ConnectedHealthInitiative

March 31, 2022

Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, District of Columbia 20504

RE: Connected Health Initiative Response to the Office of Science and Technology Policy's Request for Information on Strengthening Community Health Through Technology (87 FR 492)

We write on behalf of ACT | The App Association's Connected Health Initiative[1] (CHI) to provide comments to the Office of Science and Technology Policy (OSTP) on how digital health technologies are used now and should be used in the future to transform community health, individual wellness, and health equity.[2]

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 improvements in their health through policies that allow for connected health technologies to advance health outcomes and reduce costs. CHI members develop and use connected health technologies across a wide range of use cases. We actively advocate before Congress, numerous U.S. federal agencies, and state legislatures and agencies, where we seek to promote responsible pro-digital health policies and laws in areas including reimbursement/payment, privacy/security, effectiveness/quality assurance, health data interoperability, and the rising role of artificial/augmented intelligence (AI) in care delivery (among other areas). We share OSTP's commitment to leveraging innovation in science and technology to lower barriers for all Americans to access quality healthcare by meeting people where they are and prioritizing those traditionally underserved by healthcare.

Access to traditional healthcare facilities remains one of the major social determinants of health and is often stratified along income and racial lines. As co-founders of the Health Equity and Access Leadership Coalition, CHI co-released a report highlighting how wearable devices, among other innovations, can contribute to reducing the divides in health outcomes across racial lines.[3] The remote collection of health data through wearables can help ameliorate disparities in access by allowing personalized diagnostics to occur outside of traditional healthcare institutions. For example, fitness trackers that collect valuable data, such as sleep patterns, activity, and stress levels can automatically share relevant information with clinicians, therapists, or coaches so that they can use granularized data to create more personalized care routines without requiring an in-person visit. Certain mental health apps also show untapped potential to significantly benefit engaged users' mental health.[4]

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[1] http://connectedhi.com.
[2] 87 FR 492.
[3] *See* Appendix 1.
[4] https://www.sciencedirect.com/science/article/abs/pii/S0165032717316786

Amid the COVID-19 pandemic, many turned to digital health platforms, tools, and services to consult with caregivers to avoid the risk of exposing themselves or others to the virus. Wearable ownership and use increased in 2020, with 43 percent of respondents using wearables, compared to 33 percent in the year prior.[5] Additionally, during COVID-19, more than half of all owners and users of wearables reported using them to manage a diagnosed health condition.[6] Sixty-two percent of physicians reported in a recent study that they believe wearable devices would increase the overall quality of care for their patients.[7] The Administration should, regardless of congressional action, appropriately preserve exemptions and allowances made for all digital health modalities (both synchronous and asynchronous) past the end of the public health emergency (PHE); many such allowances now clearly highlight that many legacy restrictions on digital health tools' use no longer serve the public interest.

Care providers, patients, and others who rely on innovative digital health products and services expect their data is secured, particularly their sensitive biometric data. Aside from advocating federal privacy legislation, CHI leads advocacy for the development of frameworks that will responsibly support the development, availability, and use of such AI innovations, including by developing good machine learning practices specifically for AI development and risk management of AI,[8] as well as targeted recommendations on how to improve transparency for caregivers and patients.[9] Patients, as well as stakeholders throughout the healthcare value chain, have strong interoperability, data security, and privacy expectations, and, as such, ensuring that the data collection and use practices reflect those expectations by utilising the most advanced technical protection mechanisms (e.g., end-to-end encryption) is a market-driven necessity.

In contemplating how to address health equity by bridging the digital divide, we strongly urge OSTP to recognize that the use of patient-generated health data (PGHD) is integral to the future of the American healthcare system. The demonstrated benefits of the monitoring and timely action on PGHD include reduced hospitalizations and cost, avoidance of complications, and improved care and satisfaction, particularly for the chronically ill. For example, the Department of Veterans Affairs has long provided a compelling use case for virtual chronic care management, which ultimately resulted in a substantial decrease in hospital and emergency room visits.[10] Emerging technologies like telemedicine tools, wireless communication systems, portable monitors, and cloud-based patient portals that provide access to health records are revolutionizing remote monitoring (RM).[11] In addition to helping low-income communities, healthcare providers will also benefit from the cost savings resulting from responsible use of PGHD. Monitoring of PGHD demonstrably improves patient engagement and management of chronic and persistent diseases. OSTP should also work closely with both the National Telecommunications and Information Administration and Federal Communications Commission as they implement legislation intended

[5] https://rockhealth.com/insights/digital-health-consumer-adoption-report-2020/
[6] Ibid.
[7] https://vitalconnect.com/5-key-attributes-medical-wearables-seeking-adoption-hospitals/
[8] The CHI's good machine learning practices for FDA-regulated AI are available at https://bit.ly/3gcar1e.
[9] The CHI's *Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem* is available at: https://bit.ly/3n36WO5.
[10] 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.
[11] 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.

to provide and maintain new broadband infrastructure needed to support digital health and to mitigate disparities in the healthcare context.

CHI also urges OSTP to support the use of health data and PGHD through artificial intelligence (AI) in research, health administration and operations, population health, practice delivery improvement, and direct clinical care. The Administration's policies should contribute to investments in building infrastructure, preparing personnel and training, as well as developing, validating, and maintaining AI systems with an eye toward ensuring value, ultimately offering a pathway for the voluntary adoption and integration of AI systems throughout the care continuum.

Further, the Administration's approach must embrace the critical role digital health technologies can play in advancing value-based care to make the American healthcare system more equitable and effective. Evidence clearly shows that digital health technologies helped expand access to healthcare during the COVID-19 pandemic and can address the massive toll chronic illnesses take on Americans and our healthcare system, but underutilization of digital health technologies is still present, and policy needs to better enable connected health technologies to improve health outcomes and reduce costs. CHI's Value-Based Care Task Force, recognizing a failure to date to meet Congress' mandate of a shift from the traditional fee-for-service approach to one that incents value and better outcomes in the Medicare and CHIP Reauthorization Act of 2015 (MACRA), has identified key challenges to the responsible use of digital health technologies in advancing value-based care and developed corresponding recommendations to policymakers on how to overcome them.[12] We strongly urge the Administration to consider and act on the recommendations in this report, which is also appended to this comment.

CHI shares OSTP's vision of a seamless and interoperable healthcare ecosystem that leverages the power of PGHD and can be realized through the trusted framework. Providers of public and private health plans and their beneficiaries now expect access to seamless and secure patient data across the care continuum, where "[i]ndividuals are able to easily integrate and compile longitudinal electronic health information across online tools, mobile platforms and devices to participate in shared decision-making with their care, support and service terms."[13] We support, and urge new policy activities related to this request for information to align with parallel efforts by this Administration to develop the trusted framework for the responsible use of PGHD, and we detail many of the actions the Administration can, and should, take ensure that all Americans have access to quality healthcare and are able to lead healthier lives through receiving care in their communities. To help OSTP in identifying opportunities for ways it can best connect underserved communities across America with digital health innovations, we have developed an agency-by-agency list of recommendations detailing steps that can be taken today, without Congressional action. We encourage OSTP (and others) to leverage these suggestions, and commit to assist in putting them into practice in any way the CHI can.

[12] https://www.connectedhi.com/blog/2021/7/14/the-value-based-care-revolution-will-stall-without-health-tech.
[13] ONC, *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap* at 73.

We thank OSTP in advance for its consideration of our views and look forward to engaging further in the future.

Sincerely,

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RECOMMENDED STEPS FOR STREGNTHENING COMMUNITY HEALTH THROUGH TECHNOLOGY

(Recommendations provided by Executive Agency, organized alphabetically)

Agency for Healthcare Research & Quality (AHRQ)

AHRQ plays an important role in developing knowledge, tools, and data needed to improve the healthcare system and help Americans, healthcare professionals, and policymakers make informed health decisions. CHI appreciates AHRQ's efforts to date to explore the cost savings and improved patient outcomes associated with digital health innovation through evidence reviews. Over the last few years, CHI engaged with AHRQ to propose several evidence reviews to explore the benefits of digital health tools and services in the context of disease prevention, as well as medication adherence. As AHRQ is a trusted and valuable resource for legislative and agency policymakers, we believe such explorations play a key role in informing any potential regulatory action.

AHRQ must play a leading role in examining ways to explore the benefits of digital health tools, not just Medicare telehealth services (which are in practice a very limited set of live voice/video condition-specific services and do not include asynchronous products and services). AHRQ can do this today through rapidly completing new evidence reviews and other studies on such topics as quickly as practicable. In these activities, it is critical that AHRQ no longer be constrained by legacy methodologies that have resulted in numerous digital health-related reviews ignoring the obvious benefits of new technologies' use throughout the continuum of care.

Centers for Medicare & Medicaid Services (CMS)

CMS has incredible opportunity to leverage the immense value of health innovations, including telehealth and remote patient monitoring as well as other modalities and technologies, that improve healthcare outcomes and secure significant cost savings, and provide support to digital health to transform community health, individual wellness, and advance health equity.

Physician Fee Schedule (PFS)

CMS has enabled the expanded use of telehealth (which is restricted to live voice/video calls in Medicare due to statutory restrictions). CHI supports the expansion of support for such services both during and after the PHE.

CMS has also enabled the use of remote physiologic monitoring (RPM) services for both acute and chronic conditions in Part B, representing a monumental step forward in advancing the use of digital health tools in the care of America's most vulnerable populations. CMS' policies for RPM payments should be aligned with the vision of the creator of the CPT codes capturing these activities, the American Medical Association's (AMA) Digital Medicine Payment Advisory Group (DMPAG). Moreover, glaring gaps in coverage remain for RPM's use in Medicare, particularly with respect to Federally Qualified Health Centers (FQHC) and rural health clinics (RHC) that are effectively prevented from using such technologies entirely. CHI welcomes the opportunity to provide detailed recommendations, consistent with our advocacy to CMS on its Physician Fee Schedule, on how CMS can align its approach to RPM with the CPT codes it is utilizing to support such services.

New use cases continue to emerge that fall outside of even the newest payment allowances made by CMS shine light onto inequities and disparities in healthcare that can and should be addressed through improved CMS payment policies. These use cases must be addressed rapidly to responsibly enable new technologies such as AI to improve beneficiary outcomes. As the CPT process finalizes and valuates new CPT codes to address them, CMS should rapidly activate and pay for new CPT codes developed to address these new use cases. CHI has recently pulled together a list of recommended steps that should be taken by CMS as soon as possible based on the consensus of the digital health community, which include:[1]

- **Remote Supervision:** CMS must enable greater efficiencies in medical workforce and patient safety by permanently allowing the supervision of professionals through real-time audio/video technology across as many services

[1] [cite to CHI's 11 Feb 2022 letter to CMS]

as possible. CMS has already changed the definition of "direct supervision" during the PHE for supervision of diagnostic tests, physicians' services, and some hospital outpatient services, enabling a supervising professional to be immediately available through "virtual presence" using real-time audio/video technology instead of being physically present. In the 2021 Fee Schedule, CMS finalized the continuation of this policy through the end of the CY in which the COVID-19 PHE ends. CMS should make permanent "virtual presence" for physician services including Remote Therapeutic Monitoring Treatment Management Services (CPT® Codes 98980 and 98981). Such non-face-to-face services do not require hands-on involvement by clinical staff/auxiliary personnel, but do require complex care coordination, device interrogation, and ongoing patient communication, and virtual presence would allow billing providers to leverage clinical staff for those tasks.

- **Remote Physiologic Monitoring:** We continue to support CMS' payment for remote physiologic monitoring (RPM) CPT® codes 99091, 99453, 99454, 99457, and 99458. Given the demonstrated role of RPM tools in treating chronic and acute illnesses (and the increasing number of COVID-19 cases negatively impacting underserved beneficiaries), CMS should continue flexibilities for RPM services where applicable and provide new policy-level clarifications, including:
    - CMS should revisit the 16-day data requirement for CPT® codes 99453 and 99454. 16 days of monitoring over a 30-day billing period is an excessively high bar on patient compliance, with no known medical necessity for such an established number.
    - CMS should permanently permit RPM services to be furnished to both new and established patients, and for consent to be obtained verbally. During the PHE, making RPM services more widely available has proven to be efficacious and supportive of CMS' program integrity goals, demonstrating that limiting RPM services to established patients only has no benefit. Reinstating such a limitation would be counterproductive to caring for beneficiaries, particularly those with acute conditions.
    - CMS should consider allowing multiple providers the ability to report RPM practice expense (PE) CPT® codes 99453 and 99454. Under current policy, only one provider, in a 30-day billing period, may bill CPT® codes 99453 and 99454 for a given patient. That undercuts the ability for multiple specialists from remotely monitoring a single patient, even when monitoring and treatment by multiple patients is medically necessary.
    - CMS should consider clarifying if there are any extraordinary provider documentation requirements when reporting RPM and RPM Treatment Management Services (RPM-TMS) codes.
- **Remote Therapeutic Monitoring:** We support CMS' adoption, coverage, and payment of Remote Therapeutic Monitoring (RTM) and Remote Therapeutic Monitoring Treatment Management Services (RTM-TMS) CPT® codes 98975,

98976, 98977, 98980, and 98981. While the community is excited about using new RTM tools to improve beneficiary care, several areas of need for clarifications have emerged:

- At present, the RTM codes are general medicine codes, which means RTM services cannot be furnished by clinical staff/auxiliary staff personnel under general supervision. We encourage CMS to work with CPT® and to consider creating temporary Healthcare Common Procedure Coding System (HCPCS) codes that mirror the current RTM-TMS codes (CPT® codes 98980 and 98981) but which are evaluation and management (E/M) services, and therefore are billable by physicians/QHPs. CMS should further categorize these new temporary HCPCS codes as care management services so they may be billable under "incident to" general supervision.
- CPT® has signaled that it intends to create various supply codes (CPT® codes 98976, 98977, and, in 2023, 989X6 for cognitive behavioral therapy). Given that CPT® codes 98976 and 98977 presently have the same valuation, CMS should consider streamlining these and future codes by combining them into a single, general supply code (similar to RPM CPT® code 99454) for RTM supply.
- As current RTM-TMS codes are categorized as general medicine codes, CMS has not clarified which other non-physician providers, other than physical therapists and occupational therapists, may bill them. CMS should consider clarifying which non-physician providers are allowed to bill RTM-TMS codes, as permitted by provider benefit category and scope of practice.
- Similar to our proposals for RPM, CMS should revisit whether 16 days of monitoring is excessive for RTM services which are premised in therapy adherence and therapy response.
- CMS should permit multiple providers the ability to report RTM per-patient per-30 days, in step with similar updates we request CMS make for RPM above.
- In the CY 2021 PFS, CMS addressed an important array of ongoing concerns related to RPM use in the PFS. Given the similarity between the RPM and RTM code families, those concerns and questions for RPM are germane to RTM services. Therefore, we ask that CMS clarify the following for RTM:
    - CMS should clarify that, similar to RPM and RPM-TMS, the new code family of RTM and RTM/TMS are subject to the same clarifications governing RPM codes, particularly in areas including consent; synchronous/real-time audio conversations being considered as part of "interactive communications"; and the

availability for RTM to be used for both acute and chronic disease treatment.

  - That like RPM, the RTM-TMS codes are general medicine codes that can be billed without restriction as to which medical specialties may perform RTM services.
  - That both during the PHE and permanently, RTM can be furnished to both new and established patients, and that consent may be obtained verbally.
  - That during the PHE, CPT® codes 98975, 98976, and 98977 are subject to similar waivers RPM codes enjoy whereby "at least two days of data" would satisfy the requirement for 16-days of data for patients with a COVID-19 diagnosis or those suspected of having COVID-19.
  - That a patient's automated subjective inputs are included within the scope of RTM as long as (1) such data points are collected by devices that meet the FDA's definition of a medical device under the Food, Drug & Cosmetic Act and (2) where the data cannot be corrupted by fallible and unreliable self-reported data (i.e., transcribed by the patient).

- **Artificial Intelligence (AI):** CMS' efforts to responsibly bring AI to the Medicare system in a way that will advance health equity and benefit all patients. Consistent with detailed recommendations provided to CMS separately,[2] we encourage CMS to:
  - Leverage, and utilize as a baseline for taxonomy of medical AI, the CPT Editorial Panel's Appendix S[3] to harmonize CMS' the framework of medical AI, along with the CHI AI Task Force's general health AI policy recommendations,[4] recommended good machine learning practices for FDA-regulated AI,[5] and recommendations addressing how to create and maintain the trust of both healthcare professionals and patients in health AI tools.[6]

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[2] https://actonline.org/wp-content/uploads/CHI-AI-Ltr-to-CMS-Feb-9-2022.pdf.

[3] https://www.ama-assn.org/practice-management/cpt/cpt-appendix-s-ai-taxonomy-medical-services-procedures.

[4] The CHI Health AI Task Force's deliverables are accessible at https://actonline.org/2019/02/06/why-does-healthcare-need-ai-connected-health-initiative-aims-to-answer-why/.

[5] The CHI's Good Machine Learning Practices are available at https://bit.ly/3gcar1e.

[6] The CHI's recommendations on necessary policy changes to enhance transparency for healthcare AI are available at https://bit.ly/3Gd6cxs.

- Recognize that Software as a Medical Device “SaMD” (including AI SaMD) is appropriately categorized and paid for as direct practice expense (PE). CMS must update is PE methodology to properly classify SaMD and AI software as direct PE.
- Reinforce its commitment to engaging in dialogue with digital health community to inform new steps forward towards an expanded and nationally-harmonized approach to AI’s use in Medicare.

- **Medicare Diabetes Prevention Program:** CMS is long overdue to offer virtual Medicare Diabetes Prevention Program (MDPP) services yet continues to refuse to propose meaningful changes that would do so. We strongly encourage CMS to, in its CY 2023 PFS rule, permanently expand the MDPP to support virtual providers and virtual encounters.
- **Medicare Telehealth Services:** CMS should continue support for telehealth services beyond the end of the PHE to the maximum extent possible. We urge for the appropriate expansion of Medicare telehealth services in the CY 2023 PFS. We also support CMS’ decision to retain all services added to the Medicare telehealth services list on temporary (Category 3) basis until the end of CY 2023, and strongly urge CMS to propose support for such services past the end of CY 2023 in light of COVID-19’s ongoing effects.

  Further, although we support CMS’ position on mental health services via audio-only telehealth, we strongly urge CMS to reconsider requiring the billing physician or practitioner to have furnished an in-person, non-telehealth service to the beneficiary within the six-month period before the date of the telehealth service. It is questionable whether such a restriction is medically necessary and is inconsistent with CMS’ general approach to telehealth services. CMS should, in the case of mental health services use its mandate to provide maximum flexibilities for telehealth services thereby ensuring equitable access to all.

Another area overdue for action by CMS in its Physician Fee Schedule is diabetes prevention. About one in three Americans have prediabetes, which puts them at heightened risk generally, and specifically for COVID-19. While there is a significant and growing body of empirical evidence showing the benefits of connected health technology for diabetes, this condition 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.[7] However, diabetes care is well-suited to digital medicine innovations because it 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:

- Immediately removing in-person requirements from Medicare DPP services for the remainder of the COVID-19 PHE under emergency authority.
- Including 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.[8]

[7] Seema Verma, *CMS Encourages Eligible Suppliers to Participate in Expanded Medicare Diabetes Prevention Program Model*, CENTERS FOR MEDICARE & MEDICAID SERVICES, (Apr. 20, 2018) https://www.cms.gov/blog/cms-encourages-eligible-suppliers-participate-expanded-medicare-diabetes-prevention-program-model.

[8] 85 Fed. Reg. 50074 (Aug. 17, 2020).

- 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."[9] CMS has the regulatory authority in the DSMT authorizing statute,[10] 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.

Quality Payment Program (QPP)

In the context of Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)[11] implementation, we encourage the Biden-Harris Administration to prioritize an outcome-based approach, like those identified by Congress in MACRA, as opposed to an approach dependent on quantitative metrics. An outcome-based approach can support the inclusion of digital health tools in providing patient care as any part the Quality Payment Program (QPP).

Utilization of digital health tools in the Merit-based Inventive Payment System (MIPS) and in Alternative Payment Models (APMs) and the ideal of a value-based U.S. healthcare ecosystem remains unrealized, and MACRA's implementation has not approached realizing congressional goals for the widespread development and uptake of APMs due to significant vulnerabilities in the existing process (e.g., a complete lack of coordination between the Physician-Focused Payment Model Technical Advisory Committee and the Center for Medicare & Medicaid Innovation, neither producing successful physician-led models). As a result, APMs that encourage the responsible use of innovative digital health tools are severely lacking.

CHI strongly encourages the Biden-Harris Administration to undertake a new effort to identify regulatory changes needed at the federal level to advance value-based care in the American healthcare system by leveraging digital technologies, with a focus on eliminating healthcare disparities. Such an effort should also prioritize new ways to

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

[10] 42 U.S.C. 1395x(qq).

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

incent innovation by private payers to systemically advance value-based care. CHI commits to work with HHS and any impacted stakeholders to develop a consensus path forward that will bring the vision of value-based care to fruition.

Initially, CMS can make major progress in QPP towards this goal through:

- Through the continued evolution of the Prompting Interoperability (PI) Program, 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 incented physicians to purchase and use electronic health records (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.
- HITECH permits a professional to satisfy the demonstration of meaningful use of CEHRT and information exchange through attestation. HITECH also permits reporting via “other means specified by the Secretary,” granting the Secretary the authority to allow provider attestation across all EHR reporting programs. CMS should create broad categories of PI objectives allowing physicians to attest “yes/no” to the use of CEHRT itself to achieve those categories. CMS should reevaluate the need for numerator/denominator requirements in its EHR reporting programs.
- Giving Medicare Advantage (MA) health plans the flexibility to use telehealth and RPM services as a basic benefit of service. Under its existing authority, CMS can provide a menu of remote monitoring or consumer-oriented information technology categories that primary care and specialty doctors would use for care improvement.
- Developing, and publicly releasing, a comprehensive 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.
- Using Medicaid waiver authority to permit states to include dual eligibles in their telehealth programs and establish programs for dual eligibles like Diabetes Prevention Programs, as age appropriate.
- Waiving Medicare’s telehealth restrictions (under Social Security Act Sec. 1834(m)) for all shared savings programs and alternative payment models (APMs), including payment bundles and medical home demonstrations.

Medicare Advantage

CMS should provide MA plan sponsors with the discretion to make the determination that different digital health services are clinically appropriate, and to offer those services to beneficiaries as needed. CMS should make clear that those services that do not meet the definition of Medicare telehealth services (in other words, all services that are not live voice/video calls) do not face the onerous restrictions of Section 1834(m) of the Social Security Act. Currently, regulations provide that MA plans to cover Part B benefits provided via electronic exchange as "additional telehealth benefits" (including RPM) and as a basic benefit as defined in § 422.101. We strongly encourage CMS to re-approach its implementation of Section 50323 of the Bipartisan Budget Act of 2018 to ensure MA plans' alignment with CMS' established approaches to Medicare fee-for-service telehealth services, as well as to remote patient monitoring and other "remote communications technology" that CMS has expressly stated do not fall under 1834(m) and its restrictions.

In addition, CMS should also modify its Medicare Advantage (MA)/Part D and Accountable Care Organization risk adjustment policy to incorporate diagnoses from digital health-enabled remote encounters, including audio-only telehealth services where clinically appropriate.

Medicare Shared Savings Program

CMS should exercise its statutory authority under 42 U.S.C. 1395jjj(f) to waive Medicare Shared Savings Program 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 APMs to reduce costs and 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.

Home Health Prospective Payment System (HHPPS)

CMS has included remote monitoring expenses used by a Home Health Agency (HHA) to augment the care planning process as allowable administrative costs that are factored into the costs per visit. Such a change ensures that remote patient monitoring is utilized on a cost per visit basis when it is used by an HHA to augment the care planning process and will result in a more realistic HHA Medicare margin calculation. Remote monitoring 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. However, CHI strongly urges CMS to align its definition in the Home Health Prospective Payment System (HHPPS) of "remote patient monitoring" with that captured in relevant CPT codes. While CMS correctly and proactively distinguishes between "remote monitoring" services and "telehealth" in this and other rulemakings, CHI suggests that CMS, in the HHPPS, contribute to a common definition of "remote patient monitoring" across its beneficiary programs (e.g., consistency with relevant CPT codes).

The HHPPS is also overdue for modernization to permit the use of digital health innovations that would benefit both providers and beneficiaries. CHI requests that CMS undertake a new effort, including a public consultation, to address ways the HHPPS can be modernized and improved, and we commit to work with CMS and any other impacted stakeholders to develop and advance consensus policy changes.

Centers for Medicare and Medicaid Innovation (CMMI)

Even CMMI's newest models do not adequately focus on exploring innovative technological healthcare delivery mechanisms. A 21st century healthcare system should embrace the array of new technologies available, such as RPM technologies and asynchronous store-and-forward methods, which enable the delivery of healthcare solutions beyond the four walls of a hospital room or doctor's office. The Biden-Harris Administration should prioritize a new CMMI path which embraces the use of new technologies in Medicare and Medicaid that will widely benefit beneficiaries.

CMMI should also take new steps to reduce the burdens for potential model applicants. CMMI should articulate consistent requirements that are applicable to all models being tested, rather than developing separate requirements for each. The burden for applicants and participants could be reduced through uniform processes, expectations, principles, and rules that span models like population health and chronic conditions that are being tested. To align payers with the goals of the CMMI models and incent their participation, CMS should build upon the QPP to encourage the development of models that are based on existing structures and payment models and allow existing networks to apply as Advanced APMs to make these entities eligible for Medicare bonuses and programs like MIPS and the QPP. In exploring the benefits of telehealth as defined in 1834(m), CMS should use its established authority to waive the backward-facing and outdated restrictions. CMMI should also focus on exploring new and innovative remote monitoring technologies (which are not telehealth under 1834(m) and therefore do not face its geographic, originating site, etc., restrictions). We further urge CMMI to build upon the successes of the Veterans Health Administration in its use of connected health technologies.

CMS should further exercise its statutory authority, such as 42 U.S.C. 1315a(d)(1), in the case of CMMI Models 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 APMs to reduce costs and 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.

CMMI should also recognize and build upon the incredible successes of some Medicaid systems, such as the University of Mississippi Medical Center, the University of Virginia, and Boston Children’s Hospital. In these states (and some others), Medicaid programs have taken steps to support not only telehealth but—more importantly—remote monitoring innovations that bring PGHD into the continuum of care based on demonstrated improvements to patient outcomes and significant cost savings. CMMI can and should play a crucial role in proliferating these successes.

Durable Medical Equipment (DME)

CMS should, under its existing authority, discard the arbitrary limitations it places on DME payments to support the responsible uptake and use of digital health technology innovations. CMS' approach today to DME either entirely excludes or insufficiently supports the use of software in medical equipment that is increasingly essential to cutting-edge care. CMS is long overdue to provide a pathway for coverage under DME for software as a medical device (SaMD) that is primarily utilized for a medical purpose even when there are other uses of the software or the product the software is in. DME coverage of software should also extend to SaMD therapeutics cleared by the FDA. In addition, support for such software in DME should be unbundled, with needed updates to the software supported as DME supplies when they are integral to the functioning of the underlying DME software.

CMS can take modest steps today to improve the DME program. For example, while CMS established that "therapeutic continuous glucose monitors (CGMs)" can be billed to CMS for both the DME component and an all-inclusive supply allowance, in 2018, local Medicare contractors issued a coverage determination that resulted in rejection of the supply allowance if a smart tablet or smartphone-compatible mobile medical app is used in conjunction with the CGM device and biosensors. This interpretation by Medicare contractors was not dictated by law and resulted in a programmatic policy that would ignore the many efficiencies of secure connected medical 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 and appears to have intervened to address the decisions of local Medicare contractors in this specific instance; however, due to the continued confusion created by Medicare contractors and CMS' policy correction regarding CGMs, CHI strongly urges CMS to ensure that the use of dual-use connected technology as DME is permitted widely through its DME rules.

DME enabled by internet connectivity and new, innovative features can and should be permitted to meet CMS' requirement for face-to-face encounters. Care providers can leverage connected health technology to obtain DME PGHD for continual evaluation and treatment of conditions. Such capabilities negate the need for an annual demonstration of medical necessity through their ongoing collection and transmission of PGHD. Therefore, CMS should eliminate this annual certification requirement when RPM can demonstrate medical necessity.

Food and Drug Administration (FDA)

The U.S. Food and Drug Administration (FDA) can advance the agency's patient safety mandate and the Administration's priorities through enabling the responsible use of cutting-edge digital health tools. The FDA's approach to emerging technologies will also

continue to influence the wider healthcare ecosystem that is working to shape new coverage policies, developing clinical practice guidelines, and pioneering new software-driven medical tools that save lives.

CHI encourages FDA to take several actions that will provide a pathway for the benefits of connected health tools to be realized by clinicians and patients throughout the care continuum while also enhancing patient safety. We offer the following recommendations for consideration:

- **Support the Digital Health Center of Excellence:** CHI supports the creation of the FDA's Digital Health Center of Excellence (CoE) as the central place within the agency for the advancement of digital health technology such as mobile health devices, software as a medical device (SaMD), wearable medical devices, and technologies used to study medical products. We urge you to prioritize the Digital Health CoE as it continues to build capacity and expertise.

  Digital health policy is most appropriately dealt with by the Digital Health CoE with Center for Devices and Radiological Health's (CDRH). CHI, therefore, remains concerned with the Center for Drug Evaluation and Research's (CDER) proposed approach to the Prescription Drug-Use-Related Software (PDURS) that departs from the CDRH work to modernize the FDA's approach to the regulation of SaMD. We recommend that PDURS policy development be primarily led by the Digital Health CoE to ensure alignment with the widely-supported approach developed by CDRH for SaMD.

- **Improve the Medical Device Regulatory Process While Protecting Patient Safety:** CHI commends the FDA's risk-based approach to the regulation of medical devices. Specifically, CHI applauds the FDA's use of enforcement discretion for low-risk devices. We support the FDA pursuing all opportunities to modernize and streamline the medical device approval process, particularly for SaMD. For Americans to benefit from the latest advancements in medical devices, there must be enhancements to the FDA's approval process so there is a reduction in time-to-market while still ensuring patient safety and caregiver trust. The FDA has made significant progress in crafting the Software Pre-Certification Pilot Program (in which CHI members participate) based on extensive public input at multiple stages, public workshops, and the experiences from the pilot program. It is essential that the FDA continue to support and build on its significant investment in this important effort under the Administration, laying the groundwork for a full Software Pre-Certification Program. CHI commits to support FDA moving the Software Pre-Certification Pilot Program forward in order to effectively and responsibly speed time-to-market for trusted developers of SaMD.

  CHI also commends FDA's continued development of digital health-related

guidance documents and urges for continued consultations with impacted stakeholders as they are developed.

- **Deliver the Promise of Artificial Intelligence and Machine Learning-Enabled Technology to American Patients:** Artificial/augmented intelligence (AI) and machine learning (ML), powered by streams of data and advanced algorithms, have incredible potential to improve healthcare, prevent hospitalizations, reduce complications, and increase patient engagement. Yet, applications of AI in healthcare have also given rise to a variety of potential challenges for policymakers to consider, including quality assurance, adaptiveness, ethics, oversight, notice/consent, and data bias. The FDA must take a leading role in responsibly bringing AI medical devices to the marketplace, and we support FDA's continued leadership to develop a governance framework for AI meeting the definition of a medical device under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

  As part of its commitment to responsibly advance AI in healthcare, CHI has assembled a Health AI Task Force consisting of a range of innovators and thought leaders. CHI's AI Task Force has developed a range of resources, including a position piece supporting AI's role in healthcare, a set of principles addressing how policy should approach the role of AI in healthcare, and a terminology document targeted at policymakers.[12] Even more recently, CHI's AI Task Force has developed good machine learning practices, specifically for AI development and risk management of AI meeting FDA's definition of a medical device,[13] as well as recommendations on ways to improve transparency for caregivers, patients, and others necessary for the appropriate uptake of AI tools across the care continuum.[14] We urge FDA to build on these digital health community consensus recommendations, and to directly address the role of AI in new standalone guidance providing a scalable, risk-based approach be taken when handling regulatory and enforcement discretion.

- **Fully Leverage Real-World Data (RWD) and Real-World Evidence (RWE) in FDA Processes and Decision-Making:** CHI stands in agreement with the FDA's public acknowledgement that RWD and RWE can and should play an important role in the FDA's efforts to address patient protection at the supplemental phase, monitor post-market safety and adverse events, and to make regulatory decisions. CHI members widely use RWD and RWE to support product design, clinical trials, and studies to innovate. The use of RWD and RWE has been critical to the response to the ongoing public health emergency. We

[12] The CHI Health AI Task Force's deliverables are accessible at https://actonline.org/2019/02/06/why-does-healthcare-need-ai-connected-health-initiative-aims-to-answer-why/.

[13] CHI's good machine learning practices are available at https://bit.ly/3gcar1e.

[14] CHI's recommendations on necessary policy changes to enhance transparency for healthcare AI are available at https://bit.ly/3Gd6cxs.

encourage FDA to fully leverage this important data by engaging our members in its processes, particularly in the supplemental and post-market phases. Noting our appreciation for FDA's ongoing efforts with respect to RWD and RWE, FDA should prioritize widespread changes to processes and policies when it comes to using RWD and RWE to make timely informed decisions. We urge FDA to finalize relevant guidance as soon as practicable, consistent with our recommendations filed with FDA.[15]

- **Enable Digital Health Technologies to Better Assist in Clinical Trials:** Traditionally, in the context of clinical trials, there has been a limited use of DHTs that leverage PGHD due to the costs associated with distributing, connecting, tracking, and maintaining mobile devices during an investigation. With the revolution of smartphone adoption, clinical investigations can now largely discard these concerns, particularly when embracing the "bring your own device" (BYOD) model. Such models may utilize specialized instruments as accessories to smartphones/tablets/etc., enabling a much more complete evaluation of a patient's condition across a diversity of types of data and use cases.
- **Advance Interoperable Data Exchange:** CHI supports FDA's efforts to ensure the safe, secure, and effective exchange using de-identified data between devices, products, technologies, and systems. We believe that FDA can and should lead in collaborative efforts addressing medical device interoperability between all stakeholders through collaboration with other federal agencies.
- **Continue the Development of Cybersecurity Best Practices for Medical Devices:** CHI supports FDA's continued efforts to guide medical device makers in addressing the cybersecurity threats faced by SaMD and software in a medical device (SiMD). We commend FDA's efforts to encourage the timely sharing of threat indicators between both the public and private sector so that new threats may be addressed rapidly and effectively. We encourage FDA to continue this work while ensuring that the distribution of critical security updates is not delayed by overly burdensome reporting requirements.
- **Maintain International Digital Health Policy Leadership:** CHI supports FDA's ongoing efforts to address emerging technology issues with other regulators[16] and within the International Medical Device Regulatory Forum (IMDRF), producing important frameworks for regulatory approaches that utilize a risk-based and scalable approach (such as the IMDRF's *Software as a Medical Device (SaMD): Clinical Evaluation*[17]). As our members' new technologies begin to enter regulatory processes, FDA's leadership in correlating this arena to existing domestic law and regulation is needed more than ever. We encourage

[15] https://www.regulations.gov/comment/FDA-2021-D-1128-0046.

[16] *E.g.*, https://www.fda.gov/news-events/press-announcements/fda-brief-fda-collaborates-health-canada-and-uks-mhra-foster-good-machine-learning-practice.

[17] http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170921-samd-n41-clinical-evaluation_1.pdf.

FDA to continue the FDA's engagement in the IMDRF, and for FDA to clarify IMDRF guidance and positions where consistent with U.S. law.

CHI also appreciates FDA's commitment to driving innovation and patient protection by leveraging the public-private partnership model and welcomes such engagement. For example, we welcome FDA's participation in a new CHI dialogue on digital health and quality assurance aimed at bringing the ecosystem closer together in responsibly advancing the use of connected digital health tools, which will also feature digital health innovators, providers, payors, and patients that will share needs and expectations about new digital health technologies and what needs to be demonstrated to drive adoption in health systems and plans.

Indian Health Service (IHS)

Digital health innovations offer immense value to those who rely on the IHS and should be fully leveraged to assist American Indians and Alaska Natives who need comprehensive health services. In partnership with the Federal Communications Commission, IHS should advance broadband coverage to all who rely on the IHS and pair such efforts with new deployments of telehealth, RPM, and other digital health tools.

National Institutes of Health (NIH)

NIH plays a key role in developing knowledge, tools, and data needed to improve the health care system and help Americans, health care professionals, and policymakers make informed health decisions. CHI appreciates NIH's efforts to date to explore the role of digital health technologies in improving care, and strongly recommends that NIH set an imperative for increased exploration of digital health tools in healthcare, including the growing role of AI in healthcare. CHI also supports NIH's efforts to modernize its governance of health data to responsibly enable new research and development, including NIH's genomic data sharing policy.[18]

National Telecommunications and Information Administration (NTIA)

National Telecommunications and Information Administration's (NTIA) implementation of the Infrastructure Investment and Jobs Act (the Act), including the Broadband Equity, Access and Deployment program, the Middle-Mile Broadband Infrastructure Program,

[18] [cite to CHI comments to NIH]

and the Digital Equity Planning Grant Program,[19] is absolutely essential to realizing connected healthcare communities across America. With approximately 133 million Americans suffering from some form of chronic illness, particularly for those that live in rural areas, our healthcare system requires a shift to support continuous contact with patients. The issue is complicated for Americans with chronic conditions in underserved communities across rural, suburban, and urban geographies. Lack of access to broadband and/or audio-visual capable devices is another major impediment to receiving high quality technology-enabled care for many Americans, including seniors in minoritized and marginalized communities where there were significant health disparities before COVID-19 that have become much worse during the pandemic. For example, according to the Federal Communications Commission, 628,000 tribal households lack access to standard broadband.[20] An even greater light now shines on the inequities and disparities across American society, and in healthcare specifically, due to the COVID-19 pandemic.[21] Based on data from 14 participating states, the Centers for Disease Control and Prevention (CDC) reported that age-adjusted COVID-19–associated mortality among American Indian and Alaska Native persons was 1.8 times that among non-Hispanic Whites.[22] Likewise, in an October 2020 article Government Technology reported that less than half the population in certain parts of Alabama, which are minoritized communities, have internet access, and two of these Alabama counties have no internet access at all.[23] Marginalized urban communities have also been excluded from broadband service and need to rely on audio-only visits, because even when cities have broadband, many residents of these communities do not have access to it in their homes. A June 2020 report of the National Digital Inclusion Alliance describes data showing that the United States has more than three times as many urban as rural households living without home broadband of any kind.[24] Connected health technologies offer the ability to bridge the digital divide and provide needed disease prevention and treatment to America's most vulnerable citizens – as long as there is access to a robust broadband network to facilitate patients sharing essential data with their caregivers from their homes.

CHI supports the Administration's commitment to effectively allocate $48 billion to fund the various programs created in the Act. Realizing Congressional goals in the Act, and

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[19] *Infrastructure Investment and Jobs Act Implementation*, 87 Fed Reg 1123 (Jan. 10, 2022).

[20] https://www.reuters.com/article/us-health-coronavirus-usa-rights-trfn/coronavirus-crisis-threatens-internet-opportunity-for-native-americans-idUSKCN24T06B.

[21] CHI has co-released a new report, titled Advancing Health Equity Through Technology, which addresses disparities in America's healthcare system and offers numerous recommendations for federal-level action, will assist NTIA in exploring the relationship between the digital divide to health inequities. This report is appended to the CHI's comment.

[22] https://www.cdc.gov/mmwr/volumes/69/wr/mm6949a3.htm.

[23] https://www.govtech.com/network/pandemic-worsens-internet-disparity-in-alabama-black-belt.html.

[24] https://www.digitalinclusion.org/digital-divide-and-systemic-racism/.

the future of the United States digital economy, will require a robust and sustainable internet infrastructure that supports the use of technologies in underserved communities across the country to improve patient outcome and improve the care team experience. A consistently growing body of evidence demonstrates that connected health technologies improve patient outcomes, reduce hospitalizations, enrich patient engagement, and reduce costs. Digital health tools, increasingly powered by artificial/augmented intelligence (AI), leverage patient-generated health data (PGHD) and social determinants of health (SDOH), and include a wide range of digital health products, including mobile medical solutions, digitally enhanced screening and treatment technologies, clinical decision support, and cloud-based patient portals. With the growing number of communities and populations on the wrong side of the digital divide, access to broadband to support a connected continuum of care is increasingly vital to America's healthcare system, especially as remote patient monitoring solutions continue to grow in use and capability.

Building on the above, we offer the following recommendations to NTIA:

- **A Policy Development Process that is Inclusion of All Viewpoints and Needs:** We encourage NTIA to work with as diverse a set of stakeholders as possible, including those at the frontlines providing healthcare to America's most vulnerable populations and communities, to shape grant program requirements and commend NTIA's collaborative approach initiated through this call for written views and its listening sessions. We also support NTIA's efforts to work with other federal agencies to ensure that new grants authorized by the Act build on lessons learned in effectively using broadband-enabled connected health tools to serve communities of need, including the Federal Communications Commission, the Centers for Medicare and Medicaid Services, state Medicaid policymakers, and others.
- **Technology and Modality Neutrality:** No two communities in America are identical, and there are numerous broadband-enabled technologies that can be used to meet and sustain connectivity needs for connected healthcare depending on their unique needs. To ensure that grants are used most effectively to respond to local needs, requirements should be flexible and avoid technology and/or modality mandates. For some deployments, laying fiber may be the most effective path to success, while in others (such as where macro sites alone will not be sufficient to manage traffic congestion) small cell deployment can add density to a network to help manage increasing traffic. NTIA's grant requirements should reflect modality/technology neutrality across its requirements for deployments.
- **Alignment with Existing Federal Definitions and Metrics:** We urge NTIA to align its definitions and requirements with existing agencies and requirements where possible. For example, we support NTIA's reliance on the FCC's definition of broadband. Further, health sector agencies can offer immense help to NTIA in addressing certain underserved populations and use cases (e.g., the Office of

the National Coordinator for Health IT's efforts on social determinants of health[25]). NTIA is strongly encouraged to build on and align with existing federal agency insights and approaches, not only to leverage these other agencies' expertise, but to avoid the confusion that can be caused by conflicting federal definitions.

- **Consider a Broad Range of Health Indicators in Grant Awards and Administration:** Access to technology, access to broadband, and digital literacy are SDOH, and NTIA determinations of need in evaluating and overseeing grant applications should ultimately lead to connecting the most number of underserved Americans as possible and enabling key connected health use cases. Better broadband maps, developed in collaboration with the FCC (including its Connect2Health effort[26]), will drive more efficient and equitable access to broadband connectivity that will enable the use of a suite of digital health tools and services. More accurate and granular mapping, supplemented by new insights provided in SDOH datasets, can greatly assist in identifying unconnected and underserved communities for this purpose.

  CHI recognizes access to broadband internet as a SDOH and we believe it is vitally important to continue and broaden efforts to provide broadband internet access to all Americans. Several of CHI's members participated in a COVID-19 telehealth impact study in 2020. Over 64 percent of respondents indicated technology challenges for patients as a barrier to sustainable use of telehealth. Perceived barriers for patients included lack of access to technology and internet/broadband, and low digital literacy. Ensuring access to broadband access and two-way audio-visual technologies would have a tremendous impact on alleviating challenges to access of digital health technology. In addition, initiatives to measure and strengthen digital literacy, with an emphasis on programs designed with and for historically marginalized and minoritized populations would help ensure that these communities can effectively use digital health tools once they have access to them.

- **Flexibility in Requirements for States and Territories:** America faces a growing digital divide across a wide range of populations, in both urban, suburban, and rural areas of the country, and all should benefit from the grants authorized by the Act. States and territories should, for example, use competitive bidding processes to minimize costs when determining funding awards and amounts. NTIA can best support states and territories administering grants by enabling their ability to flexibly shape and manage programs, within the technology-neutral parameters set by NTIA, to best meet the unique and evolving needs of their populations. NTIA should provide support to states and territories in the leadup to grant awards and as those authorities administer the grants they

[25] https://www.healthit.gov/topic/health-it-health-care-settings/social-determinants-health.

[26] https://www.fcc.gov/about-fcc/fcc-initiatives/connect2healthfcc.

receive. A partnership between NTIA and its state and territory grantees, and the communities the Act is intended to benefit, will result in the most effective leveraging of funding, which may include building onto existing public and/or private programs intended to address equity and inclusion, particularly in the healthcare context.

While providing this flexibility, NTIA can also assist states and territories through the development of guidance and key use cases (which should include connected healthcare scenarios).

- **Ensuring Transparency and Oversight while Minimizing Compliance Burdens:** As the ongoing public health emergency of COVID-19 continues to exacerbate the existing need for broadband-enabled remote care, particularly in unserved and underserved communities, we urge NTIA to include program rules that allow rapid deployment and implementation while avoiding overburdensome administrative/compliance requirements. We urge NTIA to draw on its extensive experience in administering the Broadband Infrastructure Program (BIP) and Broadband Technology Opportunities Program (BTOP), and experiences from other federal programs, to ensure transparency and oversight while avoiding overburdening grantees with reporting obligations. States and territories should be encouraged to develop grant administration plans that prioritize transparency, build on existing resources at all levels, and that consistently consult with their underserved communities including health departments, medical providers, and community health organizations.

CHI commits to continued collaboration with NTIA to bring broadband-enabled connected health innovations to all Americans, especially those in unserved and underserved communities.

HHS Office for Civil Rights (OCR)

CHI is a longtime advocate for certainty and clarity regarding HIPAA requirements, and urges OCR to work with us to:

- Provide up-to-date and clear information about what is expected of technology companies for compliance with the HIPAA rules, and identify the implementation standards that can help technology companies conform to the regulations;
- Provide more clarity on HIPAA obligations for companies and services that store data in the cloud; and
- Engage regularly with technology companies to provide compliance assistance.

OCR seeks to engage in ongoing outreach to the range of stakeholders affected by the HIPAA rules, including the developers and range of users of connected health technologies. For example, we recommend that OCR convene a working group to

investigate whether current rules or internal practices within a large organization hinders data sharing for research and population health initiatives due to misperceptions about HIPAA. These regulatory processes should result in more clarity for providers, technology makers, and patients to understand how all stakeholders can most efficiently make healthcare information interoperable without incurring liability while allowing for seamless care coordination.

CHI urges OCR to update their guidance for providers and physicians and to undertake targeted educational campaigns to better reach their intended audience. We suggest that in order to address some of the "grey" areas physicians continue to encounter, such as whether HIPAA permits text messaging, how to distinguish between patient-directed third-party access to protected health information and a third-party access request for information, and even distinctions between how to share mental health information generated by a general medical facility versus substance use disorder information generated in a Part 2 facility, OCR creates situational guidance similar to the "Health App Use Scenarios & HIPAA" guidance document from 2016. In creating these guidance documents, we urge OCR to strategize ways to alert physicians, patients, and other health care industry stakeholders to new and existing guidance during the development process, and in ways that target the intended audience.

CHI also recommends that OCR:

- Issue guidance specifically related to text messaging and chat services as soon as practicable. Such guidance would help CEs understand how they may or may not use text messaging and chat services in the course of patient care, including care coordination and communication with family and caregivers, and decrease fear of HIPAA violations leading to OCR enforcement. Similarly, CHI encourages OCR to provide clarity as to how push notifications will be treated under HIPAA.
- Remedy a lack of clarity with respect to sample Business Associate (BA) Agreement language around the topics developers care about, such as cloud storage and PGHD; and a lack of bargaining power on the part of startups. CHI strongly encourages OCR to provide sample BA language or transparency measures, through its regulatory changes and/or issuing guidance targeted at both developers and providers, provide such clarity regarding BA Agreements (e.g., CHI encourages OCR to issue guidance specifically for providers as to when they need a BAA with and external technology partner).
- Answer questions around connected device maintenance and authorization that are currently unanswered and create unnecessary steps that disrupt treatments and care continuums.
- Reinforce the important role encryption has in protecting personal health information, as the use of encryption is critical to meeting obligations under the above-noted HIPAA security and privacy rules. OCR should issue guidance clarifying that certain telehealth, CBTS, and RPM tools that are fully end-to-end encrypted are mere "conduits," and, therefore, do not require BA Agreements. The guidance should clarify that the providers of such telehealth services should

only store electronic protected health information (ePHI) on a temporary basis incident to the transmission service. Specifically, the guidance should clarify that some storage of call related metadata counts as "random or infrequent," so long as that information is being used to support the service and the storage is for a temporary period of time necessary to support the service. This clarity would enable patients and providers to rely on highly secure means of communication without putting all parties through unnecessary red tape.

- Ensure that the revised HIPAA regulations do not curtail AI innovations by taking a technology neutral approach to any regulation, and that OCR ensure (through future guidance or rulemaking) that emerging technology innovators have clarity as to when HIPAA rules may be triggered.

Office of the Inspector General (OIG)

Anti-Kickback Statute (AKS)

As clinicians remotely monitor patients at home who may have COVID-19 and other acute and chronic conditions, there are ongoing concerns that any equipment or access to software platforms provided free of charge may inadvertently trigger liability under the AKS. HHS' Office of the Inspector General (OIG) should clarify that providing access to software-based platforms for patient generated health data (PGHD) analytics or telemedicine at no/low cost does not violate the AKS. Additionally, the operative definition for "remuneration" in this statutory provision, at 42 U.S.C. 1320a–7a(i)(6), is broad, and we recommend that the HHS OIG also provide clear guidance that giving patients a device to communicate with a care team is not considered a beneficiary inducement. These clarifications will enable the provisioning of RPM, telehealth, and other tech-driven healthcare tools without triggering AKS liability.

Furthermore, OIG should clarify that utilization of a device with multiple functions, such as a smartphone or e-tablet, does not violate the AKS and the CMP when it is primarily used for managing a patient's healthcare, including the social determinants – e.g., finances, scheduling, and transportation – that impact a patient's health. Multi-function devices are essential to the successful and responsible application of connected health technology to improve outcomes and reduce costs. However, many existing interpretations of the AKS regulations and guidance prohibit such devices from reaching the patients who need it most. Multi-function devices offer the ability in clinical trials to validate the identity of trial participants and allow health care functionality to be integrated into the other digitized aspects of a patient's life, such as their email and text message communications, personal finances, or navigation, making patients more likely to use a multi-function device, while also giving providers real-time information about a patient's status (e.g., blood pressure or heart rate).

Office of the National Coordinator for Health Information Technology (ONC)

ONC's support for the 21st Century Cures Act's trusted exchange framework and common agreement provisions comes at an important time. At a time when millions of patients' traditional medical care has been disrupted by the COVID-19 pandemic, CHI appreciates ONC's finalizing regulations that will equip individuals with their own medical data and facilitate the sharing of that information in standardized manner. Recently, as part of an effort to allow health organizations to focus efforts exclusively on COVID-19 response, the agency delayed implementation of those regulations. While some aspects of the rule are now in effect, enforcement of provisions on application programming interfaces (APIs)—which are software tools that will allow different systems to more easily communicated—were postponed from May 2022 until December 31, 2022. As the current delay has afforded the healthcare industry an additional seven months to implement these regulations, ONC should commit to the new timeline for implementation and indicate that it will not postpone the regulations further in the future. ONC's finalized rule generated significant support from a wide variety of groups—including EHR developers, health care providers, and public health organizations. Despite those benefits and broad support, ONC—under this new interim final rule—delayed implementation of the API requirements for seven months to the end of 2022, which is six years after Congress first required them via Cures. As ONC has already decided to provide that additional implementation time via the interim final rule, ONC should not delay enforcement further—both because of the importance of these provisions to improve patient care but also because the necessary changes would not represent a significant burden on the industry.

ONC, in the final rule establishing API requirements, explicitly indicated that it would only update the current version of EHR requirements (the 2015 edition) instead of creating a new version given that the changes build on existing capabilities. For example, referring to the data that APIs would need to provide patients and providers, ONC indicated that the updates "were intentionally limited to a modest expansion that most health IT developers already supported, were already working toward, or should be capable of updating their health IT to support in a timely manner." As the necessary changes to support the API requirements are both limited and related to existing capabilities, EHR vendors and providers have sufficient time to make the upgrades laid out in the regulations, and further delays beyond those outlined in the interim final rule are unwarranted and would be opposed by us in the future. By committing to enforce the API requirements according to the timelines currently in place, ONC can provide patients, technology developers, and health care providers with clarity on the evolution of health information technology capabilities and ensure that data is made available when and where it's needed.

Unfortunately, CHI continues to collect experiences of flagrant disregard for and/or gross misinterpretation of information blocking rule requirements from across the healthcare ecosystem, particularly by developers of certified health IT. We urge ONC

(and OIG) to complete needed rulemakings that will clarify requirements and set expectations for enforcement as soon as practicable.

Further, CHI supports the U.S. Core Data for Interoperability (USCDI), which currently reflects the same data classes referenced by the 2015 Edition Common Clinical Data Set (CCDS) definition and includes Clinical Notes and Provenance. CHI further supports the USCDI expansion process, which should occur annually based on stakeholder input. We also support the "glide path" for additions to the USCDI which should reflect technology and competitive neutrality principles as it incrementally expands data classes.

Finally, CHI notes its support for ONC's Model Privacy Notice (MPN) effort,[27] and recommends that the MPN be updated through a collaborative process that engages the public.

[27] https://www.healthit.gov/topic/privacy-security-and-hipaa/model-privacy-notice-mpn.