April 20, 2020

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: *Connected Health Initiative Recommendations for CY2021 Revisions to Payment Policies under the Physician Fee Schedule and Quality Payment Program*

Dear Administrator Verma:

The Connected Health Initiative (CHI) appreciates the opportunity to provide input and suggestions to the Centers for Medicare and Medicaid Services (CMS) on its forthcoming proposed changes to the Medicare Physician Fee Schedule (PFS) and the Quality Payment Program (QPP) for Calendar Year 2021. CHI proposes a variety of 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 dedicated to connected health technologies that improve health outcomes and reduce costs. We seek to advance 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 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.[1] 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.[2]

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," "remote physiologic monitoring," "communication technology-based services," 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 devices, software as a medical devices, mobile medical apps, and cloud-based portals and dashboards, are able to fundamentally improve and transform American healthcare.[3] 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, there is low utilization of digital health innovations prior to the COVID-19 public health emergency, despite the ability to drastically improve beneficiary outcomes as well as to generate immense cost savings. Further, CMS should seek to enable the use of health data and patient-generated health data (PGHD) through AI.

There are varied applications of AI systems in health care such as research, health administration and operations, population health, practice delivery improvement, and direct clinical care. Payment and incentive policies must be in place to invest in building infrastructure, preparing personnel and training, as well as developing, validating, and maintaining AI systems with an eye toward ensuring value. Payment policies must incentivize a pathway for the voluntary adoption and integration of AI systems into clinical practice as well as other applications under existing payment models.

The need for rapid modernization of Medicare incentives is more imperative in light of the ongoing COVID-19 crisis in the United States. 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' continued efforts to advance the range of connected health innovations that will help American healthcare improve outcomes and cost savings are essential.

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

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

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

III. Connected Health Initiative Recommendations for the Proposed CY2021 Physician Fee Schedule

Building on the above, CHI urges CMS to include the following in its proposed CY2021 PFS:

a. CMS Should Activate and Pay for Automated Point-of-Care Retinal Imaging

Based on a proposal from the American Academy of Ophthalmology, AMA's Current Procedural Terminology (CPT) Editorial Panel has accepted a new category 1 CPT code for automated point-of-care retinal imaging, 9225X, which permits billing for the use of FDA-cleared autonomous AI systems that detects diabetic retinopathy.[4] CHI strongly recommends that CMS activate this CPT code and value it consistent with the Relative Value Scale Update Committee's (RUC) recommendation. Specifically, we suggest that the code be reimbursed at a value of $55 ($34 for the augmented intelligence (AI) system, $21 for the technical component). It is vital that this code be reimbursed at an appropriate value to encourage continued AI innovation.

b. CMS Guidance for Remote Physiologic Monitoring (CPT Codes 99453, 99454, 99457, and 99458)

CHI notes its strong support for CMS' activation of and payment for four CPT codes developed by the AMA's CPT Editorial Panel to address remote physiologic monitoring: 99453, 99454, 99457, and 99458.

We appreciate CMS' acknowledgment that questions remain as to use of RPM codes and the meaning of key terminology ("physiologic parameters," "digitally transmitted data," etc.), but support an ongoing and thoughtful approach to provide clarity on RPM by enlisting the assistance of the FDA Center for Digital Health, associations such as CHI, and medical societies which are on the frontline of representing medical professionals who are implementing such care. We would support a deliberate, inclusive, and collaborative approach to develop any guidance on RPM codes.

Further, in its recent COVID-19 Interim Rule, CMS provided certainty that RPM codes can be billed for acute conditions, as well as chronic conditions, on a permanent basis. CHI strongly supports this important clarification and requests an update in the PFS be to align with this change.

[4] https://www.ama-assn.org/system/files/2019-08/may-2019-summary-panel-actions.pdf.

c. CMS Should Request Data and Feedback on the Range of Digital Health Innovations in Addressing the COVID-19 Public Health Emergency, and on Making COVID-19 Public Health Emergency Allowances for Digital Health Permanent

CHI acknowledges the many steps CMS took to remove existing barriers to the use of digital health tools and services in addressing the COVID-19 public health emergency. We believe that it is crucial for CMS to collect as much data and experiences on the impact of these tools during the public health emergency and examine through its draft CY2021 PFS whether such barriers continue to serve the public interest. CMS can take an important step down this path by requesting data and feedback on the use of digital health tools (telehealth, communications-based technology services (CBTS), remote physiologic monitoring (RPM), and others) from the stakeholder community. The input received should feed into a broad examination of whether the public health emergency allowances made for digital health should be made permanent, whether through existing or future authorities from Congress.

d. CMS Should Provide Guidance for the Use of Digital Health in Alternative Payment Models

Through the CY2021 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 such as AI, and enhanced data analytics. 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.

CMS should explicitly endorse the use of digital medical technologies' in Alternative Payment Models (APMs). CHI supports Congress's goal of realizing innovative APMs and continues to work with stakeholders to find eligible alternatives to Merit-based Incentive Payment System (MIPS). APMs, with their financial and operational incentives, should demonstrate the best uses of digital health tools. To date, CMS has not discussed digital health tools' key role in the success of APMs which should have the flexibility to use connected health technologies for patients with specific at-risk chronic conditions. 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.

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 PFS and QPP possible.

Sincerely,

Brian Scarpelli
Senior Global Policy Counsel

Alexandra McLeod
Policy Counsel

Connected Health Initiative
1401 K St NW (Ste 501)
Washington, DC 20005