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The Honorable Xavier Becerra
Secretary
United States Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Becerra,

State and local health departments rely on data from hospitals, doctors' offices, laboratories, and other health care facilities to inform a range of public health initiatives that could help respond to larger crises. As one example, health departments receive reports of COVID-19 infections and other conditions of public significance, including those that require immediate action by health officials. These data help authorities follow up with individuals directly to conduct case investigations, identify outbreaks within communities, evaluate disease control programs, set critical policy to protect the most vulnerable, and connect people to other health services or treatments. However, gaps in the data available to public health authorities have hindered the exact actions that could help the country emerge from the COVID-19 pandemic, save lives, and restart the economy.

Our organizations—The Pew Charitable Trusts, the Council of State and Territorial Epidemiologists (CSTE), and the American Medical Informatics Association (AMIA)—identified a critical opportunity for the Department of Health and Human Services (HHS) to improve a core public health function: case reporting. Given the current pandemic, we ask that you prioritize these efforts urgently. Case reporting by providers to public health occurs when an individual is diagnosed with a condition of public health significance, such as COVID-19 or measles, and is required by state law. However, case reporting today remains largely paper-based and is often done using fax or phone, leading to incomplete and delayed data—therefore limiting agencies' ability to take critical, life-saving actions.

To address challenges with case reporting, we encourage HHS to:

- Update payment programs to incentivize and require providers to submit case reports electronically as soon as possible;
- Update criteria for electronic health records (EHRs) to use consensus-based standards for electronic case reporting (eCR);
- Ensure EHRs make all of the data necessary for public health action available via updates to the United States Core Data for Interoperability (USCDI); and
- Require that EHRs make data available to public health free of charge in the same way that patients can access data via application programming interfaces (APIs).

Taking these steps will ensure that EHRs will have the functionality to support eCR, and providers will have incentives to implement and use these capabilities.

Case reports offer the foundation to public health data needs

We are now in the second year of a public health crisis that has exposed deadly gaps in our public health data infrastructure. However, COVID-19 is just the latest threat highlighting these deficiencies. It is not the last public health threat we will face, nor is it the only danger presently facing the public. Alongside

COVID-19, public health authorities are still combatting vaping-related illnesses, chronic diseases such as diabetes and hypertension, and HIV, among other threats. A strong public health infrastructure can help address these and future threats. Case reporting is one of the five key pillars of the Centers for Disease Control and Prevention (CDC)'s Data Modernization Initiative, and core to the public health data infrastructure.[1] Policy levers, similar to those implemented by the Centers for Medicare and Medicaid Services (CMS) to encourage providers to use electronic health records, are needed now to incentivize timely and complete transmission of data from health care to public health in the form of an eCR.

Case reports help public health officials identify disease hotspots as well as changes in disease trends, track morbidity and mortality, identify health disparities, and conduct timely case investigations and contact tracing to reduce community spread. Public health officials can track outbreaks to find the origin of threats and identify effects on subpopulations, like individuals with certain comorbidities or different racial groups. However, CDC has estimated that, for some conditions, public health agencies receive only a tenth of the reportable notifications they should receive.[2] The COVID-19 pandemic has further illuminated ongoing challenges with case reporting due to an overreliance on manual processes to enter and share information, as well as the transmission of incomplete data. Case reporting today mostly occurs through outdated manual processes—fax, email, or phone—despite that most health care providers have the necessary data stored electronically in the patient's EHR. This lack of electronic reporting has consequences; in addition to introducing more risks for errors, it can delay detection and response times, allowing diseases to spread further and putting more lives at risk.

eCR refers to the automated, electronic transmission of a subset of clinical data—such as diagnoses, symptoms, lab results, and medications—for patients with diagnosed conditions or diseases of public health significance. Such public health-notifiable conditions include sexually transmitted infections, tuberculosis, hepatitis, or emerging threats such as Zika and COVID-19.

A switch to eCR would bring the following benefits:

- *Easing provider burdens:* Because eCR is automated, providers of care are not required to disrupt clinical workflow and spend time fulfilling public health reporting responsibilities. eCR operates seamlessly in the background, requiring *no* action from the clinical care team or office staff, which enables providers to spend more time with patients or performing other critical patient-centered functions. eCR also greatly reduces the time health care and public health agencies must spend on follow-up investigation calls to obtain necessary data.
- *Providing data more quickly*: eCR enables real-time data access for public health authorities, meaning they don't have to wait days—or even weeks—for faxes or mail to be received and entered in the system. As a result, they can conduct case investigations and contact tracing faster to help slow the spread of communicable diseases.
- *Addressing underreporting:* Given the estimates of gross underreporting of cases, eCR is trigger-based, meaning the data are automatically sent from the EHR upon entry of certain diagnoses. Public health authorities can thus obtain more accurate case counts to drive policy and implement interventions quickly.
- *Providing complete data to address disparities*: Paper forms often lack needed information. Electronic reporting allows critical demographic data—like race and ethnicity—to be rapidly submitted, informing public health responses and polices to protect the most vulnerable populations. Additionally, clinical data—such as pregnancy status, vaccination status and underlying health conditions—that may help inform decisions can be easily submitted.
- *Mitigating data errors*: Manual data entry into electronic systems from paper reports is sluggish and introduces a greater risk of error. Electronic reporting addresses this by reducing opportunities for transcription errors.

- *Improving cost effectiveness:* Public health authorities, which are significantly under-resourced, often employ individuals simply to enter data into databases or contact providers to obtain needed information, such as phone numbers or clinical notes. Electronic submission of data would obviate the need for those roles and enable public health authorities to redeploy resources toward rapid implementation of interventions and other meaningful functions.

A transition to eCR is both necessary and feasible, given recent advances fueling electronic data exchange in health care and its prominence in the CDC Data Modernization Initiative.[3] In fact, the shift to eCR implementation has already begun, with over 7,000 facilities now sharing COVID-19 case reports electronically.[4] Additionally, recent regulations have required EHRs to have application programming interfaces (APIs), which are tools that can help gather and exchange standardized information among different systems and can be leveraged to support case reporting to public health agencies.

Update CMS payment programs to require eCR as soon as possible

Health care providers have not prioritized electronic case reporting on their own, resulting in significant data gaps. Addressing that deficiency requires federal action, specifically through CMS implementing policies to require adoption of eCR; this can happen through the Promoting Interoperability program and/or conditions of participation in Medicare. This requirement should be put in place *as soon as possible* to support the current need for COVID-19 response and to provide long-term value for all reportable conditions. CMS should select one—or both—of the options below:

(1) *Update the Promoting Interoperability program*: CMS should make electronic case reporting a required, rather than an optional, component to obtain credit under the Promoting Interoperability program. In the Promoting Interoperability program, CMS outlines different criteria for how hospitals and health care providers must use their EHRs, such as by sharing patient data with other clinicians caring for an individual. This program has proven effective in driving adoption of certain functionalities within EHRs, such as increasing the percent of hospitals submitting electronic lab data to public health from 55% to 92% over the course of several program years.[5] A similar increase in adoption and use could also occur for electronic case reporting if it was a required component. Under the current iteration of the Promoting Interoperability program, there is a single public health reporting objective that contains six potential measure options, of which electronic case reporting is one; however, reporters only need to select two to receive credit. As such, providers can select other activities, many of which they are already doing, for public health participation and receive full credit without submitting case reports electronically. Making case reporting a requirement would ensure this change occurs.

(2) *Conditions of Participation:* CMS should consider including electronic case reporting as a condition of participation in the Medicare program. CMS has recently used these conditions to advance EHR-based priorities. For example, CMS required that hospitals notify primary care physicians when their patients have been admitted, discharged, or transferred from the facility. A new condition of participation for electronic case reporting optimally would include two components. First, hospitals and providers must use an approach that meets requirements from the Office of the National Coordinator for Health Information Technology (ONC) (listed below) for electronic case reporting. Second, CMS should set a threshold for the percent of reportable encounters transmitted through electronic means. For example, CMS could indicate that at least two-thirds of all encounters with patients that have a reportable condition have been reported electronically to public health officials; the remaining third could be transmitted manually. CMS could enforce this requirement in the same way it oversees other tenets of conditions of participation, namely through periodic audits and inspections.

Update EHR certification to require eCR and refer to specific standards for implementation
Despite more providers and hospital systems implementing EHRs over the last decade, the systems they use often lack the capability to digitally send case reports to public health agencies, necessitating the use of manual and paper-based reporting.

This deficiency in EHR capabilities stems from deficits in federal EHR certification requirements, which lists eCR as an optional function. As such, many vendors have not included eCR as part of the standard functionality of their systems. ONC should update EHR certification provisions in two ways:

(1) Support for eCR should be mandatory—not optional—as part of the base definition for EHRs. This shift would ensure that all EHRs obtaining federal certification have eCR capabilities.
(2) ONC should require adherence to the specific consensus-based eCR standards and implementation guides developed by Health Level Seven (HL7) with input from public health stakeholders. Adherence to these standards (called the Electronic Initial Case Report, Reportability Response, and Electronic Reporting and Surveillance Distribution) would make it easier for public health agencies to prepare their own systems to accommodate a highly standardized report that contains all the necessary data.[6] Following these standards would also ensure EHRs use automated triggers to send reports for appropriate conditions.[7]

Requiring eCR as part of EHR certification will ensure that public health agencies get the data they need, in a standard way, from health care providers and facilities in real time.

Ensure that USCDI contains all of the data necessary for public health reporting
As part of implementing the 21st Century Cures Act, ONC developed the USCDI as the national standard data set that EHRs must be able to exchange. The data set consists of multiple data classes, each with various constituent data elements.

ONC should include all data elements needed for public health case reporting as part of USCDI. Specifically, ONC should include the following public health data elements:

- Newly proposed data elements within the existing "problems" data class: date of diagnosis, date of onset, and date of resolution. This information will give public health officials data to understand possible exposure; calculate the disease's incubation period; and provide needed information for case investigation and contact tracing.
- "Specimen" data class, and all associated data elements (specimen collection data, specimen source site, specimen type). These data will help public health officials understand the types of specimens if the optimal tests are performed, and potentially provide data on the efficacy of certain tests.
- "Travel information" data class, and all associated data elements (travel history dates, travel history location, travel plans dates, and travel plans location). Travel information helps public health officials understand the location and timeline of potential infections; whether the individual traveled to high-risk areas; and if they were infectious while traveling, which can aid in the identification of contacts exposed.
- "Work information" data class, and all associated data elements (combat zone period, employment status, farmworker status, job, retirement data, usual work, veteran status), which will help with understanding and identifying potential transmission and infection risk. For example, farmworkers may be at a higher risk of exposure to Lyme disease than other individuals.

- "Observations" data class, and all associated data elements associated with pregnancy (Apgar score, estimated date of delivery, gestational age, gestational age at birth, last menstrual period, M3 results, number fetal deaths at delivery, and pregnancy status). Information related to pregnancy helps officials determine impacts of infection associated with pregnancy (for example, pregnant women are at a higher risk of severe outcomes from COVID-19 infections), as well as the need for follow-up and risk assessment for these patients, including whether certain conditions have worse fetal or perinatal health outcomes.
- Death date, which allows for epidemiological analysis to understand a disease's severity.

Including data needed for public health as part of the USCDI will ensure that all EHRs are able to document and exchange this information in a standard manner, particularly with public health agencies.

Require API use for public health as free of charge

As mentioned, recent ONC rules implementing the Cures Act will spur greater use of APIs to extract information from EHRs in a standard way. The Cures Act indicate that these APIs must be made available to health care providers "without special effort," and ONC has indicated that excessive costs for API use would be considered special effort. Removing fees that hamper the use of APIs for public health reporting would eliminate a cost barrier to providers who are sending public health officials needed information. Through this change, entire communities would benefit; this approach would also align with existing policies that allow patients to access data for free given the societal benefits involved. Therefore, ONC should update its regulations governing API fees to prohibit costs for API-based public health reporting, just as fees associated with patient access to data are banned.

Conclusion

Thank you for prioritizing the urgent need to implement eCR to improve the public health response to COVID-19. Broad implementation of eCR will transform public health reporting and responses beyond COVID-19, and serve as a longstanding infrastructure investment that will improve the ability of public health to address other disease threats.

Should you have any questions, or if we can be of assistance, please contact Molly Murray, health information technology officer at The Pew Charitable Trusts, at 202.770.5376 or mmurray@pewtrusts.org.

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The Pew Charitable Trusts is a non-profit research and policy organization focused on improving patient care and public health. Pew's health information technology (health IT) initiative focuses on advancing the interoperable exchange of health data and improving the safe use of electronic health records (EHRs).

The Council of State and Territorial Epidemiologists (CSTE) is an organization of 56 member states and territories representing applied public health epidemiology and serves as the professional home for 2,000 applied public health epidemiologists nationwide. CSTE provides technical advice and assistance to partner organizations and to federal public health agencies such as the Centers for Disease Control and Prevention (CDC). CSTE supports effective public health surveillance and sound epidemiologic practice through training, capacity development, and peer consultation.

The American Medical Informatics Association (AMIA) is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, and public health experts who bring meaning to data, manage information, and generate new knowledge across the health and health care enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across settings and patient populations.

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