APRIL 21, 2020 | ISSUE NO. 7

CHEHARDY SHERMAN WILLIAMS
MURRAY, RECILE, STAKELUM & HAYES, LLP

COVID - 19 HEALTHCARE UPDATES

The Chehardy Sherman Williams Healthcare Practice Group is constantly monitoring the way the COVID-19 Pandemic is affecting the industry.

Providers May Waive Copays for Telehealth Services During COVID-19 Outbreak

On March 17, 2020, the Office of Inspector General (OIG) for the Department of Health and Human Services (HHS) announced that OIG will not bring any enforcement action against physicians or other healthcare practitioners who reduce or waive cost-sharing obligations for telehealth services provided to Medicare or other federal healthcare program patients during the national COVID-19 emergency. This policy applies to a broad category of telehealth services, including telehealth visits, virtual check-in services, e-visits, monthly remote care management, and monthly remote patient monitoring. The policy applies to a physician or other practitioner, or hospital or other eligible entity to which the physician or other practitioner has reassigned his or her right to bill. There is no requirement that health care providers waive copays or any other cost-sharing obligations.

For more information, please click here and here.

Subscribe to our newsletter for more updates:

WWW.CHEHARDY.COM

FDA & USDA Issue Guidance for Industry & Inspectors

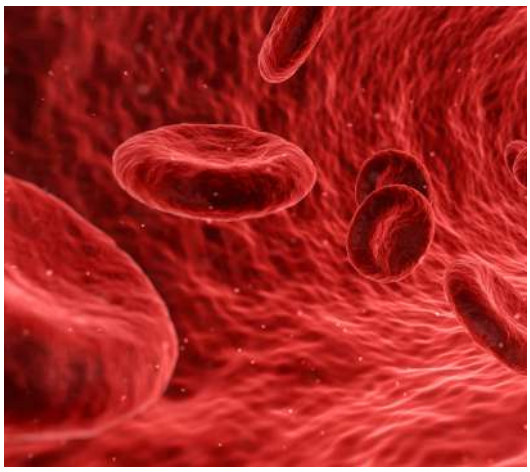
As the novel Coronavirus (COVID-19) crisis has continued to escalate, both the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) have taken additional action to provide industry, the public, and inspectors with guidance concerning food safety and how to respond in the event that food industry personnel test positive for COVID-19. Importantly, FDA does not anticipate that food products would need to be recalled or be withdrawn from the market when a food employee tests positive for COVID-19 because there is currently no evidence to support the transmission of COVID-19 associated with food or food packaging. Similarly, USDA says that it is not aware of any reports at this time of human illnesses that suggest COVID-19 can be transmitted by food or food packaging.

Liability Immunity Relating to Implementation of Countermeasures to COVID-19

The Secretary of the Department of Health and Human Services (HHS) recently made a declaration to provide liability immunity to drug and medical device manufacturers, distributors and users relating to the implementation of countermeasures to the COVID-19 pandemic (the Declaration). The Declaration was effective February 4, 2020. The ability to make this Declaration flows from the Public Readiness and Emergency Preparedness (PREP) Act, enacted in 2005, which authorizes the HHS Secretary to issue a declaration to provide liability immunity to "Covered Persons" against any claim of loss arising out of or relating to the manufacture, distribution or use of certain medical countermeasures arising out of a health emergency (Covered Countermeasures). The liability immunity does not apply to claims involving "willful misconduct" as defined in the PREP Act.

APRIL 21, 2020 | ISSUE NO. 7

FDA Now Allows Treatment Of Life-Threatening COVID-19 Cases Using Blood From Patients Who Have Recovered



Section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act permits the FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product for certain emergency circumstances. The FDA may issue an EUA in response to emergencies involving chemical, biological, radiological and nuclear (CBRN) agents, including emerging infectious disease threats such as COVID-19.

Under this authority, the FDA is facilitating access to experimental treatments for the ongoing COVID-19 pandemic to include use of "convalescent plasma," in cases where the patient's life is seriously or immediately threatened. This isn't an approval of the procedure as a certified treatment, but rather an emergency clearance that applies only on a case-by-case basis, and only in extreme cases, as a means of helping further research being done into the possible efficacy of plasma collected from patients who have already contracted, and subsequently recovered from, a case of COVID-19.

To review more information on the emergency clearance, please click here.

OCR Issues Guidance to Help Ensure First Responder and Others Receive Information About Individuals Exposed to COVID-19

The U.S. Department of Health and Human Service's (HHS's) Office for Civil Rights (OCR), which is responsible for HIPAA enforcement, issued Guidance on how covered entities may disclose protected health information (PHI) about an individual who has been infected with or exposed to COVID-19. The OCR clarified that an individual's PHI may be disclosed without an individual's HIPAA authorization in the following circumstances:

- When the disclosure is needed to provide treatment,
- When the notification is required by law, such as a state law requiring reporting of confirmed or suspected cases to public health officials,
- When first responders may be at risk for an infection, or
- To notify a public health authority or its employees in order to prevent or control the spread of disease.

For more information, please click here.

Should you have any specific questions or needs, please contact the Chehardy Sherman Williams Healthcare Team

~ David Sherman, George Mueller, Adam Stumpf, Chris Martin, Adrienne Ellis & Rory Bellina