April 14, 2021

The Honorable Micky Tripathi
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street SW, 7th Floor
Washington, D.C. 20201

Re: **The Gravity Project's Comments on ONC's U.S. Core Data for Interoperability Draft
Version 2 and the Need to Include the Social Determinant of Health Data Class Now**

Dear National Coordinator Tripathi:

The Gravity Project submits these comments on draft version 2 of the United States Core Data for Interoperability, released for public comment by the Office of the National Coordinator for Health Information Technology on January 12, 2021. The Gravity Project develops and tests consensus-based standards that facilitate capture and exchange of social determinants of health (SDOH) data across a variety of systems and settings of care and social services, by convening stakeholders across the nation through an open and transparent collaborative process. We thank you for the opportunity to provide these comments.

The Biden-Harris Administration affirmed on day one that health equity must be an immediate national priority.[1] The COVID-19 pandemic has highlighted the considerable gaps and disparities in health and health care in underserved communities across the nation. In a recent interview, you explained the priority for "health equity by design" and the role of social determinants of health data.[2] The Gravity Project's submitted Social Determinants of Health data class enables exactly that—health equity by design—by integrating terminology and FHIR API-based exchange for clinical care and community referrals and interventions.

The Office of the National Coordinator (ONC) categorized the Gravity Project's submission as Level 2, yet failed to include the SDOH data class in the draft version 2 released for public comment on January 12.[3] Instead, ONC proposed another "modest expansion" of the

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[1] The White House, The Biden-Harris Administration Immediate Priorities (2021), available at https://www.whitehouse.gov/priorities/.

[2] Mike Miliard, ONC chief Micky Tripathi talks public health data systems and 'health equity by design', Healthcare IT News (Mar. 12, 2021), available at https://www.healthcareitnews.com/news/onc-chief-micky-tripathi-talks-public-health-data-systems-and-health-equity-design; Heather Landi, ONC leader Tripathi says health IT agency focused on 'healthy equity by design', Fierce Healthcare (Mar. 15, 2021), available at https://www.fiercehealthcare.com/tech/onc-leader-tripathi-says-health-it-agency-focused-healthy-equity-by-design.

[3] Office of the National Coordinator for Health Information Exchange, United States Core Data for Interoperability: Draft Version 2, p. 3 (Jan. 2021), available at https://www.healthit.gov/isa/sites/isa/files/2021-01/Draft-USCDI-Version-2-January-2021-Final.pdf.

core structured health data the nation needs for interoperability and health care.[4] For the reasons below, **the Gravity Project urges ONC to add the SDOH data class to version 2 so that health IT developers may begin integrating health equity by design _now_** while they are designing and preparing the real-world testing and certification criteria for implementation in 2022 and 2023 under ONC's and the Centers for Medicare & Medicaid Services' (CMS) regulations. This assures that providers, patients,[5] payers, community-based organizations, app developers, and stakeholders across the nation may begin using these SDOH data sets for better health care and better health.

We are not alone in urging ONC to meet this need. When the Gravity Project made its submission last October, stakeholders across the nation amplified the Gravity Project's submission with formal letters of support:

- AcademyHealth
- American Academy of Family Physicians (AAFP)
- American Health Information Management Association (AHIMA)
- AmeriHealth Caritas
- BlueCross BlueShield Association (BCBSA)
- Blue Shield of California
- Codentx
- HHS Administration for Children and Families (ACF)
- Highmark Health
- Lucy Johns
- Lyft
- Jim Meyers
- National Committee for Quality Assurance (NCQA)
- National Partnership for Women & Families (NPWF)
- Nebraska Health Information Initiative (NEHII)
- New York eHealth Collaborative (NYeC)
- OCHIN
- Onyx
- Providence St. Joseph Health
- Stewards of Change Institute
- University at Buffalo School of Nursing
- University of California San Francisco (UCSF)

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[4] Id., p. 3; see Office of the National Coordinator for Health Information Technology, 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 85 Federal Register 25642, 25665 (May 1, 2020), available at https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-07419.pdf.

[5] For brevity, these comments refer to "patient" and "care," given that many federal programs and initiatives are rooted in a clinical or medical model. Health and health care, however, embrace more than clinical settings and extend well beyond clinical treatment of episodes of illness and exclusive dependency on medical professionals. Any effort to improve patient and family engagement must include terminology that also resonates with the numerous consumer and community perspectives not adequately reflected by medical model terminology. For example, people with disabilities and others frequently refer to themselves as "consumers" or merely "persons" (rather than patients). Similarly, the health care community uses the terminology "caregivers" and "care plans," while the independent living movement may refer to "peer support" and "integrated person-centered planning."

When CMS requested information on accelerating adoption of standards related to social risk data,[6] many organizations—31 letters at last count—also explicitly highlighted and supported the Gravity Project's work:

- Aligning for Better Health
- American Academy of Pediatricians
- American Association of Medical Colleges (AAMC)
- American Health Information Management Association (AHIMA)
- American Medical Association (AMA)
- American Medical Informatics Association (AMIA)
- America's Health Insurance Plans (AHIP)
- AmeriHealth Caritas
- Anthem
- Aunt Bertha
- BlueCross BlueShield Association (BCBSA)
- Cigna
- Colorado Office of eHealth Innovation
- Epic
- Health Record Banking Alliance (HRBA)
- Health Level Seven International (HL7)
- Highmark Health
- Humana
- Kaiser Permanente
- Lantana Consulting Group
- Movement Is Life
- National Association of Community Health Clinics (NACHC)
- National Committee on Quality Assurance (NCQA)
- New York eHealth Collaborative (NYeC)
- Pew Charitable Trusts
- Protecting Privacy to Promote Interoperability (PP2PI)
- Providence St. Joseph Health
- RTI International
- UnitedHealth Group
- WEDI
- Wolters Kluwer

On January 7, 2021, CMS issued guidance to state health officials specifically encouraging states to review and participate in the Gravity Project's work to develop the SDOH data class.[7]

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[6] Centers for Medicare & Medicaid Services, Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally- Facilitated Exchanges; Health Information Technology Standards and Implementation Specifications, 85 Federal Register 82586, 82641-82642 (Dec. 18, 2020), available at https://www.govinfo.gov/content/pkg/FR-2020-12-18/pdf/2020-27593.pdf.

[7] CMS State Health Officials Letter No. 21-001 on Opportunities in Medicaid and CHIP To Address Social Determinants of Health, p. 34 (Jan. 7, 2021), available at http://www.medicaid.gov/federal-policy-guidance/downloads/sho21001.pdf.

In the comments that follow, the Gravity Project repeats its submission and urges the ONC to include the SDOH data class in USCDI version 2.

I. The Gravity Project and Its Expertise

The Gravity Project began in 2018 after a diverse group of national experts and stakeholders concluded that a concerted strategy was urgently needed to achieve consensus-based, comprehensive coding standards for SDOH data capture in electronic health record (EHR) systems. Experts have long known that social and environmental determinants explain most of a person's and population's health status. For the past sixteen months, the COVID-19 pandemic has highlighted this reality daily across the nation.

Since its creation, the Gravity Project has provided critical leadership to convene experts, stakeholders, and interested members of the public nationwide and has coordinated a structured, comprehensive, and efficient approach to:

- Understand the value and use of SDOH data for clinical care and population management;
- Analyze gaps in existing terminology and codes used to represent SDOH-related activities in clinical and community care settings;
- Develop standard terminology, vocabulary, and codes to represent and use SDOH concepts in EHRs and digital health technologies;
- Develop an HL7® FHIR® Implementation Guide for clinical care to support the capture and nationwide exchange of SDOH data using FHIR release 4 with FHIR-based application program interfaces (APIs);
- Develop a reference implementation to support real-world pilots and implementations, including nationally recognized screening tools and community-referral platforms (e.g., PRAPARE, UniteUs, Aunt Bertha, Accountable Health Communities (AHC)); and
- Analyze and develop bi-directional mapping between non-health care data and relevant health IT standards (FHIR resources, profiles) for use in clinical care and non-clinical settings.

The Gravity Project's work is open source for public use nationwide and agnostic regarding the screening tools available in the marketplace. While the work has initially focused on patient encounter data, the Gravity Project recognizes that other critical use cases exist, such as quality measurement, population and public health, risk stratification, and research. Again, the global pandemic highlights these diverse needs and intersections now.

We bring the depth and breadth of these and many other efforts to bear in our comments below.

II. The Importance of Social Determinants of Health Data and the Gravity Project's Submitted Social Determinants of Health Data Class

The value of collecting and coding SDOH data for clinical care and other use cases, including SDOH-related assessments, goals, health concerns, and interventions, is well established in the literature.[8] As the (then) Institute of Medicine summarized the evidence in 2014, in its opening paragraph of *Capturing Social and Behavioral Domains in Electronic Health Records, Phase I*:

> *Substantial empirical evidence of the contribution of social and behavioral factors to functional status and the onset and progression of disease has accumulated over the past few decades. . . . Electronic health records (EHRs) provide crucial information to providers treating individual patients, to health systems, including public health officials, about the health of populations, and to researchers about the determinants of health and the effectiveness of treatment. Inclusion of social and behavioral health domains in EHRs is vital to all three uses.[9]*

In addition to the Institute of Medicine's considered findings, leaders like Kaiser Permanente have documented substantial exchange and use because they have already integrated the collection and coding of SDOH data and activities such as assessments and referrals into their current systems.[10] A study of EHR vendors with the largest market shares, by authors at HHS's Center for Medicare and Medicaid Innovation and Office of the Assistant Secretary for Planning and Evaluation as well as NORC, finds the same.[11] The wholesale support among the Gravity

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[8] E.g., Abigail Arons, Sarah DeSilvey, Caroline Fichtenberg & Laura Gottlieb, Documenting social determinants of health-related clinical activities using standardized medical vocabularies, 2 J. Am. Med. Info. Ass'n 81, __ (Apr. 2019), available at https://doi.org/10.1093/jamiaopen/ooy051; see also Institute of Medicine, Capturing Social and Behavioral Domains in Electronic Health Records, Phase 1 (2014), available at https://www.ncbi.nlm.nih.gov/books/NBK195994/pdf/Bookshelf_NBK195994.pdf; Institute of Medicine, Capturing Social and Behavioral Domains in Electronic Health Records, Phase 2 (2014).

[9] Institute of Medicine, Capturing Social and Behavioral Domains in Electronic Health Records, Phase 1, p. 1 (2014), available at https://www.ncbi.nlm.nih.gov/books/NBK195994/pdf/Bookshelf_NBK195994.pdf; see also Institute of Medicine, Capturing Social and Behavioral Domains in Electronic Health Records, Phase 2, p. 1 (2015) ("To provide better patient care, improve population health, and enable more informative research, standardized measures of key social and behavioral determinants need to be recorded in electronic health records (EHRs) and made available to appropriate professionals."), available at https://www.ncbi.nlm.nih.gov/books/NBK268995/pdf/Bookshelf_NBK268995.pdf.

[10] Nicole Friedman & Matthew Banegas, Toward Addressing Social Determinants of Health: A Health Care System Strategy, 22 Permanente J. __ (Oct. 22, 2018) ("The novel electronic health record-based tools developed by KPNW [Kaiser Permanente Northwest] have led to standardized, measurable, and actionable SDH data being used to tailor and target specific resources to meet the identified needs of our patients."), available at https://doi.org/10.7812/TPP/18-095

[11] Maysoun Freij, Prashila Dullabh, Sarah Lewis, Scott R. Smith, Lauren Hovey, Rina Dhopeshwarkar, Incorporating Social Determinants of Health in Electronic Health Records: Qualitative Study of Current Practices Among Top Vendors, 7 JMIR Med. Inform. e13849 (June 7, 2019) (in a study of EHR vendors with large market shares, "Vendors indicate they are actively developing products to facilitate the collection and use of SDH data for their clients and are seeking solutions to data standardization and interoperability challenges through internal product decisions and collaboration with policymakers. Due to a lack of policy standards around SDH data, product-specific decisions may end up being de facto policies given the market shares of particular vendors. However, commercial vendors appear ready to collaboratively discuss policy solutions such as standards or guidelines with each other, health care systems, and government agencies in order to further promote integration of SDH data into the standard of care for all health systems"), available at https://medinform.jmir.org/2019/2/e13849/.

Project's 1,800+ collaborators nationwide, across diverse stakeholder segments, illustrates the ecosystem's deep need for, and the immediate value of, collecting and coding SDOH data for interoperable exchange and care.

While SDOH explain 80-90 percent of health status at a population level, there is no consistent method to structure and document SDOH data and to use and exchange these data during a health care encounter. This omission highlights the urgency of a standard approach across the national health system. The Gravity Project and its national, consensus-based collaboration are working to fill this void. Implementation of the standards for coding and exchange being developed and tested through the Gravity Project is necessary to drive reductions in missed appointments, cost savings from preventable health events, culturally competent care, increased care plan compliance, reduced administrative burden, promoting effective investment in community health programs, and leveraging critical data to improve patient outcomes. Integrating SDOH in health care is essential for the Triple Aim to improve care, health, and value, and has become a core expectation of the Federal Health IT Strategic Plans for 2015-2020 and 2020-2025.[12]

A set of open, national standards is needed for SDOH to resolve inconsistency when patients move among health care providers and between health and human services systems. Because there is no national standard yet, those EHR and population health system vendors which do collect and record some SDOH data elements are primarily implementing these elements as custom, non-interoperable fields. The lack of a national standard creates risks to individual patients by creating gaps in medical histories for patients who move among providers by preference or necessity. It creates risk to the health of populations since broad groups of patients may be assigned to incorrect or ineffective treatment due to misaligned clinical decision support tools. Furthermore, the lack of standards creates an onerous administrative burden since critical data cannot be efficiently shared among providers using different health record or client management systems.

Health care's transition from a fee-for-service model to value-based care adds an additional imperative for SDOH, since these elements will become increasingly necessary to establish appropriate and equitable payment for and reimbursement of health care service providers. Going forward, tangible evidence will be needed to demonstrate improvement in quality of care while sustainably lowering health care cost. SDOH reporting standards not only provide the data necessary to drive improvements to patient care, they also enable a clear record and justification for effective financing and capitalization of health services.

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[12] Office of the National Coordinator for Health Information Technology, *Federal Health IT Strategic Plan 2015-2020*, p. 11 (Sept. 2015) ("Many health and social determinants outside of care delivery influence individuals' health and well-being, and the federal government can play an important role to guide the inclusion of these determinants into the electronic information stream for decision-making by individuals, providers, and communities, as well as the organizations and technology developers that support them."), available at https://www.healthit.gov/sites/default/files/9-5-federalhealthitstratplanfinal_0.pdf; Office of the National Coordinator for Health Information Technology, 2020-2025 Federal Health IT Strategic Plan, p. 11 (Oct. 2020) ("The shift to value-based care has created new incentives . . . [that] place greater importance on addressing SDOH [social determinants of health] and patient health behaviors . . . ."), available at https://www.healthit.gov/sites/default/files/page/2020-10/Federal%20Health%20IT%20Strategic%20Plan_2020_2025.pdf; see also id., pp. 9, 23, 29.

III. The Gravity Project's Submission for USCDI Version 2: The Social Determinants of Health Data Class

On October 23, 2020, the Gravity Project submitted to ONC, for inclusion in the U.S. Core Data for Interoperability (USCDI) version 2, an initial set of eleven SDOH domains (e.g., food insecurity, housing instability and homelessness, transportation insecurity, social isolation, and stress), across core clinical activities (e.g., assessments, diagnoses, goals, interventions, and outcomes), using key national code systems and value sets (e.g., LOINC, SNOMED-CT, ICD-10-CM, and CPT/HCPCS).[13]

The Gravity Project submitted two alternative approaches, both of which included the same initial SDOH substantive domains and six core activities using four nationally recognized code systems and value sets. ONC categorized one alternative as Level 2 for potential inclusion in USCDI version 2, preferring the approach which organized the SDOH data class first by the six activities, then incorporating under each activity the substantive domains and corresponding code systems and value sets for each:[14]

Gravity Project's submission to USCDI: A New SDOH Data Class

Activities	Domains / Data Elements	Code Systems / Value Sets

• Assessments
• Problems/Health concerns
• Goals
• Interventions
• Outcomes
• Consent
	• Food insecurity
	• Housing instability & Homelessness
	• Housing inadequacy
	• Transportation insecurity
	• Financial stress
	• Employment
	• Education
	• Veteran status
	• Social isolation
	• Stress
	• Interpersonal violence
		• LOINC
		  ▪ Assessments
		  ▪ Goals
		  ▪ Outcomes (e.g., quality measures
		• SNOMED-CT
		  ▪ Problems/Health concerns (clinical)
		  ▪ Interventions (clinical)
		• ICD-10-CM
		  ▪ Problems/Health concerns (billing)
		• CPT/HCPCS
		  ▪ Interventions (billing, where available)

Organizing the SDOH data class by activities that reference the various relevant code panels and profiles for SDOH allows stakeholders to add SDOH substantive domains and code sets in real time as consensus is reached on each.

In summary, the Gravity Project's approach represents social risk and social needs data for capture and exchange across the first set of substantive domains organized to reflect diverse

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[13] Letter from Gravity Project to The Honorable Donald Rucker, National Coordinator for Health Information Technology, on Submission To Include Social Determinants of Health in the U.S. Core Data for Interoperability, Version 2, for Better Care and Better Health Nationwide (Oct. 23, 2020), available at https://www.healthit.gov/isa/sites/isa/files/webform/uscid_webform/1701/Gravity%20Project%20to%20ONC%20on%20SDOH%20Data%20Class%20for%20USCDI%20v2%20%2810-23-2020%29.pdf.

[14] See https://www.healthit.gov/isa/uscdi-data/social-determinants-health.

factors that affect health status. The Gravity Project will continue to add additional domains beyond this list as soon as our thorough, collaborative process will allow, but this list comprises the domains that the Gravity Project can support for USCDI v2. For each domain, the Gravity Project has standardized terminology, vocabulary, and value sets for six activities:

- Assessments (LOINC),
- Goals (LOINC, SNOMED-CT),
- Problems/Health Concerns (ICD-10-CM, SNOMED-CT),
- Interventions (SNOMED-CT, CPT/HCPCS),
- Outcomes (LOINC), and
- Consent.

We urge ONC to add this SDOH data class to version 2 now. The principal barrier to exchange among providers is the absence of a common standard for representation and exchange of structured SDOH data. ONC's (and CMS's) regulations implementing a FHIR-based API (release 4) approach to the national need for interoperability, combined with the Gravity Project's rapid work to augment terminology gaps and develop an HL7 FHIR SDOH Implementation Guide, should go a long way to overcoming that barrier to exchange among providers and other SDOH data users, including patients, community-based organizations, and payers.

The Gravity Project's work to develop national, consensus-based standards for capture and exchange of structured SDOH data with FHIR-based APIs also takes a major step forward to help providers and community-based organizations use and exchange the same data and integrate it within their various workflows. This work also enables third-party app developers to leverage FHIR-based API access and contribute new digital health tools that might improve workflows and usability of the SDOH data.

Except for the Gravity Project's work, we are not aware of any other national standards initiatives that are mapping social risk data to Z codes for use in claims. The Gravity Project is working to establish Z codes to document social risk across clinical systems (e.g., EHRs) and non-clinical systems (e.g., community referral platforms such as UniteUs and Aunt Bertha). On December 4, 2020, the Gravity Project formally submitted to the ICD-10-CM Coordination and Maintenance Committee new codes to represent data concepts across nine SDOH domains.[15]

We note that the Gravity Project has not yet completed the full set of gap analysis and code set development for all initial substantive domains. Likewise, the FHIR Implementation Guide is just completing the ballot reconciliation process and will be ready for publication by June, 2021. This tracks the approach ONC took with the social, psychological and behavioral data certification criterion in the 2015 Edition, where ONC noted in the proposed rule that some code sets remained to be finished but identified the structural placeholder in the proposed rule and identified the appropriate standard(s) in the final rule.

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[15] Submission from Gravity Project to ICD-10-CM Coordination and Maintenance Committee on Multi Domain Social Determinants of Health ICD-10-CM Application (Dec. 4, 2020), available at https://confluence.hl7.org/display/GRAV/ICD-10+Coding+Submissions.

Conclusion

For the reasons above, **the Gravity Project urges ONC to add the Social Determinants of Health data class to version 2 so that health IT developers may begin integrating health equity by design** _now_ while they are designing and preparing the real-world testing and certification criteria for implementation in 2022 and 2023 under ONC's and CMS's regulations, and providers, patients, payers, community-based organizations, app developers, and stakeholders across the nation may begin using them for better health care and better health.

Thank you very much for the opportunity to provide these comments. The Gravity Project looks forward to working with the Office of the National Coordinator, the Centers for Medicare & Medicaid Services, individuals and patients, other federal agencies (e.g., Administration for Community Living, Department of Housing and Urban Development, Department of Transportation, Department of Veterans Affairs, and Department of Defense), providers, community-based organizations, vendors, developers, and stakeholders across the nation to leverage technology to achieve national goals articulated by the Triple Aim. If you have additional thoughts or questions, please contact Mark Savage at Mark.Savage@ucsf.edu.

Sincerely,

The Gravity Project

cc: Steven Posnack, Deputy National Coordinator for Health Information Technology
     Elise Anthony, Executive Director, Office of Policy