August 21, 2017

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5517-P
P.O. Box 8013
Baltimore, Maryland 21244-8013

RE: Comments of the Connected Health Initiative regarding *Medicare Program; CY 2018 Updates to the Quality Payment Program* (CMS-5522-P)

I. Introduction and Statement of Interest

The Connected Health Initiative (CHI) writes to provide comments to the Center for Medicare and Medicaid Services (CMS) in response to its proposed payment and policy changes to the Quality Payment Program (QPP).[1] This rulemaking provides a crucial opportunity to improve frameworks for the Merit-based Incentive Payment System (MIPS) for MIPS-eligible clinicians or groups under the Physician Fee Schedule (PFS) as well as incentives for participation in certain alternative payment models (APMs) and criteria for use by the Physician-Focused Payment Model Technical Advisory Committee (PTAC) in making recommendations on physician-focused payment models.

CHI, convened by ACT | The App Association, is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of remote patient monitoring (RPM), and support an environment in which patients and consumers can see improvement in their health.[2] This coalition of leading mobile health companies and stakeholders urges Congress, the Office of the National Coordinator for Health Information Technologies (ONC), the Food and Drug Administration (FDA), the Center for Medicare & Medicaid Services (CMS), and other regulators, policymakers, and researchers to adopt frameworks that encourage mobile health innovation and keep sensitive health data private and secure.

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[1] *Medicare Program; CY 2018 Updates to the Quality Payment Program*, 82 Fed. Reg. 30010 (June 30, 2017).

[2] http://connectedhi.com.

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

A consistently growing body of evidence demonstrates that the wide array of connected health technologies available today – whether called "telehealth," "mHealth," "store and forward," "remote patient monitoring," or other similar terms – improve patient care, reduce hospitalizations, help avoid complications, and improve patient engagement, particularly for the chronically ill.[3] These tools, which include wireless health products, mobile medical device data systems, telemonitoring converged medical devices, and cloud-based patient portals, are revolutionizing the medical care industry by allowing the incorporation of patient-generated health data (PGHD) into the continuum of care. To illustrate the effectiveness of these diverse solutions, we have appended to this comment a non-exclusive list of studies we strongly urge CMS to review.

Despite the proven benefits of connected health technology to the American healthcare system, these solutions are largely ignored by the current Medicare system. For example, Medicare spending on telemedicine approached nearly $30 million in 2016, representing a negligible fraction of the $588 billion that Medicare spent overall.[4] Moreover, remote monitoring technologies are unreasonably restrained by the CMS decision[5] to bundle monitoring with other codes, resulting in a lack of reimbursement for remote monitoring solutions.[6]

CMS has relatively recently begun to take steps to better utilize connected health technology in several components of Medicare, such as for the Medicare Shared Savings Program. However, the protracted pace at which the system is being altered to incorporate connected technologies leaves the Medicare system, and the millions of Americans it serves, with outdated, inefficient, and ineffective treatment methods.

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[3] *See* Hindricks, et al., The Lancet, Volume 384, Issue 9943, Pages 583 - 590, 16 August 2014 doi:10.1016/S0140-6736(14)61176-4.

[4] http://www.politico.com/tipsheets/morning-ehealth/2017/08/10/telemedicine-money-jumping-221812.

[5] We appreciate, however, that CMS has called for comment on unbundling remote patient monitoring codes in the proposed Medicare Physician Fee Schedule and we will provide comments under separate cover.

[6] For example, Medicare considers CPT Code 99091 ("Physician/health care professional collection and interpretation of physiologic data stored/transmitted by patient/caregiver") as "bundled" into payment for other basic services (e.g., an office visit provided the same day or other services incident to the service provided) and therefore does not currently make separate payment for 99091.

With the passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Congress has very clearly directed CMS to evolve the Medicare program to maximize care quality over quantity, arguably requiring the system to embrace enhancements like connected health technology. Through this rulemaking, CMS has an unprecedented opportunity to improve the American healthcare system by leveraging a wide array of connected health technologies – those available today, as well as future innovations.

We urge CMS to utilize every opportunity available to move towards a truly connected continuum of care through its implementation of MACRA. CHI provides specific input below on key opportunities for CMS under this rulemaking.

III. CHI Supports CMS' Acceptance of Connected Health Technology in the MIPS Clinical Practice Improvement Activities

We continue to support the overall approach by CMS to the 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.[7]

By specifically calling for an inventory that "shall include activities such as…remote monitoring or telehealth" under the Care Coordination performance subcategory,[8] 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.

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[7] 82 FR p. 51-52.

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

In its rulemaking, CMS requests input on how health IT, either in the form of an electronic health record (EHR) or as a supplemental module, could better support the feedback related to participation in the QPP and quality improvement in general.[9] We believe that the CMS evaluation must reflect the fact that remote monitoring 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, which contribute to the improvement of beneficiary health outcomes by reducing healthcare disparities in support of the feedback loop related to Quality Payment Program participation. A diversity of application program interfaces (APIs) are available to assist in bringing PGHD into the continuum of care, which will be enabled by appropriate steps by HHS to ensure interoperability. Further, we urge CMS to consider shifting away from rigidly requiring the use of certified EHR technology (CEHRT) to an outcomes-based approach that would permit the responsible use of non-CEHRT by MIPS caregivers. 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 while also measuring such improvement."[10]

In response to specific IA changes and additions proposed by CMS:

- CHI supports the CMS proposal to provide an Advancing Care Information (ACI) Program bonus for glycemic-referring services performed in population management.[11] We strongly encourage CMS to utilize every opportunity available to facilitate the incorporation of PGHD and/or data from non-clinical settings into the continuum of care.
- CHI supports the new proposed IA_CC_XX, "Primary Care Physician and Behavioral Health Bilateral Electronic Exchange of Information for Shared Patients," which would facilitate care coordination through support for primary care and behavioral health practices using the same EHR system for shared patients or have an established bidirectional flow of primary care and behavioral health records.[12] CHI envisions interoperability between systems facilitated through open APIs, and urges CMS to vigilantly promote interoperability and competition through this and other IAs.

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[9] 82 FR p. 469.

[10] 82 FR p. 51-52.

[11] 82 FR p. 178-181.

[12] 82 FR p. 1038.

- CHI supports the new proposed IA_PM_XX, “Provide Clinical-Community Linkages,” which would facilitate care coordination through support for individual MIPS-eligible clinicians or groups that coordinate with primary care and other clinicians. The proposal would engage and support patients, promote the use of health information technology, and employ quality measurement and improvement processes.[13] We urge that this IA provide these clinicians with maximum flexibility to meet the goals of this IA.
- CHI strongly supports proposed changes to IA_BE_14, “Engage Patients and Families to Guide Improvement in the System of Care,” which CMS would use to support engagement with patients and families to improve the system of care. These changes would leverage digital tools for ongoing guidance and assessments outside the encounter, including the collection and use of patient data for return-to-work and patient quality of life improvement.[14] We believe that CMS’ proposal to require platforms or devices eligible for this IA, such as consumer-grade devices that capture PGHD, be endorsed by care teams to provide clinicians with much-needed flexibility. We applaud CMS’ rationale that “the use of digital technologies that provide either one-way or two-way data between MIPS-eligible clinicians and patients is valuable, including for the purposes of promoting patient self-management, enabling remote monitoring, and detecting early indicators of treatment failure.”[15] We agree with CMS’ proposal to change the weight of this IA from “medium” to “high.”[16]

[13] 82 FR p. 1039.

[14] 82 FR p. 1044-45.

[15] 82 FR p. 1045.

[16] *Id.*

- CHI supports proposed changes to IA_BE_15, “Engagement of Patients, Family, and Caregivers in Developing a Plan of Care,” in which CMS would remove the requirement that the EHR technology be certified for engagement with patients, family, and caregivers in developing a plan of care and prioritizing their goals for action in the EHR.[17] Consistent with our general views above, removing this restriction would provide clinicians necessary flexibility to accomplish their goals, which are increasingly disconnected from the onerous requirements and costs associated with the CEHRT designation.
- CHI supports proposed changes to IA_BMH_7, “Implementation of Integrated Patient Centered Behavioral Health Model,” which would clarify that the list of chronic illnesses to which IA applies for the management of behavioral and mental health is not limited to the examples noted in the IA.[18] These changes to the IA are critical in order to realize their full potential, and ensure clinicians are not limited to specific chronic conditions, to the detriment of American Medicare beneficiaries who suffer from other conditions. We support changes to the MIPS program that provide this very important guidance to clinicians.
- CHI supports proposed changes to IA_CC_1, “Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop,” which remove the requirement that the EHR technology be certified for care coordination in the performance of regular practices. These practices include providing specialist reports back to the referring individual, MIPS-eligible clinician, or group to close the referral loop, or where the referring individual, MIPS-eligible clinician, or group initiates regular inquiries to specialist for specialist reports which could be documented or noted in the EHR technology.[19] Consistent with our general views above, removing this restriction will provide needed flexibility to help clinicians accomplish their goals.
- CHI supports proposed clarifications IA_PM_2, “Anticoagulant Management Improvements,” to provide clarity as to what actions qualify for this IA.[20]

[17] 82 FR p. 1045-46.

[18] 82 FR p. 1046-47.

[19] 82 FR p. 1047.

[20] 82 FR p. 1051-52.

IV. The Advancing Care Information (ACI) Program Should Facilitate Practitioners to Flexibly Attain Relevant and Interoperable Data

The MACRA ACI program provides CMS with an important opportunity to vastly improve the Meaningful Use program, the precursor to the ACI program. We believe that the ACI program should utilize an outcome-based approach that encourages practitioners to incorporate PGHD flexibly into their activities. While patient access to data is important, clinicians also need interoperable data from a variety of sources to integrate seamlessly into their work flow. Third-party applications will play a major role in satisfying this need to secure data quality, and to ensure physicians receive the most relevant data in a useable format, when and where they need it.

CMS has already taken steps to support the interoperable exchange of health information by including API utilization within its view, download, and transmit (VDT) criteria, as well as within related measures regarding secure messaging and PGHD. CMS has included this objective into its proposed ACI program.[21] CHI supports PGHD's inclusion in the ACI program's certification criteria which is consistent with the direction of HHS health technology policy, such as the ongoing ONC effort to develop a PGHD framework.[22] We support the linkage of various IAs with key ACI measures, namely "Patient Generated Health Data or Data from Non-Clinical Settings" and "Patient Generated Health Data." We broadly support CMS leveraging ACI program measures to continue to create alignment between ACI, IA, and the quality component of MIPS.

We urge CMS, as well as ONC, to ensure that providers utilizing connected health solutions are not encouraged to limit the innovative features of their products and services because of overly-prescriptive ACI program requirements. ACI program measures should therefore provide flexibility for physicians and other clinicians to select the most effective approaches for their patients via outcome-based measures that are agnostic to the processes used to meet those goals. For example, CMS is proposing to increase flexibility in the use of EHRs by allowing physicians to use the 2014 or 2015 edition of CEHRT certification, or a combination of both, in the 2018 performance year. CHI supports this proposal as it will provide needed flexibility, particularly for small practices. This policy would provide more time for health IT vendors, particularly those who lend to smaller developers, to develop innovative services tailored to medical specialties. The policy would ultimately avoid forcing these specialists to select less ideal vendors because of timeframe restrictions.

Finally, CHI supports CMS' proposal to offer a bonus for the use of 2015 edition EHRs. The adoption and implementation of a new EHR, or the upgrade from one edition to another, requires considerable resources and time. This bonus will help recognize

[21] 81 FR 28227.

[22] https://www.healthit.gov/policy-researchers-implementers/patient-generated-health-data-pghd.

caregivers' investment in health IT and encourage the adoption of newer and more innovative technologies.

V. 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. Such a step would also be consistent with CMS endorsement of telehealth and remote monitoring in MIPS.

Further, the current restrictions of 1834(m) are particularly inappropriate for Medicare services. 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).[23] 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.[24]

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

[24] *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).

In the draft QPP rulemaking, CMS states:

> The study of the potential value and efficacy of telehealth and remote patient monitoring has become more prevalent in recent years as technology has enabled greater utilization of these services. Studies and case studies from health systems have shown value in using telehealth platforms for activities such as e-visits, and remote patient monitoring, as well as for higher intensity care through real-time videoconferencing, particularly to enable older adults to receive care more rapidly from their homes and with minimal burden.[25]

While this statement, as well as CMS' commitment to allow the Next Generation Model provide flexibility to ACOs to use telehealth services to improve access to appropriate care for ACO beneficiaries,[26]is encouraging, 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 five 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 – including the unbundling of CPT Code 99091 – would enable the success of APMs.

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[25] 82 FR p. 749-750.

[26] 82 FR p. 750.

VI. Conclusion

We appreciate the opportunity to submit comments to CMS on this matter and look forward to the opportunity to further work on the QPP. Thank you for your consideration.

Sincerely,

Brian Scarpelli
Senior Policy Counsel

Joel Thayer
Associate Policy Counsel

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