April 21, 2020

Robert R. Redfield, MD
Director
Centers for Disease Control and Prevention
1600 Clifton Rd.
Atlanta, GA 30329-4027

Dear Dr. Redfield:

The Health Innovation Alliance (HIA) writes to commend you for the work you are doing to fight the coronavirus pandemic, and to share our thoughts with you on how to modernize the public health data tools and infrastructure so that current and future pandemics will take a lower toll on the country and the world. HIA is a diverse coalition of patient advocates, healthcare providers, consumer organizations, employers, technology companies, and payers who support the adoption and use of data and technology to improve health outcomes and lower costs.

The tools used by our public health service are outdated and methods for the reporting, collection, analysis, and use of public health data are inadequate, slow, and unreliable. Despite the potential for this data to help slow infection and better treat patients, it is not readily available electronically at the point of care, across electronic medical records, disparate hospital systems, or state databases. Additionally, there is no automated mechanism for sending case reports directly to public health authorities or providers on the front lines.

Fortunately, the Centers for Disease Control and Prevention (CDC) has an opportunity to rebuild its infrastructure on a solid foundation of modern technology, best practices, and open standards. As part of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Congress appropriated $500 million as part of an effort to modernize public health data surveillance and analytics infrastructure. This investment is long overdue. We encourage you to work directly with the private sector in developing this modern infrastructure, and recommend that any effort be guided by the following principles:

1. **Standardized Data.** Public health data should be standardized and reported electronically in the same way across all systems nationwide in all jurisdictions as a condition of investment. To accomplish this, the Office of the National Coordinator for Health Information Technology (ONC) should work with Standards Development Organizations (SDOs) to adopt a standard vocabulary set to facilitate the capture of structured data. CDC should work with the private sector to identity core (public health, clinical) and supplementary health data and include social determinants and population characteristics.

2. **Modern Tools.** Actionable information should be made available to all actors who need it to maximize public health and clinical outcomes. Specifically, any modern public health data

framework should require that usable information be available at the point in time it is needed, within workflow, and across public health and clinical systems. Such a system would have:

    a. Automated electronic reporting of case reports to local, state, and national authorities.
    b. Electronic lab results that are reported automatically to provider and local, state, and national public health authorities. Implementation guides should be standardized across jurisdictions. Any test result should be reported automatically in a standard format from the lab to a clinician, the appropriate public health authority, and the patient.
    c. Immunization data should be standardized and shared with immunization registries. Immunization status should be available at the point of care for clinicians, including pharmacists, to determine the need for vaccinations.
    d. Syndromic surveillance reporting to public health entities should be standardized, electronic, and be uniform across all jurisdictions.
    e. In all cases, standardized results should be available to clinical actors within their workflow.

To facilitate this, ONC should work with SDOs to adopt standard implementation guides and to rapidly move pilots to production as quickly as possible. Specifically, the Electronic Initial Case Report (eICR) and the Reportability Response to build a complete workflow must be advanced. Its use should be required.

3. **Translating Public Health Data Into Patient Outcomes.** Providers are a front-line defense against the virus, but they need to be armed with the right information to effectively do their work. This means knowing a patient's lab results, vaccine status, and any medications used. The ability to accurately track test results, along with when treatments and vaccines are administered, will be a key to fighting the virus and future pandemics. Even though the Department of Health and Humans Services (HHS) has already allowed pharmacists to test for COVID-19 and anti-bodies, few pharmacies have access to real-time information to know which patients need a vaccine. They don't know whether a patient has been: 1) vaccinated; 2) already tested and what the result is; or 3) treated with a prophylactic or an anti-viral. That data is siloed in claims systems and electronic health record (EHR) systems and is not shared at the point-of-care (should the patient need hospitalization) or with public health officials who are tracking the development of the pandemic, working on courses of treatment, or coordinating vaccine development.

In order to populate this data in real time, we need to implement a system that connects those at the point-of-care with payers and the appropriate public health authorities. This technology could be built off of the existing ePrescribing and claims adjudication processes that run nearly four billion pharmacy transactions per year seamlessly and in real-time. HHS needs to:

- Fund a data hub that collects and pushes information to provider offices, hospitals, and pharmacies. We estimate the cost based on similar federal and other country data hubs to be close to $200 million.
- Approve private-sector standards for electronic lab results and vaccine status.

4. **Robust Data and Analysis.** Valuable public health data should be available on a secure hybrid cloud architecture so that deidentified information can be made available widely for research

and analytics. The operating models for research, development, and deployment should include funding from both government and the private sector. Usage fees for non-network participation could be charged to encourage participation. The technical aspects of this data infrastructure should include anonymization and deidentification protocols; open-source data science and reporting tools; ledger-based technology (e.g., blockchain) for trust-based ownership, custodianship, and interoperability; support for both unstructured and structured data; integration engines and standard messaging protocols (such as FHIR); and out-of-the-box data extracting, predictive analytics tools, and reporting. Aggregated, big data can be the engine for powerful artificial intelligence (AI) solutions already used in private-sector efforts. For example, AI can predict the spread of disease, assess current resources, and better manage the flow of supplies to meet capacity issues, like where to direct masks, ventilators, and clinicians. CDC should have an AI strategy as part of its data and analysis goals.

5. **A Modern Data Framework Requires Interoperability and Privacy.** Current law and privacy restrictions make it difficult to share health data -- and almost impossible to do so in real-time. In fact, patients have difficulty getting their own health information from their own doctor's office, much less getting one office to send a record to another office. This problem is largely due to the outdated Health Insurance Portability and Accountability Act (HIPAA), confusing federal regulations, and conflicting state laws intended to protect patient privacy. Recent controversies around contact tracing are largely premised on the notion that health data can't be protected and digitized at the same time. That is not true. The real threat is the absence of uniform rules that apply to all health data regardless of where the data is collected, stored, used, or shared.

   We recognize CDC can do little to affect the national privacy framework – HHS and Congress must act to set a uniform, nationwide law outlining how health information can and will be shared going forward. Any such law must establish strong privacy protections for patients and their families. We simply note that the necessity to use technology and big data nationwide and globally cannot be achieved through a patchwork of conflicting state laws. In the absence of Congressional action, CDC can set privacy protection standards and expectations around the data it collects, uses, and shares with other entities.
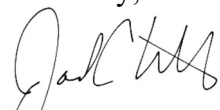
6. **Public-Private Partnership.** The CDC should use high-performance computing systems through pooled supercomputing capacity to allow researchers to run large amounts of calculations in epidemiology, bioinformatics, and molecular modeling. Such supercomputing should be done in a public-private partnership with the best tools and minds across research, technology, and government institutions to help deliver the best and most timely results.

We believe these concepts should guide CDC in developing its report to Congress as required by Title VIII of H.R. 748, the Coronavirus, Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136). This report is an opportunity to present a plan detailing how CDC will execute a surveillance system that produces real-time, actionable data health care providers can use to fight COVID-19. Attached to this letter are more detailed thoughts about the attributes of a modern data infrastructure.

This pandemic has raised awareness of the need to modernize healthcare and bring it into the digital age. While health systems, plans, wholesalers, and manufacturers have each developed impressive data capabilities, times like these remind us how much more we could accomplish by sharing all this

information to benefit public health. We look forward to working with you to build a modern public health data and analytics infrastructure.

Sincerely,

Joel C. White
Executive Director