



March 2nd, 2021

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

Re: Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement NPRM, RIN 0945-AA00

To Whom it May Concern,

Thank you for the opportunity to provide comments on the Department of Health and Human Services' proposed rule to modify the HIPAA Privacy Rule ([RIN 0945-AA00](#)). I'm writing on behalf of Nourish California, a statewide nonprofit organization working to shape the programs and policies that should connect—but sometimes stand between—Californians and the food they need to thrive. Nourish California engages in advocacy to end hunger, disrupt poverty, and to ensure that all Californians are well nourished. We are writing to express support for key provisions contained in the proposed rule and outlined below that will improve patient's access to food and to offer our insights from relevant work we have led within California to improve information sharing between health care providers and providers of nutrition and food services.

Background

Over the last year, Nourish California in partnership with the California Office of Health Information Integrity (CalOHII) and the California Primary Care Association began a rigorous stakeholder feedback process to help inform the development of a new version of [California's State Health Information Guidance](#) (SHIG). The SHIG is a set of materials that provide authoritative, but non-binding guidance from the state of California on federal and state laws that affect disclosure and sharing of health information. The new version of the SHIG will provide clarification of federal and state law and illustrate a path to protecting patient privacy while providing for the sharing of patient information — with the goal of connecting patients to food and nutrition assistance. As part of the stakeholder feedback process, nearly two dozen stakeholder interviews were conducted, eighty-one organizations were surveyed, and eight virtual convenings were held with health care providers, health plans, nutrition program administrators, county and state government officials, public health departments, community-based organizations, and other stakeholders. From this work, several challenges limiting information sharing were identified:

- **A lack of clarity on what data can be shared between health care providers, health plans and third parties involved in providing nutrition supportive services**, including social services agencies, CalFresh outreach contractors, food banks, local WIC agencies, community based organizations, and public health agencies. This lack of clarity included not understanding when personally identifiable information versus protected health information could be shared, and when a patient authorization is required. Stakeholders reported that clear guidance from regulators on what type of information could be shared, with whom it can be shared, and when authorizations and business associates agreements are required would be helpful.
- **Burden of privacy compliance on community-based organizations.** Community-based organizations reported instances in which they were required by health care providers to enter into Business Associates Agreements (BAA) and to fully comply with HIPAA to share information. Some reported the legal costs associated with entering into BAAs and complying with HIPAA was prohibitive for information sharing and several stakeholders reported that they were unable to accept the financial liability of complying with HIPAA. We also learned of some instances in which community-based organizations would enter into such agreements without understanding the legal and potential financial ramifications. In many cases, BAAs and the requirement to comply with HIPAA prevented organizations from sharing information entirely about patients who otherwise may have been able to access food and nutrition services provided by food banks, senior nutrition providers, social services, and WIC agencies among other providers of food and nutrition services. These are especially unfortunate consequences in instances where the parties do not have a business associate relationship.
- **Inconsistency in information sharing processes.** There did not appear to be any standard way in which health care providers or health plans treated information sharing with social services agencies, CalFresh outreach contractors, local WIC agencies, community-based organizations, and public health agencies related to nutrition and food. For example, one community-based provider who offered medically-tailored meals reported that some medicaid managed care health plans required them to enter into BAAs and comply with HIPAA, while others did not.
- **Obstacles to enrolling likely-eligible Medicaid enrollees into government nutrition programs.** Health plans and health care providers are increasingly supporting population-based activities associated with enrolling likely-eligible, but not yet enrolled patients into SNAP and WIC. To be effective, such efforts require matching patient information with program enrollment data. Although such efforts have been found to be effective, we learned there is inconsistency in interpretation of information sharing rules governing government health plans, federal nutrition programs, and HIPAA.

CalOHII has begun developing state health information guidance to address some of the challenges that arose from the stakeholder feedback process and an advisory group has been formed to vet the guidance.

The guidance is set to be released in the spring of 2021. Many of the root challenges could be remedied with appropriate guidance from the Department and similar improvements to California’s privacy laws.

Recommendations

- **We support the proposal to permit covered entities to disclose PHI to third parties that are not health care providers or business associates for the purposes of care coordination and case management for individuals.** Third parties who directly provide food or coordinate a patients’ enrollment into nutrition programs often require the disclosure of protected health information (PHI) to provide treatment. For example, PHI is necessary to: connect cardiac patients to medically-tailored meals; adjust home-delivered meals for older adults who have hypertension; provide medically-supportive foods for individuals living with diabetes; and tailor emergency food for individuals who are homeless and have a limited ability to cook or store certain foods. There are many, many more examples. Express regulatory language specifying that PHI can be shared with third parties who are engaged in care coordination and case management for individuals will remove the widespread perception that such sharing is not permitted and encourage greater care coordination. These third-party treatment providers that are not business associates of covered entities should also not be forced into business associate arrangements. This leads to more limited instances of information sharing even though it is permitted under HIPAA. We believe the Department has struck the right balance of protecting patient privacy while encouraging greater information sharing by limiting the situations in which PHI can be disclosed to care coordination and case management of individuals.
- **In addition to the recipients identified in the proposed rule, we encourage the Department to specify the types of organizational entities to be included as recipients of PHI in regulatory text.** As explained above, there are many instances in which PHI is required for nutrition-related care coordination and case management. However, there is often wide variance in the interpretation of to whom PHI can be shared without a patient’s authorization. We anticipate that interpretation of what constitutes a “social services agency, community-based organization, or HCBS provider” may be similarly varied. Health care providers and health plans would benefit from greater regulatory clarity that PHI can be shared with the following entities, without a patient authorization for individual care coordination and case management: local WIC agencies, food banks, organizations providing medically-tailored and medically-supportive foods, providers of breastfeeding education or support, and providers of home-delivered or congregate meals. Each of these entities provide individual care coordination and case management that may require PHI to be disclosed. We fear health care providers and health plans will not feel comfortable sharing the information necessary to connect patients to nutrition support without specificity that these specific entities can be recipients of PHI without a patient’s authorization.

- **We encourage the Department to clarify when Business Associates Agreements and authorizations are or are not required.** It is our experience that many health plans and providers default to requiring a BAA. We fear that this will continue without greater clarity on when BAAs are or are not required. The proposed rule recognizes that there are some instances of disclosures with community based organizations that do require a BAA, including when the disclosure is made “on behalf of” the disclosing covered entity. Additional clarity is needed to prevent the practice of requiring entities to enter into BAAs even when they are not required by law. For example, is the analysis of whether a BAA is warranted impacted by the fact that a third-party providing nutrition-related interventions to individuals also receives payment from a covered entity? What about when the parties are working together to conduct research and evaluation on a food-related intervention?
- **We encourage the Department to broaden the situations in which PHI can be shared by health plans and health care providers for population-based activities to include establishing eligibility for or enrollment into other government programs that provide public benefits.** To support the health of their patients, health plans and health care providers are increasingly supporting population-based activities associated with enrolling likely-eligible, but not yet enrolled patients into SNAP and WIC. To be effective, such targeted outreach efforts may require protected health information about the individual to be shared with other government programs. For example, if a plan would like to conduct targeted outreach to newly pregnant mothers enrolled on Medicaid who are likely eligible, but not yet enrolled on WIC, protected health information may need to be shared. Historically HIPAA has recognized that information sharing with public entities is a little different. The HIPAA Privacy Rule permits government health plans to disclose protected health information relating to a patient’s enrollment in the health plan to other agencies that administer government programs providing public benefits if the sharing of such information is expressly authorized by statute or regulation (45 CFR 164.512(k)(6)(i)). The federal Medicaid confidential data standard appears to authorize the disclosure of information concerning Medicaid recipients enrollment when used for the purpose of providing services for beneficiaries (42 C.F.R. 431.302). However, health plans who have attempted to share information with local WIC agencies, social service agencies, and SNAP outreach organizations for the purposes of helping Medicaid or Medicare enrollees enroll into these programs have been denied by state administrators out of privacy concerns. This unfortunately results in less patients having access to supportive services that they did not know they were eligible for or that require complicated and overly burdensome application processes for which they need additional support to enroll. We encourage the Department to explore updated guidance that expressly permits sharing PHI by public sector health care entities with other state and local government programs for the purposes of helping patients establish eligibility for or enroll into government programs (e.g., SNAP and WIC). We believe this limited instance of permitting PHI disclosure would significantly benefit a population of

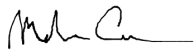
individuals who face significant obstacles to nutrition access, in particular benefiting older adults, individuals with disabilities, and individuals with limited English proficiency.

- **We encourage the Department to ensure the updated guidance supports enrollment and retention in WIC, a federal program which relies on the disclosure of protected health information by health care providers:** To assist local WIC agencies in certifying patients who may be eligible to participate in the WIC Program, health care providers provide specific information (including protected health information such as hemoglobin and hematocrit lab values, proof of pregnancy, and assessments of nutritional risk) about their patients to local WIC agencies. Health care providers also share information about which foods or formula may be provided as part of a participant's food benefits, information necessary to tailor food packages based on allergies or health conditions, information necessary to provide breastfeeding assistance/education, and information necessary to provide medically necessary therapeutic formula for infant participants. Some health care providers also provide birth notifications to certify newborns or newly pregnant women for WIC. We believe such disclosures of protected health information should be permitted without a patient's express authorization. It is unclear however whether some of these activities would be "population-based" and therefore require the minimum necessary standard for disclosures. Additional guidance may be helpful to help health care providers make decisions about what information can be shared with local WIC agencies via access within Electronic Health Records, access within Health Information Exchanges, via secure data transfers, etc. The United States Department of Agriculture could serve as a helpful partner to the Department to identify guidance that supports information sharing and associated enrollment and retention in WIC.
- **We support the proposal to modify provisions on individuals' right of access to PHI to no later than 15 calendar days.** Individuals require access to certain PHI from their health care provider in order to enroll in some federal nutrition programs. For example, PHI from health care providers may be needed to show proof of pregnancy for enrollment in WIC, to assist CalFresh enrollment workers in verifying medical conditions for SNAP work requirement exemptions, and to modify meals served through the Child and Adult Care Food program. Without timely receipt of such information, patients risk food insecurity. California is one of at least eight states that have statutory requirements to provide patients with copies of their health records in less time than the Privacy Rule's current 30-day limits. We believe California's success with a shorter time limit demonstrates the ability of covered entities to comply with similar rules.
- **We encourage the Department to expand the list specifying when electronic PHI (ePHI) must be provided to the individual at no charge.** As noted above, there are many situations in which individuals may require ePHI for enrollment in federal nutrition programs and, in some cases, to receive emergency food assistance tailored to their nutritional needs. We encourage the department to specify that in cases where a patient requires ePHI for enrollment into a federal nutrition program that the ePHI must be provided at no charge. We also encourage the

Department to specify that ePHI must be provided at no charge when necessary for accessing emergency food assistance.

Thank you for the opportunity to comment. If you have any questions regarding the information shared, I would be happy to share additional information.

Sincerely,



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