



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES **Office for Civil Rights**

Updated Guidance on HIPAA and Contacting Former COVID-19 Patients about Blood and Plasma Donation – August 2020

Does the HIPAA Privacy Rule permit a covered health care provider or health plan to use protected health information (PHI) to identify and contact individuals who have recovered from COVID-19 to provide them with information about donating plasma that could be used to help patients with COVID-19?

Yes. Generally, a covered health care provider (e.g., a hospital, pharmacy, or laboratory) or health plan may use PHI to identify individuals who have recovered from COVID-19 to provide them with information about how they can donate their plasma containing antibodies to SARS-CoV-2 (the virus that causes COVID-19) for use in potentially treating patients with COVID-19.¹

The HIPAA Privacy Rule permits HIPAA-covered entities (or their business associates on the covered entities' behalf) to use or disclose PHI for treatment, payment, and health care operations, among other purposes, without an individual's authorization.² Health care operations include case management and care coordination activities that do not meet the definition of treatment (e.g., where a health plan undertakes case management or care coordination, or where a health care provider undertakes such activities in a manner that is not connected to the care of a specific individual).³ When using or disclosing PHI for health care operations, the covered entity must make reasonable efforts to limit the use or disclosure of PHI to the minimum necessary to accomplish the intended purpose of the use or disclosure.⁴

¹ Plasma collected from individuals who have recovered from an infection is called "convalescent plasma." The Food and Drug Administration (FDA) has issued guidance to provide recommendations to health care providers and investigators on the administration and study of investigational convalescent plasma collected from individuals who have recovered from COVID-19 (COVID-19 convalescent plasma) during the public health emergency. See FDA, "Investigational COVID-19 Convalescent Plasma: *Guidance for Industry*" (May 2020), available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigational-covid-19-convalescent-plasma>.

² See 45 CFR 164.502(a)(1)(ii) and 164.506.

³ See 45 CFR 164.501 (defining "health care operations," and "treatment"). Additional discussion of the difference between treatment and health care operations under the HIPAA Privacy Rule can be found in the 2000 Final Privacy Rule, 65 FR 82462, 82626 (December 28, 2000).

⁴ See 45 CFR 164.502(b) and 164.514(d).

The use of PHI to identify and contact individuals who have recovered from COVID-19 to inform them about how to donate plasma is permitted as a health care operations activity to the extent that facilitating the supply of donated plasma would be expected to improve the covered health care provider's or health plan's ability to conduct case management for patients or beneficiaries that have or may become infected with COVID-19.⁵

A covered health care provider or health plan may identify and contact individuals for this purpose, without authorization, to the extent that this activity does not constitute marketing. Marketing is a communication about a product or service that encourages the recipient of the communication to purchase or use the product or service.⁶ Generally, the HIPAA Privacy Rule prohibits the use or disclosure of PHI for marketing purposes without an individual's authorization.⁷ Thus, communications that inform or encourage individuals who have recovered from COVID-19 regarding the means and benefits of donating plasma, and that encourage such individuals to use any particular blood or plasma donation center(s) for such donations, would constitute marketing, unless the communication meets an exception to the definition of marketing. Under one exception, a covered health care provider or health plan is permitted to make such communication for the covered entity's case management and related health care operations activities,⁸ provided that the covered entity receives no direct or indirect payment from, or on behalf of, the third party whose service is being described in the communication (*e.g.*, a blood or plasma donation center).⁹

While the HIPAA Privacy Rule permits a covered entity to use PHI to identify and contact its own patients or beneficiaries who have recovered from COVID-19, a covered entity generally cannot disclose PHI to a third party, including another HIPAA-covered entity, without the individuals' authorization, for the third party to make marketing communications about the third party's products or services, unless the third party is making the communication on behalf of the covered entity (*i.e.*, as a business associate). For example, a covered health care provider or health plan cannot disclose PHI about individuals who have recovered from COVID-19 to a blood or plasma donation center, for the donation center's own purposes.¹⁰ In such cases, the covered health care provider or health plan would need to obtain the individuals' authorization prior to making such a disclosure.

⁵ See 45 CFR 164.501 (definition of "health care operations" (1): "Conducting . . . case management and care coordination . . . and related functions that do not include treatment . . .").

⁶ See 45 CFR 164.501 (definition of "marketing," ¶ 1).

⁷ *Id.*

⁸ See 45 CFR 164.501 (definition of "marketing," ¶ (2)(ii)(C)).

⁹ See 45 CFR 164.501 (definition of "marketing," ¶¶ (2)(ii)(C), (3)).

¹⁰ A disclosure to the blood or plasma donation center, for the blood or plasma donation center's own purposes, is not considered to be made for the health care operations of the covered health care provider or health plan. However, a covered health care provider or health plan may disclose PHI about individuals who have recovered from COVID-19 to a blood or plasma donation center that is working with the provider or plan to improve the provider's or plan's ability to conduct case management for individual patients or beneficiaries, or for patient or beneficiary populations, that have or may become infected with COVID-19, if the covered provider or plan enters into a business associate agreement with the blood or plasma donation center.