



**Nutrition  
Incentive Hub**

CREATED BY GUSNIP NTAE CENTER



## **Business Associate Arrangements**

HIPAA Issue Brief 4 of 5

**Resource Created by:** Center for Health Law and Policy  
Innovation of Harvard Law School

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## About this Brief and the Series

This resource was created for the GusNIP Nutrition Incentive Program Training, Technical Assistance, Evaluation, and Information Center (NTAE) by the Center for Health Law and Policy Innovation of Harvard Law School. It is part of a series of briefs intended to educate GusNIP Produce Prescription grantees on patient privacy laws; these briefs should not be considered legal advice. For specific legal questions, consult an attorney.

In this fourth brief of the series, readers will learn more about Business Associate Arrangements—a common but resource intensive approach to structuring information sharing from health care providers to third parties.

The other briefs in this series cover the following foundational HIPAA compliance topics relevant to Produce Prescription grantees:

- **Introduction to Patient Privacy Laws for Produce Prescription Grantees (Issue Brief 1)**  
This brief discusses patient privacy laws for Produce Prescription grantees.
- **Developing HIPAA-Compliant Approaches to Information Sharing (Issue Brief 2)**  
This brief discusses different approaches to structuring the collection and dissemination of participant information in a manner compliant with HIPAA.
- **HIPAA, Program Evaluation, and Research (Issue Brief 3)**  
This brief discusses approaches to navigating HIPAA for programmatic evaluation and research.
- **Developing a Privacy Program (Issue Brief 5)**  
This brief reviews key technological and other considerations for developing a privacy program.

A Business Associate is a person or entity that performs certain functions on behalf of a health care provider or other entity subject to HIPAA (a “Covered Entity”) that involve the creation, receipt, maintenance, or transmission of PHI. HIPAA permits Covered Entities to disclose PHI to Business Associates if the parties enter into a Business Associate Agreement (“BAA”).

A BAA contains satisfactory assurances that the Business Associate will (1) limit its uses and disclosures of PHI to only those purposes for which it was engaged, (2) help the Covered Entity comply with its duties under HIPAA, and (3) safeguard PHI. The BAA also sets forth the HIPAA-related rights and responsibilities of each parties.<sup>1</sup> HIPAA requires that all Covered Entities and their Business Associates sign written BAAs.<sup>2</sup>

### Business Associate Agreements

Business Associate Agreements are contracts between a Covered Entity and its Business Associates. These are required under HIPAA in order to allow for the disclosure of PHI by the Covered Entity to the Business Associate for the uses specified in the agreement. A grantee that signs a Business Associate Agreement agrees to take on all of the obligations described in the Agreement and to comply with all other applicable provisions of HIPAA.

**In general, GusNIP Produce Prescription grantees are *unlikely* to meet the definition of a Business Associate, as they are not performing activities on behalf of Covered Entities that involve the transmission of PHI.**

However, some grantees may have an already established relationship working “on behalf of” their health care provider partner or may be planning collaborations with their health care provider partner that could cause them to be Business Associates. For example, a grantee that is also contracted to provide, on behalf of a Covered Entity, population health services such as regular nutrition education and programming to the Covered Entity’s patients living with or at risk for a diet-related chronic illness may be a Business Associate.<sup>3</sup>



Health care providers are often eager to enter into a BAA with any third party with which they share information, such as Produce Prescription grantees, even when HIPAA may not require it. This preference may be motivated by an abundance of caution in interpreting the law, administrative simplification, and/or other factors.

It is important to note that Business Associates are directly liable under HIPAA and subject to civil and criminal penalties for uses or disclosures of PHI that are not authorized by the BAA or required by law. As these arrangements require significant investment in HIPAA compliance and expose grantees to compliance risk and possible liability, grantees should be realistic about the tasks and responsibilities under HIPAA they have the capacity to incur before becoming a Business Associate.



### **Before signing a BAA, GusNIP Produce Prescription grantees should:**

- Work with health care provider partners to consider the feasibility of alternative approaches to structuring information sharing, such as through written Authorizations from participants or by sharing information under the scope of the Treatment Exception. (*For more information, see the second brief in this series: Developing HIPAA-Compliant Approaches to Information Sharing.*)
- Read every part of the Business Associate Agreement carefully and ask for clarification as may be necessary.
- Conduct a realistic assessment of whether the grantee is able to meet the responsibilities and obligations described in the contract.
- Explore whether and how health care provider partners are able to support compliance with contract obligations. Common examples of resources provided by a health care partner include a HIPAA-compliant portal for storing and transmitting information, HIPAA-compliant technology and security support, adoption of privacy and security policies and procedures, HIPAA training/training resources, and easing liability insurance requirements.
- Consult an attorney. Pro bono legal help from local law firms that are experienced in HIPAA may be an option.

## References

- <sup>1</sup> U.S. Dep't of Health & Human Servs., *Business Associates*, HHS.GOV, <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/index.html> (last visited Apr. 22, 2021); *see also* 45 C.F.R. 164.504(e).
- <sup>2</sup> U.S. Dep't of Health & Human Servs., *Business Associates*, HHS.GOV, <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/index.html> (last visited Apr. 22, 2021).
- <sup>3</sup> *See* U.S. DEP'T OF HEALTH AND HUMAN SERVS. ET AL., *Permitted Uses and Disclosures: Exchange for Health Care Operations* (2016), [https://www.healthit.gov/sites/default/files/exchange\\_health\\_care\\_ops.pdf](https://www.healthit.gov/sites/default/files/exchange_health_care_ops.pdf).

## About

### Acknowledgments

The Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) advocates for health and food justice, with a focus on the needs of systemically marginalized individuals. CHLPI works with a range of stakeholders to expand access to high-quality health care and nutritious, affordable food; to reduce health and food-related disparities; and to promote more equitable and sustainable health care and food systems. CHLPI's Health Law Lab advances health care system efforts to address social determinants of health and health-related social needs, improve health equity, and mitigate health disparities.

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### The Nutrition Incentive Hub

The Nutrition Incentive Program Training, Technical Assistance, Evaluation, and Information (NTAE) Center is led by the Gretchen Swanson Center for Nutrition. In partnership with Fair Food Network, they created the Nutrition Incentive Hub, a coalition of partners to support this work. These partners are practitioners, retail experts, researchers, and evaluators from across the country bringing decades of experience and leadership in technical assistance, training, reporting, and evaluation. The Nutrition Incentive Hub is dedicated to building a community of practice to maximize program impact and ensure that all Americans have access to the healthy foods they need.

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