June 20, 2023

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule
Mary E. Switzer Building, Mail Stop: 7033A
330 C Street SW
Washington, DC 20201

Submitted via: www.regulations.gov.

Re: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) RIN 0955-AA03

Dear ONC Staff:

The National Independent Laboratory Association (NILA) appreciates the opportunity to provide comments on *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) RIN 0955-AA03*. We are pleased to share our comments on the request for information (RFI) regarding Laboratory Data Interoperability. We also would like to provide ONC with general comments about interoperability, many of which stem from our member laboratory experiences during the COVID-19 pandemic.

Background:
NILA represents independent community and regional clinical laboratories that collaborate with physician practices, hospitals, outpatient care settings, skilled nursing facilities, and homebound patients. NILA is comprised of community-based laboratories that range in size from small to large multi-state regional laboratories. There are over ninety members of NILA and many of those provide a full range of testing services, while others are focused primarily on providing routine and emergency (STAT) diagnostic services to allow physicians to manage chronic diseases.

General Comments:
Community and regional clinical laboratories served on the front lines of the COVID-19 pandemic. In the wake of that response, we learned many lessons that will serve us as we prepare for the next large-scale threat to public health. Data reporting requirements during the COVID-19 emergency response imposed significant burdens and costs on laboratories, particularly the small, and medium-sized community laboratories that we represent. The disparate reporting requirements of each state required a unique and individual interface or electronic reporting format. If there had been true interoperability in place, the reporting requirements and the data fields used to capture that data would have been the same throughout—this was not the case. Instead, clinical laboratories added staff for the sole purpose of data reporting at a time when staff were critically needed for other duties such as conducting and performing COVID-19 tests and other clinical laboratory tests.

Further, laboratories had to pay for additional interface software to report data across many different jurisdictions. Unlike other areas of health technology, there has been little incentive or investment in connecting laboratory information technology with public health. As a result, laboratories lacked the required technology and workforce early in the pandemic to respond to new public health data reporting mandates, further slowing the pandemic response.

Public health information systems and independent clinical laboratory infrastructure need financial investments to allow all laboratories to receive and communicate patient data to public health authorities more effectively. While public health departments need investments to build an infrastructure that will allow for more streamlined reporting and consistency across state reporting requirements, this is not sufficient without additional investments in community and regional clinical laboratory infrastructure. As we saw with the COVID-19 pandemic, it is not only public health laboratories that report results to public health departments—community and regional clinical laboratories are now responsible for a much higher volume of public health reporting than before. Interoperability and a set of standards would support this.

NILA supports the role of community and regional clinical laboratories in the US health care system and believes strongly that federal investments should be made in those community and regional clinical laboratories, as well as public health departments, to ensure interoperability. We support the development of technology that would streamline reporting and improve the consistency and accuracy of data collected and shared. Importantly, inconsistent data requirements across all states and jurisdictions and the federal government, as well as requirements to collect and report data that laboratories do not always have, hinders laboratories' ability to report this data and hinders collaborative work with other entities within the healthcare system.

Laboratory Data Interoperability Request for Information (RFI):
ONC is seeking public feedback that may be used to inform future rulemaking regarding the adoption of standards and certification criteria to advance laboratory data interoperability and exchange. Within this RFI the agency has asked specific questions of stakeholders to which we offer the following responses.

Laboratory Data Interoperability Request for Information
We seek public comment generally on any topics identified for the Consolidated Appropriations Act, 2023, Section 2213(b) study on the use of standards for electronic ordering and reporting of laboratory test results, such as the use of health IT standards by clinical laboratories, use of such standards by labs and their effect on the interoperability of laboratory data with public health systems, including any challenges of the types identified above. We also seek comment on whether ONC should adopt additional standards and laboratory-related certification criteria as part of the ONC Health IT Certification Program.
Preamble FR Citation: 88 FR 23847 **Specific questions in preamble?** Yes
Please see our responses on the following topics: *2. The utility and maturity of existing HL7 v2 and C-CDA standards supporting laboratory interoperability and the impact of moving to FHIR-based laboratory data exchange.*

Laboratory Data Interoperability Request for Information

Laboratories have found great utility in the HL7 v2.x specifications for the exchange of laboratory orders and results with referring providers, public health agencies, payers and health information exchanges. Over the past 10-15 years, laboratories have made substantial investments in establishing HL7 v2 connectivity. Unfortunately, the version of HL7 v2 utilized is not standard across interfaces, laboratories or trading partners. Each interface is unique and typically configured to exchange the bare minimum information to fulfill its purpose. There is typically little, if any, use of standard coding systems such as LOINC or SNOMED and the content and format of each interface is subject to "negotiation" between the trading partners. In many cases, a working interface is established by trial and error as opposed to adherence to a pre-determined specification, and mapping between local order and result codes is often required. While laboratories would have benefited from the establishment of appropriate standards, the fact is that thousands of working interfaces have already been built and are in use today. While they may not be equipped to support the true vision of interoperable healthcare, the cost and burden of replacing these working interfaces will be substantial and must be accounted for. There must be an appropriate value proposition to any proposed standard method of data exchange. There has been extremely limited adoption of the HL7 eDOS standard for the exchange of laboratory directory of service. Thus, a mature FHIR service that could support all the required elements of eDOS should be able to gain acceptance more readily.

3. What barriers would additional health IT certification criteria for laboratory interoperability create for developers and other interested parties, and how might this affect adoption and use of such technology?

As mentioned in the response to question 2 above, a major barrier would be the thousands of existing laboratory interfaces that would certainly not comply with the certification criteria. The burden on vendors and providers to update these interfaces is significant and needs to be addressed via appropriate incentives. Since most laboratories were not considered "eligible providers" under the original meaningful use criteria, they had no incentive to use certified health IT, and thus, there was limited demand on LIS software developers to certify their systems. Thus, today, many LIS are not designed to support most certification requirements. For example, the LIS may not be able to store key patient attributes related to SDOH or SOGI. In addition, LIS may not be able to store standard code values such as LOINC and SNOMED within the LIS. What would be the market-based incentives for LIS vendors to enhance their products to provide the enhanced interoperability? Additionally, the provider's cost of adopting and using certified technology would also have to be accounted for.

4. Would developers of laboratory information systems or in vitro diagnostics systems that have not traditionally submitted products for certification under the Program seek out and benefit from certification to criteria relevant to such developers' products?

While our shared goal of a truly interoperable healthcare ecosystem would certainly benefit by establishing certification criteria for LIS and IVD software systems, it is not clear how developers of these systems would benefit or receive a return on their investment. These systems are typically overly complex and the switching costs to change them are high. Costs would either need to be covered by existing maintenance/support costs or otherwise passed on to the provider. Providers would incur the costs of the certified software in addition to then having to bear the burden of updating existing interfaces to use the certified interoperability standards.

Thank you for your attention to our comments. As you consider these and other comments, NILA and its member laboratories are happy to serve as a resource and provide further information as needed. If you have questions or wish to discuss further, please contact Kay Moyer, Director of Regulatory Affairs, CRD Associates at kmoyer@dc-crd.com.

Sincerely yours,

Mark Birenbaum, PhD
Executive Director
National Independent Laboratory Association