AMERICAN CLINICAL LABORATORY ASSOCIATION

December 2, 2022

The Honorable Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Request for Information; National Directory of Healthcare Providers & Services [CMS-0058-NC]

Dear Administrator Brooks-LaSure,

Please accept the comments of the American Clinical Laboratory Association (ACLA) on the Centers for Medicare & Medicaid Services' (CMS) Request for Information (RFI) on establishing a National Directory of Healthcare Providers & Services (NDH).[1] ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers. ACLA members are at the forefront of driving diagnostic innovation to meet the country's evolving health care needs and provide vital clinical laboratory tests that help clinicians identify, monitor, and prevent infectious, acute, and chronic disease. ACLA works to advance the next generation of health care delivery through policies that expand access to lifesaving testing services.

We appreciate the opportunity to provide our feedback and comments on the RFI and on how an NDH might address the current fragmentation of healthcare provider directories. We offer comments and recommendations in the following areas: (1) CMS's implementation of an NDH, and (2) the burdens of establishing an NDH.

I. Implementation of an NDH

a. What work related to developing FHIR standards for an NDH, such as building and refining [Implementation Guides], still needs to be completed?

CMS states that to align with national standards for interoperability, an NDH could be built on the standards established by the Office of the National Coordinator for Health Information Technology (ONC). Specifically, CMS says an NDH could use HL7 Fast Healthcare Interoperability Resources (FHIR) APIs to enable data exchange. We agree with the use of HL7 FHIR and urge CMS to collaborate with ONC regarding which would be the right version to use. Such collaboration is essential for developing FHIR standards for an NDH.

CMS suggests that the HL7 FHIR Validated Healthcare Directory (VHDir) Implementation Guide is ready to be implemented. We respectfully disagree. To date, there has not been significant implementation experience, the Implementation Guide has never been published, and the

[1] 87 Fed. Reg. 61018 (Oct. 7, 2022).

September 2018 ballot is currently classified as an "idle ballot".[2] HL7 classifies "idle ballot" items as those items that have not returned to ballot after three or more cycles and have not been published. This Implementation Guide was developed in 2018 and the balloted versions reference FHIR 3.2.0 and 3.5.0, so it may need to be updated to FHIR 4.0.1. We suggest CMS validate the Implementation Guide's status with HL7 before proposing that it be used in service of an NDH.

b. Would an NDH as described provide the benefits outlined in the RFI?

CMS suggests that with collaborative input from industry and federal partners, it can develop an NDH that serves all stakeholders, builds and maintains trust in the data, advances public health goals, improves data exchange, streamlines administrative processes, and promotes interoperability. These are lofty goals, and it is not clear yet how all of this could be accomplished through establishment of an NDH.

ACLA would support implementation of an NDH in reasonably timed phases if the NDH is appropriately designed to achieve its objectives in an operationally feasible manner. CMS should articulate what it expects the NDH to accomplish in each phase of its development, prior to implementation of each phase. It is important for all stakeholders to know CMS's plans to measure its own activity and progress toward pre-defined goals for implementation of the NDH in each of the phases, in the same way that providers are evaluated regularly against pre-established metrics. Stakeholders should have a clear understanding of the benefits of an NDH in each phase, and what aspects of implementation of previous phases fell short and why.

II. Burdens of Establishing the NDH

a. Would an NDH as described reduce the directory data submission burden on providers?

The NDH could be beneficial but only if all entities, including payers, use and contribute to the NDH, and if all entities get provider information from it. An NDH should be designed so that providers enter information and data only once (except as further entries may be necessary for reasonably timed periodic updates), and so that "downstream" directories pull the information and data from the NDH, rather than requiring duplicate data entry. Additionally, providers should not be expected to submit information and data that is not in their possession, or that has been collected or created by another entity that is the "source of truth" for the data.

ACLA recognizes that an NDH could be beneficial for providers in processes such as enrollment and credentialing, and there is a potential for an NDH to decrease the associated burdens if it is adopted universally. Data in an NDH could make credentialing and enrollment processes for Medicaid programs and for other payors easier by providing much of the essential information to payors. However, if not all entities use the NDH, and some payors continue to require enrolling providers to adhere to their own verification processes, the creation of an NCH

[2] *See* HL7 FHIR® Implementation Guide: Validated Healthcare Directory, *available at* http://www.hl7.org/Special/committees/tsc/BallotManagement/Reports/IdleBallotItems_by_wgid.cfm?wg_id=25.

could represent a new and duplicative database that could increase provider burden.

b. What issues should CMS anticipate throughout an NDH system development life cycle?

CMS suggests that, in its initial stages, an NDH could serve as a "centralized data hub" for directory and digital contact information, which would contain the most accurate, up-to-date, and validated data in a publicly accessible index. However, the NDH would need to be utilized broadly for it to be effective and serve its intended purpose. CMS should anticipate that it may be challenging to obtain buy-in for a system that requires providers to report information that is duplicative of other reporting, without confirmation that the providers contributing the information will benefit from such a system. ACLA members would not be supportive of additional or duplicative reporting requirements without the benefit of all information being accessible in one place—and used broadly by many types of entities.

c. What benefits and challenges might arise while integrating data from CMS systems (such as NPPES, PECOS, and Medicare Care Compare) into an NDH?

CMS notes that it is "not specifically requesting comment on replacing [NPPES, PECOS, and Medicare Care Compare] with the NDH."[3] CMS should develop a concrete plan for how it might integrate data from these systems into an NDH, and it should clarify for stakeholders whether it intends for providers to have to contribute information and data both to an NDH and to these systems. Only after the agency articulates its plans for reducing burdens and increasing completeness and accuracy of the directories through integrating the systems can stakeholders provide meaningful input on the benefits and challenges of such integration.

Thank you for your consideration of ACLA's comments and recommendations on these important policy issues.

Sincerely,

Adam Borden
Senior Vice President, Policy & Strategy
American Clinical Laboratory Association

[3] 87 Fed. Reg. at 61025.