FDA and OCR Issue Guidance to Help Providers Harness the Potential of Recovered COVID-19 Patients

Individuals who have recovered from COVID-19 may play an integral role in helping providers and investigators develop treatments to help other patients. As the number of COVID-19 cases continue to rise in the United States, so do the number of patients who have recovered from the disease. Recovered individuals may carry COVID-19 antibodies which, when isolated into convalescent plasma, have the potential to be used to develop treatments which may help other patients recover from the virus.

Last month, the Food & Drug Administration issued an industry guidance to health care providers and investigators related to the administration and study of investigational convalescent plasma collected from individuals who have recovered from COVID-19 as a potential treatment for COVID-19 . The guidance includes information about pathways for investigational use, including clinical trials, expanded access and single patient emergency INDs. The guidance also addresses patient eligibility for emergency INDs, the collection of COVID-19 convalescent plasma, donor eligibility, donor qualifications, specimen labeling and record keeping.

The increasing demand for COVID-19 antibody convalescent plasma donations has led the Office of Civil Rights ("OCR") at U.S. Department of Health and Human Services to issue guidance regarding the interplay between the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and a provider's right to contact former COVID-19 patients about blood and plasma donation. In general, the HIPAA Privacy Rule permits HIPAA covered entities (or their business associates on their behalf) to use or disclose protected health information ("PHI") without patient authorization for treatment, payment or and health care operations. Under the HIPAA Privacy Rule, health care operations includes activities such as populations-based activies related to improving health, as well as case management and care coordination activities. Accordingly, OCR concluded that the use of PHI to identify and contact patients who have recovered from COVID-19 regarding blood and plasma donation is permitted as a population-based health care operations activity since the supply of donated blood and plasma is expected to improve the provider's ability to conduct case manage for patients population that have or may become infected with COVID-19. Consistent with this understanding, the guidance permits communications that inform or encourage recovered COVID-19 patients about the manner and benefits of donating blood and plasma. It also permits communications encouraging recovered patients to use a particular blood and plasma center for such donations, as long as the provider is not receiving direct or indirect payment from, or on behalf of, the particular blood and plasma center. However, it is important to note that the use of PHI in this manner is only permissible to the extent the activity does not constitute marketing. In this context, marketing of a specific blood and plasma center would require a patient authorization prior to use of PHI. Furthermore, the OCR guidance was limited to the use of PHI to identify and contact the provider's former COVID-19 patients and is not intended to allow the disclosure of information to a third party (except for the business associate acting on behalf of the covered entity) without the patient's authorization.

For more information about regulatory guidance on COVID-19 related FDA requirements and permissible uses and disclosures of protected health information please contact our firm.

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