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Contacting Recovered COVID-19 Patients about Blood and Plasma Donations

Researchers are studying whether convalescent plasma from recovered COVID-19 patients is a safe and effective treatment for the disease.^[1] On June 12, 2020, the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) issued guidance stating that HIPAA allows physicians and their practices to contact recovered COVID-19 patients about donating blood and plasma to support this effort.^[2] According to OCR Director Roger Severino, "This guidance explains how health care providers can connect COVID-19 survivors with blood and plasma donation opportunities and further public health consistent with patient privacy."^[3]

The Privacy Rule permits covered entities or their business associates to use protected health information (PHI) for "health care operations" without patient authorization.^[4] "Health care operations" include "population-based activities" related to "improving health" and "case management."^[5] According to OCR, using PHI to contact recovered patients qualifies as a population-based activity because it will facilitate blood and plasma donations that may improve clinicians' ability to manage other COVID-19 cases.^[6]

The OCR guidance contains several cautionary points:

1. Practices must make reasonable efforts to limit their use or disclosure of PHI to the minimum necessary to accomplish the intended purpose of contacting patients about donations.^[7]
2. To avoid violating HIPAA provisions that prohibit unauthorized use of PHI for marketing purposes, practices must not accept any direct or indirect payment from, or on behalf of, blood or plasma donation centers mentioned in the communications.^[8]
3. **IMPORTANT:** While the Privacy Rule allows practices to use PHI to identify and contact their own patients to discuss donation opportunities, practices are prohibited from providing PHI to blood and plasma centers or other third parties who are not contracted Business Associates without patient authorization.^[9]

Senior Risk Management Consultants are ready to help with questions and provide more information. You can reach a Consultant Monday - Friday 8:30 am - 5:00 pm MST at 800.352.0402 x2137, 602.808.2137, or rm_info@mica-insurance.com

[1] U.S. Food and Drug Administration Center for Biologics Evaluation and Research. (2020, May 1). *Investigational COVID-19 convalescent plasma: Guidance for industry*. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigational-covid-19-convalescent-plasma>

[2] U.S. Department of Health and Human Services Office for Civil Rights. (2020, June 12). *Guidance on HIPAA and contacting former COVID-19 patients about blood and plasma donation*. <https://www.hhs.gov/sites/default/files/guidance-on-hipaa-and-contacting-former-covid-19-patients-about-blood-and-plasma-donation.pdf?language=en>

[3] U.S. Department of Health and Human Services Office for Civil Rights. (2020, June 12). *Guidance on HIPAA and contacting former COVID-19 patients about blood and plasma donation* [Press Release]. <https://www.hhs.gov/about/news/2020/06/12/guidance-on-hipaa-and-contacting-former-covid-19-patients-about-blood-and-plasma-donation.html>

[4] U.S. Department of Health and Human Services Office for Civil Rights *Guidance* 2020; Security and Privacy, 45 C.F.R § 164.502(a)(1)(ii) (2013). https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=fa07dbd4510816e6ce29d6c79ce8ccac&mc=true&r=SECTION&n=se45.2.164_1502; Security and Privacy, 45 C.F.R § 164.506 (2013). https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=fa07dbd4510816e6ce29d6c79ce8ccac&mc=true&r=SECTION&n=se45.2.164_1506

[5] U.S. Department of Health and Human Services Office for Civil Rights *Guidance* 2020; Security and Privacy, 45 C.F.R § 164.501 (2013). <https://www.ecfr.gov/cgi-bin/text-idx?SID=ed4c5bdc961b65a1cd48d9f5b11a76c4&node=45:1.0.1.3.78.5.27.2&rgn=div8>

[6] U.S. Department of Health and Human Services Office for Civil Rights *Guidance* 2020.

[7] U.S. Department of Health and Human Services Office for Civil Rights *Guidance* 2020; Security and Privacy, 45 C.F.R § 164.502(b) (2013). https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=fa07dbd4510816e6ce29d6c79ce8ccac&mc=true&r=SECTION&n=se45.2.164_1502; Security and Privacy, 45 C.F.R § 164.514(d) (2013). https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=fa07dbd4510816e6ce29d6c79ce8ccac&mc=true&r=SECTION&n=se45.2.164_1514

[8] U.S. Department of Health and Human Services Office for Civil Rights *Guidance* 2020; Security and Privacy, 45 C.F.R § 164.501 (definition of "marketing," ¶ (1), (2)(ii)(C) & (3) (2013). <https://www.ecfr.gov/cgi-bin/text-idx?SID=ed4c5bdc961b65a1cd48d9f5b11a76c4&node=45:1.0.1.3.78.5.27.2&rgn=div8>

[9] U.S. Department of Health and Human Services Office for Civil Rights *Guidance* 2020.

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