January 11, 2023

Melanie Fontes Rainer
Director
Office for Civil Rights
Department of Health and Human Services
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW Washington, DC 20201

Dear Director Fontes Rainer:

As participants in the recent 2022 White House Conference on Hunger, Nutrition, and Health, the Center for Health Law and Policy Innovation of Harvard Law School (CHLP) applauds the critical commitments made by the Department of Health and Human Services ("HHS" or the "Department"). **Meaningful progress towards the goal of better integrating nutrition and health will require engagement by bodies across the Department. We write today to raise up a pivotal role of the HHS Office for Civil Rights ("OCR"): guidance on the implications and applications of patient privacy law to nutrition programming.**

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 Food is Medicine 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 on navigating HIPAA when partnering with health care organizations to address food insecurity. We worked with the GusNIP Nutrition Incentive Program Training, Technical Assistance, Evaluation, and Information Center (NTAE) on a series of issue briefs to fill the need for information, education, and creative solutions so that produce prescription project grantees are empowered to navigate privacy obligations. We have also developed various resources for health care organizations, including a resource on text message campaigns to support Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) participation among eligible individuals.

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. Organizations take many forms and go by many names. In the food and nutrition space, for example, CHLPI works with:

- Community-based organizations (CBOs) contracted by health plans to provide medically-tailored meals[1] covered by private insurance, Medicaid, and Medicare plans to health plan members.
- CBOs that manage nutritional assessment and the design of medically-tailored meals that are then prepared and delivered to patients by a network of local food pantries.
- CBOs that manage a produce prescription program.[2]
- 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 and social services agencies that conduct screening and support enrollment in critical health-related benefit programs such as WIC.

Within and across each iteration are unique information needs, program goals, collaborative activities with HIPAA-covered entity plans and providers, and partnership structures.

2. Uncertainty is a significant barrier to partnership.

Several questions regarding HIPAA commonly emerge amid the development of community-clinical partnerships. These include:

- Under what circumstances is patient authorization necessary and sufficient for a HIPAA-covered entity to share information with a CBO?
- Under what circumstances might a community organization providing food and nutrition services be deemed a HIPAA-covered entity? 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.
- Under what circumstances is the CBO providing food support doing so for or on behalf of a HIPAA-covered entity?
- What is expected of community organizations in terms of compliance?
- 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?

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[1] We are using the term "medically-tailored meals" to refer to fully prepared meals designed by a Registered Dietitian Nutritionist to address an individual's medical diagnosis, symptoms, allergies, and medication side effects.

[2] We are using the term "produce prescription" to refer to 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.

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 where a business associate relationship does not seem to exist) because the answers to these questions are unclear.

Moreover, many CBOs—especially smaller CBOs and CBOs beginning their foray into Food is Medicine programming—struggle to understand and adapt to the requirements of HIPAA. Health care is a new and complex regulatory landscape for them; the investments in legal and other compliance support needed to situate one's program are costly. As a result, meaningful partnerships to improve health outcomes, strengthen wraparound services, and support tailored plans to address nutrition and food insecurity while also protecting patient privacy are regularly stymied.

This is a glaring equity issue. We have accounts of how challenges understanding HIPAA impede Food is Medicine programming in, for example, a more rural community where the local, volunteer-run food pantry looks to fill otherwise unmet need.

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, education and training materials, and model language for HIPAA-mandated agreements; however, these resources rarely target or address CBOs and social service providers.

We recognize that OCR may be considering still the proposed rule from 2021, which would codify application of the treatment exception to social service organizations. We commented at the time 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.[3] 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-

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[3] 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.

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 asserted 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 did not articulate circumstances under which this relationship may arise.

We believe that a more responsive solution to the barriers that HIPAA creates for care coordination with food insecurity and nutrition programming would be the creation of sub-regulatory resources that speak directly to these initiatives. And for the reasons described throughout this letter, such resources must recognize that Food is Medicine interventions adapt to individual patient needs and the infrastructure—available resources and the local providers of those resources—in different communities.

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We urge OCR to play its part in propelling Food is Medicine programs by better enabling both meaningful and legally-compliant patient privacy. We would be happy to work with OCR on this issue, to elaborate on our comments in this letter, and to bring additional resources to life.

Sincerely

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on behalf of

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CC:
Secretary Xavier Becerra