ConnectedHealth

May 10, 2018

Mr. Gil Alterovitz
Presidential Innovation Fellow
The White House
1800 G Street, NW
Washington, District of Columbia 20006

Dear Mr. Alterovitz:

ACT | The App Association's Connected Health Initiative (CHI) represents a broad consensus of healthcare and technology leaders that seek a policy environment that encourages the use of connected health innovations and supports an environment in which patients and consumers can see improvement in their health. CHI works with Congress, the Department of Health and Human Services and other regulators, policymakers, and researchers to create an environment that supports innovation that improves consumer and patient health outcomes in mobile health technologies while keeping sensitive health data private and secure. Our members' products will enable the American healthcare system to improve patient care and outcomes, lower healthcare costs, and support American prosperity and job growth.

We appreciate the administration's request for ideas on current steps it can take to support the use of connected health technology without the need for congressional action or development of new burdensome regulations. As a representative of the connected health community, CHI has identified numerous actions the Administration can take in this vein. Appended to this letter, we offer a non-exhaustive list of key recommendations that we urge you to consider, provided alphabetically by agency name. We welcome the opportunity to discuss our views in more detail.

Connected health innovations are essential tools to improve healthcare for all Americans while reducing rising healthcare costs. We appreciate your attention to these requests and look forward to collaborating on this vital issue.

Sincerely,

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Centers for Medicare and Medicaid Services (CMS)

The Centers for Medicare and Medicaid has noted[1] that connected health innovations including telehealth and remote monitoring (RM) services enabled by innovative technologies improve healthcare outcomes and secure significant cost savings.[2,3] The following examples prove the benefits of these innovations:

- Numerous studies have demonstrated that remote monitoring services improve healthcare, reduce hospitalizations, help avoid complications, and improve satisfaction, particularly for the most chronically ill and patients with high healthcare costs.[4] Prominent examples include:
    - Flagstaff Medical Center found that by implementing a remote heart failure monitoring solution six months prior to its program enrollment (as opposed to after the program enrollment), they decreased the average number of hospitalizations by 42 percent, from 3.3 to 1.9 patient admissions. They reduced the average number of days hospitalized by 64 percent, from 14.2 to 5.2 days, as well as the average total charges by 67 percent, from $138,600 to $44,673. They found comparably significant reductions when they implemented the solution 30 and 90 days before the program.[5]
    - CHRISTUS Health reduced the average cost for congestive heart failure readmissions from $12,937 to $1,231 after implementing a remote monitoring system.[6]

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[1] CMS, *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) at 146-152 (CMS CY2018 PFS). *See also* CMS, *MLN Matters: Summary of Policies in the Calendar Year (CY) 2018 Medicare Physician Fee Schedule (MPFS) Final Rule, Telehealth Originating Site Facility Fee Payment Amount and Telehealth Services List, and CT Modifier Reduction List* (2018), *available at* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM10393.pdf#page=3.

[2] http://www.thirdway.org/report/make-telehealth-an-easy-way-for-patients-to-get-care

[3] http://cchpca.org/research-catalogues

[4] *See, e.g.*, Hindricks, et al., The Lancet, Volume 384, Issue 9943, Pages 583 - 590, 16 August 2014, doi:10.1016/S0140-6736(14)61176-4 (http://bit.ly/2p01URM). *See also* U.S. Agency for Healthcare Research and Quality ("AHRQ") Service Delivery Innovation Profile, Care Coordinators Remotely Monitor Chronically Ill Veterans via Messaging Device, Leading to Lower Inpatient Utilization and Costs (last updated Feb. 6, 2013), *available at* https://innovations.ahrq.gov/profiles/care-coordinators-remotely-monitor-chronically-ill-veterans-messaging-device-leading-lower.

[5] Riley, W.T., Keberlein, P., Sorenson, G. et al, Program evaluation of remote heart failure monitoring: healthcare utilization analysis in a rural regional medical center. Telemed J E Health. 2015;21:157–162.

[6] *See* Use Case Study: Christus Health –Remote Patient Monitoring Solution, St. Michael Health System Expansion Program. HIMSS 2014 (demonstrating a return on investment of $9.91 per $1.00 invested in RMRM and reduced costs over time), *available at* http://www.himss.org/ResourceLibrary/genResourceDetailPDFReg.aspx?ItemNumber=22361.

- The University of Virginia's (UVA) remote monitoring program for patients with certain chronic conditions decreased readmissions by 37 percent and saved the UVA Medical Center $500,000 in annualized Medicare costs.[7]

- The Veterans Administration (VA) found that using home telehealth reduced bed days of care by 59 percent, reduced hospital admissions by 35 percent, and saved $1,999 per year per patient.[8]
- A study[9] examined the impact of the Health Buddy Program, a care coordination approach that integrates a telehealth tool with care management for chronically ill Medicare beneficiaries. Patients who used the Health Buddy program experienced spending reductions between 7.7 and 13.3 percent, or $312 to $542 per quarter.
- One study[10] found the average estimated cost of a telehealth visit is between $40 and $50, compared to the $136 to $176 average estimated cost of for in-person acute care. In addition, the study found that patient issues were resolved during the initial telehealth visit an average of 83 percent of the time. Telehealth visits also saved an estimated $126 in commercial insurance and $45 in Medicare costs. These savings were a result of fewer emergency room visits, and for commercial insurance, a lower rate of reimbursement for telehealth.
- A recent meta-review[11] analyzed 14 studies regarding the impact of telemedicine in the management of three chronic diseases: congestive heart failure, stroke, and chronic obstructive pulmonary disease (COPD). The review found beneficial results from telehealth and remote monitoring, particularly in reductions in the use of service (i.e., hospital admissions/readmissions, length of hospital stay, and emergency department visits).

[7] University of Virginia data, "UVA-C3 executive summary – 8.25.15"

[8] Darkins A. Telehealth Services in the United States Department of Veterans Affairs (VA). 2014. PowerPoint presentation accessed at http://c.ymcdn.com/sites/www.hisa.org.au/resource/resmgr/telehealth2014/adam-darkins.pdf on December 7, 2015.

[9] Baker LC, Johnson SJ, Macaulay D, Birnbaum H. Integrated Telehealth and Care Management Program For Medicare Beneficiaries With Chronic Disease Linked To Savings. Health Affairs. September 2011. Vol. 30, No. 9, 1689-1697.

[10] Yamamoto D. Assessment of the Feasibility and Cost of Replacing In-Person Care with Acute Care Telehealth Services. December 2014. Accessed at http://www.connectwithcare.org/wp-content/uploads/2014/12/Medicare-Acute-Care-Telehealth-Feasibility.pdf on December 8, 2015.

[11] Bashshur RL, Shannon GW, Smith BR. The Empirical Foundations of Telemedicine Interventions for Chronic Disease Management. Telemedicine and e-Health. Vol. 20, No. 9, September 2014.

Despite the above, Medicare provided just $13.9 million for telehealth reimbursements in 2014, which included $12,482,270 for provider fees at the distant site (location of the provider) and $1,452,160 for originating site fees (location of the patient).[12] Thus, the payment for telehealth is paltry compared to overall Medicare spend. Although Medicare had covered a very limited number of remote patient monitoring services, the overall spend was also limited.

Regarding telehealth, which in Medicare includes only live two way audio visual calls, Section 1834(m) of the Social Security Act allows for the payment of such services.[13] Still, there remain numerous restrictions to payment.[14] These include:

- Originating site restrictions - the patient may only receive services in certain locations, like a physician's office, rural health clinic, or hospital;
- Geographic restrictions - the patient must be in a rural Health Professional Shortage Area (HPSA) either outside of a Metropolitan Statistical Area (MSA) or in a rural census tract, or in a county outside of a MSA;
- Limitations on the providers that may furnish telehealth services - Medicare-defined physicians and practitioners may provide these services; however, physical or occupational therapists may not;
- Limitations on store-and-forward technologies - asynchronous "store-and-forward" technology is currently only permitted in federal telehealth demonstration programs conducted in Alaska or Hawaii;
- Restrictions of telehealth coverage to specific Current Procedural Terminology® (CPT) codes specified by HHS in an annual process;

Until January 1, 2018, CMS reasonable reimbursement was extremely limited for remote monitoring – including store-and-forward and other asynchronous technologies – of biometric data. However, in its CY2018 Physician Fee Schedule (PFS), CMS "unbundled," or provided separate payment for, Current Procedural Terminology® (CPT) Code 99091, which governs "physician/health care professional collection and interpretation of physiologic data stored/transmitted by patient/caregiver." This action allows reimbursement for doctors incorporating patient generated health data into their practice and treatment efforts and serves as an incredibly important step towards unlocking the potential of connected health technology to improve American healthcare.

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[12] http://ctel.org/2015/05/cms-medicare-reimburses-nearly-14-million-for-telemedicine-in-2014/

[13] While "interactive telecommunications systems" are not defined in any relevant part of the Social Security Act, CMS chose to define "interactive telecommunications systems" in its 2001 Physician Fee Schedule final rulemaking to include at a minimum, audio and video equipment that permits real time consultation between the patient and physician, or practitioner at the distance site. *See* 66 Fed. Reg. 55, 281 (Nov. 11, 2000).

[14] *See* 42 CFR § 410.78.

To shift to a value-driven approach, the Medicare system must leverage the wide array of advanced connected health technology solutions available today, and those to be developed in the future. We believe the following items are within CMS' existing statutory authority and could be implemented immediately to leverage the efficiencies of connected health innovations in the context of CMS' Physician Fee Schedule (PFS):

- CMS has taken a very important step forward in the unbundling of CPT code 99091. Moving forward, CMS must continue to follow the path it has laid out in the final CY2018 PFS,[15] where it committed to carefully consider new CPT codes adopted by the CPT Editorial Panel. Further adoption of unbundled CPT codes that better categorize and value the use of RM will result in improved care and reduced programmatic costs.
- CMS should exercise its statutory authority, such as 42 U.S.C. 1315a(d)(1)[16] (in the case of Centers for Medicare and Medicaid Innovation [CMMI] Models) and 42 U.S.C. 1395jjj(f)[17] (in the case of the Medicare Shared Savings Program), to waive payment and program requirements as appropriate to allow for one-sided and two-sided risk models under a waiver of telehealth restrictions. This would help providers that use alternative payment models (APMs) to reduce costs meet statutory requirements. CMS recently exercised relevant waiver authority on several aspects of telehealth for two-sided risk models only. Doing so more broadly would further the success of APMs.
- Waive Medicare's telehealth restrictions (under Social Security Act Sec. 1834(m)) for all shared savings programs and APMs, including payment bundles and medical home demonstrations.

[15] CMS CY2018 PFS at 146-152.

[16] 42 U.S.C. 1315a(d)(1) provides that "The Secretary may waive such requirements of subchapters XI and XVIII and of sections 1396a(a)(1), 1396a(a)(13), and 1396b(m)(2)(A)(iii) of this title as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b)."

[17] 42 U.S.C. § 1395jjj(f) states that the Secretary "may waive such requirements of…title XVIII of this Act as may be necessary to carry out the provisions of this section."

- CMS can waive Medicare's telehealth restrictions under Social Security Act Sec. 1834(m) for all shared savings programs and APMs, including payment bundles and medical home demonstrations. CMS has already authorized, in its Final Rule for Comprehensive Care for Joint Replacement (CJR) Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services, a waiver of the rural geographic requirement and will allow telehealth services to be covered in patients' homes or places of residence.[18] However, we are concerned that CMS created new codes to side step the parity requirement for in-person and virtual services and assigned a zero practice expense to the new codes. We urge CMS to seek input from stakeholders on the typical practice expense for such services.
- When applying section 1834(m) to an accountable care organization (ACO), CMS can waive the ACO's election to ensure the limitations on originating site and the use of store-and-forward technologies do not apply. CMS should not prevent an ACO from paying home-based video conferencing services in connection with the provision of home health services (considering the Section 1895 conditions for which payment for such services would not be made) when such payment is not more expensive than the furnishing of a home health visit.
- CMS can optimize the ability of multiple provider types (including physical therapists, occupational therapists, respiratory therapists, and speech-language pathologists) to use telehealth services to effectively manage patients within alternative payment models by offering waivers and incentive payments more broadly to other Medicare providers.

[18] CMS, *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).

- There is a significant and growing body of empirical evidence showing the benefits of connected health technology for diabetes.[19] Yet diabetes imposes a significant burden on CMS' Medicare program and its beneficiaries, with a spend of more than $104 billion every year treating this preventable disease.[20] However, diabetes is well-suited to digital medicine innovations because diabetes care requires interpretation of many kinds of data that can be captured through automation and biosensors. CMS can address the burden diabetes places on the Medicare program by:
    - Include virtual diabetes prevention program providers who are CDC-recognized as part of the Medicare Diabetes Prevention Program (MDPP) under section 1115A(c) of the Social Security Act. CHI supports this proposed expansion, and the classification of the MDPP in Part B, as a timely and necessary step to address the diabetes crisis in the United States. CMS has already acknowledged the use of connected health tech products and services will be vital to the success of the MDPP.[21]
    - Supporting virtual Diabetes Self-Management Training (DSMT), which would eliminate cost- and time-consuming barriers to utilization of DSMT. CMS should also define certified diabetes educators (CDEs) as providers of DSMT. A 2014 report by the American Medical Association-convened Physician Consortium for Performance Improvement National Committee for Quality Assurance found an overwhelming majority of DSMT is carried out in primary care offices by non- "qualified diabetes educators."[22] CMS has the regulatory authority in the DSMT authorizing statute,[23] which states a certified DSMT provider is "a physician, *or other entity or individual designated by the Secretary"* [emphasis added] that provides DSMT and other Medicare services, to define a CDE. Recognizing CDEs as providers of DSMT care, including in telehealth, would help to address this gap in diabetes care.

[20] https://blog.cms.gov/2018/04/30/cms-encourages-eligible-suppliers-to-participate-in-expanded-medicare-diabetes-prevention-program-model/

[21] *Id.* at 46417.

[22] American Medical Association-convened Physician Consortium for Performance Improvement National Committee for Quality Assurance. Adult Diabetes: Performance Measures. January 2014.

[23] 42 U.S.C. 1395x(qq)

Regarding durable medical equipment (DME), CMS has established that "therapeutic continuous glucose monitors (CGMs)" can bill CMS for both the DME component and an all-inclusive supply allowance. However, Medicare's local contractors have issued a coverage determination that will result in rejection of the supply allowance if a smart tablet or smart phone compatible app is used in conjunction with the CGM device and biosensors. This interpretation by Medicare contractors is not dictated by law and has resulted in a programmatic policy that ignores the many efficiencies of secure connected technologies that have the ability to ease the burdens on patients while reducing costs to Medicare in DME payments. CMS has the ability to change their course under existing authority, but has not intervened to address the decisions of local Medicare contractors. CHI strongly urges CMS to re-examine its approach for CGMs supply allowance, and urges CMS to embrace the most efficient solutions for care that will reduce programmatic waste.

In the context of Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)[24] implementation, we encourage the Administration to consider the following:

- Using an outcome-based approach, like those identified by Congress in MACRA, (as opposed to an approach dependent on quantitative) can support the inclusion of telehealth and remote monitoring in providing patient care as any part the Quality Payment Program (QPP).
- In MACRA, Congress specified that telehealth and remote monitoring would be made available to ensure care coordination within the QPP Merit-based Inventive Payment System (MIPS) Clinical Practice Improvement Activities (IAs). Based on input from CHI, CMS adopted an IA under the MIPS program that supports doctors' review of patient generated health data (PGHD). We support this important step by CMS and urge it to search for further opportunities to bring PGHD into the care continuum. CHI supports CMS' commitment to revisit the IA table periodically to ensure it makes necessary changes and seeks public input on the best process for making future changes.

[24] Medicare Access and CHIP Reauthorization Act of 2015, Public Law No. 114-10, 129 Stat. 87 (2015).

- Through the development of the Advancing Care Information (ACI) and Meaningful Use (MU) programs, CMS should reduce the reliance on CMS program participation and the use of certified electronic health record technology (CEHRT). The Health Information Technology for Economic and Clinical Health (HITECH) Act incentivized physicians to purchase and use EHRs. Digitizing medical records has helped reduce issues associated with paper charts and records, including legibility, access, and loss. However, excessive regulation and overly-prescriptive federal requirements have created unintended consequences. Program participants are now bound to use poorly-functioning CEHRT products—built primarily to measure and report on CMS requirements—and are disincentivized from adopting truly useful technology. CMS should identify methods to reduce the overreliance on CEHRT in its programs and allow for physician and patient choice to drive the adoption and use of health IT products, such as by leveraging the value of connected health technology innovations that build on CEHRT. Through rulemakings such as its Inpatient Prospective Payment System CMS has the ability to broaden current measures to focus on functions that physicians find useful rather than narrowly outlining how certain technology must be used. CHI welcomes the opportunity to provide further detail to CMS.
- Through MIPS, CMS should give Medicare Part C, Advantage (MA) health plans the flexibility to use telehealth and RM services as a basic benefit of service. Under its existing authority, CMA can provide a menu of remote monitoring or consumer-oriented information technology categories that primary care and specialty doctors would use for care improvement.
- CHI believes CMS should share our vision of a diverse array of connected health products and services, including telehealth and remote monitoring, playing an integral role in the success of APMs. However, in the current final MACRA rule, CMS does not mention these technologies in this context, nor in their role in the success of APMs. We believe CMS' total omission of connected health technologies in the APM section of the final MACRA final rule is a missed opportunity to improve care and reduce costs through new innovative APMs.
- Medicaid waiver authority can be used to encourage states to ask for waivers to include dual eligibles in their telehealth programs, and establish programs for dual eligibles like Diabetes Prevention Programs, as age appropriate.

- Adequately explore, track, and release data in a timely fashion from the Center for Medicare and Medicaid Innovation's (CMMI) innovation grants regarding the use of telehealth and remote monitoring. We do not believe CMMI adequately explored such benefits to date. CHI supports CMMI's ongoing consideration of public input on new directions it should take to improve its operations, and we have provided detailed views to CMMI during its consultation process.[25]

[25] Letter from CHI to DEA Assistant Administrator John Martin (Apr 19, 2018), *available at* https://bit.ly/2jHwAXT.

Drug Enforcement Administration (DEA)

CHI urges the Drug Enforcement Administration (DEA) to reduce its regulations to foster innovation and competition in the electronic prescribing of controlled substances (EPCS),[26] particularly as the opioid epidemic continues to grow. These regulations currently prevent innovators, and particularly small business innovators, from participating in the EPCS market. Specifically:

- The DEA's requirements under section 1311.116 that require testing by a DEA-approved certifying body are unnecessarily rigid. CHI recommends that digital healthcare innovators be given the flexibility to demonstrate compliance with DEA biometric subsystem requirements through attestations and documentation that demonstrates their compliance, while also being able to utilize testing by a DEA-approved certifying body. Such flexibility would preserve DEA oversight of EPCS service providers while eliminating a rigid and costly compliance barrier for digital health innovators.
- The DEA's requirements under section 1311.116 require the co-location of EPCS software with the physician's device in order to issue an electronic prescription. Advancements in technology make the need for co-location unnecessary and this requirement ignores the advent of secure cloud computing-enabled approaches that allow independent devices to perform the same task. Removal of this requirement would make EPCS offerings more efficient and affordable for clinicians.

[26] Comments of CHI, *CMMI: Innovation Center New Direction* (Nov 20, 2017), *available at* https://bit.ly/2jHwAXT.

Office of the Inspector General (OIG)

We believe that the OIG could provide clarification on questions regarding anti-kickback laws to reflect realistic engagement program requirements. Such issues include ensuring that giving patients a device (e.g., a tablet) to communicate with a care team is not considered patient inducement; or that providing physician platforms for telemedicine is not violating the anti-kickback statute.

In its efforts to address fraud and abuse in Medicare and state health programs, the OIG recognized in its December 2016 safe harbor rulemaking that "[t]he transition from volume to value-based and patient-centered care requires new and changing business relationships among health care providers," and assured that "we will use our authorities, as appropriate, to promote arrangements that fulfill the goals of better care and smarter spending."[27] Both the Inspector General and the Chief Counsel to the Inspector General have indicated that OIG is interested in exploring ways to permit greater flexibility for value-based arrangements, while still guarding against the problems the fraud and abuse laws were designed to prevent.

In its fall Semiannual Report to Congress, OIG declined to propose new safe harbors in response to public comments, stating that they required more study and that questions about the application of the anti-kickback statute should be addressed on a case-by-case basis like the advisory opinion process.[28] OIG's position is particularly challenging for digital medicine and mHealth applications where provision of data and/or data analytic tools may be considered an illegal inducement even when they have no inherent or standalone value. This leaves stakeholders in a cycle where health care providers are unwilling or unable to pay for data (either because it is not a reimbursable expense or expectations that access to data or data platforms should be free after one has paid for equipment or last-mile connection, and vendors and manufacturers are barred from providing data or data services as part of a paid-for product or service).

[27] Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88368, 88370 (Dec. 7, 2017).

[28] OIG Semiannual Report to Congress—April 1, 2017, through September 30, 2017, Appendix G, available at https://oig.hhs.gov/reports-and-publications/archives/semiannual/2017/sar-fall-2017.pdf.