

November 2, 2020

Seema Verma
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma,

On behalf of the nearly 30 member companies of the Electronic Health Record (EHR) Association, we are pleased to offer our comments to the Centers for Medicare and Medicaid Services (CMS) on its request for information with comment period (IFC) for the Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, which was published in the Federal Register on September 2, 2020.

The EHR Association's member companies serve the vast majority of hospitals, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs across the United States. Our core objectives focus on collaborative efforts to accelerate health information and technology adoption, advance information exchange between interoperable systems, and improve the quality and efficiency of care through the use of these important technologies.

We appreciate and strongly support the need for public health data reporting to enable local, state, and national jurisdiction to have situational awareness of the COVID-19 pandemic in all its aspects. Encouraging providers to report as fully and as quickly as possible on the new data requirements is essential to support the COVID response. EHRA members have worked with their clients to rapidly react to the new and quickly changing public health data requirement, partnering with healthcare delivery organizations to define, calculate, and share data in a matter of weeks or even days.

Unfortunately, these efforts do not come without a cost, as healthcare organizations struggle to balance providing care for their patients with the numerous requests for data. This effort has been exacerbated as new data requirements were mostly introduced without full understanding of what would be required by providers, laboratories, and their IT suppliers to collect and submit the data: e.g. software updates, deployment, and workflow changes across all stakeholders.

AdvancedMD	Cerner Corporation	Epic	MEDHOST	Nextgen Healthcare
Allmeds, Inc.	CPSI	Flatiron Health	MEDITECH, Inc.	Office Practicum
Allscripts	CureMD	Foodhold Technology	Medsphere	Sevocity - Division of Conceptual Mindworks, Inc
Athenahealth	eClinicalWorks	Greenway Health	Modernizing Medicine	STI Computer Services
BestNotes	eMDs	Harris Healthcare Group	Netsmart	Varian Medical Systems
Bizmatix	Endosoft	Lumeris	Nextech	

Neither providers, laboratories, nor their IT suppliers were involved in the early discussions by HHS and other regulatory authorities as requirements were established. Data requirements bring with them considerations of how to collect that data, what the impact will be on provider documentation workflows, and which changes are necessary for public health agencies to receive the additional data. Without stakeholder involvement, federal agencies made choices about data collection and reporting that were not fully informed, resulting in approaches that are not the most efficient and expedient, or that do not consider the effort necessary to put the new reporting in place. We include specific examples in [Appendix A](#).

As suppliers of key reporting capabilities, developers have reached out, and our efforts to work with HHS and others remain ongoing, offering feedback on the feasibility of new data requirements with the goal of preparing organizations that use our software to report such data promptly, efficiently, and without undue burden. Despite these efforts, we continue to face challenges gaining early insight in order to identify better ways to effectively collect and/or report the relevant data.

In this context, we are concerned with the penalties being put in place for providers, particularly when providers have made every effort to provide all the data they have available. These providers have acted in good faith, yet are now facing penalties. We urge CMS to consider enforcement discretion when considering assessing any penalties until such time it is reasonable that a provider should have in place all the necessary reporting capabilities and can be reasonably expected to submit all data.

More importantly, we urge CMS to work with other agencies in HHS, in particular CDC and ONC, to proactively prepare for ongoing and future public health emergencies, and use CMS regulatory levers to ensure all providers are part of the public health reporting infrastructure and that a core data set for public health is established. A clear process must be in place, with all stakeholders involved, to react to new and emerging data requirements, streamline reporting requests to ease duplicate/overlapping submissions, identify alternative reporting/query flows, and connect all players to a modernized public health infrastructure. CMS is in a unique position to work with the relevant stakeholders to establish such processes with active stakeholder engagement and drive adoption.

For example, to further raise the level of reporting and connectivity, we note that currently the Promoting Interoperability program provides flexibility and optionality for public health capabilities. Reporting categories are optional, and, for case reporting, only certain vocabulary is standardized, not the report format itself. As a result, key reporting capabilities, specifically electronic case reporting, were not sufficiently adopted. Electronic case reporting also would have provided a better foundation to more rapidly add additional data requirements as an emergency unfolds. We suggest that CMS coordinate with ONC on future updates to these and other programs establishing a core set of public health reporting requirements, with applicable standards that can be adopted at the national, state, and local level.

We note also that wielding Conditions of Participation to enforce compliance feels especially harsh. The IFC indicates that reporting requirements will be published in the [“COVID-19 Guidance for Hospital Reporting and FAQs For Hospitals, Hospital Laboratory, and Acute Care Facility Data Reporting,”](#) and yet

this document appears to be updated at will, with no date of publication and no change log. This places another undue and opaque reporting burden on providers to keep up with changes.

As the nation turns its eyes to a COVID-19 vaccine, we anticipate that additional reporting needs will quickly arise, representing an opportunity for proactive collaboration for a rapid response.

Unfortunately, reporting requirements are already being published without stakeholder input, such as the CDC's "[COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations.](#)"

We firmly believe that a more open and transparent process for formulating data requirements will result in increased provider readiness and thus compliance, reducing the need to resort to penalties. The EHR Association offers our expertise and continues to be ready to engage with all parties to strengthen our nation's public health infrastructure.

Sincerely,

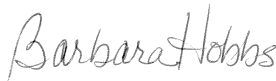


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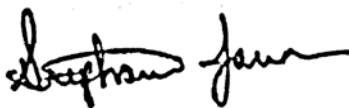
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About the HIMSS EHR Association: Established in 2004, the Electronic Health Record (EHR) Association is comprised of nearly 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families. The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.

Electronic Health Record Association
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the Clinical Laboratory Improvement Amendments (CLIA), and Patient
Protection and Affordable Care Act; Additional Policy and Regulatory Revisions
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Appendix A

On June 4, 2020, HHS announced new requirements for electronic lab reporting (eLR). The newly requested elements are not used in the performance of the test, and thus performing laboratories do not have the capability to capture or retain this information. As a result, the onus fell on ordering providers to capture this information and send it along with the order to the lab, which is subsequently required to send it to public health. This has a number of unintended consequences.

Providers are required to collect the data upon order entry using Ask-at-Order-Entry questions for the additional data. However, such data is not supported in the current ELR reporting standards used for certification and local adaptations by public health jurisdictions. To the extent already included in an order they are kept to a minimum to only those clinically relevant to perform the test. Any questions necessary to perform the test are also individual data points rather than involving follow-up questions. The new data requirements are actually better addressed in registration and clinical documentation processes outside of the order entry process (either just before or after) and then included in case reports by the ordering provider, thus reducing impact on the ordering workflow and subsequent laboratory data management requirements.

Similarly on the laboratory reporting side, device identification is requested. Test kit/platform identifiers are not supported in the current ELR reporting standards used for certification and local adaptations by public health jurisdictions. They are also not included in result reporting back to the ordering provider, who also may be required to submit test reports to public health. Device identification is limited and at best at the model level in textual form, not the desired UDI format.

New data requirements continue to emerge at the local, state, and federal level, which are also expected to be added to ELR reports, such as school related information in New York, gender and ethnicity data in Oregon, and others. All data that is not relevant to the performance of the test is relevant as part of case reporting.