April 29, 2022

Micky Tripathi, PhD, MPP
National Coordinator for Health Information Technology
U.S. Department of Health & Human Services (HHS)
Office of the National Coordinator for Health Information Technology (ONC)
330 C Street, SW
Room 7033A
Washington, DC 20201

Electronic Submission to HealthIT.gov/USCDI


Dear Mr. Tripathi:

The National Association for the Support of Long Term Care (NASL) appreciates the opportunity to share our comments with the HHS Office of the National Coordinator for Health Information Technology (ONC) regarding the Draft US Code for Data Interoperability Version 3 (Draft USCDI v3).

NASL is a trade association representing the providers of ancillary care and services and products for the long term and post-acute care (LTPAC) sector. NASL members include rehabilitation therapy companies; providers of clinical laboratory and portable x-ray services; suppliers of complex medical equipment and other specialized supplies; and health information technology (health IT) companies that develop and distribute full clinical electronic medical records (EMRs), billing and point-of-care health IT systems and other software solutions serving the majority of LTPAC providers (i.e., assisted living, home health, inpatient rehabilitation facilities, long term care hospitals and skilled nursing facilities). NASL also is a founding member of the Long Term & Post-Acute Care Health IT Collaborative, which formed in 2005 to advance health IT issues by encouraging coordination among provider organizations, policymakers, vendors, payers and other stakeholders.

NASL is pleased to submit these comments and welcomes the opportunity to work with ONC in further developing and expanding the standardized set of health data classes and data elements contained in the US Code for Data Interoperability (USCDI) that are essential for nationwide, interoperable health information exchange. We appreciate that ONC is setting a baseline dataset that will foster greater health data exchange, which in turn will improve care for all Americans.
We understand that the ONC adopted the \textit{USCDI Version 1} as a standard in the \textit{Cures Act Final Rule} in May 2020 and requires its use for certain \textit{2015 Edition Cures Update Health IT Certification Criteria}. To be clear, there is no federal government requirement for LTPAC providers to use certified health IT. Nonetheless, NASL and our health IT members support the use of federal health IT standards and remain active participants in various federal health IT initiatives that seek to inform ONC and other federal agencies such as the Centers for Medicare & Medicaid Services (CMS).

NASL is well aware of the intersections of the USCDI and the information blocking provisions of the \textit{Cures Act Final Rule}. We appreciate ONC’s efforts to ensure that standards like the USCDI are used to align interoperability requirements and national priorities across the federal government, with industry-based initiatives such as Carequality and CommonWell as well as with the Trusted Exchange Framework & Common Agreement (TEFCA). As the nation continues to recover from the COVID-19 pandemic, we believe that necessary changes to our nation’s public health infrastructure will demand even greater use of health IT and standardized data.

\section*{Overview}

NASL supports the Biden Administration’s efforts to expand and specify additional data elements important to improving health equity. Because this initiative takes a government-wide approach, NASL is eager to hear how federal agencies have identified, defined and intend to use these important data elements.

\textbf{The lack of harmonization around clinical data collection as required by myriad federal agencies and programs remains an ongoing challenge.} We fully appreciate that data serves many masters – from treatment to payment to operations and beyond. We believe that focus on these other uses for clinical data (\textit{e.g.}, for regulatory compliance or to satisfy payment requirements) has diverted clinician and programmer attention from the standardization that is necessary for semantic interoperability, perhaps contributing to slower progress toward greater, meaningful health information exchange.

Providers across the health care spectrum are beholden to payers’ data demands in order to secure appropriate reimbursement for their services. This is particularly true for the clients that NASL members serve, to include LTPAC and behavioral health providers operating on slim margins and who have not received federal health IT incentive funding. As noted in our response to ONC’s \textit{Request for Information: Electronic Prior Authorization Standards, Implementation Specifications & Certification Criteria} and in separate communications with the Centers for Medicare & Medicaid Services (CMS), NASL has expressed our concern with the non-standardized approach to data, which is characterized by tremendous inconsistencies and variations around the timing and type of information that is requested by payers such as Medicare Advantage (MA) plans.
From the provider’s perspective, the real concern is that fulfilling the variations in data required by multiple payers demands countless hours of much-needed staff time that desperately is needed for patient care. From a health IT developer perspective, the concern can be summed up in one word – volume. The sheer volume of payers whose data needs must be met by LTPAC health IT vendors on behalf of their provider clients can be overwhelming due to the lack of standardization. According to the Kaiser Family Foundation (KFF), there are 3,834 Medicare Advantage plans available nationwide for individual enrollment in 2022, which represents an 8 percent (8%) increase over 2021. There are 50 State Medicaid programs and countless other insurers. The task for health IT vendors to program systems and solutions to account for each plan’s unique data needs (e.g., unique formats, differing submission timelines and other process variations) is daunting and pulls critical resources away from efforts to advance interoperability. The health IT systems and solutions that NASL health IT vendor members develop and distribute must be able to track Medicare, Medicaid and untold combinations of MA plans that LTPAC patients and residents may rely on for their care needs. With KFF reporting that 42 percent (42%) of the total Medicare population were enrolled in a Medicare Advantage plan in 2021 and this trend expected to continue, the penetration of MA plans in LTPAC settings will only increase. This means more and more unique forms and prior authorization requests – requests that we simply do not have the resources to manage. Again, without a more standardized approach from payers such as MA plans, we fear that our collective efforts to advance interoperability will be blunted.

**NASL Recommendation**

NASL recommends that ONC work with CMS to facilitate greater standardization among MA payers, which surely would help to reduce provider burden and free up resources to focus on interoperability. For example, by requiring CMS contractors such as Medicare Advantage plans to use a single dataset and format for their data collection needs (i.e., standardized forms/formats), CMS could streamline the way these federal contractors obtain the data that they require, which would relieve provider burden and conserve the limited resources that health IT developers have to program for an expanding number of payers.

In 2020, health IT developers set aside any planned development timelines in order to respond to the urgent needs and systematic changes that COVID-19 demanded. In the first few months of the pandemic, CMS issued more than 130 blanket waivers, many of which prompted edits or other code changes to software programs like those that are developed by NASL members. Countless actions taken by the federal government (and state governments) to mitigate the impact of COVID-19 on healthcare services and operations have had a direct impact on the health IT systems and solutions that providers rely on in caring for their patients, paying their staff, public reporting on the pandemic and seeking reimbursement for their collective services. Unwinding these changes – whenever the COVID-19 Public Health Emergency (PHE) ends – is likely to require similar efforts and resources.
NASL appreciates that the ONC recognizes the ongoing burden that COVID-19 has placed not only on health care staff serving on the frontlines, but on the resources available to health IT developers who support them. The ONC’s measured approach of including data elements in its DRAFT USCDI Version 3 that would impose minimal new development burden and complement existing data elements in the USCDI is especially welcomed by the LTPAC sector. As federal COVID-19 policies continue to evolve, NASL urges ONC to assert its role as the nation’s coordinator of health IT to press other federal agencies to look for opportunities to streamline their efforts by harmonizing existing program requirements with any additional data needs.

**NASL Recommendation**

NASL recommends that the ONC encourage federal agencies such as CMS and the Centers for Disease Control & Prevention (CDC) to issue policies that align with federal health IT standards that can advance interoperability, protect patient privacy and ensure secure exchange of health information.

As longtime advocates working to advance interoperability, we agree that standards are needed now. Yet, the glaring gaps in adoption and use of health IT across the healthcare spectrum and the ongoing need to focus health IT resources on implementing relatively new reporting requirements due to COVID-19 has us questioning whether the pace of review set by the ONC, the Health Information Technology Advisory Committee (HITAC) and its Interoperability Standards Workgroup is too rapid to allow for relevant input from all stakeholders.

The adoption and use of health IT represents a cultural shift in documenting care, clinical workflow and clinical decision-making. Physicians, who have had more than a decade to become acclimated to the use of health IT in hospitals and ambulatory care settings, still struggle with this massive sea change in how care is documented. Now, clinicians in the LTPAC sector, where the use of health IT has not been incentivized, face similar struggles as these fundamental shifts in clinical care and operations take hold.

No matter the care setting, relying on data received from external sources still connotes a very different sort of risk calculation than the liability associated with trusting data gathered within one’s own organization. This inherent skepticism around data received from outside entities remains a barrier to true interoperability and prompts NASL to ask whether adding Security as a data class within USCDI might mitigate that distrust for data gathered from external sources.

**NASL Recommendation**

NASL recommends that the ONC prioritize the data that clinicians deem necessary for the clinical record, which may help to mitigate any skepticism about data.
received from external entities as it is vital to inform and advance treatment and care planning for their patients.

We at NASL applaud the dedication and alacrity with which the HITAC, and its Interoperability Standards Workgroup (ISWG) in particular, have incorporated new data elements and data classes into the USCDI. Even so, as we reflect on the Biden Administration’s health equity initiative, NASL respectfully suggests that the ONC consider expanding participation on the HITAC ISWP to an even broader group who can ensure that the sometimes unique clinical documentation and health information sharing needs of all clinicians – e.g., nurses, rehabilitation therapists, pharmacists, etc. – are considered as additional data classes and elements are reviewed for incorporation into future editions of the USCDI.

Newly Proposed Data Classes & Data Elements

In order to provide the best input that we can, NASL focused our comments on the new data classes and specific data elements proposed in the DRAFT USCDI Version 3 (USCDI v3).

Proposed Data Classes

Health Insurance Information Data Class as Proposed

Data related to an individual’s health insurance coverage.

**NASL Recommendation**

NASL recommends that specific dates and/or guidance regarding which dates (or date ranges) should be included or associated with the health insurance data element, Coverage Status. Individuals who receive care in long term and post-acute care settings frequently transition between different types of health insurance coverage. For example, a patient may transfer from a hospital to a Skilled Nursing Facility (SNF) under the Medicare Part A benefit. For a patient who needs longer term care than is provided under Medicare Part A, coverage then transitions to the patient’s Medicare Advantage or other health insurance plan, or possibly to Medicaid coverage. Because of such routine transitions in coverage, it is important to have detailed date-related information associated with coverage status. This level of detail also is critical for alignment with reporting requirements and other uses for this type of data.

Health Insurance Information Data Class as Proposed

Health-related matter of interest, importance, or worry to a patient, patient’s family, or patient’s healthcare provider.

NASL has reviewed the proposed Health Status Data Class in detail and has a variety of recommendations. Many of our suggestions either align with or otherwise support several of the
recommendations made by HITAC’s Interoperability Standards Workgroup (ISWG), which we cite for ease of reference.

**NASL Recommendation**

NASL recommends that Health Concerns remain under its own Health Concerns Data Class (see ISWG Recommendation 02). Most of the clinical information in the USCDI represents the clinical information needed or imparted by clinical professionals. Health concerns represent a uniquely patient-centric data class. Keeping the current Health Concerns Data Class serves to maintain a central repository for individual/patient input into the clinical record, which we at NASL believe is important for greater patient-centric care planning.

**NASL Recommendation**

NASL also recommends that the proposed Health Status Data Class be renamed Health Status/Assessments Data Class (see ISWG Recommendation 01). The current USCDI does not easily accommodate the results of standardized assessments such as the Minimum Data Set 3.0 (MDS 3.0) or the Outcome & Assessment Information Set (OASIS). These standardized, patient assessment instruments are used in long term and post-acute care settings and integral to the process by which an individual’s health status is established. NASL views the “Assessment & Plan of Treatment” reference in the USCDI as a “term of art,” which reflects the working assumptions and conclusions made by clinical professionals based upon available data. The current Assessment & Plan of Treatment Data Class also refers to data that is less structured and more akin to clinicians’ progress notes than to the specific data sets captured in standardized patient assessment instruments like CMS’ MDS 3.0 and OASIS.

NASL does not object to keeping both Pregnancy Status and Smoking Status as data elements within a new Health Status/Assessments Data Class (see ISWG Recommendation 07).

**NASL has concerns about how Functional Status, Disability Status & Mental Function are classified within the proposed Health Status Data Class.** Each of these three categories represent multifactorial concepts that cannot be expressed as a single data element. We also are concerned that the current descriptions of these data categories are too ill-defined and do not align with use cases being developed by the PACIO Project and within various HL-7 workgroups.

**NASL Recommendation**

To facilitate capture of this important data and to improve alignment with existing CMS and other federal health IT initiatives such as the PACIO Project, NASL recommends that the USCDI refer to definitions of these data elements found in the International Classification of Functioning, Disability & Health (ICF).
The ICF offers a framework for describing functioning and disability as it relates to a health condition. The ICF framework supports the generalization of concepts while taking a hierarchical approach that supports the use of broad and specific terms in describing an individual’s function. The ICF framework can be used to reflect myriad types of human activity and participation. For example, one such use of the ICF is communicating an individual’s performance broadly in terms of his or her mobility as well as more detailed nuances such as changes in basic body positions that may be translated into computer processable codes such as the ICF Code d4500 Walking short distances.

ICF definitions have been foundational to CMS’ development of its Standardized Patient Assessment Data Elements (SPADEs) as required under the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act). The IMPACT Act also requires that CMS standardize and make interoperable the patient assessment data captured by the four post-acute care settings (Skilled Nursing Facilities (SNFs), Long Term Care Hospitals (LTCHs), Inpatient Rehabilitation Facilities (IRFs) and Home Health). Over the past seven years, CMS has mapped these data in its Data Element Library (DEL). Even though data within the DEL does not map exactly to ICF codes, it brings another measure of alignment that may prove useful in advancing interoperability.

**NASL Recommendation**

NASL supports the HITAC ISWG’s Recommendation 04, which recommends that ONC consider referencing the ICF model as a value set applicable to the renamed Health Status/Assessments Data Class.

NASL further agrees with the HITAC ISWG’s recommendation that the data element labeled “Mental Function” in the proposed Draft USCDI v3 should be changed to “Mental/Cognitive Status” (see ISWG Recommendation 03).

**Proposed New Data Elements**

**New Data Elements as Proposed – Laboratory Data Class**

**Specimen Types**

Type of specimen (e.g., nasopharyngeal swab, whole blood, serum, urine, wound swab) on which a lab test is performed.

**Result Status**

Representing the stage of completeness of a result of a laboratory test.

**NASL Recommendation**

NASL agrees with the HITAC ISWG’s Recommendation 10 that USCDI v3 specify
SNOMED-CT as an applicable vocabulary standard for the Specimen Type data element in the Laboratory Data Class. Also, ONC should consider specifying the following value sets defined by HL7®:

- HL7VS-specimenType
- FHIR v2 Specimen Type

NASL also agrees with HITAC’s ISWG Recommendation 11 that ONC specify the applicable vocabulary standard for the Values/Results data element within the Laboratory data class as SNOMED CT for qualitative lab result, and UCUM for numerical results.

Additional Recommendations
While there is much work to be done to better define Social Determinants of Health (SDOH) data elements, NASL was pleased that ONC prioritized some SDOH data elements that moved from Level 2 to USCDI v2. NASL believes that other data elements – to include those needed for Advance Directives – are similarly “ready for prime time.”

**NASL Recommendation**
NASL recommends that ONC consider the work being done on Advance Directives Interoperability (ADI) by the [PACIO Project](https://pacio-project.org) and to move the Advance Directives Data Class from Level 1 to Level 2. Based on NASL member involvement in these activities, we strongly believe that Advance Directives should advance as a data class within USCDI in the near future.

NASL applauds the tremendous efforts of the HITAC and its Interoperability Standards Workgroup, in particular. We stand ready to support their efforts and welcome the opportunity to contribute to their ongoing work on future iterations of as their work continues. Thank you for your consideration of our comments.

Sincerely,

Cynthia Morton, MPA
Executive Vice President

cc: Mary Greene, MD
Director, CMS Office of Burden Reduction & Health Informatics