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By electronic submission

The Honorable Donald Rucker, M.D.
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: Including Social Determinants of Health in the U.S. Core Data for
Interoperability, Version 2, for Better Care and Better Health
Nationwide**

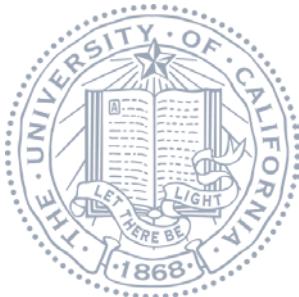
Dear National Coordinator Rucker:

The Gravity Project submits two alternative approaches to include key social determinants of health in the U.S. Core Data for Interoperability, version 2, for better care and better health nationwide.

The Gravity Project began out of recognition by a broad group of stakeholders that a concerted strategy for achieving consensus-based comprehensive coding standards for SDOH capture in EHR systems was urgently needed. Since its creation, the Gravity Project has provided critical leadership in convening appropriate stakeholders and coordinating a structured, efficient, and comprehensive 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 delivery settings;
- Develop standard terminology, vocabulary, and codes to refer to and implement SDOH concepts in the EHR context.

Experts have long known that social and environmental determinants of health explain most of a person's and population's health status. For the past nine months, the COVID-19 pandemic has highlighted this reality daily across the nation. The Gravity Project's submissions would add critical domains such as food insecurity, housing instability, transportation insecurity, social isolation, and stress to the USCDI, integrated with core



clinical activities such as assessments, diagnoses, interventions, and outcomes. This letter summarizes the submission, to accompany the Office of the National Coordinator's template for submitting data classes and data elements to version 2 of the USCDI.

Personal Background

I am the chair of the National Academies of Science, Engineering, and Medicine consensus panel on “Integration Social Care into the Delivery of Healthcare to Improve the Nation’s Health” (<https://jamanetwork.com/journals/jama/fullarticle/2752359>) and previously served on the committee to integrate social and behavioral determinants of health into the electronic health record (<https://www.nejm.org/doi/full/10.1056/NEJMp1413945>). Both multi-stakeholder panels have worked to develop the high level frameworks for the important work of enabling clinicians and healthcare systems to fully address the health needs of patients. As a physician myself caring for patients in the safety net setting, I know well the importance of these efforts in helping us better care for patients. As the Vice Dean for Population Health and Health Equity in the University of California, San Francisco School of Medicine, I can attest to how important concrete implementation plans, enabled by enlightened policies and regulation, are to moving this work forward. I am pleased to see the proposal of the Gravity Project and to provide my letter of support for your consideration.

USCDI Submission

The Gravity Project submits *two* alternative approaches for adding a new data class, *Social Determinants of Health*, to USCDI version 2. The approaches are intended to provide options for consideration by ONC for the structural organization of the new data class since each approach has strengths that should be carefully considered.

Submission 1: SDOH data class, organized by SDOH domains

The Gravity Project is submitting a new SDOH data class for inclusion in USCDI v2 that will contain functional domains organized to reflect diverse factors that affect health status. The taxonomy of submitted domains are described by *Food Insecurity, Housing Instability and Homelessness, Inadequate Housing, Transportation Insecurity, Financial Strain, Social Isolation, Stress, Interpersonal Violence, Education, Employment, and Veteran Status*. Additional domains beyond this list will be added in the future, but this list contains domains that the Gravity Project can support for USCDI v2. Each of these domains will contain a repeated set of elements with specific vocabularies for: Assessments (LOINC); Goals (LOINC); Problems/Health Concerns (ICD-10-CM (billing) and SNOMED-CT (clinical)); Interventions (SNOMED-CT and/or CPT/HCPCS); Outcomes (LOINC); and Consent. (See attachment 1 for an outline.) The approach also includes data elements supporting Consent, if and where needed, related to the use and sharing of SDOH data to and among relevant stakeholders.

This approach has the benefit of consistency *with* and logical evolution of the 2015 Edition Health IT certification criteria. While previously adopted certification criteria specified 8 domains and specific standards (Financial resource strain, Education, Stress, Depression, Physical activity, Alcohol use, Social connection and isolation, and Exposure to violence), the Gravity Project's submission would be an expansion of prior practice under a newly minted *class* for SDOH. In addition, the proposed changes broaden the scope of prior vocabularies that limited users to *assessment* of conditions, but *did not* specify a standard for other critical activities, including goals, health concerns, interventions, or outcomes. The addition of these

standards will enhance interoperability among users that are not only interested in measuring or recording the existence of a condition but documenting and initiating, including ordering, substantive interventions to improve patient health. Should ONC want to consider how these SDOH submissions would interact with the existing module in the 2015 Edition, we are ready and willing to contribute to this discussion.

Submission 2: SDOH data class, organized by SDOH activities in clinical care

The Gravity Project also submits a new SDOH data class for inclusion in USCDI v2 organized instead by data elements that reference SDOH activities and tools used by some providers in their current clinical care workflows. The data elements in the new SDOH data class, listed along with their appropriate vocabularies will be: Assessments – LOINC; Problems/Health Concerns – ICD-10-CM (billing) and SNOMED-CT (clinical); Goals – LOINC; Interventions – SNOMED-CT (clinical) and CPT/HCPCS (billing); Outcomes – LOINC; and Consent. Each element will contain a taxonomy of SDOH health status (code sets) that can be leveraged to describe conditions across multiple domains (e.g. Food Insecurity, Housing Instability and Homelessness, Inadequate Housing, Transportation Insecurity, Financial Strain, Social Isolation, Stress, Interpersonal Violence, Education, Employment, and Veteran Status). Organizing the SDOH data class by activities that reference the various relevant code panels and profiles for SDOH allows stakeholders to add SDOH domains as consensus is reached on each. (See attachment 2 for an outline.)

By including an externally maintained list of domains, activities and value sets, this approach can accommodate SDOH data domains as they mature and are added. As additional domains, vocabularies, and value sets are published, the hierarchy and nomenclature of the named data elements would remain consistent. The addition of these new standards will enhance interoperability among users and will reduce regulatory lag for updates to USCDI for SDOH domains.

We note that, at the time of submission on October 9, 2020, the Gravity Project will not have completed the full set of gap analysis and code set development, but we expect all to be resolved by the time ONC would make its decision in May-June, 2021, about the final definition of version 2. This tracks the approach ONC took with the social, psychological and behavioral data certification criterion in the 2015 Edition, where ONC noted 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.

Need and Maturity

The SDOH Data class is undergoing rapid development and iterative cycles of maturation due to the urgent need for standard methods to aid health care delivery to patients. Inclusion as a standardized SDOH data element in USCDI is a necessary step so the field can move forward, and stakeholders can properly plan and prepare for inclusion of these critical data in patient care.

The value of collecting and coding SDOH data for clinical care and other use cases, and the value of collecting and coding assessments, goals, health concerns, and interventions of SDOH

for clinical care, are well established in the literature.¹ They are also core expectations of the Federal Health IT Strategic Plans, both for 2015-2020, and the current draft for 2020-2025.² 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.³

In addition to the considered findings by the Institute of Medicine, 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.⁴ A study of EHR vendors with the largest market shares, by authors at HHS's Centers for Medicare and Medicaid Innovation and Office of the Assistant Secretary for Planning and Evaluation as well as NORC, finds the same.⁵ The wholesale

¹ 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).

² 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: Draft for Public Comment, p. 11 (Jan. 15, 2020) ("The shift to value-based care has resulted in new incentives . . . [that] place greater importance on addressing social determinants of health and patient health behaviors"), available at https://www.healthit.gov/sites/default/files/page/2020-01/2020-2025FederalHealthIT%20StrategicPlan_0.pdf.

³ 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.

⁴ 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>

⁵ 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

support among the Gravity Project's 1,200+ 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.

The Gravity Project

The Gravity Project is a public, nationwide Social Determinants Health Collaborative that includes diverse members across the health care continuum that have contributed to the development of practical and actionable use cases for SDOH. This group has and will continue to:

- Develop use cases to support documentation of specific social domains across screening, diagnosis, goal setting, and intervention activities within the EHR and related systems;
- Identify common data elements and their associated value sets to support the use cases;
- Identify the substantial gaps in current data elements and value sets, develop consensus-based recommendations to fill them, and submit them to the respective coding authorities;
- Develop a consensus-based set of recommendations on how to best capture and group these data elements for interoperable electronic exchange and aggregation;
- Create a HL7 Fast Health Interoperability Resource (FHIR) Implementation Guide based on the defined use cases and associated data sets.

This work has culminated in the detailed understanding that is articulated in the structured USCDI submission documents. In short, the two submissions presented are not a casual assemblage but a consensus view based on careful, detailed, holistic analysis of practical necessities of patient care and technical requirements of the EHR and related systems.

Whether ONC includes the SDOH data class and respective data elements defined, respectively, in *Submission 1* or *Submission 2*, the Gravity Project frames a consistent approach to defining data elements and supporting terminologies and value sets necessary to describe priority social domains (e.g. Food Insecurity, Housing Instability and Homelessness, Transportation Insecurity) across six core health care activities (Assessments, Problems/Health Concerns, Goals, Interventions, Outcomes, and Consent).

The matrix of use cases outlined will enable:

- Documentation of SDOH data in conjunction with the patient encounter;
- Documentation and tracking of SDOH related interventions to completion;
- Gathering and aggregating SDOH data for use beyond the point of care.

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/>.

Inclusion of elements are a crucial update that will provide necessary tools toward improved patient care and respond to a growing need for such tools due to structural changes to health care reimbursement models.

Conclusion

Thank you very much for the opportunity to provide these comments for consideration and possible inclusion in USCDI v2 update. Please feel free to contact me if I can provide additional details.

Sincerely,

A handwritten signature in black ink, appearing to read "Kirsten Bibbins-Domingo".

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