Coppersmith Briefs

OCR Guidance on Contacting COVID-19 Survivors about Blood Donation

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The U.S. Department of Health and Human Services, Office for Civil Rights (OCR) has issued guidance explaining how HIPAA permits health care providers to contact their patients who are COVID-19 survivors to inform them about blood donation to help others with COVID-19. *See* Guidance on HIPAA and Contacting Former COVID-19 Patients about Blood and Plasma Donation.

Blood plasma collected from individuals who have recovered from COVID-19 (called COVID-19 convalescent plasma or "CCP") contains antibodies scientists believe could help in the treatment of patients fighting COVID-19. The FDA has approved investigational (research) use of CCP, because the safety and efficacy of CCP has not yet been determined. As such, administration of CCP by a health care provider must be under an investigational new drug (IND) mechanism (either traditional IND, expanded access IND, or single-patient emergency IND application), and the CCP must be obtained from an FDA-registered blood establishment. *See* Investigational COVID-19 Convalescent Plasma: Guidance for Industry. There is demand for CCP, due to the continued prevalence of COVID-19 cases and the lack of proven treatments.

As we explain below, as long as health care providers are not paid to contact their patients about blood donation, that contact is permitted by HIPAA. But providers should not disclose lists of patients to third parties without patient authorization, unless it is part of an approved research protocol.

The Legal Basis for Contacting COVID-19 Survivors

Health Care Operations

OCR explained that a health care provider may identify and contact its patients who have recovered from COVID-19 to inform them about plasma donation as a "health care operations" function. (See 45 C.F.R. § 164.501 (defining health care operations).) OCR confirmed that use of Protected Health Information (PHI) to identify and contact COVID-19 survivors for this purpose falls within "population-based activities relating to improving health … because facilitating the supply of donated blood and plasma would be expected to improve

the provider's ability to conduct case management for patient populations" that may be battling COVID-19. Providers are permitted to use and disclose PHI without patient authorization, for the provider's own health care operations (see 45 C.F.R § 164.506(c)(1)), and to disclose PHI to other providers for limited categories of health care operations (including population health activities) if the recipient providers share a patient relationship (see 45 C.F.R § 164.506(c)(4)).

Marketing Communications Prohibited

However, providers may not be compensated by a third party for making that communication with the provider's patients. The HIPAA Privacy Rule defines "marketing" as a communication about a product or service that encourages recipients of the communication to purchase or use the product or service. (See 45 C.F.R. § 164.501.) OCR has concluded that encouraging a patient to donate blood is encouraging the patient to use a service.

Generally, HIPAA prohibits the use or disclosure of PHI for marketing purposes without a patient's authorization, unless one of the exceptions to the definition apply (45 C.F.R. § 164.508(a)(3)). The OCR guidance notes that one of the marketing exceptions is relevant here: A health care provider is permitted to make a marketing communication to its patients for the provider's population-based case management and related health care operations activities, if the health care provider "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 and plasma donation center)." So, the provider can't receive any remuneration from the blood and plasma donation center.

This marketing exception does not permit a health care provider to disclose PHI to a third party for the third party to make marketing communications about its products and services. A provider should therefore not disclose patient PHI to a blood and plasma donation center, unless the patient provides authorization in advance.

Research

Another possible legal basis for contacting COVID-19 survivors is under the HIPAA rules related to research (which OCR did not discuss in its guidance). There are three primary ways providers may contact patients for COVID-19 related research, or disclose patient information to organizations conducting that research:

Patient Recruitment: Providers are free to tell patients about opportunities to participate in research, whether the research is occurring at the provider or at other sites. Contacting patients to recruit them for a research study does not require a HIPAA authorization, because this supports a provider's "healthcare operations" or "treatment" (if the clinical trial involves treatment). *See* 45 C.F.R. §164.506; NIH CLINICAL RESEARCH AND THE

HIPAA PRIVACY RULE 3-4 (Feb. 2004) [NIH Pub. 04-5495] at 4, 9-10. This would not permit providers to disclose patient information to third parties.

However, if the research is federally supported research (such as an NIH-funded study), the federal Common Rule (45 C.F.R. Part 46) requires Institutional Review Board (IRB) approval in advance of patient recruitment activities. (*See* 45 C.F.R. §46.116(g).) The research site should comply with these stricter requirements if the Common Rule applies.

Individual Authorization: A provider may contact patients to ask for a HIPAA authorization to disclose the patient's information to organizations conducting CCP research. That authorization must meet the requirements in 45 C.F.R. §164.508.

IRB Waiver of HIPAA Authorization: A provider may disclose patient information to organizations conducting CCP research, if an IRB waives the requirement to obtain authorization. The waiver must meet the requirements of 45 C.F.R. 164.512(i)(1)(i). If the waiver requirements are met, the IRB may allow disclosure of patient information to the research organization to contact patients about participating in the research, or may allow disclosure of patient medical records for retrospective data research. A provider may rely on outside IRBs for this analysis, but should ask for documentation of the IRB's waiver of authorization for the provider's records.

About the Authors

Kristen Rosati is one of the nation's leading "Big Data" and HIPAA compliance attorneys; she also has deep experience in data sharing for research, development of artificial intelligence, clinical integration, health information exchange, clinical research compliance, biobanking and genomic privacy, and data breaches. Kristen is a Past President of the American Health Law Association (AHLA) and serves on the program planning committees for AHLA Academic Medical Centers and Teaching Hospitals Institute and AHLA Artificial Intelligence Convener Session.

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