Five Key Regulatory Considerations for Virtual Ketamine Clinics

 The off-label use of ketamine to treat anxiety, depression, and other behavioral health disorders —coupled with the COVID-19 telehealth era—has spurred the opening of virtual ketamine clinics nationwide. Some clinics offer a full suite of health care services, including telehealth visits, prescribing, pharmacy dispensing, and counseling services, while others are focused on more niche areas like group coaching sessions. In the wake of public reports detailing investigations into a number of digital health companies prescribing controlled substances, it is more important than ever to ensure your business model complies with the various regimes regulating the use of ketamine to treat behavioral health issues.

Read the client alert **here**.

Significant Drug Pricing Reform Measures in the Inflation Reduction Act of 2022

 On August 16, President Biden signed the Inflation Reduction Act of 2022 into law,[1] which includes some of the most significant drug pricing-related changes since the passage of the Medicare Prescription Drug Improvement and Modernization Act of 2003.

The healthcare-related portions of the law introduce many important changes, most notably allowing the Medicare program to negotiate with pharmaceutical companies for reduced prescription drug prices under Medicare Part B and Medicare Part D (commonly known as the Prescription Drug Benefit for America's senior population) for certain single-source drugs, or rather those drugs and biologicals without generic or biosimilar competitors. The law will also require drug makers to pay the government a rebate for any drug whose price increases faster than the pace of inflation. It also modifies several aspects of the Part D benefit to cap Medicare beneficiaries' out-of-pocket costs.

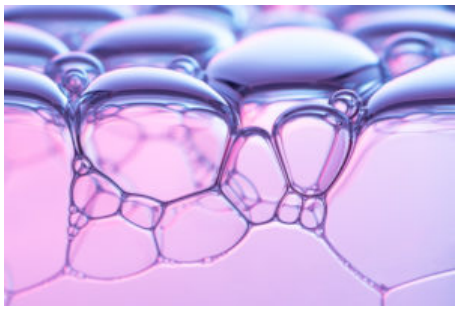
Heath Ingram, **Matt Wetzel** and **Roger Cohen** provide a high-level summary of these provisions and other important considerations in this **client alert**.

CMS Continues to Modernize by Expanding Reimbursement for Digital Health Services

The COVID-19 Public Health Emergency ("PHE") fundamentally changed the healthcare industry, forcing healthcare providers and patients onto their computers and phones to enable continuation of care when patients were mandated to stay home across the country. Prior to the COVID-19 PHE, approximately 12,5000 Medicare beneficiaries received telehealth services and only 106 telehealth services were reimbursable. By October 2020, over 24.5 million (of 63 million) Medicare beneficiaries received telehealth services.

Read the **client alert**.

Goodwin Virtual Series: Foundations in Healthcare Compliance for Life Sciences Companies



In the ever-evolving life sciences industry, compliance is top-of-mind for investors, business leaders, the public and the government. Life sciences companies are subject to increased enforcement efforts and greater public scrutiny, and boards, investors, and other key stakeholders call for more and better compliance controls. As a result, there are increased expectations on what compliance programs should cover and what resources should be dedicated to making these programs successful.

With the growing importance of compliance for emerging life sciences companies, Goodwin and the Berkeley Research Group are pleased to announce our inaugural **Foundations in Healthcare**

Compliance series, a multi-part training series where participants will learn from experienced lawyers and professionals about the various considerations when building and growing a compliance program in the life sciences industry.

This five-week series is designed for new compliance officers, in-house counsel or their delegates and investor clients seeking more information about compliance in the life sciences market. We will offer CLE credit for lawyer attendees and non-lawyer compliance certification (HCCA), if available.

For further information and to request an invitation to the series check out the **Foundations in Healthcare Compliance mini site**.

Biden Executive Order Targets Competition in Healthcare, Life Sciences to Spur Economic Activity

On July 9, 2021, President Joe Biden issued an **Executive Order** (the "Order") designed to promote competition in the American economy. The Order describes the administration's concerns with competition in several markets, including healthcare, noting that industry consolidation has exacerbated racial, income and wealth inequality and emphasizing that robust competition is critical to the United States economy.

In this Order, to combat these concerns, the Biden administration affirms (i) its policy to support legislative reforms that would lower prescription drug prices, including by allowing Medicare to negotiate drug prices and by imposing inflation caps; and (ii) its policy to support the enactment of a public health insurance option.

Read the **client alert**.

Disrupt + Innovate + Transform: Key Regulatory Issues for Digital Health

Companies Webinar


Goodwin Life Sciences and Healthcare partner **Roger Cohen** and associate **Anne Brendel** along with Life Sciences and FDA associate **Steven Tjoe** kicked off Goodwin's multi-part webinar series "Disrupt + Innovate + Transform: A Healthcare Webinar Series" with "Key Regulatory Issues for Digital Health Companies" discussing the key regulatory issues affecting digital health, telemedicine and healthcare IT companies. The webinar series will be presented by a cross-disciplinary team of Goodwin lawyers exploring the topics that are most relevant for the healthcare industry today. From ever-changing regulatory guidelines to digital health, women's health and privacy, Goodwin will take attendees through these topics and more and provide guidance to help you navigate the current healthcare landscape.

View the Video:

For information on upcoming webinars in the Disrupt + Innovate + Transform: A Healthcare Webinar Series, visit our **mini site**.

Goodwin Webinar – Healthcare Issues + Trends: The False Claims Act and Other Government Enforcement

Healthcare companies are facing unprecedented challenges as a result of the COVID-19 crisis. This includes heightened enforcement risks. A key area of risk is the federal False Claims Act (FCA), a powerful tool for the DOJ to seek substantial penalties including three times the amount of money a company received in federal funds.

Join members of Goodwin's Healthcare team as they discuss recent enforcement developments and ways to mitigate risk from a panel of Goodwin lawyers with experience helping healthcare companies, their executives and medical professionals navigate enforcement investigations.

To register for this event, please visit the registration page **here**.

Qualifying for Immunity Under the U.S. PREP Act During COVID-19

 As part of the U.S. government's response to the COVID-19 pandemic, on March 10, 2020, the Secretary of Health and Human Services ("Secretary") issued a Declaration pursuant to the Public Readiness and Emergency Preparedness Act ("PREP Act"), 42 U.S.C. § 247d-6d. This Declaration activated immunity from personal injury, property damage, and other types of claims for companies and certain professionals who manufacture, distribute, or use "covered countermeasures"— certain drugs and devices, or components thereof, that may be used to treat COVID-19 patients or combat the COVID-19 pandemic.[1] The PREP Act provides broad immunity from liability, but applies only to products and persons that qualify for the immunity under the PREP Act and the limits established in the Secretary's Declaration.

Read the Alert >>

Update: U.S. Health and Human Services Clarifies Broad Eligibility of Providers for Payments Under $30 Billion CARES Act Healthcare Provider Relief Fund

 As discussed in Goodwin's prior Client Alert, on April 10, 2020, the U.S. Department of Health and Human Services (HHS) began disbursing $30 billion to Medicare providers and suppliers under the Public Health and Social Services Emergency Fund (PHSS Emergency Fund). HHS is requiring providers to agree to certain terms and conditions or return the payments. A number of the terms and conditions created some confusion as to whether providers who have not provided services directly related to COVID-19 may keep the payments. HHS has now clarified that providers may keep payments distributed under the PHSS Emergency Fund regardless of whether they have or will provide services directly related to COVID-19.

Read the Alert >>

U.S. Health and Human Services to Begin Disbursing $30 Billion of CARES Act Healthcare Provider Relief Fund

 On Friday, April 10, 2020, the U.S. Department of Health and Human Services (HHS) announced it will begin disbursing $30 billion of the $100 billion of the Public Health and Social Services Emergency Fund recently allocated by the Coronavirus Aid, Relief, and Economics Security Act (CARES Act), signed March 27, 2020. Inclusive of the $30 billion, the $100 billion funding will be used to reimburse healthcare providers and facilities.

Read the Alert >>