

February 16, 2021

Mr. Jeff Zients
Coordinator of the COVID-19 Response and Counselor to President Joseph R. Biden, Jr.
The White House
Washington, DC 20500

Dear Mr. Zients:

On behalf of the undersigned organizations, as well as our members and stakeholders, we appreciate your efforts as well as the work of the COVID-19 Task Force to address the pandemic. The steps that have been put in place by the Biden Administration are focusing the country on a path toward appropriately targeted mitigation strategies and more rapid action around executing broad-based vaccinations.

Our organizations represent the health information and technology professionals working on COVID-19, including public health, healthcare delivery, health information exchange (HIE), health IT software development, and governmental agencies on the front lines of this crisis. Their expertise provides us with a unique perspective on the next steps required to efficiently advance our nation's approach to the pandemic.

We include our recommendations focused on two areas: (1) immediate actions, and (2) longer-term plans. Many of these ideas echo support for actions the Administration has already implemented. Our organizations want to reinforce the importance of these steps and pledge our support to work with you, the COVID-19 Task Force, and the leadership at the Department of Health and Human Services (HHS) on these activities. Also included are additional proposals we encourage you to address.

Our organizations urge you to maximize the role of health information and technology in enabling the evolving strategies the Administration develops, and the value provided by our communities in tackling COVID-19, particularly on accelerating vaccination distribution and administration. Our recommendations are as follows:

Immediate Actions

- *Capitalize on Health Information and Technology and Data Systems to Support a Robust, Federally-Coordinated, Comprehensive COVID-19 Vaccination Plan*
- *Exercise Regulatory Flexibilities and Enforcement Discretion to Ease Burden*
- *Adopt an "All-Hands-on-Deck" Approach to Vaccine Distribution and Administration*
- *Emphasize the Importance of Interoperability and Data Sharing in the Broader Vaccination Effort*
- *Support a Public Health Campaign to Democratize Data and Information Through Innovative Digital Solutions*

Longer-Term Plans

- *Generate Digital Vaccination Credentials for Individuals*
- *Establish Formal Feedback Loop for COVID-19 Related Tools and Technologies*
- *Develop a National Patient Identification Strategy*

Details on our recommendations and policy priorities follow:

Immediate Actions

- *Capitalize on Health Information and Technology and Data Systems to Support a Robust, Federally-Coordinated, Comprehensive COVID-19 Vaccination Plan*

Sustained leadership and execution from the federal government is critical for moving forward to best address the pandemic and ensure that health information and technology is being properly utilized. We highlight our support for President Biden’s Executive Order on [Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats](#) as well as the [National Strategy for the COVID-19 Response and Pandemic Preparedness](#) as two examples where federal direction has already been helpful to state, territorial, local, and tribal governments on how best to proceed.

The Biden Administration has an opportunity to build on these efforts by ensuring that stakeholders are utilizing and following guidance related to [Technical Standards and Reporting Data to the Centers for Disease Control and Prevention \(CDC\)](#). Our organizations propose nationally defined and adopted reporting specifications and standards—to be met by states and localities and all health system stakeholders. We recommend simplifying report submissions using an approach where data is submitted once and shared broadly across all authorized stakeholders. Our organizations volunteer to work with the Administration, states/local jurisdictions, and other stakeholders to ensure that the reporting specifications and standards as well as reporting processes are clear, concise, and able to be implemented. Where there are opportunities to improve or where gaps exist in the guidance, we want to work with the Administration to make sure those issues are addressed.

In alignment with the Biden Administration’s [Executive Order on Ensuring an Equitable Pandemic Response and Recovery](#) that establishes the COVID-19 Health Equity Task Force, health information and technology systems can play an important role in ensuring equity in vaccine distribution across populations as well as regions. Improved reporting will help identify gaps in vaccination distribution and drive targeted approaches for those hard-to-reach populations. More reporting guidance from the federal government can help set clearer expectations and track whether vaccine doses are making it to the populations that are in most need.

In addition, opportunities exist to expand federal leadership and the work of the Office of the National Coordinator for Health Information Technology (ONC) in relation to the community’s work on pandemic preparedness and response. Given the significant role that ONC plays in many of our recommendations as well as outreach to our communities, we recommend that Micky Tripathi, the National Coordinator, be included in the work of the COVID-19 Task Force. Such a step will establish continuity in the broader federal COVID-19 response and improve coordination as it relates to health data. We also support an increased consultative role for ONC in evaluating upcoming government procurement in the COVID-19 response. ONC’s expert involvement will help ensure that the data policies included in a procurement align with federal interoperability standards as well as implementation specifications and that broader health IT interoperability needs are fulfilled.

Appropriate funding for vaccine distribution and administration tracking and reporting systems should be a federal, state, territorial, local, and tribal priority. The COVID-19 public health emergency has underscored the critical need for a large-scale upgrade to the US public health infrastructure. It is essential that our nation integrate any approach to managing immunizations into a broader public

health infrastructure that optimizes data collection and state/local health department access to critical data to manage ongoing and emergent public health crises.

The greater public health and health IT community has emphasized the foundational investments necessary to upgrade the nation's public health data systems infrastructure through the [CDC's Data Modernization Initiative](#). With the \$50 million included in fiscal year (FY) 2021 appropriations, the Data Modernization Initiative has been appropriated \$100 million of the initial \$1 billion requested by the [Data: Elemental to Health Campaign](#), with an additional \$500 million in supplemental funding through the Coronavirus Aid, Relief, and Economic Security Act (CARES) Act.

This investment has been critical, but it will not be enough to modernize and maintain our public health surveillance. For the current system to truly evolve, the federal government must commit to long-term funding to complete essential system upgrades at all levels, and annual sustained funding to support ongoing maintenance, upgrades, and public health and analytics workforce development as technology advances.

- ***Exercise Regulatory Flexibilities and Enforcement Discretion to Ease Burden***

The federal government should look at broader federal regulatory flexibilities and enforcement discretionary opportunities to reduce administrative as well as clinician burden in vaccine distribution and administration. For example, many of these flexibilities would come from the HHS Office of Civil Rights (OCR) oversight and enforcement of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)—[OCR's recent announcement](#) on enforcement discretion for use by certain providers of web-based scheduling applications for COVID-19 vaccination appointments is a positive step. We recommend exploring the continued and potentially additional temporary use of regulatory flexibilities to reduce burden related to the following vaccination-related processes while creating a robust preparedness program that utilizes health information and technology that is fully conformant under HIPAA:

- Continue the already established relaxation of oversight of Business Associate Agreements (BAA) for purposes of data sharing or entering into a technology/data sharing arrangement for pandemic response
- Modify security oversight on novel technologies such as quick response (QR) codes used to simplify an individual's COVID-19 vaccination registration
- Streamline the informed patient consent process for vaccination purposes, while ensuring that trust is established and transparency is maintained
- Accelerate research into the pandemic response with an adjusted BAA/Consent/HIPAA Security Regulation for research subjects
- Allow provider health systems to help small community providers with vaccination distribution and administration without violating the Physician Self-Referral Law or Anti-Kickback Statute

We also encourage further investigation into potential flexibilities related to the Americans with Disabilities Act (ADA) and the Family Educational Rights and Privacy Act (FERPA) and how each could positively impact broader vaccination distribution and administration initiatives.

- ***Adopt an "All-Hands-on-Deck" Approach to Vaccine Distribution and Administration***

Our organizations bring a significant number of key stakeholders to this vaccination effort. Still, there are opportunities to involve additional groups and better leverage existing infrastructure in these broader distribution challenges.

Various levels of IT connections already exist between most stakeholders in healthcare, and a federally-coordinated response should try to ensure that those connections are maximized and even further amplified. Electronic health record (EHR) technology must remain at the center of any response effort, as EHR data should be leveraged and scaled to inform public health decision-making. In addition, pharmacies are poised to help vaccinate more individuals for COVID-19, and by utilizing existing health IT platforms, including state and local immunization information systems (IIS) and HIEs, pharmacies and their public health partners will be better equipped to transmit required vaccination data to governmental health agencies at all levels after administering each dose.

Health plans have data on their beneficiaries that can support other partners as well as the government. For example, health plan information could help identify sustainable supply chain opportunities as well as leverage data to identify populations and communities with gaps in vaccination coverage for needed prioritization. The creation of mass vaccination centers or events, complemented by the [Federal Emergency Management Agency's efforts](#), are leveraging digital systems for tracking and reporting, even outside of traditional healthcare locations. The United States Digital Service is working with CDC on projects to enhance COVID-19 related reporting from non-traditional sites as well.

Moreover, EHRs are essential in capturing real-time COVID-19 test results, as well as information related to vaccine administration, and reporting them to state disease surveillance systems, health plans, and across state or national borders when necessary. HIEs can also be useful in working with health systems, providers, and laboratories to import their information. Overall, health information and technology systems are creating analytics, visualization, and reporting (e.g., dashboards) that can be used by health officials to inform their response to the pandemic based on vaccination rates as well as support public transparency efforts related to vaccination priorities and policies.

Our organizations want to work with the federal government to enable a bi-directional exchange of IIS information back to EHRs to support broader vaccination and surveillance initiatives. HIEs could also play a significant role where these IIS-EHR connections are not already in place, and lining up interoperability standards and connectivity to serve this goal would be the first step.

This effort could build on the series of investments ONC recently [announced](#) to help increase data sharing between HIEs and IIS. These projects expand [ONC's Strengthening the Technical Advancement and Readiness of Public Health Agencies via Health Information Exchange \(STAR HIE\) Program](#) by helping communities improve the sharing of health information related to vaccinations. Through these collaborations, public health agencies can get additional help identifying and tracking patients who have yet to receive their second dose of a COVID-19 vaccine, and better identify those who may be high-risk and have not yet received a first vaccine dose.

Linking together immunization and clinical data to address high-risk populations, addressing vaccination gaps among certain populations, and identifying potential adverse vaccine reactions reinforce the importance of these entities all working together. We foresee that Micky Tripathi, in his role as National Coordinator, can work to ensure all vital health IT systems are fully integrated into the federal government's COVID-19 response.

As the US rebuilds its [collaboration](#) with the World Health Organization (WHO), there exist substantial opportunities to ensure an expanded sharing of lessons learned and model practices between our COVID-19 response and the actions taking place in other nations. Federal planning on COVID-19 vaccine distribution and administration can only benefit from the experiences of other countries, and we should resume our leadership position in WHO on global health and security issues. Our organizations may also be able to contribute to this effort and maximize our cross-national information sharing capabilities.

- ***Emphasize the Importance of Interoperability and Data Sharing in the Broader Vaccination Effort***

The interoperability of vaccination data is a key driving factor in our government’s response to COVID-19. This sentiment ties into the Administration’s [National Strategy](#), particularly for Goal 2 (Mount a safe, effective, comprehensive vaccination campaign), Point 8 (Bolster data systems and transparency for vaccinations). Interoperability enriches data completeness—the more information that is available and accessible, the better case can be made to the public about the efficacy and safety of the vaccines.

Given the importance of IIS to our broader national response, our organizations recommend that the Administration work with stakeholders to create a national IIS policy framework that provides guidance about how health departments should structure their IIS as well as the concomitant reporting requirements. We encourage a national policy framework that defines a minimum data set for reporting purposes, ensures policies include all age groups across the lifespan or state residency, and emphasizes the importance of utilizing [CDC’s Guidance on Technical Standards](#). This framework would also uniformly adopt standards for data transport and ensure greater consistency in data element adoption. We emphasize our recommendation that standards that currently exist be leveraged—all IIS should adopt a minimum set of common standards, including HL7 V2.5.1 Release 1.5 and SOAP Web Services. In addition, this framework would allow for uniform policies to promote comprehensive data capture, broad, secure access to records, opt-out consent policies for IIS participation, and cross-jurisdictional data exchange to support complete, accurate, and timely consolidated immunization records.

Going forward, our organizations recommend that the federal government mandate that all vaccination administration sites report data to IIS registries and query data from IIS registries, adhering to existing standards and standardized reporting protocols. It is important to note that IIS data have the ability to fuel data insights broadly at all levels—but complete, accurate, and standardized capture of data is essential to serve the needs of local, state, and federal vaccination responses. IIS are governed by state and local laws, so if IIS data capture is robust, these systems can effectively share data up to the federal level for broader surveillance purposes (as well as with health plans, health systems, etc.), and across state lines.

The federal government should also work with our organizations to explore the creation of a National COVID-19 Vaccination Registry, for research and analytics purposes, to track vaccinations on a local and nationwide basis, and connect with IIS. Waiving or limiting connection fees should incentivize the use of a national registry.

Moreover, the opportunity exists for the federal government to leverage the work of the CDC-sponsored [Immunization Integration Program \(IIP\)](#), which brings together clinicians, EHR developers, IIS, public health, HIEs, and other key stakeholders to improve interoperability, information sharing, and management. The purpose of the project is to increase immunization data quality and data use through collaboration, measurement, and technical support to improve IIS and EHR interoperability.

- ***Support a Public Health Campaign to Democratize Data and Information Through Innovative Digital Solutions***

We recommend that the federal government, in coordination with public health partners, launch a joint communications strategy to ensure that individuals have greater access to accurate COVID-19 vaccination information through the use of mobile applications and other digital technologies as well as communication mediums. Leveraging technology in developing these outreach campaigns can also enable responding to common questions about both vaccines as well as the technology designed to monitor and track population health measures to ensure equity in vaccine uptake, including:

- Where individuals can receive a vaccination
- What it means to be vaccinated (e.g., not necessarily “immune”)
- The benefits of mask-wearing and other steps one should continue to take to mitigate COVID-19 risks
- Plans for distributing vaccines in their locality/state/region
- Surveillance data on COVID’s spread across one’s own community, vaccination coverage—including among priority populations—and, simplified epidemiological science for the general public

We applaud the creation of CDC’s [V-safe After Vaccination Health Checker](#), as a public reporting tool for COVID-19 vaccine adverse events that also allows CDC to remind individuals of their second vaccination dose, when applicable. There may also be collaboration opportunities with IIS and participating provider organizations to enable push notifications with reminders to individuals about receiving a second dose. In addition, the Administration should explore leveraging the [Federal Communications Commission’s Lifeline Program](#) for expanded outreach to vulnerable communities with push messages on COVID-19 vaccination sites and second dose reminders. Overall, digital technologies could be empowered to strengthen health as well as digital health literacy, democratize data, better engage communities, and restore the trust of the American people in our journey through the pandemic.

These technologies may also help contribute to expanding the use of COVID-19 contact tracing applications, and reaffirm how an individual’s health information is protected and secured while using these technologies. Many COVID-19 contact tracing applications and software integrations deliver value to the user as well as society more generally (e.g., a public good) and leveraging these applications to support vaccination administration, dosing, and testing may likely improve vaccination rates as well as allow the public to feel more secure in returning to group functions. To support the use of digital technologies for a broader public education campaign around vaccinations, the public should be educated on how their relevant health data and information is stored, protected, and reported as well as the benefits that contact tracing applications play in broader societal mitigation strategies.

Longer-Term Plans

- ***Generate Digital Vaccination Credentials for Individuals***

Our organizations encourage the Administration to work with technology developers to immediately begin development of standards and exchange requirements to enable individuals to digitally verify their vaccination status. An electronic vaccination record will provide assurances to interstate transportation, businesses, schools, and other entities, helping to fully reopen the economy, restore commerce, and resume travel.

The work of the [Vaccination Credential Initiative \(VCI\)](#) is underway and includes several high-profile technology organizations. The coalition is composed of public and private partners committed to empowering individuals with digital access to their vaccination records based on open, interoperable standards. This access will allow each individual to protect and improve their health, as well as demonstrate their vaccination status to safely return to in-person functions while protecting their data privacy. This effort may also serve as a global model for the development of digital vaccination credentials.

- ***Establish Formal Feedback Loop for COVID-19 Related Tools and Technologies***

Given the level of technological innovation and reimagined administrative processes created to speed vaccinations to more individuals, our organizations ask the Administration to support research to study the effectiveness of the various tools and technologies that have been adopted and propagated across the ecosystem thus far. It will be critically important to understand the effectiveness of any interventions and strategies used to tackle COVID-19 vaccinations when thinking about the future inevitable public health emergencies.

Our recommendation aligns with President Biden’s Executive Order on [Ensuring a Data-Driven Response](#) that directs federal agencies across government to collect, produce, share, and analyze data and collaborate with respect to COVID-19 response and recovery efforts. Allowing for appropriate privacy protections, we want to ensure that data with non-personally identifiable information is open to the public, and scientific research into the efficacy of the tools and technologies used in the response is promoted.

- ***Develop a National Patient Identification Strategy***

Our country lacks a national strategy to accurately match patients to their health information. This inability to match patients with their records can lead to serious quality and safety issues, from medical errors to lost diagnoses, duplicate testing, adverse drug events, and other poor outcomes, all at a significant financial cost to our healthcare system. Public health data linkages are also hampered between IIS and disease surveillance systems, as well as core “cradle to grave” national health statistics such as linkage of a birth record to the CDC’s [Vaccine for Children](#) program. Although HIPAA called for the creation of a unique patient identifier to address this issue in 1996, for nearly two decades, Congress has banned federal dollars from being used to promulgate a unique patient identifier. A narrow interpretation of this archaic ban has prevented HHS from leading on efforts to advance a national patient identification strategy, to the detriment of patients, providers, and public health.

The COVID-19 crisis has made clear just how important this issue is—without the ability to match patients accurately to their health information, critical information is lost and individual and public health suffers. The success of our nationwide response to COVID-19 and vaccination distribution and administration hinges on accurate information. Our organizations plan to continue working with Congress to remove the ban so that our community can move forward with developing a National Patient Identification Strategy. Such a strategy would be committed to improving patient matching to support secure information sharing as part of a broader effort to improve care quality, effectiveness, affordability, and safety.

Our organizations appreciate the opportunity to contribute our ideas on maximizing the role of health information and technology in targeted COVID-19 mitigation strategies and more rapid action around executing broad-based vaccinations. We are committed to being a valuable resource to you, the COVID-19 Task Force, and HHS Leadership in addressing COVID-19, particularly on accelerating vaccination distribution and administration. Please leverage our organizations as well as our members and stakeholders in your efforts moving forward.

We would welcome the opportunity to further discuss these issues with you and your leadership team. Please feel free to contact Jeff Coughlin, the Healthcare Information and Management Systems Society's Senior Director of Government Relations, at jeff.coughlin@himss.org or 703.562.8824, with questions or for more information.

Thank you for your consideration.

Sincerely,

American Health Information Management Association
American Immunization Registry Association
American Medical Informatics Association (AMIA)
Association of Public Health Laboratories
Consortium for State and Regional Interoperability (CSRI)
Council of State and Territorial Epidemiologists
eHealth Initiative
Electronic Health Record Association
Healthcare Information and Management Systems Society
National Association of County and City Health Officials
Personal Connected Health Alliance
Strategic Health Information Exchange Collaborative