HL7® International

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Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-0058-NC
P.O. Box 8013
Baltimore, MD 21244-8016

Submitted electronically to:
http://www.regulations.gov

Re: CMS Request for Information; National Directory of Healthcare Providers & Services

Dear Administrator Brooks-LaSure:

Health Level Seven (HL7) International welcomes the opportunity to submit comments on CMS' National Directory of Healthcare (NDH) Providers and Services Request for Information (RFI). HL7 is the global authority on healthcare interoperability and a critical leader and driver in the standards arena. Our organization has more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare consumers, providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

HL7 standards, implementation guides and related tools provide both a fundamental and innovative backbone to achieving our national goals of an interoperable health system that serves patients well. They similarly support the establishment of an NDH that could serve as a "centralized data hub for healthcare provider, facility, and entity directory information nationwide." CMS notes in the RFI that an NDH could use HL7® *FAST* Healthcare Interoperability Resources (FHIR®) APIs and the Validated Healthcare Directory (VHDir) FHIR Implementation Guide (IG), which describes the technical design considerations for collecting, validating, verifying, and exchanging data from a central source of provider data using FHIR standards, for example. HL7 and its FHIR Accelerators including in particular the Da Vinci Project and FHIR at Scale Taskforce (*FAST*)- stand ready to support CMS with NDH establishment through HL7 standards and services. Our collaboration

with both CMS and the Office of the National Coordinator for Health IT (ONC) is and will continue to be essential in establishing and maintaining a truly effective, meaningful health care interoperability ecosystem in America.

HL7's detailed feedback on the NDH RFI is below. We offer overarching comments, recommendations and implementation perspectives. In addition to our leadership and Policy Advisory Committee, HL7's Public Health Work Group contributed to these comments, as well as HL7's Accelerator's *FAST* and the Da Vinci Project, and Argonaut Project. *FAST* is a critical cross-stakeholder initiative that identifies (FHIR) scalability gaps, defines solutions to address current barriers, and identifies needed infrastructure for scalable FHIR solutions. *FAST* gathered their members to provide in-depth feedback on the NDH RFI and their insights are central to this HL7 submitted response. More information on *FAST* can be found at:
https://confluence.hl7.org/display/FAST/FHIR+at+Scale+Taskforce+(FAST)+Home

HL7 and *FAST,* in particular, look forward to the opportunity to work closely with CMS to further discuss the details of the initial use cases that can be supported by a FHIR-based NDH solution. We are quite interested in supporting CMS on critical questions around architecture; data validation, verification, and attestation requirements; and data retention and security, including role-based access considerations. We also would be happy to support bringing together industry leaders who could share their lessons learned related to directory development and maintenance, and the critical work needed to ensure data accuracy and data quality and management. Our ultimate goal is to practically aid CMS in phasing in a truly valuable, actionable, and trusted NDH and informing the process through historical experience.

Should you have any questions about our attached comments, please contact Charles Jaffe, MD, PhD, Chief Executive Officer of Health Level Seven International at cjaffe@HL7.org or 734-677-7777. We look forward to continuing this discussion and offer our assistance to ONC.

Sincerely,

Charles Jaffe, MD, PhD
Chief Executive Officer
Health Level Seven International

Andrew Truscott
Board of Directors, Chair
Health Level Seven International

HL7 Responses to CMS NDH RFI

HL7's overarching comments on the CMS NDH RFI are below.

HL7 appreciates the recognition and consideration of the work we have done to date, including the HL7 FHIR *FAST* National Healthcare Directory implementation guide (IG). As noted in the RFI, we understand and support the need to create one authoritative national source of truth to address current healthcare directory limitations, particularly in relation to digital endpoints. Building on the work of the Office of the National Coordinator for Health Information Technology (ONC) and the Federal Health Architecture (FHA), and specifically the Validated Healthcare Directory (VHDir) FHIR IG, significant time and attention have been dedicated to this issue, and we agree with CMS that it is critically important to develop a central hub of standards-based healthcare directory information that can then feed downstream systems and directories using FHIR-based APIs. This must be a truly national directory, including both public and private commercial directory information. Having a national single source of truth will help address three major pain points in healthcare today: 1) the burden on providers and payers associated with having to update countless directories and/or verify that information in many places often, 2) the impact on the ability to receive and deliver quality care when directories include inaccurate or incomplete information, and 3) the ability to effectively and efficiently transmit secure, standards-based electronic healthcare information across the care continuum without known digital endpoints. Additionally, we would urge that any National Directory effort would necessitate significant functional testing of National Directory services needed to keep the data highly available and updated. CMS would benefit from adding a requirement, which seeks to ensure the National Directory is continuously interoperable by being version aware, as numerous versions can affect interoperability across an integrated ecosystem.

Recommendation: A Phased Approach

Although the list of use cases that could be well served by a comprehensive National Directory of Healthcare Providers & Services (NDH) is long, HL7 believes it is important to start with a targeted focus that will make enough information available to be valuable, but be implementable in the short-term. One way to ensure the success of the NDH, and to incentivize stakeholders to buy in, is to move forward with a minimum viable product (MVP) by early 2024. This will help illustrate the importance and value of the directory, and it will help to begin to address a critical need in the industry. It will also ensure the NDH can best support other Federal interoperability initiatives from TEFCA, and the work of industry to leverage FHIR such as the work of the CARIN Alliance, the Da Vinci Project, the Gravity Project, and more. As a result, we suggest starting with the following use cases:

    1) enable electronic exchange through endpoint discovery,
    2) find providers and payers,
    3) identify provider organizational affiliations, and
    4) identify an initial set of provider and payer relationships for CMS-regulated payers.

The NDH MVP must include digital endpoints. The lack of an authoritative central directory of digital endpoints creates a significant gap in our ability as a healthcare industry to move many critical interoperability initiatives forward. But, endpoint information alone is not enough. This information must be anchored, and it must be in service of the current requirements for electronic data transfer. Considering requirements like the Interoperability and Patient Access final rule (CMS-9115-F) and the ONC 21st Century Cures Act final rule (85 FR 25642), and understanding upcoming requirements around things such as patient cost transparency and payer-to-payer data exchange, we feel it is necessary to initiate the NDH MVP by focusing on providers, payers, and their organizational affiliations. Generally, individual providers will not have an endpoint – the endpoint will be an organizational endpoint. As a result, it is necessary to understand provider affiliations. And, to support critical interoperability requirements, it is necessary to support the opportunity for providers and payers to exchange information with one another, and to support payer-to-payer data exchange. As such, including both providers and payers in the NDH MVP is necessary.

To provide enough information for endpoint discovery, and to support finding providers and payers in the NDH MVP, additional initial data subject areas will need to be included beyond endpoints and organizational affiliation. As a floor, HL7 and *FAST* recommend that CMS also include no less than provider demographic information and provider and payer identity information (such as NPI or TIN) to start.

HL7 also recommends CMS consult the HL7 *FAST* National Healthcare Directory IG. A diverse set of stakeholders were engaged in the development of this IG, and evaluating the data elements indicated for must support, and the cardinality of data elements as defined in the IG, will provide CMS with a valuable starting point to implement inclusion of the initially recommended data and continue to iterate and build from there. The IG also provides a solid set of requirements that can be validated as conformant with the IG. This requirements-based foundation is essential for the NDH to be successful and actionable. HL7 and *FAST* are happy to work directly with CMS to further evaluate and discuss how to leverage this IG for an NDH MVP and plan how to iterate and expand beyond the MVP over time. However, given the public consensus process that drove this IG, we feel this is a solid foundation with which to start.

There is significant value in also including provider and payer relationships in the NDH. However, for the MVP, trying to include this information for commercial payers could add too much complexity and negatively impact initial implementation. As a result, we recommend starting by requiring only those payers CMS regulates provide information regarding their provider networks. In the Interoperability and Patient Access final rule, CMS has already required Medicare Advantage, Medicaid, and Children's Health Insurance Program (CHIP) to make provider directory information available via FHIR APIs. In addition, Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges (FFEs) are subject to provider directory requirements. Having this initial set of payers also expose this information via the NDH would not add additional burden. And, it would provide a real-world example of the value of having such information in a national directory. Over time, in future iterations of the NDH, CMS could consider also including such relationships for commercial payers.

Ultimately, for an NDH to support everything from patient cost transparency to Medicare Advantage network adequacy requirements, it will be necessary that the directory indicate which providers are contracting with or available to contract with which payers. We appreciate this is not an insignificant amount of information and that there are real complexities involved, particularly for commercial payers. But, over time, incorporating these relationships could reduce provider and payer burden by having these data available to downstream systems and only needing to update these data in one external, central source. Starting with CMS-regulated payers as a first step, and over time, as appropriate, phasing in possible commercial payer relationships is one way to start exposing this valuable information.

With time, additional stakeholders covering additional use cases can be added to the NDH – including critical use cases relevant to public health and health equity. Additional stakeholder outreach is needed to identify the best path forward for including these stakeholders and their priority use cases, and this initial discovery could be conducted in parallel with the initial development of the NDH MVP.

Recommendation: A FHIR-Based Solution
We do believe the NDH should be a FHIR-based solution in that the solution should be FHIR-enabled, but providers and payers should have the optionality to leverage an application to update and pull data from the NDH. It should not be required that providers and payers themselves have a FHIR server or be equipped to use a FHIR-based API to send or receive data from the NDH. If pure FHIR connectivity was required, it could unnecessarily exclude stakeholders from updating and/or retrieving information from the NDH. Thinking about a solution like the Patient Access API, CMS could allow and/or provide an application – a user interface – for those stakeholders unable to leverage a FHIR-based transaction. This would be particularly beneficial for providers and payers that do not yet have FHIR capabilities or do not yet have the resources to develop them. This would also facilitate timelier implementation

across stakeholders. The structure, built on a standards-based foundation, will support iterating and scaling up to incorporate more data for more stakeholders in service of more use cases as needed and appropriate over time.

In addition, with our focus of taking FHIR to scale, HL7 and *FAST* can work with HL7 community of IG developers to ensure that related IGs are developed, they are leveraging the data available in the NDH for their use cases. This could further support ensuring the NDH is the FHIR-based central source of truth for needed shared data, and it would reduce burden on end-users of IGs across uses cases.

Regarding consumer access to data available via the NDH, we believe it is important to note that we view the NDH as a backend service, but do see value in the appropriate data available via the NDH being publicly accessible to support consumer-focused use cases. We do not, however, view the NDH as something that a consumer would directly access. Instead, providers, payers, and third parties such as app vendors would have direct access to the NDH and could surface a patient app that would then make data from the NDH available, as appropriate, to a consumer. The HL7 *FAST* National Healthcare Directory IG does include the ability to suppress certain data for certain use cases. For instance, CMS may not want to make certain billing information or a provider's home address accessible to a consumer-facing app. Ensuring the most appropriate data are available downstream for each relevant use case is something a FHIR-based solution can support. We would be happy to further discuss with CMS.

Recommendation: Integrate/Leverage Existing CMS Systems and Incentivize Stakeholders
We believe it is vital to leverage the existing CMS data systems available. Not only does this provide CMS a solid base of data to build from, but it will ensure an NDH, from the start, serves its purpose as the "central hub" that can seed all other systems. The two primary CMS systems HL7 and *FAST* suggest to CMS consider for initial integration are the National Plan and Provider Enumeration System (NPPES) and the Medicare Provider Enrollment, Chain, and Ownership System (PECOS). The limitations of both systems are well documented, but so is their value. As much as we feel it is important to build off these existing systems, we feel it is equally important that we not perpetuate inaccurate or outdated data. We also understand that it will be necessary at the start to provide incentives for stakeholders to support ensuring the data that are integrated from these systems are the best possible data.

CMS has an opportunity to incentivize stakeholders to support this initial integration process. If CMS makes known that by a specific date, provider and payer information updated and attested to as up-to-date in NPPES and PECOS will be seeded in the NDH, a base set of information could be established for an MVP launch. CMS could then leverage existing program requirements to further incentivize stakeholders. For instance, if a provider has updated their information for inclusion in the NDH, they could be granted the ability to deny requests to update their data in any other system under CMS authority and could instead direct inquirers to the NDH. Or, payers subject to Section 116 of the No Surprises Act of the 2021 Consolidated Appropriations Act, which obligates impacted payers to validate provider directory information every 90 days and make certain changes within two business days, could be granted the ability to forgo this 90-day validation process for data elements pulled from the NDH. Providers would not be burdened by payers to validate their information every 90 days, and payers would have significantly less burden around data validation. This would be a significant incentive for both providers and payers, and it would lower the cost of doing business for both. It would also ensure more accurate and up-to-date information is available for patients.

CMS could then take this a step further in future iterations of the NDH and set a date beyond which data available in the NDH must be pulled from the NDH and inquirers would no longer be permitted to go directly to a provider to ask for this information. Of course, if there is information needed that is not available via the NDH, providers would need to supply that information independently. But, moving toward the required use of the NDH for available data would significantly reduce provider burden and ensure widespread use of the NDH. One consideration here is the potential for friction with some current state requirements. CMS may need to provide guidance or regulation to ensure alignment with NDH requirements and state requirements. Such alignment would also greatly reduce burden

on states, who at this time expend significant effort updating, validating, and maintaining provider information. Over time, instead of independently conducting this work, states could just leverage the NDH. CMS also has an opportunity to enhance the data currently available in CMS systems. Because it is critical that the NDH be a truly national directory, it must include commercial payer information. Just as CMS should leverage the data available in NPESS and PECOS, CMS should work closely with industry to pull data from available commercial directories to seed the NDH MVP as well.

Recommendation: Moving to an Automated Future

Currently, updating directory information is a heavy, manual effort. Having one truly national, central source of truth in an NDH would address some of this burden. However, finding ways to automate some of this process in future iterations of the NDH would not only even further reduce burden, it would increase accuracy and reduce the need for incentives and disincentives for manual effort. We encourage CMS to expand support for interoperability standards that could facilitate the development of a modern digital framework that leverages Electronic Health Record (EHR) systems, practice management systems, and ultimately payer-based systems to create an automated feedback loop between the systems providers and payers use every day to do their work and the NDH. For instance, with EHR vendor cooperation, engagement, and support, when a provider logs into their EHR system, the EHR could capture that this doctor is who they say they are via security controls, including multi-factor authentication and the like, and they have the right to practice at this location, for this provider network, as part of the relevant contractual relationship. This information could flow from the EHR to the NDH providing up-to-date data without any additional effort from the provider. HL7 and *FAST* are happy to discuss this and other future state options for iterating on and improving the NDH over time. HL7's Security Work Group could also be a valuable resource for CMS to consult on this scenario, as well as the broader privacy and security questions in NDH implementation.

Recommendations and Perspectives: Public Health and Related Issues

Below are HL7 perspectives to individual RFI questions derived from HL7 Public Health Work Group feedback. Both the RFI question and HL7 input is provided here for reference.

RFI Question: Are there other CMS, HHS (for example, HPMS, Title X family planning clinic locator, ACL's Eldercare Resource Locator, SAMHSA's Behavioral Health Resource Locator, HRSA's National Practitioner Data Bank, or HRSA's Get Health Care), or federal systems with which an NDH could or should interface to exchange directory data?
HL7 Input: The more diverse set of organizations listed in this question are important and could be notable sources of validation for provider attested information, or as a starting point in the validation process, where CMS would then validate that a provider in the directory offered those services.

RFI Question: What types of data should be publicly accessible from an NDH (either from a consumer-facing CMS website or via an API) and what types of data would be helpful for CMS to collect for only internal use (such as for program integrity purposes or for provider privacy)?
HL7 Input: From a consumer perspective, if they are seeking a service, that likely would be done in a local environment, through a known community resources (e.g., United Way or a social service agency). Those agencies would localize the experience for a client either searching on the web or in-person. A consumer-facing CMS website would likely not be used by a "consumer/client" but may be by an agency (e.g., United Way/social service) to subscribe and then expose the information to their clients, potentially with their own branding. Clarification needs to be made between what data are appropriate for a national level directory and data that are purely local.

RFI Question: Are there particular data elements that CMS currently collects or should collect as part of an NDH that we should not make publicly available, regardless of usefulness to consumers, due to its proprietary nature? To

the extent that an NDH might collect proprietary data from various entities, what privacy protections should be in place for these data?

HL7 Input: CMS should be mindful of scenarios where data would need to be restricted to specific users - such as women's health clinics / shelters, mortuaries, etc. Refer to the National Directory Restriction profile as reference at: https://build.fhir.org/ig/HL7/fhir-directory-exchange/StructureDefinition-NatlDirEx-Restriction.html

RFI Question: We want an NDH to support health equity goals throughout the healthcare system. What listed entities, data elements, or NDH functionalities would help underserved populations receive healthcare services? What considerations would be relevant to address equity issues during the planning, development, or implementation of an NDH?

HL7 Input: Regarding equity, the NDH should include many of the community resources accessed by underserved and economically challenged populations. These would be all the entities that are anticipated to respond to a request from a clinician/provider who has identified a patient/client with a specific Social Determinant of Health (SDOH) need. See more on HL7 Gravity Project collaborative work with FHIR-enabled communications at: https://hl7.org/fhir/us/sdoh-clinicalcare/

Information from the United States Department of Agriculture (USDA) and state-level Supplemental Nutrition Assistance Program (SNAP) information could also be considered.

Additionally, in HL7 FHIR, the element accessibility, has a "type" value set that includes: Cultural competence and Provides services that meet the social, cultural, and linguistic needs of persons [Practitioner]. Currently provider attestation that they serve a particular population is self-attested. "Certificates" or other sources of truth to demonstrate competency in a particular area could be examined. This will be a notable effort, while also considering how to get the terminology correct and who gets to claim what. These efforts can be undertaken in conjunction and coordination with HL7's Gender Harmony and Gravity Projects.

RFI Question: How could NDH use within the healthcare industry be incentivized? How could CMS incentivize other organizations, such as payers, health systems, and public health entities to engage with an NDH?

HL7 Input: In relation to public health, Merit-based Incentive Payment System (MIPS) Promoting Interoperability incentives could be considered.

RFI Question: What provider or entity data elements would be helpful to include in an NDH for use cases relating to care coordination and essential business transactions (for example, prior authorization requests, referrals, public health reporting)?

HL7 Input: For community resources, it is important to know:

- Hours open
- Contact info (address(es), phone, email)
- Responsible party for updating the entry
- Special requirements – paperwork, eligibility
- How referrals are processed
- How programs want to receive a referral: by fax, email, SFTP, CDA, FHIR
- Participate in bidirectional information exchange
- Program's unique identifier
- Location (each needs to have its own unique identifier), for programs at multiple sites

The curation of a social determinant of health community resource list is a very localized process; it requires nurturing and support as many organizations will have no IT resources, operate on volunteerism and have limited resources to do anything but core services. Community resources expire or run out (e.g., food banks); there needs to be a way to let people know real-time the change in status.

RFI Question: The COVID–19 pandemic has highlighted a need for public health systems to be better connected to providers and with each other. Would there be benefits to including public health entities in an NDH? What public health use cases would it be helpful for an NDH to support (for example, facilitating digital contact endpoint discovery for public health reporting, or to provide additional data for public health entities' analytics)? What data elements would be useful to collect from these entities to advance public health goals?

HL7 Input: Regarding data elements, access to good, complete and validated data for follow-up by Public Health to a provider for supplemental information from a case or lab report would be optimal.

The following public health use cases could be helpful for an NDH to support:

- Use case: Referral from a clinician to a public health entity for specialty services (e.g., STI, TB, IZ) or primary care (e.g., HIV, maternal/child health, Federal Qualified Health Centers) – with bidirectional communication desired between providers;
- Use case: Referral from public health to community resources (e.g., food bank, legal aid) – with bidirectional communication;
- Use case: Surveillance of referrals based on key community needs (e.g., # or % screened and referred with food insecurity/housing instability), which would require capture of some demographics and other risk factors for analysis; and
- Use case: Surveillance of successful engagement with clients (e.g., what percent of those referred for "xx" insecurity made it to resources, received services, and/or had their referral closed.)

RFI Question: What types of entities should be encouraged to use data from an NDH? For what purposes and why?

HL7 Input: USDA's SNAP

RFI Question: What policy or operational factors should be considered for new data collection interfaces as part of a single point of entry?

HL7 Input: From a public health perspective, the concept of the NDH is not focused on filling some identified operational gap (e.g., we need a directory for broad network data messaging). Most of the essential workflow around referrals happens in a relatively contained ecosystem – a local healthcare marketplace. The hyper-locality of meaningful and accurate data means intense community engagement, verification and coaching work often need to go into curation. Accuracy (e.g., a truly unique program/location identifier utilized for bidirectional communication with referrals) creates value in that local environment daily. Being a local process, despite CMS intentions, policy may not influence many partners from other sectors (i.e., external to HHS), yet they are essential for the health outcomes CMS wants for an individual or community. HL7 encourages interagency and public-private sector dialogue and collaboration to shed needed light on these issues.

Having a standard for implementation would be helpful for certified NDH interfaces with an EHR. If a healthcare entity exists in multiple states, that certified NDH interface would be advantageous as many of the real-time operational connections would be through FHIR-enabled updates in each of the entity's sites (e.g., states); the common EHR can then more easily attach to a standardized local resource list.

RFI Question: The Healthcare Directory initiative and FAST both identified validation and verification as important functions of a centralized directory. What data types or data sources are important to verify (for example, provider endpoint information, provider credentialing) versus relying on self-reported information?

HL7 Input: Regarding community resource inventories, many of the entities will not be credentialed and will be self-reporting. If community services are included, these will need a strong curation process and validation that is not likely to be achieved with simple machine learning or algorithms.

RFI Question: What entities or stakeholders should participate in the development of an NDH, and what involvement should they have?

HL7 Input: CMS should consider the United Way, an organization with much experience in developing resource lists, but perhaps limited technical solution/implementation experience.