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: *Comments of the Connected Health Initiative to the Centers for Medicare and Medicaid Services on* Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures (84 FR 34478)

Dear Administrator Verma:

The Connected Health Initiative (CHI) appreciates the opportunity to respond to the Centers for Medicare and Medicaid Services (CMS) on its rule proposing to implement the Radiation Oncology Model (RO Model) and the End-Stage Renal Disease (ESRD) Treatment Choices Model (ETC Model), two new mandatory Medicare payment models under section 1115A of the Social Security Act.[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 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 states, where we seek to advance responsible pro-digital health policies and laws in areas including reimbursement/payment, privacy/security, effectiveness/quality assurance, FDA

[1] Centers for Medicare and Medicaid Services, *Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures*, 84 FR 34478 (July 18, 2019).

regulation of digital health, health data interoperability, and the rising role of artificial intelligence/machine learning 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 bodies such as the U.S. legislative branch. 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 bring 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. The Role of Connected Health Technology in the Success of Existing and Emerging Medicare Payment Models

Data and clinical evidence from a variety of use cases continue to demonstrate how 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 and render meaningful and actionable results. We urge CMS to review CHI's aggregation of numerous studies that demonstrate 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, 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 that could bring both drastically improved beneficiary outcomes as well as immense cost savings has been disconcertingly low. CMS coverage of remote monitoring has been relatively feeble until CY2018 when CPT® Code 99091 was unbundled. The following year (CY2019), CMS took significant steps forward in

[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.

activating and paying for three new remote patient monitoring (RPM) codes;[5] further, in the proposed CY2020 Physician Fee Schedule (PFS), a fourth code has been proposed for activation and payment in CY2020.[6] CMS also ensured utilization of RPM in existing alternative payment models such as Medicare Advantage, where RPM's eligibility for inclusion as a basic benefit has been confirmed.

Further, in the Home Health Prospective Payment System (HHPPS), CMS took an important step forward in CY2019 by allowing RPM costs incurred by a home health agency (HHA) for purposes of augmenting the care planning process to be included in allowable administrative costs that are factored into the cost per visit. Such a change ensured utilization of RPM on a cost per visit basis when 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 has also taken steps 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 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.

The above initial advancements made by CMS with respect to connected health technology are significant, but they do not reduce the critical role that CMS plays (and will play) in exploring new innovations for Medicare and Medicaid. Nor do these

[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).

changes alter the fact that, to date, the efforts of CMS in exploring the benefits of connected health technologies have been insufficient given the immense value provided by these technologies. CHI urges CMS to fully explore these technologies through the RO and ETC Models, building on recent advancements made in other payment rules. CHI commits to assist CMS in bringing its (and states') programs to the forefront of innovation in delivering care to Medicare and Medicaid beneficiaries.

III. CMS Should Embrace Connected Health Technologies' Role in the Success of the Radiation Oncology and End-Stage Renal Disease Treatment Choices Models

Building on the above, CHI offers the following specific input on CMS' proposed approach to implementing the RO and ETC Models:

- CMS' omission of any discussion of connected health technology in the proposed rule text represents an oversight and a disservice to Medicare beneficiaries. Connected health technologies are poised to make immense contributions to the success of both models. For example, interoperable connected health technologies can (and should) provide great value in the care of patients with chronic kidney disease through dialysis to kidney transplant, providing a much-needed flow of patient data to assist with benchmarks or outcomes. As a further example, telehealth visits can permit much more efficient care management by a nephrologist of patients in stages four and five of chronic kidney disease to delay the start of dialysis or get a kidney transplant before the native kidneys completely fail, particularly when the patient is in a location far away from the location of the nephrologist's practice. Yet, without any discussion or endorsement of such connected health technologies by CMS, caregivers and other key stakeholders are left to "round down" and conclude that they do not have a role in the RO and ETC Models.

  We strongly urge CMS to ensure that its final rule contains robust discussion and endorsement of the use of connected health tools in the success of the RO and ETC models and to include guidance on how Model participants should utilize connected health technologies. This crucial commentary and guidance in the final version of the rule will contribute to the success of the RO and ETC Models. Furthermore, it will advance the public interest through improved patient outcomes, enhanced engagement in care by patients, and reduced programmatic costs. Making this improvement to its rules for the RO and ETC Models would also bring them into alignment with CMS' endorsement of connected health technologies in other key payment programs, including the PFS, QPP, HHPPS, and Medicare Advantage.
- CHI has often expressed concern with the statutory burdens that limit the range of remote access technologies that may be offered and have long hindered progress in the connected health space. A notable example, Section 1834(m) of

the Social Security Act, has resulted[7] in arduous restrictions on telehealth services with no discernible connection to serving a public good. We urge CMS to utilize every opportunity to remove barriers to the use of advanced technologies within a connected healthcare system, even if just for "telehealth" (which is synchronous voice and video only under Medicare rules). The Center for Medicare and Medicaid Innovation already has the authority in 42 U.S.C. § 1315a(d)(1) to waive 1834(m)'s burdensome restrictions on telehealth in order to adequately explore, track, and release data in a timely fashion.

In addition to 1834(m)'s restrictions, co-pays represent another key reason for telehealth's disconcertingly low utilization in Medicare. Therefore, we oppose CMS' conclusion that it is not necessary to waive the co-insurance requirement for the Kidney Disease Education (KDE) benefit and certain telehealth requirements to allow the KDE benefit to be delivered via telehealth for beneficiaries outside of rural areas and other applicable limitations on telehealth originating sites for purposes of testing the ETC Model. CHI strongly encourages CMS to waive such KDE benefit requirements, which have no modern relationship to the public interest.

- Regarding program integrity, CHI generally supports measures to avoid waste, fraud, and abuse in the RO and ETC Models. 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 that connected health technologies provide. Therefore, we urge CMS to acknowledge (1) the ability of connected health technologies to improve programmatic waste; and (2) that existing and developing program integrity tools and metrics in the RO and ETC Models should be leveraged in a modality-neutral manner, with additional measures being implemented for specific modalities based on demonstrated heightened risks to program integrity specific to modalities.

[7] *See* 42 CFR § 410.78.

IV. Conclusion

CHI appreciates the opportunity to submit comments to CMS and urges its thoughtful consideration of the above input.

Sincerely,

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