



**Nutrition
Incentive Hub**

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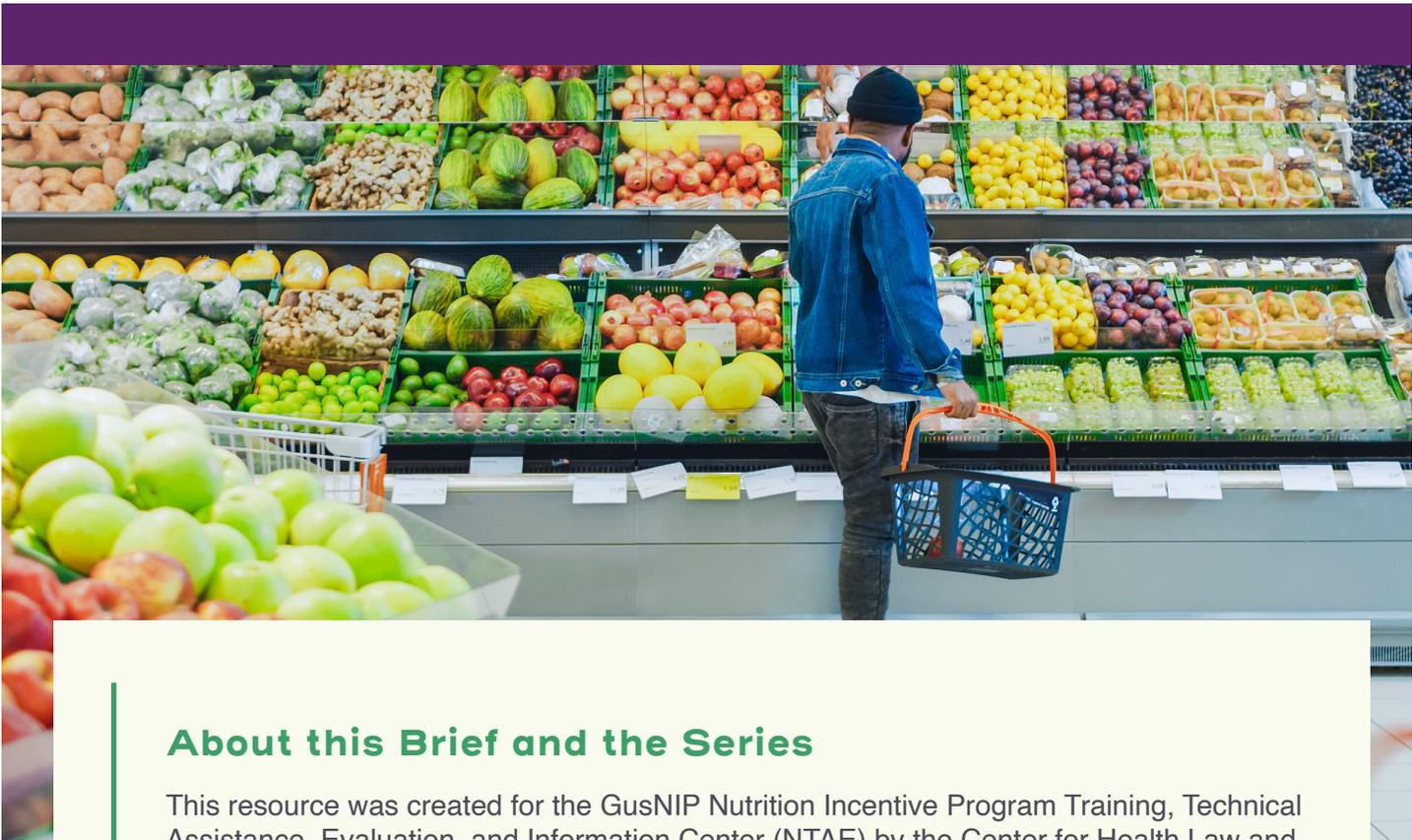
Introduction to Patient Privacy Laws for Produce Prescription Grantees

HIPAA Issue Brief 1 of 5

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

January 2022

This work is supported by Gus Schumacher Nutrition Incentive Program grant no. 2019-70030-30415/project accession no. 1020863 from the USDA National Institute of Food and Agriculture.



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 first brief of the series, readers will find an introduction to patient privacy laws for Produce Prescription grantees.

The other briefs in this series cover the following foundational HIPAA compliance topics relevant to 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.
- **Business Associate Arrangements (Issue Brief 4)**
This brief provides additional information on Business Associates and Business Associate Arrangements—a common but resource intensive approach to structuring information sharing from health care providers to third parties.
- **Developing a Privacy Program (Issue Brief 5)**
This brief reviews key technological and other considerations for developing a privacy program.



Given the nature of Produce Prescription projects—at the intersection of health care and social services delivery—Gus Schumacher Nutrition Incentive Program (GusNIP) Produce Prescription grantees may want to access, use, and share participant information protected under federal and/or state patient privacy laws.

Grantees should know about these laws because:

1. patient privacy laws impact *what information* a health care provider partner can share with other parties, such as grantees, and *how* health care provider partners can share information with those other parties;¹
2. grantee organizations may have legal obligations under patient privacy laws depending on *what* information grantees may be exposed to over the course of their work as well as *the circumstances* under which grantees gain access to participant information;² and
3. patient privacy laws can serve as helpful models for grantees looking to build information privacy into their operations, even when it is not legally required.

GusNIP Produce Prescriptions Grants: At the Intersection of Health Care and Social Services

GusNIP Produce Prescription grants are intended for groups developing county, multi-county, and/or state-wide produce prescription projects. The primary purpose of these grants is to implement Produce Prescription projects that aim to (1) improve dietary intake through increased purchase and consumption of fruits and vegetables; (2) decrease individual and household food insecurity; and (3) decrease health care use and associated costs. GusNIP produce prescription grantees are required to evaluate their projects based on these primary aims. Grantees typically partner with one or more health care entities to carry out project activities.

Grantees access, use, and share participant information for project activities in a range of ways. For example, some grantees only collect information directly from participants—the role of the health care provider partner is limited to identifying eligible participants and making referrals for the produce prescription. Some grantees use health information that a health care partner has collected but rely on a third party (e.g., a research institution) to handle that information. Other grantees have access to patient electronic health records or EHRs (i.e., electronic medical records or EMRs). Given the variety of approaches grantees may take, the obligations of grantees under patient privacy laws have the potential to vary widely.

Federal Law: HIPAA

The major federal patient privacy laws are the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, and associated implementing regulations (referred to collectively as “HIPAA”).³ Grantees will encounter HIPAA and its obligations if their activities involve the use, disclosure, and/or receipt of patient information that is protected under HIPAA.

This section introduces common terms and key provisions of HIPAA in place to protect patient privacy.

What information is protected under HIPAA?

Protected Health Information. HIPAA protections apply to a particular subset of information: health information created, used, or maintained by an organization subject to HIPAA requirements in any medium (e.g., on paper, electronically, orally) that can reasonably be tied back to an individual.⁴ This information is called Protected Health Information or PHI. HIPAA lists specific types of identifiers—categories of information—that each comprise PHI when paired with information about an individual’s physical or mental health, the provision of health care to an individual, or future payment for the provision of health care to an individual.⁵ A complete list of identifiers is provided under “HIPAA Identifiers” in the HIPAA identifiers sidebar.

Who is subject to HIPAA?

Covered Entities. Covered Entities are specific categories of individuals or organizations subject to HIPAA requirements.⁶ Doctors, community health centers, hospitals, and other health care providers that transmit PHI electronically for purposes regulated under HIPAA, as well as health plans, are Covered Entities.⁷

Most—if not all—health care provider partners involved in a Produce Prescription grant are Covered Entities. While HIPAA’s definition of health care provider is very broad (including organizations that provide services or supplies related to the health of an individual), other grantees do not typically transmit health information electronically for a

HIPAA Identifiers

The following types of information are considered elements of information that make it identifiable to an individual:

- Names
- Geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, etc.
- Telephone numbers
- Fax numbers
- Email addresses
- Social Security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers
- Device identifiers and serial numbers
- Web URLs
- IP addresses
- Biometric identifiers, including finger and voice prints
- Photographic images
- Any other unique identifying number, characteristic, or code

purpose covered under HIPAA in connection with their Produce Prescription grant (e.g., to submit a claim for payment to a health insurer, or to confirm a person’s eligibility for a service under their health care plan). As a result, these grantees are not generally Covered Entities.

Business Associates. Business Associates are individuals or organizations that access PHI in order to provide services to or on behalf of a Covered Entity.⁸ For example, a Business Associate relationship may be established when a Covered Entity hires a company to run monthly nutritional counseling sessions for patients who have diabetes or pre-diabetes on the Covered Entity's behalf.⁹

In general, Produce Prescription grantees are unlikely to meet the definition of a Business Associate in connection with their Produce Prescription grant because they are not providing services on behalf of their health care provider partner. 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.

What does HIPAA require?

HIPAA is a complicated area of law, but, at their core, requirements are designed to protect the privacy and security of patient health information.¹⁰ The following is a high-level way of thinking about key HIPAA provisions.

Privacy Rule. HIPAA's Privacy Rule defines and limits permitted uses and disclosures—the circumstances in which a Covered Entity and their Business Associates may use or disclose an individual's PHI.¹¹ The Privacy Rule balances patient privacy against the importance and need for certain uses of health information.¹² *While patients can always authorize the use or disclosure of their own PHI, the Rule governs when HIPAA-regulated entities are permitted or required to disclose or use PHI without patient authorization.*¹³ Situations encompassed under the Rule include, but are not limited to, patient treatment and the provision of health-related services, payment for services, health care operations, certain public health activities, and research.¹⁴

Health care providers are responsible for ensuring that disclosures of PHI to third parties fall into a type of permitted disclosure.

Security Rule. PHI that is stored electronically (electronic PHI or ePHI) is additionally subject to HIPAA's Security Rule.¹⁵ Security Rule standards require a number of administrative, technology-based, and physical safeguards to ensure the security, confidentiality, and integrity of ePHI.¹⁶

Health care providers typically have policies and procedures that dictate how they share PHI with third parties in a manner that safeguards the security, confidentiality, and integrity of the information (e.g., via encrypted messaging or a secure platform).

Minimum Necessary Standard. Disclosures of PHI—even when permitted under HIPAA—are generally subject to a minimum necessary standard.¹⁷ Covered Entities and their Business Associates must make “reasonable efforts” to ensure that requests, uses, and disclosures of PHI are limited to the minimum amount necessary to achieve the purpose of a particular disclosure, request, or use.¹⁸

Health care providers are responsible for determining the minimum amount of information necessary when sharing PHI. This may impact what information a health care provider partner is willing to share with other organizations involved in a Produce Prescription grant.

State Law and Patient Privacy Protections

HIPAA provides minimum standards for protecting patient privacy and limiting disclosures of PHI.¹⁹ Grantees may have additional responsibilities for handling patient information under state law.²⁰ This means that grantees must also comply with any applicable state laws that are more protective of patient information than HIPAA.

References

- ¹See, e.g., 45 C.F.R. §§ 160, 164(A), 164(E).
- ²U.S. DEP'T OF HEALTH & HUMAN SERVS., *Summary of the HIPAA Privacy Rule* (2003), <https://www.hhs.gov/sites/default/files/privacysummary.pdf>.
- ³These regulations are the Privacy Rule, the Security Rule, the Enforcement Rule, and the Final Omnibus Rule. See U.S. Dep't of Health & Human Servs., *HIPAA for Professionals*, HHS.GOV, <https://www.hhs.gov/hipaa/for-professionals/index.html> (last visited Apr. 1, 2021).
- ⁴45 C.F.R. § 160.103.
- ⁵45 C.F.R. § 160.103; 45 C.F.R. § 164.514(b)(2)(i).
- ⁶45 C.F.R. § 106.103.
- ⁷45 C.F.R. § 106.103.
- ⁸45 C.F.R. § 106.103; see 45 C.F.R. § 164.502(3); 45 C.F.R. § 164.504(e); 45 C.F.R. § 164.532(d),(e).
- ⁹See 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.
- ¹⁰See U.S. Dep't of Health & Human Servs., *HIPAA for Professionals*, HHS.GOV, <https://www.hhs.gov/hipaa/for-professionals/index.html> (last visited Apr. 1, 2021).
- ¹¹45 C.F.R. § 160; 45 C.F.R. §164(A); 45 C.F.R. § 164(E).
- ¹²See U.S. DEP'T OF HEALTH & HUMAN SERVS., *Summary of the HIPAA Privacy Rule* (2003), <https://www.hhs.gov/sites/default/files/privacysummary.pdf>.
- ¹³See 45 C.F.R. § 164.502; 45 C.F.R. § 164.524.
- ¹⁴See U.S. DEP'T OF HEALTH & HUMAN SERVS., *Summary of the HIPAA Privacy Rule* (2003), <https://www.hhs.gov/sites/default/files/privacysummary.pdf>.
- ¹⁵45 C.F.R. §§ 164.302-164.318.
- ¹⁶U.S. Dep't of Health & Human Servs., *Summary of the HIPAA Security Rule*, HHS.GOV, <https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html> (last visited Apr. 1, 2021).
- ¹⁷45 C.F.R. § 164.502(b).
- ¹⁸45 C.F.R. § 164.502(b).
- ¹⁹See Off. Of Nat'l Coordinator for Health Info. Tech., *HIPAA versus State Laws*, HEALTHIT.GOV, <https://www.healthit.gov/topic/hipaa-versus-state-laws> (last visited Apr. 1, 2021).
- ²⁰See Off. Of Nat'l Coordinator for Health Info. Tech., *HIPAA versus State Laws*, HEALTHIT.GOV, <https://www.healthit.gov/topic/hipaa-versus-state-laws> (last visited Apr. 1, 2021).

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.

GusNIP NTAE staff and University of California San Francisco consultants reviewed and edited the briefs for alignment with GusNIP goals and activities.

Suggested Citation

Landauer, R. and Downer, S. (2022, January). *HIPAA Issue Brief 1 - Introduction to Patient Privacy Laws for Produce Prescription Grantees*. GusNIP NTAE Center, Nutrition Incentive Hub. <https://www.nutritionincentivehub.org>

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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.

This work is supported by Gus Schumacher Nutrition Incentive Grant Program (GusNIP) Nutrition Incentive Program Training, Technical Assistance, Evaluation, and Information Center (NTAE) [Grant no. 2019-70030-30415/project accession no. 1020863 from the United States Department of Agriculture (USDA) National Institute of Food and Agriculture]. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the view of USDA.