October 1, 2024

Mr. Micky Tripathi
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
330 C St SW, Washington, D.C. 20201

Re: HHS-ONC-2024-0001; Health Data, Technology, and Interoperability – Patient Engagement, Information Sharing, and Public Health Interoperability

Dear Mr. Tripathi,

The Association for Diagnostic and Laboratory Medicine (ADLM) appreciates the opportunity to comment on the proposed rule, *Health Data, Technology, and Interoperability – Patient Engagement, Information Sharing, and Public Health Interoperability*. We commend ONC's continued efforts to advance interoperability in health information technology (IT), which is critical for improving patient care, reducing costs, and enhancing public health.

The proposed rule introduces several important updates, particularly in the areas of data standards, certification criteria, and information sharing, which are essential for promoting the secure and efficient exchange of health data. ADLM fully supports these efforts and would like to provide further insights based on our expertise in laboratory data and healthcare IT.

Data Standards and Certification Criteria

ADLM welcomes the inclusion of United States Core Data for Interoperability (USCDI) Version 4, which broadens the scope of data that must be exchanged between health IT systems, including key elements such as demographics, medications, and laboratory results. However, to fully realize the benefits of laboratory data exchange, ADLM strongly encourages ONC to include additional data elements in future versions of USCDI. Specifically, we recommend the incorporation of:

- Device and Test Kit Identifier: This will enable healthcare providers and public health officials to trace specific test kits and devices, improving the management of recalls and ensuring diagnostic accuracy.
- Specimen Collection Date/Time: Accurately capturing when a specimen was collected is essential for interpreting time-sensitive tests and tracking clinical progression.
- Test Performed Date/Time: Precisely recording when a test was conducted is crucial for quality management and monitoring for potential device defects. This data is also vital for secondary uses, such as training AI/ML models, where precise timing can influence the development and validation of predictive algorithms.

These additional elements will significantly enhance the quality, traceability, and interpretability of laboratory data across health systems. For example, including a Device and Test Kit Identifier allows laboratories to ensure that testing methods are consistent and can be traced in the event of equipment or reagent recalls. Meanwhile, specimen collection and test performed timestamps are essential for the accurate interpretation of many tests, where the timing of the sample can directly influence clinical decisions. Without these timestamps, healthcare providers might face challenges in understanding the context of a test result, especially in acute care situations.

Broadening the scope of standardized laboratory data reporting will benefit healthcare outcomes and help to ensure that test results can be consistently interpreted across different healthcare providers. This information promises to enhance patient safety by reducing the risk of errors in diagnosis or treatment resulting from misinterpretation of data. Standardized data reporting also improves clinical research by providing essential context for large-scale analysis of laboratory results, leading to more robust public health responses and advances in medical knowledge.

ADLM also supports the certification of FHIR-based APIs to facilitate real-time data sharing between systems. APIs are a key technology for connecting health IT systems, allowing different organizations—such as laboratories, hospitals, and clinics—to access and share data seamlessly. However, smaller laboratories often lack the technical and financial resources to implement these new standards quickly. Providing technical assistance and financial incentives to smaller laboratories will ensure that all healthcare entities can comply with these certification criteria and benefit from improved interoperability, without being disproportionately burdened by the costs of implementing new systems.

Information Sharing

The proposed rule's focus on reducing information blocking is critical to improving patient care and public health outcomes. Information blocking occurs when healthcare providers or IT vendors unnecessarily restrict access to electronic health information (EHI), preventing other stakeholders from obtaining timely data. Reducing these barriers helps ensure that patients and healthcare providers have access to the complete information needed to make informed decisions.

ADLM agrees with ONC's effort to combat information blocking and emphasizes the need for clear guidelines on the exceptions provided for privacy and security concerns. Laboratories handle sensitive patient information, and it is essential to maintain strict data security while ensuring that critical information is shared when needed. Providing clearer guidance will help laboratories balance privacy protection with the need for timely data exchange, ensuring that patients receive the right care at the right time.

The rule's emphasis on public health data sharing aligns with the broader goal of improving national and global health responses. The COVID-19 pandemic highlighted the importance of

timely, accurate, consistently annotated data sharing between public health agencies and healthcare providers. By promoting better exchange of demographic and health information, the proposed rule strengthens the capacity of public health systems to respond to emerging health threats. However, the success of this initiative depends on the standardization of data formats, ensuring that the information shared is both actionable and interpretable across different systems.

Bulk Data Export and Public Health Reporting

ADLM strongly supports the proposed enhancements to bulk data export capabilities, which are critical for public health research and reporting. Laboratories play a central role in generating diagnostic data that is essential for public health surveillance and monitoring population health trends. By enabling the standardized export of large datasets, the proposed rule will help laboratories contribute to public health efforts more efficiently.

However, it is vital that these bulk data exports are accompanied by strong privacy and security protections, ensuring that sensitive patient information remains secure throughout the process. ADLM recommends that ONC provide clear guidelines on the implementation of these capabilities to help laboratories balance data sharing with the need to protect patient confidentiality. Additionally, we encourage ONC to offer support for smaller laboratories that may struggle to implement these capabilities due to resource constraints.

We appreciate the opportunity to provide input and remain available for further discussions. If you have any questions or would like additional information, please contact Vince Stine, PhD, Senior Director, Government & Global Affairs, at vstine@myadlm.org or Evan Fortman, MPA, Manager, Government Affairs, at efortman@myadlm.org.

Sincerely,

Anthony A. Killeen, MD, MSc, PhD
President, ADLM