowledged as a basis for expanded support for RPM in the CY2019 PFS and CY2020 PFS.

- CHI agrees that remotely monitoring patients receiving infusion therapy in their home is integral to providing medical care. CHI supports and commends CMS covering remote patient monitoring services as part of the home infusion therapy services benefit, as well as CMS requiring qualified home infusion therapy suppliers to provide remote monitoring services for continuous assessment, evaluation, response, and an allowance for suppliers to use all available remote monitoring methods available. Further, we call on CMS to clarify that CPT codes 99091 and 99454 (both in place today), as well as 994X0 (proposed for activation and payment in the CY2020 Physician Fee Schedule), may be billed by eligible professionals while their patients receive the home infusion therapy services benefit.
- Regarding program integrity, CHI generally supports measures to avoid waste, fraud, and abuse in the HHPPS. The use of various connected health innovation modalities, including RPM technology, does not inherently mean that remote monitoring will translate to greater waste, fraud, and abuse; to the contrary, program integrity is more easily ensured through data analytics provided by connected health technologies. Therefore, we urge CMS to (1) acknowledge the ability of connected health technologies to improve programmatic waste; and (2) leverage existing and developing program integrity tools and metrics in the HHPPS across its beneficiary programs in a modality-neutral manner, with additional measures being implemented for specific modalities based on demonstrated heightened risks to program integrity specific to modalities.

IV. 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 HHPPS possible.

Sincerely,

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