Personal Connected Health Alliance

Personal Connected Health Global Policy Priorities

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A HIMSS ORGANIZATION

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**Personal Connected
Health** Alliance

With a mission to help people make health
and wellness an effortless part of daily life,
the Personal Connected Health Alliance
is a nonprofit organization formed by
HIMSS that convenes the global personal
connected health community, to accelerate
the technical, business, policy and social
initiatives necessary to advance the
personal connected health field.

Introduction

The rapid advance of personal health technology in the digital age has brought a remarkable increase in tools that can be used by individuals and health care providers to make better-informed choices about health and wellness. Individuals are able to monitor their own activity, heart rate, sleep patterns and a host of other biological indicators with smart phones and combined personal wellness devices such as activity trackers and smart scales. These same technologies and other medical devices in the home can transmit health data to informal caregivers or healthcare professionals to monitor patient recovery or chronic conditions. Innovations that improve outcomes through data-driven health delivery also require an appropriate regulatory framework to increase coverage, to guide the processing of personal data, and to ensure the safe and secure use of validated technology.

Policies guide the use of new technology, ensure safety and promote a seamless exchange of information. Policies are further refined and interpreted by the appropriate regulatory agencies to translate those legislative intentions into action and practical guidelines for use. Policies and regulations together create an environment where stakeholders can engage in the safe and secure transfer of information, utilizing approved payment and reimbursement mechanisms. The current state of personal connected health technologies depends in large part on policies and regulatory mechanisms at multiple levels.

It is important to start by defining *personal connected health* in the context of this document since the language and definitions used by different agencies and stakeholders have an impact on the way health technologies are reimbursed, delivered and regulated. This report considers personal connected health as the personalization of health through the use of digital technology to support individuals to make sustainable health behavior change by gaining visibility or insights into physiological processes along with other relevant personal health information and through connection to caregivers as well as health professionals and health systems. This includes all digital, electronic, or telecommunication technology that helps patients and providers to improve healthcare delivery and decision-making. In addition to the ability to increase access and quality of care, personal connected health technologies help people make healthy lifestyle choices outside the boundaries of the healthcare system or patient-provider relationship. Examples include health and wellness sensors, devices and apps we load on our smart phones and tablets. Other terms used by stakeholders, including telehealth, remote patient monitoring, (RPM) eHealth, mHealth, and health IT are included in this broad definition.

This document aims to give an overview of the key policy themes and issues related to the use and advancement of personal connected health technologies in the United States, Europe, and other regions of the world. Recommendations and possible future directions for engagement in policy and advocacy are discussed.

Policy and Legislation in the United States

Background

The current landscape of personal connect health policy in the United States is built on a number of laws enacted in the past decade that have paved the way for expanded use and access to some key health information technology tools. These policy-level changes have focused on promoting and incentivizing the use of electronic health records (EHRs), interoperability of health IT, and the expansion of digital connected health services and technologies in Medicare, the federal single-payer health insurance program for people age 65 and older. As the country's single largest payer for health care, the Centers for Medicare and Medicaid Services (CMS) has the ability to drive change and adoption of health information technology in the US.

The 2009 signing of the HITECH (Health Information Technology for Economic and Clinical Health) Act created new incentives for the expansion of health IT with standards for the use of electronic health records, incentives for Medicare and Medicaid providers to use electronic health records and health IT in a meaningful manner (Meaningful Use), and the mandate for the Office of the National Coordinator for Health Information Technology (ONC) within the Department of Health and Human Services.[1, 2] Reports and evaluations after three stages of the Meaningful Use program launched with the HITECH Act show that providers and hospitals have increased their use of EHRs, most Medicare and Medicaid eligible hospitals are receiving incentive payments,[3] and nearly all hospitals are implementing meaningful use of EHRs.[4] However, there are still gaps in the transfer of information between patient points of care, between providers and patient monitoring systems, and between patient self-management technology and provider systems.[5] Many of these gaps persist because of a lack of interoperability between EHR systems and with other personal health devices. With the aim of promoting interoperability, the ONC publishes the Interoperability Standards Advisory with regular updates that include a stakeholder comment process. However, interoperability has been advancing slowly across a large and complex system of federal agencies, health care providers, and private technology vendors.[6, 7]

The Medicare Access and CHIP Reauthorization Act (MACRA) enacted in 2015 mandated CMS to implement the Merit-Based Incentive Payment System (MIPS) for Medicare-enrolled providers. Medicare providers enrolled in the MIPS Quality Payment Program will earn a higher or lower payment adjustment in subsequent years depending on their composite score in relation to the CMS thresholds for that year. One of the components of the MIPS score includes Advancing Care Information that establishes incentives and standards for EHRs and replaces the Meaningful Use program for qualifying providers. This category also promotes patient engagement through the electronic exchange of health information and the use of certified EHR technology in line with the ONC Health IT certification program.[8, 9]

Most recently, the 21st Century Cures Act enacted in December 2016 includes a number of health IT provisions. It mandates the interoperability of all electronically accessible health information technology systems (most notably EHRs) and prohibits the blocking of electronic health records by information technology vendors.[10] ONC is responsible for creating a framework for interoperability in the network exchange of health information. The Act also established the Health Information Technology Advisory

Committee (HITAC) to advise the ONC on criteria, standards and policies for the advancement of electronic access, exchange, and use of health information. It also clarifies the definition of medical software and apps that will not be regulated under the Food and Drug Administration (FDA) such as healthy lifestyle software, electronic health record software, administrative software and those for transferring, storing or displaying medical data. The classification of medical software or app depends on the intended use of the software and the potential risk to patients; the Act gives the FDA authority to regulate any device or software that it determines to be a safety risk.

The 21st Century Cures Act also includes an important provision for CMS to investigate expanded telehealth use and report to Congress within one year. The legislation requires CMS to evaluate which beneficiaries would benefit from increased access to connected health technology services as compared to existing in-person standards of care, and the final text of the bill included the opinion (a "Sense of Congress" resolution) that the existing classification of sites eligible to receive Medicare reimbursement for telehealth services should be expanded.[11] Current Medicare definitions restrict eligible telehealth sites to rural or "critical access hospitals," but this perception of telehealth primarily as a tool for remote populations is changing. A change in the geographic limits of use would open the possibility to expand not only patient access to personal connected health technologies but also health care provider willingness to use these tools.

Major Health Information Technology Policy in the Past Decade	
2009	HITECH Act
2015	MACRA/MIPS
2016	21st Century Cures Act

State-Level Issues

Different policies and regulations at the state-level create a patchwork of personal connected health use and availability across the US. Even the federally mandated Medicare program is less restrictive for telehealth use in Alaska and Hawaii, where asynchronous store-and-forward technology (the collection and storage of clinical information for later retrieval and review by a healthcare provider) and is permitted and reimbursable under certain conditions. Overall, policy themes and issues at the state-level mirror those at the Federal level, including reimbursement, limitations on types of technologies and clinical settings, as well as cross-border licensure and legal complications.

Medicaid is the social health care program for low-income and disabled people of all ages in the United States. It is managed and administered at the state level, allowing for variation in policies regarding personal connect health service use and reimbursement. Currently all 50 states allow for some reimbursement of connected health services under Medicaid. Unlike Medicare's telehealth restrictions, however, most states do not restrict connected health technology to rural areas, and 15 states allow store-and-forward technologies. Twenty-one states allow some form of remote patient monitoring.[12]

Policy and Legislation in the
United States (continued)

Each state has different restrictions on the kinds of providers, clinical uses and rate of reimbursement for different personal connected health services.[13]

States also have the ability to require private insurance providers to reimburse for connected health services in their state. Currently 31 states have some provision requiring private insurance providers to reimburse for certain personal connected health technologies. Again, the limits and categories of allowable use vary state-by-state. One state that stands out is Mississippi, with provisions that require coverage for live audio-video telehealth, store-and-forward, and remote patient monitoring services for certain conditions under both private insurance providers and Medicaid.

The legal issue of cross-border health care delivery between states is another policy barrier to personal connected health. Physicians must be licensed in the state where they practice medicine, restricting their ability to engage in connected health services for patients in other states. Medical liability insurance coverage and the patchwork of policies for reimbursement further complicate any digital health application involving more than one state.

There is evidence that state-level policies on reimbursement for telemedicine and connected health services in their Medicaid or private insurance markets increases the use of Medicare telehealth services as well, presumably by increasing the base utilization of such programs to improving sustainability.[14] State-level policies can have a marked influence on utilization and access to connected health services.

Future Directions for the United States

A number of bills before the 115th Congress (2017–2018) have the potential to advance the adoption and use of personal connected health in the US The main focus of these proposed policies is on redefining the narrow use and application of "telehealth" in Medicare by allowing reimbursements for a larger range of providers, a wider geographic reach of telehealth, and the use of expanded connected health technologies. The current themes and trends in personal connected health policy are discussed here; the details of specific bills before Congress can be found in Appendix B.

The mandate for Medicare is to provide health insurance for people 65 or older, primarily in the treatment of illness and chronic conditions for this population. Therefore, the main focus of proposed Medicare telehealth legislation is to increase reimbursement for existing telehealth services for the remote management of patients with chronic conditions or multiple chronic conditions. At this time, live two-way audiovisual communication between a patient and provider is the only service that qualifies for Medicare reimbursement, and only for a limited subset of patients and providers.[15] This limited allowance could be expanded to include asynchronous communication involving the transmission of health data collected over time, or remote patient monitoring technologies that send regular health data from the patient to the provider for continuous tracking of patient recovery and chronic condition management. Provisions in the proposed CONNECT for Health and the CHRONIC Care Acts would

expand the allowable and reimbursable use of remote patient monitoring technologies for certain Medicare providers and Medicare Advantage plans (see Appendix B).

Medicare currently views telehealth as a tool to reach patients in remote, rural, or underserved areas and restricts reimbursable telehealth services to rural Health Professional Shortage Areas. Eliminating this geographic restriction is a key focus of efforts to advance personal connected health; provisions addressing geographic restrictions on some telehealth services are included in several bills currently before Congress, including the CONNECT for Health and CHRONIC Care Acts.

"It's great that people in rural communities can take advantage and access [remote] services but it's limiting to people in other environments who could access and benefit from these technologies as well."

Aside from these legislative initiatives currently before Congress, a number of opportunities exist to change the policy environment through regulation, rules and guidance documents in various agencies. One current issue is changing codes in the Medicare Physician Fee Schedule to recognize remote patient monitoring as a stand-alone service. The Current Procedural Terminology (CPT) codes lump the collection and analysis of physiologic data as a miscellaneous service that cannot be reimbursed on their own but rather as an addition to another procedure or service that is covered by Medicare.[16] CMS revises the Physician Fee Schedule annually and this year's revision included a request for comments and information regarding remote patient monitoring and the "unbundling" of these codes. The process of redefining the codes, providing comments and information, is an important opportunity to allow reimbursement for remote patient monitoring services under Medicare.

In addition to CMS, other government agencies periodically solicit comments or request information on telehealth, health IT and personal connected health topics. For example, the ONC requests comments and feedback on information exchange frameworks as part of its mandate to ensure a public-private partnership consensus on health IT interoperability. The House Committee on Ways and Means recently requested comments in relation to the Subcommittee on Health's Medicare Red Tape Relief Project. The Agency for Healthcare Research and Quality (AHRQ) and the National Quality Forum (NQF) request comments on research and evidence reviews (see below). Responding to these requests for stakeholder comments with targeted and detailed messages is a critical effort to increase reimbursement allowances for telehealth, expand geographic availability, allow reimbursement for remote patient monitoring, and promote interoperability in personal connected health devices.

Recent reports developed by NQF and AHRQ focus on standardizing research and evidence regarding personal connected health technology applications.[17, 18] These efforts will hopefully lead to a stronger evidence base to assess impact and lead to a standard of care recognized by all stakeholders for remote patient monitoring and patient generated health data.

Policy and Legislation in the European Union

Background

The European Union defines the policy and regulatory framework for connected health not only for its 28 (soon 27) Member States with more than 500 million residents, but — through treaties, agreements, and soft power — for the entire Europe region and beyond. However, the individual Member States, through the rules of subsidiarity, retain their powers to set the rules for healthcare delivery, including defining whether and to what extent connected health services can be covered through their health systems. Reimbursement is thus a matter of national and, in many bigger Member States, regional decision making.

The EU framework includes a number of recent regulations that have implications for future policy, innovation and advancement of personal connected health technologies. Among them is the recently enacted EU Medical Devices Regulation that clarifies the definition, classification and regulation for medical devices, including medical software, apps and monitoring devices. Software that is used to inform decisions that could have an impact on a person's health or monitor changes in health indicators and that could signal a serious health condition fall under a higher-risk category, with more stringent regulations. The focus in this regulation is on safety requirements and clinical evidence for medical devices. There is agreement that the MDR improves the conditions for better deployment of connected health technology by clarifying the difference between a medical device and a consumer device.

Personal data protection across all sectors is another key theme in European policy. The EU General Data Protection Regulation (GDPR), enacted in 2016 will take effect in May 2018 to cover the protection of personal data across all digital services and sectors; it will have implications for the Health IT sector in the EU. It provides a minimum standard for obtaining informed consent before the collection of personal data, for the security of all personal data, and it empowers individuals with the right to access, withdraw consent, erase, or transfer their own personal data. The regulation also sets standards for the accountability of all individuals and organizations that collect or process the data, including third-party cloud servers, data management and storage services. The protection is mandated across all EU Member States and applies to any data concerning an EU citizen that is collected, managed, processed, or stored by companies anywhere, including outside of the EU.[19, 20] With the threat of significant penalties, the regulation will force far-reaching data security changes and will require careful consideration of the legal basis of data protection before collecting any personal data.

> **"While the US environment is becoming more permissive, the EU is becoming more restrictive in protecting individual data privacy."**

The European eHealth Network is a body formed by EU Member State governments for promoting cooperation on healthcare IT strategy and through recommendations, guidelines and framework agreements. It was established in 2011 as part of the European Commission Decision regarding patient rights in cross-border healthcare. The voluntary Network, made up of Member State government health

authorities, is currently finalizing the multiannual work programme (MWP) for 2018–2021. The new MWP will focus on four areas: empowering patients, the innovative use of health data, enhancing continuity of care, and overcoming implementation challenges.[21] The MWP will be the basis of the work programme of the third Joint Action, the technical and research arm supporting the eHealth Network, led by the SPMS division (Serviços Partilhados do Ministério da Saúde/Shared Services for the Ministry of Health) of the Portuguese Ministry of Health.[22] SPMS recently joined the PCHAlliance, joining a number of European Ministries of Health that are seeking to deploy personal connected health technologies on the basis of PCHAlliance's Continua Guidelines for interoperability.

Future Directions for the European Union

The cross-border exchange of data is one of the four priorities for the Estonian Presidency of the Council of the EU for their six-month term (July–December 2017). The advanced IT sector in Estonia positions the Presidency to promote data flow in the EU, including data issues related to personal connected health. To this end, the Estonian Ministry of Health and Labour together with the European Connected Health Alliance convened the Digital Health Society (DHS) as a vehicle to advance the Estonian agenda with partners and stakeholders during and after Estonian Presidency. The DHS established four task forces covering the areas of interoperability standards, data donors/citizen-controlled data governance, legal framework for the free flow of data, and digital transformation in health and social care organizations. The task forces worked initially by invitation only, but will open up in advance of the eHealth Tallinn conference in October 2017.

In the realm of data privacy, while the GDPR regulation establishes a common data protection regime for the EU, in some areas any individual Member State can go beyond the regulation to establish more stringent rules for data privacy. This leaves the possibility of fragmented policies for the region as a whole and a level of uncertainty for industry and institutions concerned with health-related data. Any company or service that will process data of EU citizens in the EU or anywhere in the world will need to work with data controllers and legal experts to ensure compliance with the laws and regulations on data security and privacy in the EU.

> "There is the possibility of uneven deployment, enforcement or implementation of the GDPR regulations at the Member State level."

On the issue of interoperability, the promotion of the Continua Design Guidelines has the potential to advance on a country-by-country basis. Since the delivery of health services and the choice and procurement of relevant technology systems is the responsibility of individual Member States, the European Commission has been careful to issue any overarching regulation on specific interoperability requirements for medical devices. At the Member State or regional level, however, health systems can and do adopt interoperability standards to advance health IT systems and foster cross-border

Policy and Legislation in the European Union (continued)

cooperation and compatibility. Barriers to adoption at the country-level include concerns over data security and patient privacy, a lack of basic infrastructure needed to incorporate patient-generated data, and a lack of motivation to include patient-level data in medical decision-making. However, in health systems where the underlying infrastructure exists and decision-makers see the benefit of patient-involvement, governments recognize the obvious need for interoperability standards. One recent example is the health ministry for the Catalonia region in Spain; in July 2017 they mandated Continua compliance in glucose meters.[23]

> "Once a country has a vision to upload patient data electronically, then the idea of open standards is a no-brainer."

As in the US, there are many avenues for participating in the personal connected health policy agenda in the EU. These include occasional EC open consultations on digital health policy, the participation in the European Commission's eHealth Stakeholder Group (in which PCHAlliance is a registered member), and the involvement in EC-funded research projects (one currently active is the EURO-CAS project that is preparing an eHealth Interoperability Conformity Assessment Scheme for Europe). Visibility and participation in events such as the IHE Europe vendor-interoperability "Connectathon",[24] as well as a number of other industry, vendor, and government-level conferences, workshops and events are also critical to advancing the ongoing policy agenda in Europe. Participation, interaction, and providing targeted and timely comments, suggestions and guidance with all of the groups and stakeholders is critical to promoting advances in personal connected health in the EU.

Policy and Legislation Beyond the US and the EU

As technological advances and personal connected health devices reach every corner of the globe, the need for refined policies related to personal connected health extends to every nation. China presents a unique case of a large population with advanced IT infrastructure and large investments in the digital sector. The national health system employs thousands of data technicians, collecting data from health and social care sectors at national data centers throughout the country. New investment in health and technology by international corporations is poised to take advantage of the large healthcare market, considerable mobile phone market penetration, and sheer unlimited potential for expanding the data-management and data storage market. For example, this year the new Belt and Road Initiative, a trade and infrastructure "megaproject", will increase trade and investment along the ancient Silk Road across Asia, Russia and the EU. The project includes a health and life sciences component to drive the creation of the China Digital Health Society in cooperation with the Estonian EU Presidency initiative of the same name in Europe.

Amid this fast-paced investment the details of policymaking that drive and regulate personal connected health in China is unclear. The 2012 national eHealth strategy lacks key privacy and data sharing frameworks.[25] The development of health information systems and management of "big data" mentioned in the national health reform initiatives include the use of IT to enforce regulations and monitor healthcare provider's performance and behavior but is not explicit about the use and privacy of patient data.[26] In 2009 the Ministry of Health published the *Health Profile of Basic Architecture and Data Standards* for establishing standardized electronic health records, although there remain data silos and interoperability issues between hospitals, regions, stand-alone disease reporting systems and public-private systems.[27, 28] Advances and investments in personal connected health technologies are driven by private industry and private insurance providers, with a lack of coordination between the private sector and the national health infrastructure.[29] A new data security and privacy law took effect in June of 2017, adding to previous mandates on data protection in the country with standards for informed consent and confidentiality.[30] Although eHealth, the use of data management and IT is regularly mentioned as investment priorities for the public and private sectors in China, it is unclear how the cybersecurity mandates or health sector policies and regulations are guiding these investments and developments in the country.

India is another example of a large population facing many health challenges. A large proportion of the population is rural and access to healthcare is just one of many issues facing this developing country. India launched the National e-Health Authority (NeHA) in 2015, a regulatory body within the national government with the aim to standardize and regulate eHealth and EHRs for the future. Challenges to the development of a personal connected health system in India are familiar from other country experiences: they include interoperability, data privacy and security, and acceptance by healthcare providers.[31] There are some independent hospital-based health IT systems in place already, but interoperability standards are weak and there is no system for testing health IT systems or devices for interoperability. The intent at the national level to coordinate standards and policies offers an opportunity to develop a holistic framework of policies and regulations in coordination with the strong telecommunications infrastructure and the large pool of talented IT professionals in India.

Policy and Legislation Beyond the US and the EU (continued)

In Japan, healthcare reform is focused on reducing medical expenses as the country faces a significant aging population. Policies for this reform focus on prevention and coordinating effective care within the system. An amendment to the medical and nursing care reimbursement plan for 2018 aims to optimize the budget for care coordination, with connect health tools as one tool to achieve this goal. Remote patient care has the potential to ease medical professional's workload and can improve patient outcomes while lowering the overall healthcare cost in the long-term. The Japanese Ministry of Health, MHLW, is focusing on the utilization of big data, registry records and artificial intelligence that will be enhanced by digital connected health tools. This will require improved regulatory system including rules for medical software under the Universal Health Insurance system in Japan.

The social health insurance systems are the main target for implementing preventative health programs in Japan. Corporate health insurance companies, health insurance associations, and mutual aid associations are mandated to finance a considerable portion of the insurance cost for the elderly over the age of 75. In order to achieve this, the social insurance organizations will need to execute health improvement programs for their subscribers, and the progress of those programs will be measured and tracked by the MHLW to incentivize or penalize insurance providers for subscribers over 75. The government's indirect control over these prevention programs is expected to stimulate the use of healthcare IT. At this stage, the focus of PCHAlliance in Japan is to focus on the potential of policies to promote these connected health tools in the Japanese Health Insurance System rather than in diverse private sector programs. Success cases in the EU or other regions are expected to serve as blueprints to drive the direction for Japanese healthcare IT advancement and the views of the Japanese government on health IT for next couple of years.

There are a number of countries and regions with established personal connected health policies not presented in this review. Australia, Canada and Singapore, for example, each have specific eHealth legislation and comprehensive guidelines in place for the national health systems to move forward in the development and use of personal connected health technologies. Other countries are in the process of exploring, defining and fine-tuning policies related to personal connected health, while investment and the use of technology is increasing at a rapid pace. The potential of personal connected health to increase access to remote, rural and underserved populations is appealing to many national health systems.

In conversations with thought leaders in the field, it was suggested that institutions and government regulation bodies in countries actively developing eHealth policy are "looking to [the US and the EU] for a model to grow an enabling environment for health data," particularly in relation to the issue of privacy and data protection. These countries will need to tailor policies and standards to the local situation, infrastructure and culture, while also maintaining some degree of cooperation and interoperability for cross-border functionality. There is no doubt that personal connected technologies will continue to play a larger role in healthcare systems and delivery around the world; sound policies guiding these applications are needed to facilitate the growth and to realize the health benefits of these technologies.

The field of policy-making for personal connected health in other regions of the world can be harder to define and pinpoint, especially in low- and middle-income countries (LMIC) where an undeveloped health and technology infrastructure can be a roadblock to implementation and sustainability. Three main themes for policy around personal connected health in LMICs surface in a review of available information: poorly defined policies, sustainability of programs in resource-poor health budgets, and the issue of integrating personal connected health at the national level.

It is estimated that about half of the countries in Africa have an explicit, coherent policy in place regarding personal connected health. In general, the region is progressing beyond the initial stage of pilot programs to one of scale-up and broader interoperability considerations. For example, since 2003 Ghana has developed five eHealth policies, strategies and plans aimed at streamlining the regulation and management of health data, building capacity and transitioning to electronic medical recordkeeping.[32] Led by the Ministry of Health, the 2010 National eHealth Strategy has spurred a number of donor-funded pilot projects but the absence of any mention of eHealth or the Strategy in the most recent MOH Development Plan (2014–2017) puts into doubt the sustainability of programs and their priority within the national health system.[33, 34] In this and similar cases from LMIC scenarios, the policy may have preceded the capacity to implement personal connected health in an integrated and sustainable environment.

> **"We are going beyond the question of how do you get digital health working at all to getting it working at scale. The problem isn't a lack of policy but a lack of implementation."**

Regardless of the presence or absence of policies or guidelines, digital tools are being used for healthcare, in many cases outside of the healthcare system. WhatsApp and other messaging programs are useful to navigate complex bureaucratic communications systems, coordinate supply chain or organize personnel in some countries. In other cases, such platforms are being used in an ad-hoc manner to fill a need for digital consultation or coordination involving patient data. In published literature and case-studies WhatsApp is being used predominantly for consultations between healthcare providers and mainly in low-income country settings.[35, 36] However, the true extent of this kind of spontaneous use of apps not intended for healthcare delivery is unknown. Social messaging platforms and smartphone apps are easy to use and already a part of many patient and practitioner's daily life, but guidelines for their use, recommendations or validation of their use for clinical diagnosis, monitoring or transfer of patient information need to be developed and adapted on a country-by-country basis. Unfortunately, these spontaneous connected health interactions may violate patient privacy and security, are not integrated into the health system, and can create data silos of personal data and health records that are not coordinated with other health system records.

> **"The main challenge of next 5–10 years is to see how these extraordinary tools that can genuinely improve public health can be used at scale."**

Policy and Legislation Beyond the US and the EU (continued)

In some pilot projects for testing or measuring personal connected health technologies in a low-resource setting, data are often collected independent of the greater healthcare system. Lack of electronic health records, reliable computer or internet access, or capacity to manage and use digital resources are all barriers to the integration of wide-scale personal connected health applications. In order for a LMIC health system to implement policies and standards for eHealth and connected health applications, there needs to be a functioning IT and health system infrastructure, including trained personnel, to implement the policies and use of personal connected health technology in a meaningful way.

One resource that is currently under development, that can help countries in any stage of policy development, is the Global Digital Health Index, an interactive tool designed to assess and track progress at a national level through a maturity model of digital health.[37] In addition to data on eHealth indicators, the Global Digital Health Index can provide leaders with the steps and practical guidance for investing appropriately in digital health infrastructure, human resources, and policy development to support health outcome improvements in their countries through digital technology.

Priorities and Recommendations

As part of this personal connected health policy review and prioritization, input was solicited from thought leaders, key informants and PCHAlliance members and staff in the form of one-on-one interviews, and through a PCHAlliance member survey.

The 57 respondents to the member survey policy questions ranked priorities in the area of key policy issues and effective engagement activities, as well as their member organization's level of involvement in policy-related advocacy activities. The top three priorities for personal connected health policy issues were:

- Increase reimbursement for remote patient monitoring

- Reduce Medicare's reimbursement restrictions on personal connected health tools

- Promote interoperability standards

The open-ended questions on the member survey requested opinions on the challenges and opportunities facing personal connected health policy today. The greatest policy-level opportunities facing member organizations today include payment incentives and reimbursement for remote patient monitoring and the potential cost-savings that these applications can have for chronic condition management. Providing the evidence necessary to validate and standardize these benefits will be both an opportunity and a challenge for the future. The issue of interoperability was also discussed in many comments, with new opportunities seen at the national level and the potential benefit of empowering consumers and providers with safe and secure access to interoperable data. Challenges will be to overcome data silos and proprietary quick-fix systems, concerns over data security and legal liability, and finding solutions to interoperability and other barriers which are applicable and adoptable in many different national scenarios around the world. A shift away from the fee-for-service model of healthcare delivery to one that provides incentives for wellness to both providers and the public will foster and encourage the use of many personal connected health technologies and applications that help people make everyday lifestyle choices.

One-on-one discussions with thought leaders, key informants and PCHAlliance members resulted in specific recommendations for the Alliance as it shapes its global policy agenda.

- Increase efforts to track and respond to US and EU government regulatory and legislative bodies

The policy and regulatory field is complex and requires a deep understanding of health systems, reimbursement policies and incentives, as well as an ability to facilitate cooperation between the technology industry and health care providers. Increased effort is needed for tracking and responding to US and EU government regulatory and legislative bodies as well as for promoting partnerships and relationships that will help to guide the research agenda.

- Publish global position papers or recommendations on key policy issues

Priorities and Recommendations (continued)

As discussed above, many countries and regions in the world are looking towards the US and EU for guidance and models to build their digital health policies. PCHAlliance could promote global coordination by publishing a global position or recommendations on key personal connected health issues such as data privacy in healthcare, for example. This could include a discussion of good practices and a framework of policies, regulations and the system requirements as a whole, regardless of the country's stage of development in digital health.

- Focus advocacy for interoperability on large public and private insurance providers and present evidence on the cost-savings and benefits of interoperability

A barrier to Continua adoption in the US is the preference among some key industry players to champion their own proprietary technology. The push for interoperability will have to come from large providers or governments. As the biggest player in the US healthcare system, Medicare could make a big push towards interoperability requirements, but the evidence required to convince Congress of the cost and health benefits of connected health interoperability is lacking. Large private insurers could also make great progress in the US healthcare system by taking the initiative on adoption of interoperability standards. Targeted research on the cost-savings and benefits of interoperability in the healthcare system could contribute to the ongoing efforts to promote interoperability in Medicare and private insurance.

> **"We want to break the barrier and the proprietary model, the only way is to have open architecture and standards that are validated to be interoperable."**

- Advance the research agenda to demonstrate evidence of personal connected health tools to establish a standard of care

There is a need to provide evidence of health outcomes to establish personal connected health technologies and remote patient monitoring as a standard of care. Showing that personal connected health technologies lead to equal or better results will go a long way to convince both the medical community and the patient community, and help pave the way to solving the policy issues of reimbursement and interoperability. If the personal connected health technologies are demonstrated to be the best standard of care or treatment for particular medical conditions, then the policies required to implement that standard of care will follow.

The technological innovations to promote health and wellness choices already exist; what is needed now is evidence to prove that these applications are cost-effective and lead to measurable positive outcomes in the health and wellbeing of patients. This evidence will function to convince not only patients and health care providers but also the legislative and regulatory bodies creating personal connected health policy.

Figure 1: Personal Connected Health Global Priorities and Recommendations Summary

Key Themes	Sub-themes	Existing Opportunities	Unexplored Opportunities
Reimbursement	Coverage for more patients and more conditions	Federal/EU policy	Create guidance framework policies for key policy issues
New Allowable Technologies	Expanded geographic coverage	National Health System/State mandates and policies	Advocate for targeted research agenda
Evidence Base/ Standard of Care	Remote Patient Monitoring	Non-legislative rules and regulations (billing codes, standards, etc.)	
Data Privacy and Security	Store-and-forward/ asynchronous technologies	Public-private partnerships	
Interoperability	Patient-Generated Health Data	Stakeholder comments, committee and workshop participation	
	General Data Protection Regulation (EU) Compliance		
	Open Standards Adoption (Continua)		

Conclusion

A supportive policy environment is needed for personal connected health to realize its full potential in improving health outcomes and strengthening health systems throughout the world. Key priority areas for policy attention include reimbursement for personal connected health approaches and technologies, expanding the definitions of 'telehealth' and geographic focus to go beyond synchronous consultations in rural areas to include other connected health technologies and approaches — in particular remote patient monitoring and use of patient generated health data in urban settings, and frameworks and guidelines that facilitate interoperability and data privacy. Underpinning these priorities is the need to build a robust evidence base that can inform policy. As part of its strategic role to drive personal connected health policy and advocacy, the Personal Connected Health Alliance will use this policy review to guide its work in this area and mobilize its membership to collectively work together to make strategic advancements towards these priorities.

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Appendix B: Current Proposed Policy Legislation in the US

CONNECT For Health Act Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act of 2017 (S.1016)	This US Senate Bill is meant to remove limits in Medicare payment systems that restrict telehealth applications. The bill proposes amendments to title XVIII of the Social Security Act to expand payment for telehealth services and allow the use of remote patient monitoring services by Accountable Care Organizations (ACOs) with two-sided risk contracts.[38] Provisions in the bill would lift the restriction on the use of store-and-forward technology for remote patient monitoring of certain patients, allowing Medicare reimbursement for remote patient monitoring through technology other than live video. There are also provisions that would revise geographic limits on the use of some telehealth services. The bill also allows the broad use of telehealth technologies by Indian Health Services and dialysis patients and an expanded list of eligible health care providers that can initiate and utilize telehealth services.
	Themes: Geographic restrictions; expanded definition of telehealth services; expanded reimbursement coverage
CHRONIC Care Act Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act of 2017 (S.870)	This is a US Senate Bill that restructures Medicare payment systems regarding chronic condition management and home-care coordination. Like the above CONNECT for Health Act, it also reforms title XVIII of the Social Security Act. The Congressional Budget Office has estimated that the package of reforms contained in the CHRONIC Care Act will not contribute to the deficit since the cost-saving components balance any costs.[39, 40, 41] Telehealth-related provisions in the bill include the expansion of the CMS Independence at Home (IAH) pilot project with a requirement to evaluate the use of electronic health information systems and remote monitoring as part of the study; expanded reimbursement for telehealth consultation for patients in end-stage renal disease receiving home dialysis; lifting the geographic restrictions on reimbursable consultation between emergency rooms and stroke experts when patients present with stroke symptoms; and expanded flexibility for certain ACOs to cover telehealth services.
	Themes: Geographic restrictions; expanded definition of telehealth services; expanded reimbursement coverage; Evidence/data collection

Appendix B: Current Proposed Policy Legislation in the US (continued)

RURAL Act Reaching Underserved Rural Areas to Lead on Telehealth Act (S. 1377)	This is a bill introduced to the US Senate that would extend the discounted broadband savings for rural hospitals under the Healthcare Connect Fund to non-rural hospitals that serve a rural community.[42]
	Themes: Expanded reimbursement coverage; Geographic restrictions
Telehealth Innovation and Improvement Act of 2017 (S. 787)	This bill would mandate CMS and the Center for Medicare and Medicaid Innovation (CMMI) to test and evaluate models of care delivery using a range of telehealth services for Medicare patients regardless of geographic location.[43]
	Themes: Geographic restriction; Evidence/data collection; expanded definition of telehealth services
Medicare Telehealth Parity Act of 2017 (H.R. 2550)	The bill proposes an incremental expansion of telehealth coverage in regards to geographic regions, eligible providers, and in telehealth services allowed under Medicare.[44, 45]
	Themes: Geographic restrictions; expanded definition of telehealth services; expanded reimbursement coverage
CK-DIRT Act of 2017 Chronic Kidney Disease Improvement in Research and Treatment Act of 2017 (H.R. 2644)	Among other provisions to expand access to treatment for chronic kidney disease, this bill includes a provision that would allow telehealth (audiovisual) consultation for patients receiving home dialysis treatment under Medicare.[46]
	Themes: Geographic restrictions; expanded reimbursement coverage
HEART Act of 2017 Helping Expand Access to Rural Telemedicine Act of 2017 (H.R. 2291)	This bill would reimburse remote patient monitoring and store-and-forward telehealth services for some Medicare patients with chronic conditions and expanded geographic regions.[47]
	Themes: Geographic restrictions; expanded reimbursement coverage; expanded definition of telehealth services

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