

May 6, 2021

Department of Health and Human Services, Office for Civil Rights
Attn: Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement NPRM, RIN 0945-AA00
Hubert H. Humphrey Building, Room 509
200 Independence Avenue, SW Washington, DC 20201

Dear Secretary Becerra,

The Center for Health Law and Policy Innovation of Harvard Law School (“CHLPI”) appreciates the opportunity to provide comments on proposed regulatory revisions to HIPAA in support of coordinated care. We write specifically in regard to the proposed creation of express regulatory permission for health care providers and health plans to share information with third parties providing health-related social services or other supportive services. As described herein, we support the goals of the proposed exception but have concerns about the proposal itself.

CHLPI advocates for reforms to improve the health of underserved populations, with a focus on the needs of low-income people living with chronic illnesses. We have an active portfolio dedicated to nurturing the integration of social determinants of health interventions into health care delivery and financing. A central aspect of this work involves analysis of and education on the application of health law and policy frameworks to exciting new innovations that make our health system more equitable, outcome-driven, and cost-effective. Challenges navigating HIPAA are often front-and-center in our conversations with health care system and community-based provider stakeholders interested in partnering to improve patient health and well-being.

CHLPI strives to respond to the need for HIPAA-related technical assistance through various efforts, including the publication, in partnership with Feeding America National Organization, of a comprehensive [resource for food banks](#) navigating HIPAA when partnering with health care organizations to address food insecurity. CHLPI also addresses patient privacy recommendations in our recent report, [Mainstreaming Produce Prescriptions: A Policy Strategy Report](#).

We would like to share three core findings of this body of work:

1. Activities to support health-related social needs are varied and evolving.

Essential to effectively supporting information sharing to coordinate services across the current clinical-community divide is an understanding that activities to support health-related social needs are varied and evolving. In the food and nutrition space, for example, CHLPI works with:

- Community-based organizations (CBOs) contracted by health plans to provide meals, produce, and other food-related benefits covered by private insurance, Medicaid, and Medicare plans to health plan members.
- CBOs that partner with hospitals and health centers to run an onsite food pantry for the health care entity’s patients.

- CBOs contracted by health care provider organizations to furnish food and nutrition supports to patients in a value-based enterprise as contemplated under the new anti-kickback statute patient engagement and support safe harbor.
- CBOs that manage a “produce prescription” program (a health intervention that provides produce at low or no cost to patients who are eligible due to health risk or diet-related diagnosis, lack access to nutritious foods, and are referred by a health care provider or health insurance plan).
- CBOs and social services agencies that conduct screening and support enrollment in critical health-related benefit programs such as the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) for eligible individuals.

Within and across each iteration are unique information needs, program goals, and partnership structures.

2. Uncertainty—not requirements to obtain patient authorization—is the most significant barrier to partnership.

Several questions regarding HIPAA commonly emerge amid the development of community-clinical partnerships: *Under what circumstances is patient authorization necessary and sufficient for a HIPAA-covered entity to share information with a CBO? Under what circumstances is a business associate relationship created? What is expected of a small, community organization that enters into a business associate arrangement? How might covered entities and CBOs partnering on an innovative intervention to address health-related social needs conduct critical program evaluation and research activities in a manner that does not implicate—or otherwise complies with—HIPAA? Under what circumstances might a community organization providing food and nutrition services be deemed a HIPAA-covered entity?*

In our experience, many HIPAA-covered entities refrain from sharing pertinent information with CBOs or impose unnecessary barriers to sharing information (such as requiring a business associate agreement) because the answers to these questions are unclear. Moreover, many CBOs struggle to understand and adapt to the requirements of HIPAA. As a result, meaningful partnerships to improve health outcomes, strengthen wraparound services, and support tailored, whole person care plans for individuals are regularly stymied.

3. Federal regulators could have a significant impact by disseminating information resources.

Taking into account the first two findings, the dissemination of information resources—detailed, specific guidance and associated tools for community-clinical partnerships navigating HIPAA—would have a significant positive impact. HHS currently offers an impressive range of resources, FAQs, Security Rule technical assistance materials, and model language for HIPAA-mandated agreements; however, these resources rarely target or address CBOs and social service providers

It is because of these core findings that, while we support the goals of the proposed exception, we believe the proposed exception itself falls short.

First, the proposal raises concerns regarding patient privacy. In codifying an existing interpretation relayed in guidance, the proposal seemingly places securing patient authorization and bypassing patient consent via HIPAA’s treatment provisions on equal footing. This should not be the case. Information sharing should, as a best practice and absent extenuating circumstances, be patient-driven—especially when many third-parties contemplated to receive information are not independently subject to obligations regarding information privacy.¹ In the NPRM, the Department asks whether there are any categories of entities that should be expressly *excluded* from the provision. The answer to this question is so highly personal and individualized—based on preferences, beliefs, social circumstances, and more—that it highlights the importance of patient control over those with whom their personal health information is shared. Blanket reliance on HIPAA’s treatment provision risks exacerbating vulnerabilities and mistrust in the health care system where, for example, a patient may be contacted at home by a third party regarding sensitive information without knowing how public that information is even within the patient’s household, a patient is contacted by a third party regarding services that they would ultimately have to pay for out-of-pocket, or a patient is contacted by faith-based community organizations with which they do not identify.

Second, the proposal does little to actually respond to or resolve the underlying uncertainties that plague community-clinical partnerships—i.e., the questions we set forth above. For example, the Department asserts in the NPRM that there are instances of disclosure that will require a business associate agreement because a third-party entity is providing services to or on behalf of a covered entity. Yet the Department does not articulate circumstances under which this relationship may arise. Similarly, the Department solicits comment on the extent to which CBOs are themselves HIPAA-covered entities. CBOs are increasingly grappling with questions about their status as a covered entity as they develop more medically-tailored services, adopt common health care sector terminology (consider, for example, mainstream references to produce vouchers as “produce prescriptions”), secure NPIs, and rely on electronic transactions to facilitate integration into health plan payment operations. HIPAA’s definition of health care provider is overwhelmingly broad, with interpretation potential that extends far past providers in traditional healing professions. Guidance from the Department on this matter is critical. Without additional clarity, essential aspects of many community-clinical partnerships will continue to be a source of confusion, engender resistance to care coordination, and erect barriers to supporting patients.

Should the Department nonetheless proceed with codifying the proposed exception, we offer the following considerations:

1. The Department should not specify eligible organizational entities in regulation text. Organizations supporting health-related social needs take many forms and go by many names. In the nutrition and food insecurity space, for example, a non-exhaustive list of essential providers includes essential providers include food banks, food pantries,

¹ While in some instances third-party recipients are also covered entities (e.g., many health care providers) and some third-parties are independently subject to obligations regarding information privacy (e.g., WIC agencies), this is not the case for all potential recipients.

organizations providing medically-tailored and medically-supportive foods, senior nutrition providers, breastfeeding providers, and organizations supporting SNAP and WIC enrollment. Care coordination between clinical and community providers requires maximum flexibility to adapt to individual patient needs and the infrastructure—available resources and the local providers of those resources—in different communities. Accordingly, attempts to specify eligible organizations in text would create health equity concerns. Sub-regulatory resources providing non-exhaustive examples and highlighting a diverse range of permitted disclosures would support clarity without inadvertently excluding others in regulatory text.

2. Requiring a covered entity to identify a patient’s social needs and/or the appropriate community provider in a treatment plan as a condition precedent to disclosure may add an important level of protection for patients. However, research highlights that health care providers continue to face numerous challenges screening patients for social needs including the ability to document and track information in electronic health records, sufficient time to complete a screening in the face of competing priorities, expertise, and the lack of compensation/financial resources.² While we support screening as a best practice, absent additional, complementary policy reforms to address barriers, some providers would be able to comply with the requirement more readily than others, further entrenching longstanding inequities in social determinants of health.

Again, we appreciate and share the Department’s commitment to including health-related social needs in its initiatives to improve care coordination; however, we do not believe the proposed rule will ultimately resolve the underlying barriers to community-clinical partnerships. We also acknowledge the possibility that providing additional clarification advocated for in our letter may be outside the scope of this particular NPRM. In that case, we urge the Department to quickly disseminate guidance materials that will aid health care providers, CBOs, and social services agencies navigate HIPAA in partnerships to improve patient health.

We would be happy to work with HHS on this issue, to elaborate on our comments in this letter, and to bring additional resources to life.

Sincerely

Sarah Downer

Sarah Downer, JD
Associate Director, Whole Person Care
Clinical Instructor

on behalf of

The Center for Health Law and Policy Innovation of Harvard Law School
www.chlpi.org

² See, e.g., “Screening for Social Needs: Guiding Care Teams to Engage Patients,” American Hospital Association, June 2019, <https://www.aha.org/system/files/media/file/2019/09/screening-for-social-needs-tool-value-initiative-rev-9-26-2019.pdf>.