



**Nutrition
Incentive Hub**

CREATED BY GUSNIP NTAE CENTER



Developing HIPAA-Compliant Approaches to Information Sharing

HIPAA Issue Brief 2 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 second brief of the series, grantees will learn about different approaches to structuring how they collect and share participant information in a manner compliant with HIPAA.

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.
- **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.

All GusNIP Produce Prescription grantees are required to collect a [participant-level survey](#), in addition to other grantee- and firm-level data. Produce Prescription grantees may also choose to collect other personal and health information related to objectives in their project narrative. There are a variety of approaches GusNIP Produce Prescription grantees may take when it comes to collecting and using participant information for day-to-day operations and for reporting and evaluation activities.

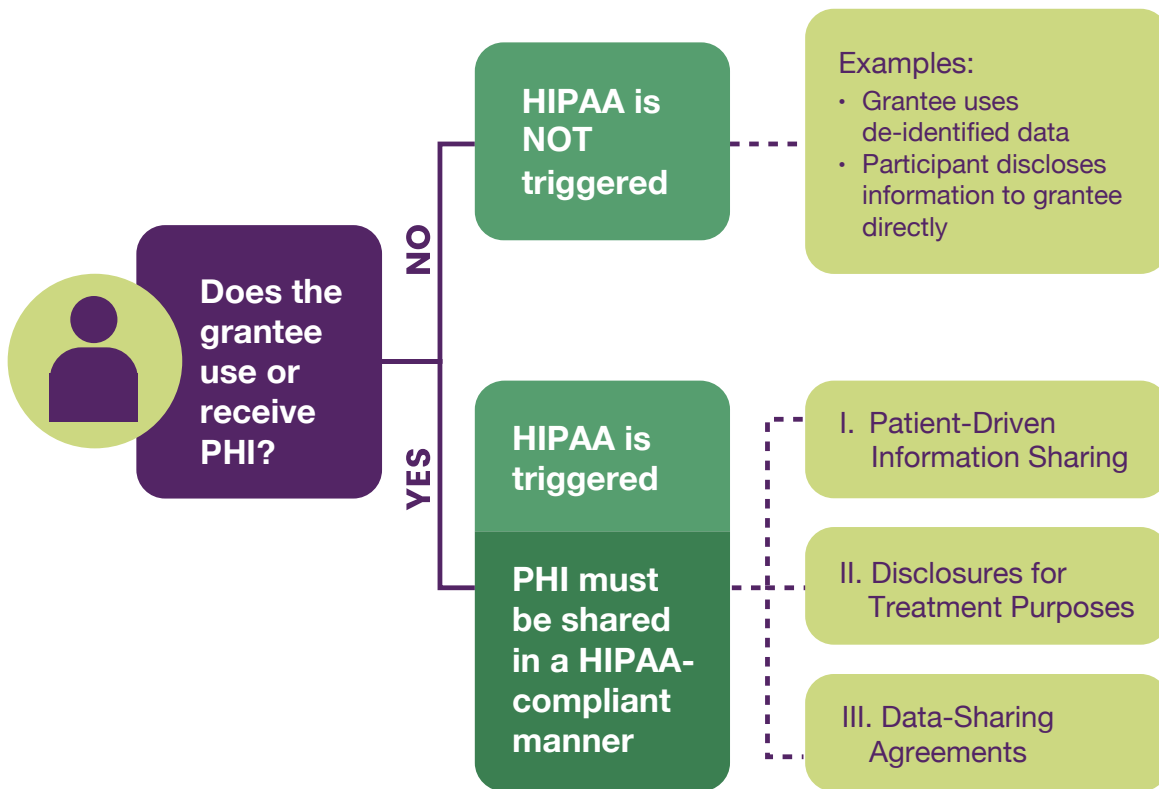
At one end of the spectrum, grantee activities may not involve any protected health information (PHI) from a health care provider. **Instead, participants may relay their personal and health information directly to the grantee through, for example, a survey.** Alternatively, grantees may receive only de-identified information—i.e., information that is not

PHI—from a health care provider. (*De-identification of information is explored in more detail in Issue Brief 3.*)

At the other end of the spectrum, grantee activities may rely on disclosures of PHI from health care provider partners (such as by accessing information from an electronic health record). In this case, the health care provider is obligated, under HIPAA, to only share information in a way allowed by the law.¹ In other words, disclosures must be what HIPAA refers to as “permitted disclosures.”

This brief introduces three categories of permitted disclosures:

- (1) Patient-Driven Information Sharing
- (2) Disclosures for Treatment Purposes
- (3) Disclosures Under Data-Sharing Agreements



(1) Patient-Driven Information Sharing

HIPAA's Privacy Rule ensures that people have ultimate control over their own PHI. Accordingly, the law permits health care providers to share a patient's PHI with others when consented to or authorized by the patient. Written Disclosure Requests and Authorizations are two straightforward approaches to enabling information sharing between a health care provider partner and a grantee in a manner consistent with HIPAA.² These approaches are also transparent—participants are involved in decisions about their information.

Written Disclosure Requests. A Written Disclosure Request is a request by a patient for the release of PHI to a specified third party, such as a grantee.

Authorizations. An Authorization is a release form that patients sign to authorize a health care provider to share PHI with a specified party (here, a grantee).³ In order for an Authorization to be valid under HIPAA, it must contain specified elements of information and certain required statements.⁴

Building Authorizations Into Your Project

Produce Prescription grantees can work with their health care provider partners to build an Authorization into the project from the beginning. The health care provider can provide patients with an Authorization form at the same time as they write the first prescription. A template Authorization form is provided in Appendix A.

When information sharing is patient-driven (such as when the patient signs an Authorization) and grantees do not otherwise have any obligations as an entity subject to HIPAA, grantees are not subject to HIPAA requirements or restrictions on how they store, use, or disclose PHI that has been shared with the grantee. For more information on whether a grantee is an entity subject to HIPAA (i.e., as a Covered Entity or Business Associate), see the first brief in this series.

Even when a grantee is not subject to HIPAA requirements, it is best practice to put into place reasonable systems for data privacy, security, and integrity. See *Issue Brief 5, Developing a Privacy Program* for more information.

(2) Disclosures for Treatment Purposes

HIPAA allows health care providers to share PHI as part of a patient's treatment.⁵ This enables, for example, a person's primary care provider to send PHI to a hospital where the patient is about to have surgery.

Included in the scope of this exception, commonly referred to as the "Treatment Exception," is that a health care provider may share information with a community-based organization or social services organization where the disclosure is "a necessary component of, or may help further, the individual's health or mental health care."⁶ The only example provided by the federal government is that the Treatment Exception permits a health care provider to share the fact that a specific individual needs "mental health care supportive housing" with a social services agency that arranges these services.⁷

In considering whether relying on the Treatment Exception is the best approach to take for getting information from a health care organization, grantees should consider the following:

- Since Produce Prescription grants support an individual's dietary and/or nutrition-related health, including food security, certain disclosures of PHI (e.g., to enroll new patients) may be a necessary component of the individual's health care and likely fall within the scope of this permitted disclosure.
- Information shared under the Treatment Exception is subject to the Minimum Necessary Standard.⁸ This means that health care provider partners may only share the minimum amount of PHI they deem necessary to achieve the purpose of a particular disclosure. Any additional information may not be shared.
- Under this approach, grantees that are not otherwise considered a Covered Entity or Business Associate are not subject to HIPAA requirements or restrictions on how they store, use, or disclose PHI that has been shared with the grantee.

In January 2021, the U.S. Department of Health and Human Services—the federal agency responsible for enforcing HIPAA—proposed new regulations that would clarify how the Treatment Exception applies to community-based organizations and social services agencies.⁹ This brief will be updated as the legal framework evolves. Grantees that use the Treatment Exception to share PHI should ensure that they are basing determinations off the current legal framework.

(3) Data-Sharing Agreements

HIPAA permits health care providers to share PHI with other organizations when the parties sign a specific agreement setting forth the terms and conditions for doing so. HIPAA creates two types of agreements: Data Use Agreements (DUAs) and Business Associate Agreements (BAAs). These agreements are introduced in the table below. *More information on DUAs is provided in Issue Brief 3. More information on BAAs is provided in Issue Brief 4.*

Type of Agreement	Description
DUA	<p>Enables a health care provider to disclose PHI to a third party for certain specific, limited purposes, including research.¹⁰</p> <p>DUAs can only be used to share a “limited data set.” While most identifiers, including names and addresses, must be removed from the data set, the following identifiers can be included: city, state, zip code, ages under 90 years, and dates that relate to an individual, such as a date of birth or important dates in a medical history.¹¹</p>
BAA	Enables a health care provider to disclose PHI to a Business Associate—a third party providing services for or on behalf of the health care provider.

Both DUAs and BAAs must contain certain content required by HIPAA, and health care providers typically have template agreements that they like to use. Grantees that sign these documents agree to take on all of the obligations described in the agreement and are restricted to using information for purposes permitted by the agreement.¹² BAAs in particular require significant investment in developing and maintaining a HIPAA compliance program. Grantees should be realistic about the tasks and responsibilities they have the capacity to incur before signing any documents. It may be helpful to consult an attorney prior to signing a DUA or a BAA, especially if any provisions (or their implications) are not clear.



References

¹45 C.F.R. § 164.502; 45 C.F.R. § 164.524.

²U.S. DEP'T OF HEALTH & HUMAN SERVS., *Summary of the HIPAA Privacy Rule* (2003), <https://www.hhs.gov/sites/default/files/privacysummary.pdf>.

³See 45 C.F.R. § 164.502(a)(1)(iv).

⁴45 C.F.R. § 164.508.

⁵45 C.F.R. § 164.501.

⁶U.S. Dep't. of Health & Human Servs., *FAQ 3008: Does HIPAA permit health care providers to share protected health information (PHI) about an individual with mental illness with a third party that is not a health care provider for continuity of care purposes?*, HHS.GOV, <https://www.hhs.gov/hipaa/for-professionals/faq/3008/does-hipaa-permit-health-care-providers-share-phi-individual-mental-illness-third-party-not-health-care-provider-continuity-care-purposes/index.html> (last visited April 22, 2021).

⁷U.S. Dep't. of Health & Human Servs., *FAQ 3008: Does HIPAA permit health care providers to share protected health information (PHI) about an individual with mental illness with a third party that is not a health care provider for continuity of care purposes?*, HHS.GOV, <https://www.hhs.gov/hipaa/for-professionals/faq/3008/does-hipaa-permit-health-care-providers-share-phi-individual-mental-illness-third-party-not-health-care-provider-continuity-care-purposes/index.html> (last visited April 22, 2021).

⁸U.S. Dep't. of Health & Human Servs., *FAQ 3008: Does HIPAA permit health care providers to share protected health information (PHI) about an individual with mental illness with a third party that is not a health care provider for continuity of care purposes?*, HHS.GOV, <https://www.hhs.gov/hipaa/for-professionals/faq/3008/does-hipaa-permit-health-care-providers-share-phi-individual-mental-illness-third-party-not-health-care-provider-continuity-care-purposes/index.html> (last visited April 22, 2021).

⁹Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 Fed. Reg. 6446 (Jan. 21, 2021), <https://www.federalregister.gov/documents/2021/01/21/2020-27157/proposed-modifications-to-the-hipaa-privacy-rule-to-support-and-remove-barriers-to-coordinated-care>.

¹⁰See 45 C.F.R. § 164.514(e).

¹¹See 45 C.F.R. § 164.514(e).

¹²U.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).

Appendix A: Sample Patient Authorization to Disclose Health Information

HIPAA requires that a valid written authorization include the following components:

1. Identification of the person or entity authorized to make the disclosure,
2. Specific and meaningful description of the information to be shared,
3. Identification of the recipient(s) of the information,
4. Description of each purpose of the disclosure,
5. Expiration date or event for the authorization,
6. Statement of patient's right to revoke the authorization in writing and any exceptions to or limitations of that right,
7. Statement addressing whether and to what extent the Covered Entity can condition its provision of services to the patient on the patient signing the authorization,
8. Statement informing patients of the risk of redisclosure by the recipient and that, once disclosed, the information is not subject to HIPAA requirements or penalties, and
9. The patient's signature and the date.

In addition:

1. When a Covered Entity receives an authorization to disclose PHI, disclosures must be consistent with that authorization. Grantees should ensure that this section accurately describes who will receive PHI and for what purposes.
2. Authorizations must be written in plain language.
3. The Covered Entity must give a copy of the authorization to the patient.
4. State laws and regulations may impose additional requirements or restrictions on written authorizations.

PATIENT AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

A copy of this completed form must be provided to the patient

Pursuant to the Health Insurance Portability and Accountability Act, 45 C.F.R. Parts 160, 164

1. Authorization

I hereby authorize _____ (HIPAA Covered Entity, hereafter known as COVERED ENTITY) to disclose protected health information as described in this authorization.

2. Extent of Authorization

I authorize the release of the following types of information in my health record (check all the apply): _____

Note: List the types of PHI collected by the health care provider that will be shared under this Authorization. Examples of information that grantees may want to include are:

- Names
- Street address, city, county, and zip code
- Birth date
- Height
- Weight
- BMI
- Medications
- Blood pressure
- Blood glucose
- A1c
- Blood lipid panel
- Insurance status

3. Recipients

I authorize my information to be shared with the following recipients (hereinafter, RECIPIENT) _____ (insert recipient(s)).

Note: List the organization(s) that will be receiving PHI collected by the health care provider. Examples may include the grantee organization, a third-party evaluator, etc.

4. Use of Information

I understand that RECIPIENT will use my information in order to _____ (insert description).

Note: Describe all of the different ways in which the individual's PHI will be used. Examples may include "to enroll me in a Produce Prescription Project," "to evaluate the impact of my participation in a Produce Prescription Project," etc.

5. Expiration

This authorization shall remain valid until _____ (insert date or event), at which time it will expire.

6. Right to Revoke

I understand that I may revoke this authorization in writing at any time before it expires. However, I also understand that my revocation will not apply to any disclosure of my health information made in reliance on this authorization before COVERED ENTITY has received my revocation.

7. Condition of Provision of Services

I understand that my treatment, payment, enrollment, or eligibility for benefits will not be conditioned on whether I sign this authorization.

8. Risk of Rediscovery

I understand that after releasing my information in accordance with this authorization, COVERED ENTITY is not responsible for any subsequent uses or disclosures of my information by RECIPIENT or any other entity or individual. My information may no longer be protected by federal or state law.

9. Signature

Patient Signature _____ Date _____

OR

Name of Patient's Representative (print) _____

Signature of Patient's Representative _____ Date _____

Authority to Sign for Patient: _____

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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