Agency: Centers for Medicare & Medicaid Services (CMS), Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator for Health Information Technology (ONC) (collectively, ASTP/ONC), Department of Health and Human Services (HHS)
Title: Request for Information; Health Technology Ecosystem
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The following comments are submitted by the American Clinical Laboratory Association (ACLA). ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers by advocating for policies that expand access to the highest quality clinical laboratory services, improve patient outcomes, and advance the next generation of personalized care.

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ACLA Comment:

Thank you for the opportunity to provide comments on this request for information (RFI).

The American Clinical Laboratory Association (ACLA) urges the Centers for Medicare and Medicaid Services (CMS) to carefully consider the role of the laboratory in the larger health interoperability ecosystem. Laboratories are often heavily dependent upon upstream actors (e.g., an ordering clinician) to provide information to the laboratory in order to be an efficient part of the system. As such, requirements applied to laboratories may be difficult to meet if ordering providers are not obligated to provide the laboratory with the underlying information necessary to meet the request. For example, laboratories may not have sufficient patient demographic information to fulfill other downstream obligations, such as public health reporting or direct patient communication of results. To ensure that CMS obtains the efficiency it seeks when making changes to interoperability requirements, CMS should be careful in applying any specific requirement to laboratories (as compared to other actors with more direct patient interaction) and evaluate the laboratory's ability to comply on a case-by-case basis. In some instances, applying a regulation to the laboratory may necessitate additional requirements imposed on the upstream providers to ensure the laboratory has the necessary information to comply.

We appreciate the CMS and ASTP/ONC consideration of the ACLA response to help inform the agency's efforts to lead infrastructure progress to cultivate this market, increase beneficiary access to effective digital capabilities needed to make informed health decisions, and increase data availability for all stakeholders contributing to health outcomes.

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Federal Register Text (Page 21037)
B.1. Patients and Caregivers

PC-2 c. Were there particular data types, such as x-rays or specific test results, that were unavailable? What are the obstacles to accessing your own or your loved ones' complete health information electronically and using it for managing health conditions or finding the best care (for example, limitations in functionality, user friendliness, or access to basic technology infrastructure)?

ACLA Comment:
Laboratories have unique challenges with interoperability with respect to particular data types. The primary role for laboratories, in most use cases, is to provide results to providers for treatment decisions. We suggest CMS work with the ASTP/ONC to deploy a mechanism to promote modern standards for EHR vendors. Laboratories have been faced with 15 plus years of legacy, and lack of consistently applied standards. This creates an obstacle for laboratory interoperability. Moving from older HL7 point-to-point interfaces between a laboratory and a provider to modern FHIR shared interface models require substantial financial investment that will not provide business return on investment. However, if modernizing interfaces provided an avenue to reduce EHR interoperability fees from EHR and middleware vendors then interface improvements would be prioritized.

Federal Register Text (Page 21037):
B.1. Patients and Caregivers

PC–5. What can CMS and its partners do to encourage patient and caregiver interest in these digital health products? a. What role, if any, should CMS have in reviewing or approving digital health products on the basis of their efficacy, quality or impact or both on health outcomes (not approving in the sense of a coverage determination)? What criteria should be used if there is a review process? What technology solutions, policy changes, or program design changes can increase patient and caregiver adoption of digital health products (for example, enhancements to data access, reimbursement adjustments, or new beneficiary communications)? b. What changes would enable timely access to high quality CMS and provider generated data on patients?

ACLA Comment:
Opportunities exist for broader implementation of digital health applications that could reduce health care costs and improve health outcomes, but that lack clear pathways for coverage by Medicare, Medicaid, and other third party payers. One example of a digital health application offered through an ACLA member laboratory is Ovia Health[1], an evidence-based, digital health platform that can improve and expand access to high-quality women's health. Ovia Health's digital health platform is currently offered primarily through employers to their employees due to the lack of a clear pathway for coverage by third party payers. Development of such a coverage pathway could extend the benefits of the app to millions of women to reduce health care costs and improve outcomes.

[1] https://www.oviahealth.com/

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Federal Register Text (Page 21037):
B.2. Data Access and Integrations

PC–8. In your experience, what health data is readily available and valuable to patients or their caregivers or both? a. What data is valuable, but hard for patients and caregivers, or app developers and other technical vendors, to access for appropriate and valuable use (for example, claims data, clinical data, encounter notes, operative reports, appointment schedules, prices)? b. What are specific sources, other than claims and clinical data, that would be of highest value, and why? c. What specific opportunities and challenges exist to improve accessibility, interoperability and integration of clinical data from different sources to enable more meaningful clinical research and generation of actionable evidence?

ACLA Comment:
Specific lab result data is generally widely available for both patients and providers, especially when an electronic laboratory order is received and where results for that order are also transmitted back to the ordering provider . Historic or longitudinal laboratory results are often harder to gather since decentralized data lives in various EHR and laboratory records or systems. This limited availability often creates problems for providers who did not order a lab test or patients who want to see historic results. We suggest CMS continue to collaborate with ASTP/ONC to deploy Interoperability requirements that do not increase burden or cost.

While order and results data are available there are other datapoints that are used by laboratories for operations, billing, or public health report. Some examples include:

- Prior authorizations often require family or personal medical history that is not widely available.
- Health plans have begun asking for medical documentation to demonstrate "intent to order" ; however, the information needed goes far beyond what is available through existing HL7 interfaces.
- Diagnosis information from a specific provider encounter to support medical necessity documentation requests.

Modern technologies such as FHIR or modern interface approach such as TEFCA may make data more available, but laboratory regulations limit the ability to access the data. For example, HIPAA "minimum necessary" rules or billing policies which limit the use of additional diagnosis information create restrictions that harm patient care while adding costs for operations. ACLA encourages CMS to better define the data laboratories can access as part of HIPAA treatment use cases through a policy FAQ or similar mechanism.

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Federal Register Text (Page 21037):
B.2. Data Access and Integration

PC–12. What are the most valuable operational health data use cases for patients and caregivers that, if addressed, would create more efficient care navigation or eliminate barriers to competition among providers or both? a. Examples may include the following: (1) Binding cost estimates for pre- defined periods. (2) Viewing provider schedule availability. (3) Using third-party apps for appointment management. (4) Accessing patient-facing quality metrics. (5) Finding the right provider for specific healthcare needs. b. What use cases are possible today? c. What should be possible in the near future? d. What would be very valuable but may be very hard to achieve?

ACLA Comment:
We suggest CMS continue to collaborate with ASTP/ONC to deploy Interoperability requirements that would be helpful, from a laboratory perspective it would be beneficial to have information shared. For example, there are certain tests covered by Medicare only if a patient has had certain tests in the past. Another example is Medicare coverage for certain tests have frequency limits. These examples are valuable operational health data use cases for patients that, if addressed, would create more efficient care navigation.

Federal Register Text (Page 21037):
B.3. Information Blocking and Digital Identity

PC–14. Regarding digital identity credentials (for example, CLEAR, Login.gov, ID.me, other NIST 800–63–3 IAL2/AAL2 credentialing service providers (CSP)): a. What are the challenges today in getting patients/caregivers to sign up and use digital identity credentials? b. What could be the benefits to patients/caregivers if digital identity credentials were more widely used? c. What are the potential downsides? d. How would encouraging the use of CSPs improve access to health information? e. What role should CMS/payers, providers, and app developers have in driving adoption? f. How can CMS encourage patients to get digital identity credentials?

ACLA Comment:
While ACLA does not have comments on specific digital identity vendors or approaches, we encourage CMS to help solve issues with digital patient identify matching. Accurately matching patients is a fundamental activity to improving data interoperability.

Addressing the obstacles created by inaccurate or difficult patient matching is crucial for improving public health outcomes. Challenges in tracking patient consent, responding to records requests, and making data more readily available hinder effective healthcare delivery. Consent tracking is particularly difficult and HIPAA breach concerns making technology approaches conservative. The result limits data availability for providers and patients.

Patient identity matching issues can also lead to challenges in historic laboratory result tracking, care coordination across different healthcare providers, inaccurate billing and reimbursement processes, and timely access to critical medical information in emergency situations. Resolving these issues is essential for enhancing patient safety, improving healthcare quality, and optimizing health outcomes.

ACLA encourages CMS to find solutions for digital identity tracking and matching that are scalable and available for all patients.

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Federal Register Text (Page 21038):
C. Providers 1. Digital Health Apps

PR-2. What are obstacles that prevent development, deployment, or effective utilization of the most useful and innovative applications for physician workflows, such as quality measurement reporting, clinical documentation, and billing tasks? How could these obstacles be mitigated?

ACLA Comment:
The lack of data availability is an obstacle that prevents effective utilization of the most useful and innovative applications for physician workflows, such as clinical documentation and billing tasks. There are a few obstacles that exist with improving patient and provider workflows with technology. First, legacy rules that were crafted prior to digitized medical records but still perpetuate today. For example, laboratories have experienced mass claim denials due the inability for laboratories to readily to respond to a payer's request to produce medical documentation to demonstrate intent to order and medical necessity for the ordered laboratory test. The submission of an electronic order from a provider to a lab through the provider's electronic interface does not happen by mistake and only happens when a provider intends to order a lab. Improvements to the regulations surrounding documentation requirements for laboratory billing should be modernized to reflect the industry practice and practical approach to healthcare operations. ACLA encourages CMS to improve the electronic signature and intent to order policies surrounding electronic laboratory orders.

Further, prior authorization for laboratory services is often denied by payers because of lack of medical necessity documented in the patients EHRs. Laboratories have limited access to this data, but innovative approaches to technology are making this information more accessible. However, HIPAA minimal data use and treatment use case policies limit technology adoption. We suggest CMS continue to collaborate with ASTP/ONC to deploy Interoperability requirements that would be helpful; from a laboratory perspective it would be beneficial to have more data shared.

Federal Register Text (Page 21038):
C. Providers 1. Digital Health Apps

PR-7. What strategies can CMS implement to support providers in making high-quality, timely, and comprehensive healthcare data available for interoperability in the digital product ecosystem? How can the burden of increasing data availability and sharing be mitigated for providers? Are there ways that workflows or metrics that providers are already motivated to optimize for that could be reused for, or combined with, efforts needed to support interoperability?

ACLA Comment:
Laboratory providers are faced with increased fees from the EHRs and integrators (vendors). There are companies that sit between the laboratory and EHR vendor, and many EHR vendors do not implement HL7 Version 2 standards for laboratory orders and results. The integrators are benefiting and are they inhibiting the adoption of standards. There are unfunded mandates and laboratories have been paying for the interoperability over the past 15 years. We need to move toward a national standard for orders and results for laboratory results.

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As ASTP found in their congressional report on laboratory interoperability, this is a complex issue. A national, consistent standard for orders and results would reduce burden and increase data availability for providers. Standards need to be capable of achieving the desired outcome and operationally feasible, but also economically scalable . Most laboratories currently utilize HL7 Version 2 standards for laboratory orders and results, which has been in production for decades and is mature enough to handle the complexities of laboratory processing. ACLA encourages CMS to find programs that could promote the modernization of laboratory interfaces and improve the business requirements needed to justify the significant expense of replacing the existing HL7 interfaces.

Federal Register Text (Page 21039):
E. Technology Vendors, Data Providers, and Networks This section is intended for all stakeholders to provide input on questions as they relate to use cases and workflows that involve technology vendors, data providers, and networks. While we certainly want technology vendors, data providers, and networks to answer questions in this section (and in other sections) from their point of view, we also invite all stakeholders to provide their viewpoints on the technology vendor, data provider, and network use cases as appropriate.

3. Technical Standards and Certification

TD–7. To what degree has USCDI improved interoperability and exchange and what are its limitations? a. Does it contain the full extent of data elements you need? b. If not, is it because of limitations in the definition of the USCDI format or the way it is utilized? c. If so, would adding more data elements to USCDI add value or create scoping challenges? How could such challenges be addressed? d. Given improvements in language models, would you prefer a non- proprietary but less structured format that might improve data coverage even if it requires more processing by the receiver?

ACLA Comment:
We would like to express our support for certain changes made to the United States Core Data for Interoperability (USCDI) version 6, specifically the establishment of the LOINC lab standard for laboratory orders, while expressing some concerns regarding the use of the Unique Device Identifier (UDI). Improvements to interoperability should focus on enabling high-quality treatment of patients and ensuring that laboratory orders contain the necessary information for timely and high-quality treatment of a patient is critical to our national interoperability infrastructure.

While ACLA supports improvements to interoperability infrastructure that will increase patient safety, it is not clear that inclusion of UDI data will achieve that objective, and it poses several challenges that could result in unintended consequences. There will be some major challenges with ensuring high quality UDI data is broadly available. The first is the limited use of UDI data in most clinical encounters and settings. Providers do not currently factor UDI information into the clinical decision-making process as it is not a critical piece of information for treatment decisions. The required inclusion of non-pertinent information to a test result can slow down the decision process and adds costs to interoperability support and implementations. Furthermore, existing LIS platforms may not broadly support the inclusion of UDI information with a test result. Updating these LIS systems can be expensive and time consuming while having limited impact on patient treatment decisions. It is also important to note that it has been clarified through litigation that FDA lacks authority to regulate laboratory developed tests (LDTs) as devices, and therefore the UDI requirement applicable to devices

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is not applicable to LDTs that are not regulated as such. ACLA is concerned that the inclusion of UDI in USCDI version 6 will not lead to broad adoption with high-quality data.

The UDI data element is not currently supported by most laboratories. If the UDI data element is to remain, we suggest that ASTP/ONC work with FDA, CMS/CLIA, public health agencies, laboratories, and instrument manufacturers to establish a practical roadmap for adoption.

The adoption of the LOINC lab standard for laboratory orders in USCDI version 6 brings numerous benefits to the healthcare industry. The change promotes standardization and harmonization of laboratory order data with the existing Laboratory data classification. While LOINC adoptions have challenges, the selection of LOINC 2.78 as the Laboratory Order standard gives providers the opportunity to align the Laboratory Order data elements with the existing Laboratory Tests data class, which has used LOINC as the standard since USCDI v1.

While we support the changes to the data foundations there are several challenges that may hamper the broad adoption of LOINC as a standard. The speed for new tests to receive a LOINC code continues to be an issue, which can take between 12-18 months to be finalized. This process creates a major issue with making new cutting-edge tests available to patients and providers. Without faster code assignment, there will be slower adoption. Further, legacy interfaces and LIS systems may not currently support the use of LOINC for orders and the costs of improvements are significant. Finally, there are challenges with the use of LOINC for reflex orders.

We commend the U.S. Department of Health and Human Services for recognizing the importance of the LOINC lab standard and incorporating it into USCDI version 6. This change demonstrates a commitment to advancing healthcare interoperability and improving patient care. Given that LOINC has not yet been adopted by all laboratories, we suggest that ASTP work with the FDA, CMS/CLIA, public health agencies, laboratories, and instrument manufacturers to establish a practical roadmap for adoption. Subject to the challenges noted in these comments, we believe that the adoption of the USCDI will have a positive and lasting impact on the healthcare industry, fostering innovation and driving improvements in healthcare delivery.

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Federal Register Text (Page 21040):
E. Technology Vendors, Data Providers, and Networks This section is intended for all stakeholders to provide input on questions as they relate to use cases and workflows that involve technology vendors, data providers, and networks. While we certainly want technology vendors, data providers, and networks to answer questions in this section (and in other sections) from their point of view, we also invite all stakeholders to provide their viewpoints on the technology vendor, data provider, and network use cases as appropriate.

4. Data Exchange

TD–16. What are the tradeoffs of maintaining point-to-point models vs. shared network infrastructure? a. Do current rules encourage scalable network participation? b. What changes would improve alignment (for example, API unification, reciprocal access)?

ACLA Comments:
We suggest CMS continue to collaborate with ASTP/ONC to deploy Interoperability requirements that would modernize and move away from legacy point-to-point interfaces and move to modern shared network infrastructure.

Laboratory legacy point-to-point interface solutions are very effective at ensuring timely and accurate laboratory results are electronically delivered to test ordering providers. These HL7 interfaces are numerous and require ongoing investment of resources to implement and maintain.

Shared network interface solutions offer some advantages such as improved efficiency, enhanced patient care, or speed of implementation. However, barrier to adoption of FHIR, TEFCA, and other modern interface approaches exist. These include:

- Added expense from EHR vendors. EHR and middleware vendors often charge per message so costs scale with usage instead of decrease through adoption of new technology standards. Even with advancements in technology and data standards labs are seeing rapidly escalating interoperability fees from vendors.
- Consent management: Proper consent management mechanisms must be in place to ensure that patients have control over who can access their lab results when shared using FHIR.
- CAP testing requirements. The CAP GEN.48500 requirement requires laboratories to certify lab result interface endpoints to ensure data is being presented accurately to providers. This testing requirement is not scalable for shared network interoperability models.

CMS must address these issues, especially the growing interoperability fees, to promote the modernization of health IT infrastructure.

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Federal Register Text (Page 21040): **E. Technology Vendors, Data Providers, and Networks This section is intended for all stakeholders to provide input on questions as they relate to use cases and workflows that involve technology vendors, data providers, and networks. While we certainly want technology vendors, data providers, and networks to answer questions in this section (and in other sections) from their point of view, we also invite all stakeholders to provide their viewpoints on the technology vendor, data provider, and network use cases as appropriate.** **4. Data Exchange** **TD–17. Given operational costs, what role should CMS or ASTP/ONC or both have in ensuring viability of healthcare data sharing networks, including enough supply and demand, that results in usage and outcomes?**
ACLA Comments: Laboratory transactions are a high percentage of all health care transactions. It would be valuable to have improved access to data, which would impact on patient outcomes.