ConnectedHealth

Date: December 13, 2024

To: President-Elect Donald Trump
Policy Advisor

From: Connected Health Initiative

Re: The Imperative for the Trump-Vance Administration to Improve and Modernize the American Healthcare System

The Connected Health Initiative (CHI) congratulates you on your victory in the 2024 Presidential Election. Beginning in 2025, your Administration has an incredible opportunity to improve and modernize the American healthcare system through commonsense and light-touch steps across a range of areas discussed below, all of which would leverage the power of digital health tools like remote patient monitoring and artificial intelligence to improve patient outcomes and reduce costs.

CHI is the leading multistakeholder policy and legal advocacy effort dedicated to improving health outcomes while reducing costs. Our work is driven by the 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 intelligence (AI) in care delivery. For more information, see www.connectedhi.com.

CHI fully agrees with your goals of unleashing innovation in, and decreasing costs across, the healthcare sector. Inefficiencies and redundancies, too often perpetuated in federal regulation, persistently stand in the way of improving patient care, reducing costs, augmenting population health management, and supporting the healthcare workforce. We strongly support the Trump-Vance Administration's new leadership and efforts to seize the opportunity to realize the potential of digital health tools and services as rapidly as possible.

There are immediate steps that can provide support for digital health tools and services that will produce positive changes in millions of Americans' lives. We strongly encourage the launch of a new healthcare-wide effort, in collaboration with impacted stakeholders, to modernize and improve the American healthcare system through the responsible uptake of digital health technologies by using risk-based and technology-neutral rules that are responsive to demonstrated harms.

Digital health tools and services that CHI members produce and leverage for a wide range of use cases will squarely support the Trump-Vance Administration's efforts to modernize governance, grow the economy, and unleash innovation. In the attached appendix, we have detailed many of the actions the new Administration can, and should, take. 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 TRUMP-VANCE ADMINISTRATION SHOULD TAKE TO IMPROVE AND MODERNIZE THE AMERICAN HEALTHCARE SYSTEM IN 2025-2029

****Executive Summary: Recommended Steps for Modernizing American Healthcare (2025-2029)****

The memo outlines strategic recommendations for the Trump-Vance Administration to enhance and modernize the American healthcare system from 2025 to 2029, focusing on digital health innovations, regulatory reforms, and improved patient outcomes across various agencies. Recommendations include:

> ***Assistant Secretary for Technology Policy (ASTP)*** – ASTP should enforce interoperability rules under the 21st Century Cures Act without delay and take new steps to support health data interoperability consistent with Congress' intent. ASTP should also consider reframing AI transparency reporting requirements as voluntary.
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> ***Centers for Medicare & Medicaid Services (CMS)*** – CMS should take overdue steps to bring the power of digital health tools, including AI, into beneficiary care. Needed steps include revising its practice expense methodology to better support Software as a Medical Device (SaMD) and integrate telehealth, remote monitoring, and AI into Medicare services; expand the Medicare Diabetes Prevention Program to include virtual providers and support digital diabetes management tools; and focus on outcome-based approaches in the Quality Payment Program to promote digital health tools. Further, CMS' CMMI should prioritize innovative healthcare delivery models using technologies such as remote monitoring.
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> ***Drug Enforcement Agency (DEA)*** – DEA must put permanent policies in place to support electronic prescribing that countless Americans have come to expect.
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> ***Food and Drug Administration (FDA)*** – FDA should streamline its regulatory processes to bring new innovations to market more efficiently, otherwise support AI and Machine Learning innovation, and streamline clinical trials.
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> ***Office for Civil Rights (OCR)*** – OCR must take new steps to support the use of digital health tools through clear Health Insurance Portability and Accountability Act (HIPAA) compliance guidance, heightened engagement with stakeholders, and ensuring regulations do not hinder AI innovations.

These recommendations aim to foster a healthcare environment that embraces technological advancements, ensuring improved patient care and cost efficiencies.

AGENCY-SPECIFIC RECOMMENDED STEPS THE TRUMP-VANCE ADMINISTRATION SHOULD TAKE TO IMPROVE AND MODERNIZE THE AMERICAN HEALTHCARE SYSTEM IN 2025-2029

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 has 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. Yet, AHRQ's approach has been hampered by unsubstantiated skepticism of the benefits digital health innovations like AI could provide.

AHRQ must play a leading role in examining ways to explore the benefits of digital health tools by promoting a fresh approach to examining the benefits of digital health tools. 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.

Assistant Secretary for Technology Policy (ASTP) [formerly the Office of the National Coordinator for Health Information Technology (ONC)]

ASTP's support for the 21st Century Cures Act's trusted exchange framework and common agreement provisions remains an imperative for supporting patients and reducing costs. CHI appreciates ASTP finalizing regulations that will equip individuals with their own medical data and facilitate the sharing of that information in a standardized manner through its information blocking rules and subsequent updates in its "HTI-1" rule. However, healthcare data interoperability goals established by Congress many years ago have clearly not been realized. The lack of interoperability is due to the extreme complexity and a lack of enforcement of existing rules, leaving good faith innovators in the healthcare technology space subject to the same inefficiencies and abuses that prompted congressional action to begin with. ASTP 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. Further, ASTP action is needed to support needed next steps in health interoperability, such as more consistent access to images for providers and updates to certification criteria for payer and public health software functionalities in alignment with CMS-establish API requirements.

CHI is also concerned with ASTP's decision during the previous Administration to outsource significant policy decisions under the Trusted Exchange Framework and Common Agreement to third parties who did not engage in adequate consultations with impacted stakeholder communities before setting deeply impactful policies. Such decisions should be subject to notice and comment periods.

CHI further has concern with ASTP's decision to implement AI transparency reporting requirements for "predictive decision support intervention" AI in the electronic healthcare record space, which were adopted pursuant to the previous Administration's AI Executive Order. These reporting requirements overlap with existing requirements, and we urge for their withdrawal (or at minimum, their conversion into voluntary reporting measures).

Centers for Medicare & Medicaid Services (CMS)

Building on leaps forward made during President Trump's previous Administration, CMS has incredible opportunity to leverage the immense value of health innovations that improve healthcare outcomes and secure significant cost savings, including telehealth, remote patient monitoring, and AI.

Software as a Medical Device (SaMD) as a Direct Practice Expense: We are encouraged that CMS recognizes that its existing practice expense (PE) methodology creates significant barriers to the uptake of digital health innovations through the classification of most SaMD as indirect practice expenses. However, CMS efforts to address this outdated and anti-innovation policy have stagnated, particularly during the previous administration.

While the existing PE methodology is meant to account for a physician practice's costs, both direct and indirect, the ongoing choice of CMS to categorize SaMD as an indirect practice expense discourages the uptake and use of SaMD, remains one of the largest barriers to meaningful Medicare payment reforms, and is long overdue for a change. CMS' indirect methodology leverages cost bases and uses physician work relative value units (RVUs) but does not account for other factors like device maintenance.

While CMS began considering SaMD an indirect cost in 2019,[1] CMS has more recently indicated an interest in revising its approach to SaMD. CMS has been cross-walking payment rates for SaMD-inclusive codes to what CMS would have paid if the SaMD product had been included as a direct input. CMS has an obligation to steward Medicare beneficiary access to leading SaMD solutions and should seize this opportunity to advance meaningful PE methodology reform. We ask CMS to make these valuable SaMDs more accessible to Medicare beneficiaries by evolving its PE methodology to reflect the value that software provides by incorporating the value of software into Current Procedural Terminology® (CPT) codes to address PE and/or work intensity for RVUs. Specifically, the value of services delivered by a physician to interpret or act on new digital health technology information should be included in work RVUs, and the value of the software used to address improvements and efficiency in patient care should be factored into practice expense RVUs.

As CMS allows for SaMD reimbursement as direct supply inputs, CMS should obtain the most accurate estimate of the per-service cost of the input as possible, particularly by relying on invoices. CMS' equipment amortization formula should only apply in the case of locally installed computer programs with an upfront payment where a useful life can be estimated and where that SaMD is only used in one service at one time.

[1] *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; et al*, 83 Fed. Reg. 59452, 59557 (Nov. 23, 2018).

CMS should also bring eligible digital health innovations into Medicare beneficiaries' care continuum by clarifying whether digital medical devices, such as SaMD, are included in existing benefit categories.

Consistent with CMS' clear authority and its obligation to improve Medicare beneficiary outcomes, we call on CMS (1) to act in its Calendar Year 2025 Physician Fee Schedule rulemaking to effect overdue changes to its PE methodology to accurately categorize and support the use of SaMD in Medicare; and (2) to then launch a standalone consultation to inform broader reforms to its PE methodology. We appreciate your attention to this important issue and look forward to working with you to broaden beneficiary access to SaMD.

Telehealth: In key Medicare payment rules (e.g., the Medicare Physician Fee Schedule) CMS has enabled the expanded use of telehealth, which is restricted to live voice/video calls in Medicare due to statutory restrictions. The previous Administration insisted on a read of the Social Security Act (SSA) that imposes outdated constraints that long ago ceased to have public benefit on where and to whom these services are made available. CHI requests that CMS revisit its read of the SSA to appropriately and permanently avoid the application of SSA Section 1834(m) restrictions on telehealth services, as well as asynchronous remote monitoring and other digital modalities.

Remote Monitoring: In the first Trump Administration, CMS enabled the use of remote physiologic monitoring (RPM) and remote therapeutic monitoring (RTM) services for both acute and chronic conditions in Medicare 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' payments for RPM should be increased to provide much-needed support for this critical modality that is vital in preventing and treating the system's most expensive chronic conditions. CMS should step forward in removing outdated barriers to innovation and use of RPM and RTM through such steps as waiving co-pay requirements for these services and providing guidance on remaining questions plaguing the RPM and RTM tech developer and provider communities to support its wider use, which is already demonstrated to improve outcomes while reducing Medicare costs.

Artificial Intelligence: While your Administration took significant steps to support AI innovation in healthcare, the Biden-Harris Administration left many opportunities on the table, in some cases taking steps that have inhibited progress for health AI across prevention, treatment, or administrative contexts. We call on CMS to take much needed steps to recognize the value of countless AI tools (over 500 of which have already been approved by the FDA) to improve Medicare beneficiaries' experience and care,

Diabetes Prevention: 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 digital health technology for diabetes prevention and treatment, this condition imposes a significant burden on CMS' Medicare program and its beneficiaries, totaling hundreds of billions of dollars each year. 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:

- Finally 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.[2]

- Supporting virtual diabetes self-management training (DSMT), which would eliminate costly 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."[3] CMS has the regulatory authority in the DSMT authorizing statute,[4] 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 the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)[5] implementation, we encourage the Trump-Vance 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 part of the Quality Payment Program (QPP).

CMS is still chasing the ideal of a value-based U.S. healthcare system. Unfortunately, utilization of digital health tools in the Merit-based Inventive Payment System (MIPS) and in Alternative Payment Models (APMs) remains unrealized. MACRA's implementation has not even begun to approach 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 of which produced 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 Trump-Vance 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.

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

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[2] 85 Fed. Reg. 50074 (Aug. 17, 2020).

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

[4] 42 U.S.C. 1395x(qq).

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

- Reducing the reliance on CMS program participation and the use of Certified Electronic Health Record Technology (CEHRT) through the continued evolution of the Promoting Interoperability (PI) Program. 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.
- Permitting a professional to satisfy the demonstration of meaningful use of CEHRT and information exchange through attestation, which is allowed under existing law. HITECH 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.
- Developing, and publicly releasing, a comprehensive vision of a diverse array of connected health products and services, including telehealth, remote monitoring, and AI, playing an integral role in the success of APMs, and provide specific incentives and credits for the responsible use of these digital health tools.
- 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 APMs, including payment bundles and medical home demonstrations.

Medicare Advantage (MA): 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 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 ensure MA plans' alignment with CMS' established approaches to Medicare fee-for-service telehealth services, including remote patient monitoring and other "remote communications technology" that CMS has expressly stated do not fall under 1834(m) and its restrictions. CMS should also fully leverage the potential of AI in accomplishing MA goals.

In addition, CMS should modify its 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 of "remote patient monitoring" in the HHPPS 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. We commit to work with CMS and any other impacted stakeholders to develop and advance consensus policy changes.

Center 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 Trump-Vance 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.

CMMI should also recognize and build upon the incredible successes of health systems such as the University of Mississippi Medical Center, the University of Virginia, and Boston Children's Hospital. In these locations (and some others), Medicaid programs have taken steps to support not only telehealth but—more importantly—remote monitoring innovations that bring patient-generated health data (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. For example, if a device is capable of acting as a pulse oximeter and heart rate monitor, then it should be eligible for coverage as DME even if the device has other non-medical capabilities. 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 ignores 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.

Part D: CHI generally supports CMS' work to provide clarity on Medicare Part D plan sponsor requirements but remains concerned that CMS is not enabling the maximum potential of digitally-enabled pharmacies that provide convenient and efficient home delivery that Americans across the country expect. CMS should take clear steps to support digitally-enabled pharmacies by avoiding applying the same requirements to each pharmacy type, as the previous

Administration proposed, which will hold back digitally-driven efficiencies from countless beneficiaries without benefit to them.

Department of Homeland Security (DHS)

Given the increasing quantity and magnitude of cybersecurity breaches in the healthcare sector, DHS' Cybersecurity and Infrastructure Security Agency (CISA) should expand its public-private partnership work, namely through the Health Sector Coordinating Council (HSCC), to support proactive to prevent, detect, and mitigate cybersecurity attacks (e.g., ransomware). Recommended actions include:

- CISA, in coordination with HHS and the National Institute of Standards and Technology's (NIST), should assist in developing tailored disaster mitigation, recovery, and business continuity plans based on NIST's Cybersecurity Framework (and standardized industry controls and processes), including through promoting secure-by-design practices.
- Support the development and use of software bills of material (SBOMs) that improve visibility into potential risks, augment risk management generally, and enhance security.
- Updating guidance, and where necessary working with Congress to update the law, to streamline the timely flow of cybersecurity threat indicators and other attack-related information between and amongst non-government entities and government agencies.

Internal Revenue Service (IRS)

There are tremendous new software-based health technologies available that can and should be eligible for health savings account (HSA)/flexible spending account (FSA) reimbursement. The IRS should clarify that hearing devices are eligible for FSA/HSA reimbursement if they contain an FDA cleared hearing aid feature and the user needs that function. Additionally, dual purpose items should be included on the list of products eligible for reimbursement so that users have assurance that if they purchase a hearing device that has both hearing aid capabilities and other capabilities, that they are eligible for reimbursement if they are using the device as a hearing aid.

Drug Enforcement Administration (DEA)

Initially noting that the Drug Enforcement Administration (DEA) is ill-suited for regulating digital health technologies, we appreciate that while DEA has temporarily expended flexibilities needed to support the electronic prescribing of controlled substances (EPCS), a policy making these flexibilities permanent is sorely needed. DEA's proposed permanent policy during the last Administration would: (1) restrict virtual prescriptions to no more than half of a provider's prescriptions; (2) require providers prescribing any controlled substances to check prescription drug monitoring programs intended to prevent diversion in all 50 states when a system linking the programs doesn't connect to every state; and (3) prohibit virtual prescribing of Schedule II drugs without an in-person visit first unless the prescriber is a specialist. Each of these restrictions harms patients and inhibits innovation.

In crafting this permanent policy:

- The DEA's requirements under section 1311.116 that require testing by a DEA-approved certifying body are unnecessarily rigid. In the10 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 smartphone). 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).

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, but further reforms are needed to streamline the pathway to market through overdue reform. 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.

Specific recommendations include:

- **Streamline reviews, approvals, and compliance:**
    - FDA should launch a focused effort to identify overburdensome regulatory and paperwork requirements faced by those engaging in FDA review and approval processes, including with public comment, and eliminate outdated and redundant requirements.

- FDA should provide confidence that the use of secure cloud-based services is fully compliant with regulatory requirements.
- FDA should increase the quality and efficiency of its 510(k) process by leveraging third party review organizations that will assist in reducing the review backlog responsible for much of the delay in navigating the FDA's process.
- FDA should develop a mechanism for validating an organization's trustworthiness generally so that individual products produced by its product development process enjoy a presumption of compliance and streamlined pathway to the market.

- **AI and Machine Learning (ML):** Because of AI and ML's incredible potential to improve treatments and patient outcomes, CHI urges FDA to build on its world-leading expertise in AI medical devices by rapidly updating relevant guidance to support AI that continuously learns and updates to improve its performance (as opposed to "locked" algorithms), which offer incredible potential for countless patients. In setting these policies, it is important that the FDA ensure that a scalable, risk-based approach be taken to regulation and enforcement discretion, which should permit the operation of low-risk AI without a human in the loop.
- **Streamline Clinical Trials:** FDA should reform its approach to clinical trials by better leveraging real world evidence to drive patient-reported outcomes, providing needed flexibility in outcomes assessments, and focusing efforts on promotion of trial creativity. FDA should also take significant steps to streamline clinical trials using widely-available technologies (such as smartphones) by supporting the "bring your own device" model, as well as reducing compliance and paperwork burdens on companies.
- **Drug Development:**
  - *Modernize Drug Shortage Regulations* – FDA should modernize its approach to regulating pharmacy compounding. More accurate and timely information regarding the supply of prescription drugs would be possible by broadening the types of data considered when making a drug shortage determination. The agency should also consider "shortages" through a broader lens, as a range of factors including cost and insurance coverage status can impede patient access.
  - *AI Use in Drug Development* – AI can and should play a central role in the development of new drugs that will save lives. CHI supports FDA developing needed guidance, and expressing support for, the responsible use of AI in drug development.
  - *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,[6] 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

[6] 83 Fed. Reg. 58574 (Nov. 20, 2018), available at https://www.govinfo.gov/content/pkg/FR-2018-11-20/pdf/2018-25206.pdf.

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.

Indian Health Service (IHS)

Digital health innovations offer immense value to those who rely on the IHS, and they should be fully leveraged to assist American Indians and Alaska Natives who need comprehensive health services. IHS must modernize its programs and efforts to support those who rely on the IHS with direct support for new deployments and continued use of telehealth, RPM, and other digital health tools.

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.

We urge OCR to engage in ongoing outreach to the range of stakeholders affected by the HIPAA rules, including the developers and 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 hinder 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 Covered Entities (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, which will provide needed 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, Communications Technology-Based Services (CTBS), 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 employing a outcome-based and technology-neutral approach to regulation, also ensuring that emerging technology innovators have clarity as to when HIPAA rules may be triggered.

Finally, we strongly urge OCR to withdraw its imposition of AI-specific liabilities on providers under Section 1557 of the Affordable Care Act, which were adopted pursuant to the previous Administration's AI Executive Order. Section 1557 already prohibits discriminatory outcomes in a technology-neutral manner, making additional requirements on providers using AI needless and, effectively, nothing more than a disincentive to leverage efficacious and safe AI tools to improve patient outcomes.

Office of the Inspector General (OIG)

As clinicians remotely monitor patients' acute and chronic conditions at home, there are ongoing concerns that any equipment or access to software platforms provided free of charge may inadvertently trigger liability under the Anti-Kickback Statute (AKS). CHI requests that HHS Office of the Inspector General (OIG) clarify that providing access to software-based platforms for 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 civil monetary penalty (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 healthcare 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).