ConnectedHealth

January 13, 2021

President-elect Joseph Biden
Vice President-elect Kamala Harris

RE: The Imperative for the Biden-Harris Administration to Improve and Modernize the American Healthcare System

The Connected Health Initiative (CHI) congratulates you on your victory in the 2020 Presidential Election. As you both made clear during the campaign and since the election, America must take new and drastic action to build the American economy back better. CHI believes that this drastic action must include improving and modernizing the American healthcare system. While the most immediate action is needed to defeat COVID-19 and overcome the turbulent economic environment created by the public health emergency (PHE), further steps to permanently progress the American healthcare system should also be prioritized, with a focus on eliminating inequities that afflict our system today.

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, U.S. Food and Drug Administration (FDA) regulation of digital health, health data interoperability, and the rising role of artificial/augmented intelligence (AI) in care delivery. For more information, see www.connectedhi.com.

With respect to the COVID-19 crisis, the most acute issue in American healthcare, we note our support for your proactive efforts to tackle the pandemic through the formation of a COVID-19 task force. We strongly support the future U.S. Department of Health and Human Services (HHS) under a Biden-Harris administration in taking all necessary measures to flatten the infection curve and defeat COVID-19 using the most innovative

and effective solutions available. Specifically, we urge the Biden-Harris administration, supported by the task force's recommendations, to support and elevate the use of internet connected digital health technologies, including telehealth, remote physiologic monitoring (RPM), and AI, among other modalities. Responsible use of such technologies will facilitate more efficient care over safe distances.

CHI shares the Biden-Harris administration's priority for new congressional action to provide relief from damage caused by the COVID-19 pandemic. As part of this negotiated effort, Congress should provide permanent policy changes that will enable connected healthcare tools to defeat the current pandemic and, once it is over, modernize American healthcare laws to reflect the value of these tools to assure Americans support of these tools will continue. Moreover, Congress should prioritize providing Americans with infrastructure that supports high-speed broadband capabilities that will enable digital health tools.

While congressional efforts continue, it will be critical that the HHS Secretary continue take all measures necessary to address to ongoing PHE in order to provide allowances for the use of the connected health technology essential to overcoming COVID-19. During this crisis, support for the use of digital health tools expanded, and for many they became a primary means of COVID-19 prevention, diagnosis, and treatment across America while helping adhere to social distancing guidelines. Under the Biden-Harris administration, PHE allowances must enable the American healthcare system to better utilize digital health technologies to address the COVID-19 pandemic.[1] Furthermore, the Biden-Harris administration should leverage every opportunity for permanent agency-level policy changes that will enable the responsible deployment and use of innovative digital health technologies to the benefit of every American patient.

There are numerous immediate steps that can provide much needed support for connected health tools in addressing COVID-19 and modernizing the healthcare system. This task force should examine whether permanent extension of any of the allowances made under the PHE can occur through agency authority rather than new congressional action. It is critical that the Biden-Harris HHS place the highest priority on leveraging new digital health technologies and capabilities to modernize the American healthcare system and improve care for all. We strongly encourage the launch of a new HHS effort, in collaboration with all impacted stakeholders, to modernize and improve the American healthcare system through the responsible uptake of digital health technologies, including through:

- Providing new positive incentives to both develop and use digital health technologies throughout the care continuum, including through new

[1] CHI has detailed many of the actions the new administration can, and should, take without congressional action to combat the COVID-19 pandemic. These recommendations are available at: https://actonline.org/wp-content/uploads/CHI-Ltr-to-BidenHarris-Admin-Coronavirus-Task-Force-112322.pdf.

modernization efforts of HHS' regulatory regime, with a focus on reducing disparities in healthcare;
- The collection and sharing of evidence demonstrating how digital health innovations improve care and reduce costs to inform policymaking decisions at all levels of government; and
- A public education campaign to advance awareness of patients' rights and opportunities with respect to digital health tools.

As a prime example, many of the policy issues raised by the use of AI require consideration of its impact on a wide range of stakeholders. The cultural, workforce training and education, data access, and technology-related changes will require strong guidance and coordination across a number of venues. Given the significant role of the government in the regulation, delivery, and payment of healthcare, as well as its role as steward of significant amounts of patient data, a federal healthcare AI strategy incorporating guidance on the issues below will be vital to achieving the promise that AI offers to patients and the healthcare sector. It is critical that U.S. policymakers collaborate with provider organizations, other civil society organizations, and private sector stakeholders to address AI's potential in healthcare.

Connected health tools will strongly support the Biden-Harris administration's efforts to make rapid progress in combatting the pandemic. In the attached appendix, we have detailed many of the actions the new administration can, and should, take during the next Presidential term (2021-2025). We appreciate your attention to these requests in our appended memo and look forward to collaborating on this vital issue.

Sincerely,

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AGENCY-SPECIFIC RECOMMENDED STEPS THE BIDEN-HARRIS ADMINISTRATION SHOULD TAKE TO IMPROVE AND MODERNIZE THE AMERICAN HEALTHCARE SYSTEM IN 2021-2025

Agency for Healthcare Research & Quality (AHRQ)

AHRQ plays an important 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 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 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 (RPM), as well as other modalities and technologies, that improve healthcare outcomes and secure significant cost savings.

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. In addition, CMS should put new Healthcare Common Procedure Coding System (HCPCS) codes into place to enable the use of digital health innovations in Medicare as appropriate.

Another area overdue for action by CMS in its Physician Fee Schedule is diabetes prevention. 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.[2] 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:

- 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.[3]
- 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."[4] CMS has the regulatory authority in the DSMT authorizing statute,[5] 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)[6] 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).

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[2] 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.

[3] 85 Fed. Reg. 50074 (Aug. 17, 2020).

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

[5] 42 U.S.C. 1395x(qq).

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

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 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.

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),[7] particularly as the opioid epidemic continues to grow. These regulations currently prevent innovators, especially small business innovators, from participating in the EPCS market. Specifically:

[7] Comments of CHI, *CMMI: Innovation Center New Direction* (Nov 20, 2017), *available at* https://static1.squarespace.com/static/57ed48b4f5e23125aa094623/t/5a3acaea085229e1ec4ee719/1513802476621/chi_comment_re_cms_cmmi_new_direction_final__w_appendix__112017.pdf.

- The DEA's requirements under section 1311.116 that require testing by a DEA-approved certifying body are unnecessarily rigid. In the 10 years since the DEA's interim rules for EPCS were put into place, many devices have been developed that can provide biometric scanning requirements that would meet certification requirements, but which have not undergone certification due to its complexities and high costs. 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, validated through appropriate market surveillance by DEA. Such an approach should be enabled through changes to the interim rule or, in the alternative, through a pilot program followed by a policy change. Providers should also be able to continue to utilize testing by a DEA-approved certifying body. Such flexibility would preserve DEA oversight of EPCS service providers, and free up DEA certification administration resources to be used more efficiently 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 to issue an electronic prescription, which does not allow for a second authentication to occur on the same device (e.g., smartphone) that provides the first authentication. Advancements in technology have long ago made this requirement unnecessary and obsolete, and the requirement has no public benefit today. Such requirements ignore the advent of secure cloud computing-enabled approaches that would allow independent devices to perform the same task. DEA's interim rules should be revised to permit the use of multiple functionalities in a smartphone to address first and second authentication requirements when distinct from one another (e.g., the first authentication is a face or fingerprint scan done by the phone, while the second authentication is the generation of a soft token done by an independent app installed on the same iPhone). CHI requests DEA make policy changes to enable efficient and secure solutions for EPCS, which will also make compliant EPCS technology more affordable for those prescribing controlled substances electronically.
- CHI also encourages DEA to lower barriers to entry by assisting in the development of an open and accessible technical standard that provides new entrants to the EPCS market with a baseline from which to innovate, which should be developed in collaboration with the private sector, academics, and others. Such a standard should provide criteria that a party can attest to for compliance purposes (consistent with CHI's recommended updates to section 1311.116 of the DEA EPCS interim rules above).
- DEA should begin implementing Section 3232 of the SUPPORT Act, which requires the agency in consultation with HHS to issue a regulation related to a Special Registration for telemedicine within a year of passage.

Food and Drug Administration (FDA)

The FDA, as the regulator of medical devices, has incredible opportunity to improve patient outcomes at reduced costs through reform of, and necessary clarifications to, its regulatory process. CHI continues to work with the FDA to remove barriers to innovation through revisions to guidance documents and other important policy changes, including in supporting the development of the Software Precertification Program. Overall, we commend the FDA's risk-based approach to the regulation of medical devices, including its use of enforcement discretion for low-risk devices.

CHI notes several ongoing challenging developments, however, that should be re-evaluated by the FDA:

- **Clinical Decision Support (CDS) Software** – We continue to be concerned with the FDA's proposed approach to CDS, which has yet to be finalized. The guidance requires significant revisions to reduce barriers to innovation in software being used for clinical decisions per Congress' intent in the 21st Century Cures Act. Areas needing revision include: the draft guidance's definition of CDS; key terms such as "a pattern or signal from a signal acquisition system" and "physiological signals;" and FDA's new proposed approach to the "independent review" of the basis for the recommendations presented by CDS, including its proposed approach to exclude "proprietary" algorithms from ever enjoying enforcement discretion.
- **Prescription Drug-Use-Related Software (PDURS)** – CHI is concerned with the Center for Drug Evaluation and Research's (CDER) proposed approach to the PDURS in recently released draft guidance,[8] which would divert from the Center for Devices and Radiological Health's (CDRH) work to modernize the FDA's approach to the regulation of Software as a Medical Device (SaMD). For example, CDER's approach to PDURS would take a situation-based approach, as opposed to the CDRH's risk-based approach to SaMD. Furthermore, CDER's proposed approach to PDURS would expose software developed by a drug company to significantly longer approval timeframes, placing PDURS at an arbitrary disadvantage to SaMD overseen by CDRH. We recommend that the FDA's approach to PDURS be brought into alignment with the widely supported approach developed by CDRH for SaMD.

[8] 83 Fed. Reg. 58574 (Nov. 20, 2018), available at https://www.govinfo.gov/content/pkg/FR-2018-11-20/pdf/2018-25206.pdf.

- **Artificial/Augmented Intelligence (AI) and Machine Learning (ML)** – Because of AI and ML's incredible potential to improve treatments and patient outcomes, CHI believes that the FDA must directly address the role of AI and ML in a new standalone guidance document. Innovative medical software will likely utilize AI and machine learning to improve the software's processes, and it is important that the FDA ensure that a scalable, risk-based approach be taken to regulation and enforcement discretion. Industry, and software developers in particular, will benefit from FDA directly addressing AI and machine learning in this guidance. CHI commends the FDA for its development of a draft framework that would address some AI's use in treatments and has developed granular recommendations for the FDA on how to appropriately address AI as a medical device regulator.[9]

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. CHI strongly recommends that NIH set an imperative for increased exploration of digital health tools in healthcare, including the growing role of AI in healthcare.

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;

[9] https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device.

- 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 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. CHI requests that HHS Office of the Inspector General (OIG) 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, we call on OIG to 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 will be implemented later this year, 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 health care industry an additional 7 month 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 7 months to the end of 2022, which is 6 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 proposed, 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. The CHI therefore urges ONC to

state its commitment to require implementation of the API portions of the Cures regulations no later than the end of 2022 so that patients and health care providers can better access and use the data in records to improve the coordination, quality, and safety of care.

CHI greatly appreciates ONC's effort to provide regulatory relief and flexibilities to support our health care system in response to the national threat of the COVID-19 pandemic. While we are supportive of the extension of certain compliance and applicability dates included in the Cures Act Final Rule, we remain concerned that the newly published timelines associated with information blocking provisions do not go far enough. To be clear, CHI acknowledges the need to propel development and adoption of APIs. However, provider compliance with the information blocking regulations by April 5th 2021, particularly given the continued strain of the pandemic on medical providers, is simply not feasible to an already over-burdened clinical workforce. CHI strongly encourages ONC to extend *provider information blocking applicability dates* to at least the end of 2021, or as long as the COVID-19 pandemic continues to impact providers' ability to implement and comply with the information blocking requirements.

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.