Introduction

As it became clear that COVID-19 would be the most challenging pandemic the world has faced in a century, disrupting nearly everyone’s daily life and posing unmatched challenges to our health care systems, the term “virtual” became a part of our everyday vocabulary. From virtual learning, to virtual conferences – even virtual weddings.

For those who work in digital health, virtual was already not only part of the vocabulary, but part of the broader mission. A mission to ensure all people – regardless of location, physical ability, or access to transportation – can access high-quality health care. A mission to ensure all providers have access to cutting-edge technology to enhance the care they provide. However, prior to COVID-19, most incentives, regulations, and laws revolved around in-person care, siloed public health data, and, in some cases, “legacy” technology.

When COVID struck, many of the regulations restricting the provision of care outside of traditional settings and via digital mechanisms fell away nearly overnight; however, many of these regulatory changes are temporary. Some examples of temporary waivers issued to enable virtual care include:

- Congress passed legislation that allowed the Secretary of Health & Human Services (HHS) to issue waivers of statutory restrictions on the reimbursement of telehealth services. Since issuing the waivers, more than 9 million Medicare beneficiaries have received care via telehealth.¹

- The HHS Office for Civil Rights (OCR) announced in March that it would exercise its enforcement discretion to not impose penalties for provider noncompliance with the HIPAA Privacy and Security Rules in connection with the good faith provision of telehealth during the COVID-19 public health emergency. This policy allows providers and patients to use technologies that may not meet all HIPAA requirements, such as Zoom (regular version), FaceTime, or Skype to provide care.²

- 9 states and 3 U.S. Territories have adopted emergency waivers to allow – to varying extents – providers not licensed in the state to provide care to patients across state lines.³
As much as COVID-19 has highlighted the promises of digital health, it has also brought to the forefront areas of the health care system that have lagged when it comes to innovation. Some things cannot change overnight, after all. For example, the health care industry is arguably the last industry supporting the fax machine. Despite more than $30 billion in federal and state government investment in the adoption of electronic health records (EHRs) and health information exchange, the fax machine is still heavily relied upon for the transmission of personal health information. For example, during the pandemic, the faxing of test results from labs to public health officials has been pointed to as one of the reasons for long reporting delays. According to the New York Times, fax reports often come in duplicates, go to the wrong health department, and/or are missing crucial patient identification information. This significantly hinders efforts to control the spread of the disease through contact tracing, in addition to timely quarantining of infected individuals.

At the eHealth Initiative (eHI), our mission is to convene stakeholders seeking to transform the health care system through innovation. At a time of immense challenge to our health care system, it is also a time to learn, discuss, and work toward a future where public policy supports the safe and effective use of technology in health care to increase access and lower costs. That is why eHI invited our members, many of whom are at the frontlines of fighting COVID-19, to join a special work group – the COVID-19 Federal Policy Work Group – to help craft a report with a set of recommendations to fully leverage health IT and digital health to fight COVID-19 and future public health challenges.

Over the course of four months, the Work Group met to discuss and form policy recommendations on five major issue areas: telehealth and remote patient monitoring; artificial intelligence and machine learning; broadband; health information exchange; and public health surveillance. If implemented by policymakers, these recommendations will help shape a modern, flexible, and technology-enabled health care system.
Recommendations

The following summarizes the Work Group’s recommendations for building a technology-enabled health care system to meet the challenges of COVID-19 and future pandemics.

An Overview

1) Telehealth and Remote Patient Monitoring

a. Permanently remove Medicare telehealth reimbursement restrictions:
   • Remove obsolete restrictions on the location of the patient
   • Maintain and enhance HHS authority to determine appropriate providers and services for telehealth
   • Ensure Federally Qualified Health Centers and Rural Health Clinics can furnish telehealth
   • Make permanent HHS temporary waiver authority during emergencies services after the public health emergency (PHE)

b. Promote cross-state provider license portability
   • Incentivize interstate provider licensure compacts that include mutual recognition
   • Ensure existing federal grants only fund work towards mutual recognition interstate licensure compacts

c. Remove barriers to the on-going utilization of remote patient monitoring devices
   • Make permanent regulations that RPM devices can be furnished to both new and existing patients and patients with both chronic and acute conditions
   • Establish permanent Stark and Anti-Kickback Statute safe-harbors that allow for providers to waive cost-sharing

2) Broadband

a. Provide additional federal funding and remove barriers to the Federal Communications Commission (FCC) COVID-19 Telehealth Program

b. Sustain and expand current federal government investment in rural broadband
3) Artificial Intelligence (AI) and Machine Learning (ML)

a. Increase federal funding for research and testing for use of AI/ML tools in three areas:
   - Research
   - Treatment
   - Public health

b. Federal government agencies should continue to collaborate amongst themselves and with private sector partners to produce best practices and adopt industry standards for data quality and validation for purposes of AI and ML

4) Health Information Exchange and Interoperability

a. Establish a permanent 100-percent Medicaid match rate for health information exchange activities

b. Better align federal regulations related to health information exchange and lab reporting standards

5) Public Health Surveillance

a. Study the potential outcomes of moving from a vertical public health surveillance system to an integrated public health surveillance system

b. Restore and protect funding for the federal Prevention and Public Health Fund
Prior to the COVID-19 pandemic, telehealth and remote patient monitoring were not prevalent in many areas of the country’s health care system. While Medicare coverage of telehealth services was required by Congress in 2001, statutory restrictions kept utilization low. Save for a few exceptions (treatment for substance use disorders, telestroke services, and end-stage renal disease), the Centers for Medicare & Medicaid Services (CMS) can only pay for telehealth services if a patient is in a medical facility in a federally defined rural area. Due to these restrictions, in 2016, CMS reimbursed $27 million in telehealth services – just 0.4 percent of Medicare fee-for-service spending.\(^5\)

In 2018, CMS began to reimburse for remote patient monitoring (RPM) codes. Because RPM services are not defined in statute, CMS stated that it would reimburse for RPM codes without geographic restrictions; however, other restrictions are in place. For example, CMS will only reimburse for RPM services if there is an existing provider-patient relationship with the ordering provider. Further, CMS requires that 16 days of data every 30 days must be collected and transmitted to meet requirements to bill some RPM codes.
When COVID-19 began to spread across the country and stay-at-home orders went into place, receiving non-urgent (and sometimes even urgent) health care services in person was no longer an option for most. It became clear that if Congress and CMS did not act quickly to lift statutory and regulatory reimbursement restrictions, the majority of Medicare beneficiaries would have no way to access care in the midst of a pandemic. Luckily, Congress passed legislation in early March to set the wheels in motion for CMS to issue waivers of Medicare telehealth reimbursement restrictions. CMS also acted to lift restrictions on RPM services. Because of these waivers, during the COVID-19 PHE period declared by HHS Secretary Alex Azar, the following can now take place:

- Providers can now bill telehealth services for patients located in their home and outside of rural areas;
- Telehealth and RPM services can be offered to both new and existing patients;
- For the most part, any Medicare-eligible provider can bill for telehealth services;
- CMS will reimburse for more than 230 telehealth services and removed the requirement to use technology with audio and visual capabilities for some services;
- Federally qualified health centers and rural health clinics can furnish telehealth services; and
- Providers can waive or offer reduced cost-sharing for telehealth services

Over the course of the PHE, the use of telehealth has increased significantly, particularly by fee-for-service (FFS) Medicare beneficiaries. The chart below, developed by CMS, shows the sharp uptick in telehealth usage with the start of the national stay-at-home order. Nationally, before the PHE, about 13,000 FFS Medicare beneficiaries received telehealth services in a week – by the last week of April, that had increased to about 1.7 million beneficiaries per week.6
Some observers have voiced concerns over whether expanded reliance on telehealth would create greater disparities in access to care, particularly among racial groups. In fact, research indicates that there are no significant barriers to accessing virtual health services among the different Medicare beneficiary demographic groups as defined by race, age, or sex. For example, of Medicare beneficiaries who utilized telehealth services during the PHE, 29 percent and 27 percent were Black and Hispanic, respectively. In comparison, 28 percent of beneficiaries were White. Across all age groups, between 25 and 34 percent of patients received telehealth services. Lastly, little disparity was evident in relation to usage by sex. Of beneficiaries who received telehealth services, 30 percent were female and 25 percent were male.

Nor does socioeconomic status tend to be a barrier to accessing virtual services. Dually eligible beneficiaries used telehealth at higher rates in comparison to Medicare-only beneficiaries, 34 percent and 26 percent respectively. And within this dually eligible population, race is still not a major barrier to access. The administration’s move to allow reimbursement of audio-only telehealth services was likely key to ensuring equity in access – nearly one-third of Medicare beneficiaries who utilized telehealth from mid-March through mid-June did so using audio-only technology.

Although these waivers are essential to ensuring Medicare beneficiaries can continue to access care, under current law, they will expire at the end of the COVID-19 PHE. This means that if Congress does not act to make permanent changes, the law will revert back to only allowing for Medicare reimbursement of telehealth services if a patient is located in a health care facility in a federally defined rural area.
To ensure that broad access to and reimbursement of telehealth continues, the Work Group recommends Congress pass legislation that addresses the following issues:

1. **Remove Obsolete Restrictions on the Location of the Patient:** Congress should permanently remove the current Social Security Act Section 1834(m) geographic and originating site restrictions to ensure that all patients can access care at home and/or other appropriate locations. The response to COVID-19 has shown the importance of making telehealth services available in rural and urban areas alike. In order to bring clarity and provide certainty to patients and providers, we strongly urge Congress to address these restrictions in statute by striking the 1834(m) geographic limitation on originating sites and allow beneficiaries across the country to receive virtual care in their homes, or location of their choosing, where clinically appropriate and with beneficiary protections and guardrails in place.

2. **Maintain and Enhance HHS Authority to Determine Appropriate Providers and Services for Telehealth:** Congress should provide the Secretary with the flexibility to expand the list of eligible practitioners who may furnish clinically appropriate telehealth services. Similarly, HHS and CMS should maintain the authority to add or remove eligible telehealth services – as supported by data and demonstrated to be safe, effective, and clinically appropriate – through a predictable regulatory process that gives patients and providers transparency and clarity.

3. **Ensure Federally Qualified Health Centers and Rural Health Clinics Can Furnish Telehealth Services after the PHE:** FQHCs and RHCs provide critical services to underserved communities and have expanded telehealth services after restrictions were lifted under the Coronavirus Aid, Relief, and Economic Security (CARES) Act. Congress should ensure that FQHCs and RHCs can offer virtual services post-COVID and work with stakeholders to support fair and appropriate reimbursement for these key safety net providers.

4. **Make Permanent HHS Temporary Waiver Authority During Emergencies:** Congress has given HHS authority under Section 1135 of the Social Security Act to waive restrictions during the COVID-19 pandemic. However, the waiver authority is specific to the COVID-19 PHE. Congress should ensure HHS and CMS can act quickly during future pandemics and natural disasters.
Physician Licensure

Even before COVID-19, the current state-based physician licensure system was a major barrier to the growth in utilization of telehealth. However, because of the lack of widespread utilization and reimbursement for telehealth, the system has continued largely unchanged since the establishment of state medical boards in the 1800s. There is no doubt that state medical licensing boards provide important patient protections; however, the system must be modernized for the 21st century.

The state-based licensure system became immediately problematic this past March, when stay-at-home orders went into place, college campuses shutdown, and many people were uprooted from everyday life. Although telehealth enabled the continued treatment of patients, many providers were hamstrung by state-level licensing requirements. How would a college mental health provider continue to treat her college student patients once students were forced to return home to states where the mental health provider likely was not licensed? Although HHS Secretary Azar could – and did – waive licensing requirement for purposes of Medicare and Medicaid reimbursement, it fell to individual states to issue emergency regulations to lift licensing requirements to allow physicians to practice across state lines. As of August 5th, 47 states and 3 US territories had issued temporary waivers related to the provision of telehealth services within their state.13

Much like the temporary waivers of Medicare reimbursement restrictions, the emergency actions by states to loosen provider licensing requirements highlight the underlying problem of outdated statutes and regulations inhibiting access through modern health care technology. To build a better system for the future, states must act to reform the physician licensing system to encourage and enable optimal use of telehealth and other virtual services. While there are many options for reform, including federal preemption of states' rights to establish a national licensing system, the Work Group recommends establishing incentives for the creation and adoption of mutual recognition interstate licensing compacts.
Interstate compacts – or a pact or agreement between two or more states - have been critical in many aspects of our nation’s history – perhaps the most well-known being the Driver License Compact. They are also not new in health care – in fact, the Interstate Medical Licensure Compact (IMLC) was established in 2017 and has been adopted by 29 states, the District of Columbia, and Guam.14 However, despite receiving more than $7 million from the Health Resources and Services Administration’s (HRSA) Licensure Portability Grant Program,15 the IMLC does not increase licensure portability – it is a system of “expedited licensure” where physicians still must obtain individual licenses from every state in which they wish to practice.

Though the IMLC does not currently advance licensure portability, the Nurse Licensure Compact (NLC) is an excellent example of how this goal can be reached. The NLC is a mutual recognition compact – meaning that if a nurse is licensed in one compact state, he or she can practice in any other compact state. Policymakers should ensure that all financial and policy incentives – including existing and new HRSA grants – encourage states to adopt a similar mutual recognition compact for physicians. This path forward recognizes the rights of states to regulate the practice of medicine within their borders, protects patients, and at the same time facilitates access to care across state lines.

Remote Patient Monitoring

Fortunately, RPM services are not statutorily restricted in the same way telehealth services are in the Medicare program. CMS first began to reimburse for RPM services – free of geographic and originating site restrictions – in 2018. Although these services are not limited by location, CMS did include some restrictions on the reimbursement for RPM services. For example, RPM services could only be billed for patients whom the provider has previously treated. Further, RPM services could only be furnished for patients with one or more chronic conditions.

Much like with telehealth services, CMS needed to act quickly to amend these restrictions during the COVID-19 public health emergency period given the impact of the pandemic on health care facilities, providers, and patients. During the COVID-19 PHE, CMS has allowed for RPM services to be reimbursed for both new and established patients, to patients with acute conditions as well as chronic conditions, and it has also amended a requirement to allow beneficiary consent to be obtained once annually.
The Work Group recommends many of these temporary policies be made permanent. Specifically, we call on CMS to allow beneficiary consent to be obtained once annually and to allow RPM services for both new and established patients and for patients with both chronic and acute conditions. While COVID-19 certainly made these changes necessary, these are changes that make sense long-term. Taking COVID-19 as an example, many who are hospitalized with the virus are expected to experience long-term and debilitating effects of the disease, including impacts on heart and lung function. Diagnoses of chronic conditions resulting from COVID-19 could take years, and clearly they could benefit from the use of RPM devices to monitor for exacerbations. Older patients are also more likely to experience post-surgery complications – should a Medicare beneficiary who underwent a joint replacement or other acute surgery not be eligible to utilize an RPM device to monitor for possible complications post-discharge? The use of RPM devices is beneficial in several scenarios, and CMS must establish permanent policies that consider all of these factors.

In addition to the RPM flexibilities announced by CMS, the HHS Office of the Inspector General (OIG) issued a policy statement stating that during the COVID-19 public health emergency period, OIG would not enforce anti-kickback statute or Stark Law sanctions for reducing or waiving beneficiary cost-sharing in Federal health programs for telehealth services, including non-face-to-face services like RPM. Under existing regulations, Medicare beneficiaries generally pay a 20 percent coinsurance on Medicare outpatient services, including telehealth services. However, many patients may not be aware that non-traditional services like RPM services are also subject to cost-sharing requirements and may be caught off-guard when they receive bills from their providers. Further, CMS should be incentivizing providers and patients to use tools that reduce hospital readmissions and utilization of higher-cost services. We urge HHS to establish a permanent anti-kickback statute safe harbor that allows providers to reduce or waive cost-sharing for RPM devices.
While digital health tools like telehealth and RPM hold great promise, the Work Group recognizes that this promise can only be realized if everyone has access to adequate broadband. This is not always the case – especially in rural areas of the country.

Overall, as one would expect, internet usage in general has increased over the past decade for all demographic groups. However, disparities between the different demographic groups still exist. As of 2019, only 63 percent of rural Americans reported having access to broadband internet connection at home. By comparison, Americans who live in urban cities are 75 percent more likely to have access to broadband at home. What access those in rural areas do have tends to be slower than in non-rural areas.

Recognizing the shortfalls in full access to digital services, Congress, through the CARES Act – a $2.2 trillion economic stimulus bill enacted in March 2020, provided a $200 million supplemental appropriation for the Federal Communications Commission (FCC) to support telehealth. These funds have already been doled out through the FCC’s COVID-19 Telehealth Program. Health care facilities in both rural and non-rural areas were eligible for the program; however, only non-profit and public health care providers were eligible.

While we urge Congress to provide additional funds to this program, we believe these funds should be more targeted, versus the current broad eligibility requirements. Both for-profit and non-profit health systems are feeling the heavy impact of COVID-19. A study of the four largest for-profit hospital systems found that admissions, surgeries, and emergency department visits dropped 20 to 40 percent during the last two weeks of March 2020, and 30 to 70 percent in April 2020. Further, rural hospitals, regardless of non-profit or for-profit status, have seen declining profit margins in recent years – only exacerbated by COVID-19. When providing additional funding to the COVID-19 Telehealth Program, Congress should target eligibility requirements to hospitals and health systems that serve rural and underserved populations, regardless of non-profit or for-profit status.
The COVID-19 Telehealth Program is essential to meet short-term needs; however, Congress must also make a sustained and meaningful investment in rural broadband infrastructure. The FCC’s Universal Service Fund (USF) programs seek to address these disparities through discounted devices and service plans for rural and low-income populations. Although those programs are essential to rural and underserved populations and must continue, they only help if there is adequate broadband available in the first place.

Building out broadband infrastructure in rural areas is extremely expensive, and there are few incentives for private investment given the lack of market for the product – there simply are not enough people in extremely rural areas to justify the expense of building broadband infrastructure. This issue is often referred to as “the last mile.”

The federal government has an important role to play when it comes to investing in public goods where there are few incentives for private market investment – for example, the federal government’s investment in basic medical research through the National Institutes of Health (NIH). Similarly, Congress must appropriate sufficient funds to build broadband infrastructure to the last mile and subsidize telecommunication companies’ service of those areas.
Artificial intelligence (AI) and machine learning (ML) are playing an increasing role in health care. Given the vast troves of health data generated today, algorithms that harness and glean insights from these data in near real-time – like those used in AI and ML – can be critical tools. This promise is especially true for combating infectious diseases like COVID-19.

During the pandemic, AI and ML tools have been employed in three main areas to help combat the disease: research, treatment, and public health surveillance. For example, the National Institute of Biomedical Imaging and Bioengineering (NIBIB), part of the NIH, established and is leading the Medical Imaging and Data Resource Center (MIDRC). The MIDRC “goals are to lead the development and implementation of new diagnostics, including machine learning algorithms, that will allow rapid and accurate assessment of disease status and help physicians optimize patient treatment.” Further, organizations have created real-time maps of the spread of COVID-19 using AI tools. In order to not lose the gains we have made during this period and to continue to lead the world in cutting-edge research and development, the federal government must continue investing in AI and ML.

Though these tools hold great promise, it is critical that organizations that utilize AI and ML do so with the recognition that such usage can also lead to unintended outcomes if issues of data quality, bias, and privacy are not fully addressed. The National Institute of Standards and Technology (NIST) is currently tackling many of these issues, including bias and trustworthiness in AI. NIST must continue to collaborate with federal partners and industry in order to produce best practice and industry standards for data quality and validation for purposes of AI and ML.
At the federal level, the American Recovery and Reinvestment Act of 2009 first established grants, administered through the Office of the National Coordinator for Health Information Technology (ONC), for statewide HIEs. The goal of HIEs is to facilitate the electronic exchange of clinical information among and between health care systems.

During COVID-19, many states looked to their HIEs to share lab results. In Nebraska, the Department of Health and Human Services Division of Public Health asked health care facilities, providers, and labs connect to eHI member the Nebraska Health Information Initiative (NEHII) to share admissions, discharge, and transfer (ADT) files, labs, and syndromic surveillance in order to help the state respond in a timely manner and provide local resources.²⁹

When well implemented and utilized, HIEs are a crucial public health tool. They can serve as a hub for longitudinal patient health information from various sources, including lab results, and allow epidemiologists to glean key insights from those data. In order to realize the potential of HIEs, there must be increased investment in them. HIEs are often run at the state or regional level, but COVID-19 has decimated the state budgets that are often critical to HIE support. To continue to support essential public health activities, Congress should establish a permanent 100-percent Medicaid match rate for health information exchange activities.

Further, in order to promote interoperability and fully leverage HIEs, the federal government needs to better align standards and requirements for lab reporting for public health purposes. Although ONC generally adopts standards for purposes of the Health IT Certification Program, CMS maintains jurisdiction over labs under the Clinical Laboratory Improvement Amendments (CLIA). ONC and CMS must work to align standards and requirements for lab reporting to facilitate the electronic sharing of lab results.
COVID-19 has brought to light the limitations and pitfalls of the US public health surveillance system. Often siloed and relying on outdated technology or paper systems hamstrung by insufficient and unpredictable funding streams, the national response to the pandemic has been negatively affected by the current system, leading our Work Group to discuss and make recommendations for modernization.

The Centers for Disease Control and Prevention (CDC) is charged with public health surveillance in the US. The CDC maintains 12 chronic disease surveillance systems, along with the National Vital Statistics System (NVSS), and National Syndromic Surveillance Program (NSSP), among others. The results of this vertical approach to public health surveillance are duplicative costs, siloed information, and generally inefficient actions.

In one glaring example of these negative results, from the early days of COVID-19, data on influenza-like-illness (ILI) in New York State showed a sharp increase in early March when only a few COVID-19 cases had been confirmed in the state. Because COVID-19 testing and diagnoses were not widely available in the early days of the pandemic, had an integrated system incorporating syndromic surveillance been utilized and leveraged effectively, public health officials may have been able to better track and predict the spread of COVID-19. Realizing that completely shifting the nation’s approach to public health surveillance will not happen overnight, we urge Congress to take a first step by authorizing and funding a study to weigh the outcomes of moving to an integrated approach to public health surveillance. While we believe an integrated system is the best approach to public health surveillance, any modern system must be digital and rely on electronic sharing.
of information. Many local health departments rely on manual queries and entries and faxing of clinical records, leading to errors, duplicative records, and missing patient information. A modern public health surveillance system must move away from paper- and fax-based transmissions. The CDC recognized this through the CDC Surveillance Strategy, but clearly, as indicated by our experience with COVID-19, there is much work left to be done. In order to move forward, the CDC should build upon existing national interoperability networks like the CommonWell Health Alliance, Carequality, and eHealthExchange to leverage already shared electronic clinical health information for public health surveillance purposes.

Perhaps the most important aspect of creating and maintaining a modern public health surveillance system is providing predictable and adequate funding. Congress took a first step in the CARES Act by allocating $500 million to the CDC for public health data surveillance and analytics infrastructure; however, this was a one-time appropriation and is not sufficient to build and maintain a modern system. The unpredictability of Congress’ annual appropriations process, which is inadequate and relies on additional emergency funds if a disaster like COVID-19 strikes, means the country will continue to be one step behind in dealing with all public health crises.

This is not a new concept – the Prevention and Public Health Fund (PPHF) was created through the Patient Protection and Affordable Care Act of 2010 (ACA) and was the first mandatory funding stream to improve the public health system. However, Congress continues to raid the PPHF to fund other programs and pay for legislation – including paying for the delay of Medicare physician fee cuts and the 21st Century Cures Act. The Bipartisan Budget Act of 2018 cut the PPHF by an additional $1.35 billion over 10 years. Given the experiences of COVID-19 and critical need to build a modern public health surveillance system, Congress must restore full funding for the PPHF and put in place additional protections to protect the funds from being diverted.
Conclusion

The United States was not prepared for the COVID-19 pandemic in more ways than one. The impact of the pandemic certainly shined a light on the outdated laws and regulations that have inhibited the growth of digital health tools to-date.

eHI convened the COVID-19 Federal Policy Work Group to consider how these outdated laws and regulations have negatively impacted the health care system overall, and especially the response to COVID-19. The recommendations were reached with multi-stakeholder input from the expert Work Group members and are targeted in key areas ripe for reform.

Policymakers have a unique opportunity to learn from this experience and the impact of a once-in-a-century global pandemic and should not wait until we are faced with the next crisis to implement new policies that will strengthen and modernize our health care system. We encourage Congress and the administration to meet this opportunity and heed the recommendations of the Work Group.

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