ConnectedHealth

June 25, 2018

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

Re: Comments of the Connected Health Initiative Regarding the Centers for Medicare and Medicaid Services Regarding *Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims* (CMS-2018-0046)

Dear Administrator Verma:

We write on behalf of ACT | The App Association's Connected Health Initiative[1] (CHI) to the Centers for Medicare and Medicaid Services (CMS) regarding proposed revisions to the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals.[2]

CHI is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of remote monitoring (RM), and support an environment in which patients and consumers can see improvement in their health. This coalition of leading mobile health companies and stakeholders urges Congress, 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.

[1] http://connectedhi.com.

[2] 83 FR 20164.

CMS' proposed revisions to the Medicare hospital IPPS for operating and capital-related costs of acute care hospitals comes at an important time. Electronic health information and educational resources are critical tools that empower patients to engage in their own care. A truly interoperable connected healthcare system includes patient engagement facilitated by asynchronous (also called "store-and-forward") technologies (ranging from medical device remote monitoring products to general wellness products) with open application programming interfaces (APIs) that allow the integration of patient-generated health data (PGHD) into electronic health records (EHRs). Data stored in standardized, interoperable formats facilitated by APIs provides analytics as well as near real-time alerting capabilities. The use of platforms to manage data streams from multiple and diverse sources will improve the healthcare sector, and help eliminate information silos, data blocking, and barriers to patient engagement.

Interoperability must not only happen between providers, but also between RM products, medical devices, and EHRs. A great example of interoperability between systems, devices, and networks can be seen in the communications technology industry, which has flourished globally. Systems should be widely interoperable in providing useable data from various sources, not just from certified EHR technology (CEHRT) and CEHRT systems. There must also be an incentive to communicate and pass information from one party to another. We also note that the Medicare Access and CHIP Reauthorization Act[3] (MACRA) provides that incentive in a value-based healthcare environment – one which engages patients, reduces costs, and documents quality metrics.

Remote monitoring of PGHD is integral to the future of the American healthcare system. The demonstrated benefits of RM services include reduced hospitalizations and cost, avoidance of complications, and improved care and satisfaction, particularly for the chronically ill.[4] The Department of Veterans Affairs provides a compelling use case for the use of virtual chronic care management, which ultimately resulted in a substantial decrease in hospital and emergency room visits.[5] Emerging technologies like telemedicine tools, wireless communication systems, portable monitors, and cloud-based patient portals that provide access to health records are revolutionizing RM and asynchronous technologies.[6] Healthcare providers will also benefit from the potential of RM's cost savings. A recent study predicted the use of RM services will help save $36 billion globally by the end of 2018, with North America accounting for 75 percent of

[3] Pub. L. 114-10 (2015).

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

[5] Darkins, Telehealth Services in the United States Department of Veterans Affairs (VA), *available at* http://c.ymcdn.com/sites/www.hisa.org.au/resource/resmgr/telehealth2014/Adam-Darkins.pdf.

[6] The global wearable medical devices market is expected to progress from US$2.73 bn in 2014 to US$10.7 billion by 2023, predicted to progress at a 16.40% CAGR from 2015 to 2023. See http://www.medgadget.com/2016/05/global-wearable-medical-devices-market-to-reach-us10-7-bn-by-2023-as-increasing-incidence-of-chronic-pain-creates-strong-customer-base.html.

those savings.[7] RM has the potential to positively engage patients dealing with chronic and persistent diseases to improve the management of such conditions.

We believe CMS shares CHI's vision of a seamless and interoperable healthcare ecosystem that leverages the power of PGHD and can be realized through the trusted framework, and we strongly encourage CMS to ensure that its efforts prioritize data generated by patients outside of the traditional care setting. CMS has recently advanced several important changes to the future MACRA-driven Medicare system, which will permit caregivers to incorporate PGHD into how they coordinate care and engage with beneficiaries.[8] CMS' revisions to the hospital IPPS should build upon these advancements and further augment the ability to bring PGHD into the continuum of care.

Based on the above, CHI offers the following specific comments on CMS' proposed revisions to the hospital IPPS:

- CHI supports changing the name of the Medicare & Medicaid EHR Incentive Based Program to the Medicare and Medicaid Promoting Interoperability Programs. We agree that this name is appropriate in that it better describes the purpose of the program and will help the stakeholder community pivot away from some legacy issues with the Meaningful Use program.
- We urge CMS to make compliance burdens for Promoting Interoperability 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. Further, CHI generally supports proposed changes to the Promoting Interoperability scoring regime and measures proposed with increased flexibility and lower compliance burdens in mind. Such changes 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 as well as the MACRA-driven Merit-based Incentive Payment System (MIPS) which provides strong incentives for the use of remote monitoring technology through certain Improvement Activities the CHI strongly supports. CMS' steps to revise the hospital IPPS generally should be made in alignment with key pro-remote monitoring changes to these important programs and others.

[7] Juniper Research, *Mobile Health & Fitness: Monitoring, App-enabled Devices & Cost Savings 2013-2018* (rel. Jul. 17, 2013), *available at* http://www.juniperresearch.com/reports/mobile_health_fitness.

[8] http://www.connectedhi.com/blog/2018/1/2/recognition-reimbursement-results-why-2017-was-a-win-for-connected-health.

- CHI specifically supports various proposed Promoting Interoperability 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.[9]
- CMS has proposed to eliminate the "Coordination of Care through Patient Engagement" objective and all associated measures which include secure messaging, use of patient generated data, and the view, download or transmit measure. CHI understands that such a change may be appropriate in CMS' rules but urges CMS to take all practicable steps to advance the use of PGHD collected via remote monitoring into the American healthcare system widely including using APIs. We are committed to working with CMS and all other stakeholders to introduce new technology-driven efficiencies into care that will save costs and improve care.

- 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 National Coordinator for Health Information Technology (ONC) is currently developing a Trusted Exchange Framework and Common Agreement (TEFCA) to advance interoperability, which the CHI has provided its detailed input on;[10] further, an information blocking rulemaking must be advanced by ONC at some point. We urge CMS to ensure its approach aligns with ONC's (as well as other agencies) and to minimize compliance burdens on affected stakeholders.
- CHI reiterates our concern with, and lack of confidence in, any presumption that the 2015 ONC CEHRT standards will facilitate seamless interoperability. We also note that the U.S. Core Data for Interoperability (USCDI), which CHI has provided comments on,[11] is not yet been finalized and will be voluntary.

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

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

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

- CHI strongly supports incentives to ensure the secure exchange of information. We do, however, urge that reporting requirements present as low a burden as possible and that the new CMS rules do not have the effect of incentivizing taxing 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 HIPAA, CHI notes its appreciation for CMS' work with HHS' Office of Civil Rights to align the Promoting Interoperability 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 Promoting Interoperability 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.

We appreciate the opportunity to submit comments to CMS on this matter and look forward to the opportunity to meet with you and your team to discuss these issues in more depth. Thank you for your consideration.

Sincerely,

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