CMS-OBRHI Submission for United States Core Data for Interoperability (USCDI) Version 4

September 30, 2022

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U.S. Department of Health and Human Services
330 C Street SW, 7th Floor Washington, DC 20201

Dear Dr. Tripathi:

On behalf of The Centers for Medicare and Medicaid Services (CMS), the Office of Burden Reduction and Health Informatics (OBRHI) and The Center for Clinical Standards and Quality (CCSQ), we submit the following recommendations for the United States Core Data for Interoperability (USCDI) version (v) 4 consideration. CMS encourages continued expansion of the USCDI to include high priority data elements necessary to support nationwide interoperability. This expansion will support clinical care, care coordination and quality improvement, while easing the burden of quality measurement. We are committed to continuing our collaborative work with the Office of the National Coordinator for Health Information Technology (ONC) and other federal partners to ensure the USCDI meets stakeholder needs and to ensure the USCDI is the central mechanism in defining the foundational set of electronic health information for interoperable health information exchange.

CMS emphasizes the need for essential health information to support effective clinical decision-making that is exchangeable across settings, and also available within settings over time in order to optimize coordination and continuity of care. We specifically urge ONC to include the additional data elements outlined below to the USCDI v4, and to better define the data class Health Status/Assessments, including the necessary data elements related to functional status, disability status and mental/cognitive status

Data Class: Health Status/Assessments; defined as "Assessments of a health-related matter of interest, importance, or worry to a patient, patient's family, or patient's healthcare provider that could identify a need, problem, or condition."

Action: CMS urges adding more specificity to the USCDI data class *Health Status/Assessment* definition to include not only the specified assessment question, but to also include the responses/results of such assessments.

Rationale: Information garnered via patient health assessments is critical for planning patient-centered care and should be exchanged between providers during transitions of care to support care coordination. For example, functional and cognitive assessments are routinely used to establish a patient's baseline ability to carry out their activities of daily living (ADLs), and to establish goals of care. In addition, assessment data collected by health professionals, as well as patient generated health data collected from surveys or questionnaires, may be used for multiple purposes: including quality reporting, prior authorization, payments, utilization review, survey and certification, and more. Interoperable exchange of functional and cognitive data is crucial for identifying and addressing health inequities.

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One of the goals of the Improving Medicare Post-Acute Care Transformation Act (IMPACT) is to support the exchange of key health data important for care planning, such as cognitive status, functional status, and special services, treatments and interventions, as well as improve quality of care and health outcomes, enhance coordination of care, and to support person centered goals. To meet these goals, CMS standardized specific patient assessment content across multiple Post-Acute Care (PAC) Settings, including for Home Health Agencies (HH), Inpatient Rehabilitation Facilities (IRFs), Skilled Nursing Facilities (SNFs), and Long-Term Care Hospitals (LTCHs). See table below for their associated assessment instruments utilized by over 30,000 PAC providers for approximately 7 million patients annually:

Care Settings	CMS Assessment Instrument
Inpatient Rehabilitation Facilities (IRFs)	IRF Patient Assessment Instrument (IRF-PAI)
Home Health Agencies (HHAs)	Outcome and Assessment Information Set (OASIS)
Long-Term Care Hospitals (LTCHs)	LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS)
Skilled Nursing Facilities (SNFs)	Minimum Data Set (MDS)
Hospice Care	Hospice Item Set (HIS)
Home and Community-Based Services (HCBS)	Functional Assessment Standardized Items (FASI)

These PAC assessments may be considered in their entirety as a value set of administrative and clinical patient information, or individual structured data elements found within the PAC assessments may be queried and used for all patients regardless of the healthcare setting. For example, specific assessment questions include mobility, mental/cognitive status, activities of daily living (ADLs), and communications. Exchange of these structured data elements, that were nationally tested and well defined, enables providers to have a shared understanding of meaning, and supports comparability across healthcare settings and care coordination during transitions of care. These standardized data elements are mapped to nationally accepted health IT standards (e.g.- Logical Observation Identifiers Names and Codes (LOINCs) and Systematized Nomenclature of Medicine - Clinical Terms (SNOMED)) to support coordinated care across all healthcare settings and are publicly available in the CMS Data Element Library (DEL). Specific data element discussion and recommendations are noted below:

Data Element: Functional Status; defined as the "Assessment of a patient's capabilities, or their risks of development or worsening of a condition or problem. (e.g., fall risk, pressure ulcer risk, alcohol use)"

Action: CMS suggests adding the functional assessment responses/results to be included in the Health Concerns/Assessments data class, just as *Laboratory Tests, Diagnostic Imaging, and Clinical Tests* Data Classes include not only the "test", but also the results/report.

Discussion/Rationale: The CMS PAC assessments noted above include well tested and defined functional status assessments which are used by PAC providers nationwide, for every patient at admission and discharge, and additional points in between. These functional assessment questions and responses are standardized across multiple healthcare settings, including with Home and Community Based Services. Functional assessments include evaluation of mobility, ADLs, Instrumental Activities of Daily Living (IADLs), as well as functional goals and more. Patients with deficits in these areas may require rehabilitative treatments, in-home supports, or long-term care placement. In addition, an individual's mobility status (e.g. gait speed, unsteadiness, poor balance) are all predictors of falls with major injury and overall outcomes. New impairments warrant diagnostic evaluation and may serve as indications for mobility devices, home modifications, preferred setting for transfer post-hospitalization, and risk benefit considerations for some pharmacologic treatments (falls risks vs anticoagulants). Some example data elements that may be used as testing criteria include the LOINCs and their related answer lists (v2.73) listed below:

LOINC	Name
86601-2	Functional status [CMS Assessment]
94848-9	Functional assessment standardized items (FASI) - version 1.0 [CMS Assessment]
88238-1	LCDS v4.00 - Functional abilities and goals [CMS Assessment]
99154-7	OASIS E - Functional abilities and goals - FU [CMS Assessment]

Action: CMS suggests removing alcohol use as an example of functional assessment.

Discussion/Rationale: As described in the required Discharge Summary note in USCDI v3 (LOINC 47420-5), examples of functional status include the following:
"Functional status assessment describes the patient's status of normal functioning at the time a care record was created. Functional statuses include information regarding the patient relative to ambulatory ability, mental status or competency, activities of daily living (ADLs) (i.e. bathing, dressing, feeding, grooming), home/living situation having an effect on the health status of the patient, ability to care for self, social activity (i.e. issues with social cognition, participation with friends and acquaintances other than family members), occupation activity (i.e. activities partly or directly related to working), housework or volunteering, family and home responsibilities or activities related to home and family, communication ability (i.e. issues with speech, writing or cognition required for communication), and perception, including sight, hearing, taste, skin sensation, kinesthetic sense, proprioception, or balance."

Alcohol may impact a person's functioning, but it is not functional status itself. Alcohol use screening questions are more similar to smoking status screening questions noted in the same data class.

Action: CMS also suggests removing pressure ulcer risk as an example of functional status. However, communicating pressure injuries, including the number, location, and stage of the pressure injuries is important to exchange, especially during transitions of care. CMS PAC

assessments include well tested and defined data elements on pressure injuries which are represented by LOINC in the DEL. CMS suggests including pressure injury data elements in USCDI v4, potentially as new "Safety Problems" data elements in the Problem Data Class, that would be geared toward exchanging health concerns that pose substantial risk to individuals or healthcare staff at transitions of care. Other data elements that should be considered include information regarding patient behaviors that pose a risk to self or others, as well as infection, high risk medications, special equipment/devices, and history of falls/fall risk. Additionally, it is essential to communicate pain findings and its impact on function for the clinical management of people who need and receive care. Pain characteristics, such as location, severity, duration, and impacts on ADLs, sleep, falls, and therapy participation, must be assessed and reassessed over time and in response to different treatments and services. The DEL includes data elements mapped to health IT standards for these topics, some of which are listed below. CMS suggests using the listed LOINCs and their related answer lists as testing criteria for the Problem data class.

LOINC	Name
93185-7	Special Treatments, Procedures, and Programs - At Discharge.
LL5385-1	Special Treatments, Procedures, and Programs – Answer List
81636-3	Pressure injury risk level
73782-5	Neonatal pressure injury risk evaluation
86708-5	Determination of pressure injury risk in last 7 days
54573-1	Determination of pressure injury risk
73783-3	Neonatal pressure injury risk total score
54880-0	Pressure injury risk by clinical judgment
54879-2	Pressure injury risk by formal assessment
54878-4	Pressure injury risk by resident has a stage 1 or greater, a scar over bony prominence, or a non-removable dressing, device in last 7D
57280-0	Risk of developing pressure injuries
46552-6	Treated for urinary tract infection in past 14 days [CMS Assessment]
57257-8	Patient/caregiver received high risk drug education [CMS Assessment]
93155-0	IRF-PAI v4.0, LCDS v5.00, OASIS E - High risk drug classes - use and indication [CMS Assessment]
83344-5	Prior device use [CMS Assessment]
94901-6	Need for and availability of a communication device [CMS Assessment]
94925-5	Paid caregiver's ability and willingness to provide management of equipment assistance during assessment period [CMS Assessment]
94909-9	Assistive devices needed [CMS Assessment]
95031-1	FASI v1.0 - Assistive Devices for Everyday Activities [CMS Assessment]
52552-7	Falls in the past year

83280-8	Has the patient had any falls since admission [CMS Assessment]
54854-5	Number of falls since admission or prior assessment [CMS Assessment]
57254-5	Standardized fall risk assessment was conducted [CMS Assessment
86677-2	Signs and symptoms of swallowing disorder during assessment period [CMS Assessment]
54557-4	Pain management during assessment period [CMS Assessment]
54559-0	Pain effect on function during assessment period [CMS Assessment]
93158-4	How often have you limited your day-to-day activities because of pain over the past 5 days [CMS Assessment]
93160-0	How often have you limited your participation in rehabilitation therapy sessions due to pain over the past 5 days [CMS Assessment]

Data Element: Disability Status; defined as Assessments of a patient's physical, cognitive, intellectual, or psychiatric disabilities. (e.g., vision, hearing, memory, activities of daily living)

Action: CMS suggests that Disability Status be more clearly defined and supports comments by the PACIO Community to clarify the meaning of disability, since disability could be interpreted as part of functioning.

Per PACIO: The PACIO Community requests ONC clarify what is meant by "Disability Status" and how it relates to the separate data element of "Functional Status." The existing definition does not describe the current conceptualization of disability. Recent literature suggests that functioning and disability is a complex interaction between a person, their health condition, personal factors (e.g. age lifestyle), and the environment. This concept is delineated in the International Classification of Functioning, Disability and Health (ICF) (https://www.who.int/standards/classifications/international-classification-of-functioning-disability-and-health). As a classification, ICF systematically groups different domains for a person in a given health condition (e.g., what a person with a disease or disorder does do or can do). Functioning is an umbrella term encompassing all body functions, activities and participation; similarly, disability serves as an umbrella term for impairments, activity limitations or participation restrictions. ICF also lists environmental factors that interact with all these constructs. In this way, it enables the user to record useful profiles of individuals' functioning, disability and health in various domains. The association between the person and the contextual factors, defined as personal and environmental factors in the ICF, provides a clearer understanding of a person's functioning and disability. Disability status considers the negative aspect of the interrelationship. For example, an individual with a health condition could be considered disabled in one environment (structural barriers exist in the community

restricting a person in a wheelchair from moving outside one's home) but not in another (accessible streets and housing allow a person in a wheelchair to go to work and community-based activities). The current definition of disability status assumes that only an assessment of physical, cognitive, intellectual, and psychiatric disabilities is required. Disability could be interpreted as part of Functional Status, whereby functioning indicates capability in a given area and poor functioning could be described as disability in that area (e.g., capability to ambulate vs. inability to ambulate). Disability often manifests on a continuum and the level of disability may depend upon certain environmental variables, such as access to assistive devices or technologies. In addition, disability may be permanent or temporary (e.g., functional abilities may decline after a stroke or a surgical procedure, but then improve with time and therapeutic interventions). If for the purposes of USCDI, ONC intends for Disability Status to represent a more binary concept of permanently disabled or not disabled, as determined by qualification for federal disability benefits, for example, the PACIO Community requests more explicit guidance to this effect.

Discussion/ Rationale: In addition to the comments provided by the PACIO community noted above, and as ONC notes in v3, there are multiple types of disabilities. CMS PAC assessments include numerous data elements that evaluate a person's hearing, vision, cognitive functioning, mobility, and performance of ADLs/IADLs. Patients may have normal functional/cognitive status, and therefore no disability, or poor functioning/cognition and significant disability. Suggested LOINCs (and their related answer lists) that could be used for testing purposes are listed in the table below:

LOINC	Name
95744-9	Hearing. Ability to hear during assessment period [CMS Assessment]
93310-1	Vision. Ability to see in adequate light during 3 day assessment period [CMS Assessment]

- **Data Element: Mental/Cognitive Status**; defined as Assessment of a patient's level of cognitive functioning. (e.g., alertness, orientation, comprehension, concentration, and immediate memory for simple commands)

Action: CMS suggests adding mental/cognitive assessment responses/results in the Health Concerns/Assessments data class, just as *Laboratory Tests, Diagnostic Imaging, and Clinical Tests* Data Classes include not only the "test", but also the results/report.

Discussion/Rationale: The CMS PAC assessments noted above include well tested and defined cognitive/mental status assessments which are used by PAC providers nationwide, for every patient at admission and discharge, and also additional points in time. Mental/cognitive assessments include evaluation of mental status, as well as screening for depression, mood changes and behavioral health issues. These assessment questions and responses are standardized across multiple healthcare settings, and are important to exchange during

transitions of care to inform care planning for all patients across all settings, including with acute care, behavioral health, and Home and Community Based Services providers. Understanding and communication of the presence and severity of mental health and cognition guides clinical decision making. For example, prescribers may select medications, the frequency of therapeutic monitoring, and implementation of medication management services based on a person's mental/cognitive status – without which medical therapy may be ineffective (missed dosing) or potentially harmful (takes too much or incorrectly). New mental/cognitive impairments warrant diagnostic evaluation of "change in mental status"– impairment may compromise a person's ability to accurately and safely take their own medications or adhere to treatments. In addition, it is critical that the USCDI v4 supports the data exchange of mental and behavioral health data elements given the high prevalence of comorbidities in the U.S. population. Some example data elements that may be used as testing criteria include the LOINCs and their related answer lists (v2.73) shown below:

LOINC	Name
46589-8	Cognitive functioning [CMS Assessment]
99140-6	OASIS E - Cognitive Patterns - SOC, ROC, DC [CMS Assessment]
95854-6	LCDS v4.00 - Cognitive patterns during assessment period [CMS Assessment]
96907-1	1MDS v3.0 - RAI v1.17.2 - Cognitive patterns - ND, SD [CMS Assessment]
46473-5	Cognitive, behavioral, and psychiatric symptoms demonstrated at least one time per week [CMS Assessment]
54605-1	Brief Interview for Mental Status (BIMS) [CMS assessment]
54635-8	Resident mood interview (PHQ-9) [Reported PHQ-9 CMS]

We thank you for the opportunity to provide comments and priority data element recommendations for USCDI v4. We look forward to continued engagement with ONC and strongly recommend the addition of these critical data elements to USCDI to support advancement of interoperability and usability of the data; improved patient care; reduced provider and patient burden; and enhanced quality measurement. We recognize there are many elements under consideration and aimed to focus our recommendations on data elements with widespread use cases across providers, payers, and patients that are critical for exchange to improve patient care and outcomes.

Thank you,

Mary G. Greene -S Digitally signed by Mary G. Greene -S
Date: 2022.09.30 17:04:54 -04'00'

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Cc: Stella Mandl, RN, *Deputy Director of the Office of Burden Reduction and Health Informatics, The Centers for Medicare & Medicaid Services*