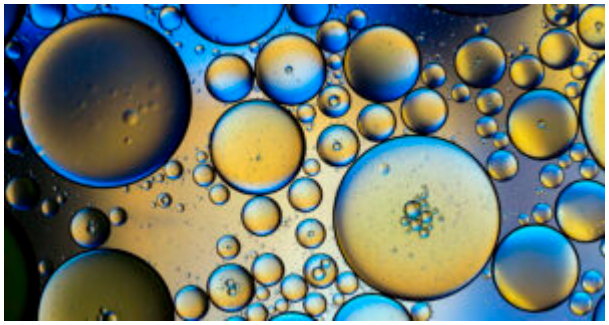
Psychedelics & Drug Development — Key Considerations for Healthcare Industry and Life Sciences Companies as Congress Seeks to Tap Into Psychedelics' Therapeutic Potential



Based on recent regulatory changes at the state and local level and the efforts by the federal government and certain foreign agencies, investors, clinical trial sponsors, life sciences companies, and investigators operating in the psychedelics industry may have reason to be optimistic about the future regulatory landscape for therapeutic psychedelic product candidate development, approval, and commercialization. The proposed Breakthrough Therapies Act is one such reason.

On March 8, 2023, US Sens. Cory Booker (D-NJ) and Rand Paul (R-KY) **introduced** an **updated version** of the Breakthrough Therapies Act. If passed, the bipartisan bill would amend the federal Controlled Substances Act (CSA) to enable the Drug Enforcement Administration (DEA) to reclassify from Schedule I to Schedule II drugs and biologics, including therapeutic psychedelics, that receive breakthrough therapy designation or are authorized for expanded access by the US Food and Drug Administration (FDA). Therapeutic psychedelics are Schedule I substances and include LSD, MDMA, and psilocybin. According to the bill's sponsors, the "legislation [would] remove regulatory hurdles that inhibit research and compassionate use access to potentially lifesaving treatments that are heavily restricted by Schedule I of the [CSA]."

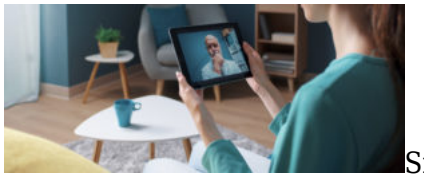
The bipartisan effort behind the Breakthrough Therapies Act signals the federal government's evolving position on psychedelic substances, their therapeutic potential, and access. This evolution, discussed in greater detail in our Client Alert, presents an important opportunity for investors, clinical trial sponsors, life sciences companies, and investigators.

Accordingly, we have identified and answered 8 key questions that stakeholders should consider as they develop and innovate in the psychedelic space:

- What Is the Difference Between a Schedule I and a Schedule II Drug?
- What Diseases and Conditions Can Potentially Benefit From Therapeutic Psychedelics?
- What Are the Key Provisions of the Proposed Breakthrough Therapies Act?
- How Does a Drug or Biologic Obtain Breakthrough Therapy Designation From FDA?
- What Is Expanded Access?
- What Are Some Key Limitations in the Proposed Breakthrough Therapies Act?
- What Is the Status of Therapeutic Psychedelics at the State and Local Level?
- What Regulatory Changes Are on the Horizon for Therapeutic Psychedelics?

Read the full client alert **here**.

DEA Publishes Temporary Rule on the Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Substances

 Since the declaration of the public health emergency due to the COVID-19 epidemic, Drug Enforcement Administration (DEA) registered practitioners have been able to prescribe controlled substances, without a prior in-person visit with a patient, subject to certain conditions as outlined in our earlier **blog post**. Additionally, DEA waived the requirement for practitioners to obtain additional registrations with DEA in the states where the dispensing (including prescribing, and administering) occurs, for the duration of the public health emergency, if the practitioner registers with DEA in at least one state and has permission under state law to practice using controlled substances in the state where the dispensing occurs.

In anticipation of the expiration of the public health emergency on May 11, 2023, on March 1, 2023, DEA and the Department of Health and Human Services issued two notices of proposed rulemakings (NPRMs), reviewed in our earlier **blog post**, to authorize the prescription of controlled substances based on a telehealth consultation in certain limited circumstances. The NPRMs received over 38,000 comments from the public, all of which DEA will review to implement revisions to the NPRMs and develop a permanent rule.

Since the permanent rule is still in development, on May 10, 2023, just one day before the end of the public health emergency, DEA and the Substance Abuse and Mental Health Services Administration published a **temporary rule** that extends the public health emergency telemedicine flexibilities**[1]** for the prescription of controlled substance medications until November 11, 2023.

The temporary rule, which took effect on May 11, 2023, allows DEA-registered practitioners to prescribe controlled substance medications under the public health emergency telemedicine flexibilities to all patients through November 11, 2023. Additionally, until November 11, 2024, DEA-registered practitioners are further permitted to prescribe controlled substance medications under the public health emergency telemedicine flexibilities to patients if the practitioner established a telemedicine relationship with the patient on or before November 11, 2023. In other words, if a provider and patient established a telemedicine relationship on or before November 11, 2023, the same public health emergency telemedicine flexibilities that previously governed the relationship will apply until November 11, 2024.

In the text of the rule, DEA notes that it plans to issue one or more final rules, based on the two proposed rules, which will extend certain telemedicine flexibilities on a permanent basis and ensure a smooth transition for patients and practitioners that rely on the availability of telemedicine for controlled substance medications.

*Follow our **blog** to receive additional updates and alerts on the DEA's proposed rules regarding extension of the COVID-19 telemedicine flexibilities for the prescription of controlled substance medications.*

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[1] In the temporary rule, the DEA references the **DEA letter** that authorized certain telemedicine flexibilities, including the waiver exceptions related to DEA registrations in individuals states and the in-person evaluation requirement.

DEA Announces Temporary Extension of COVID-19 Telehealth Flexibilities for Prescription of Controlled Medications

The Controlled Substances Act, as amended by the Ryan Haight Act, generally prohibits prescribing controlled substances via telehealth without a prior in-person examination, subject to certain very limited exceptions. Those exceptions include prescriptions issued during a public health emergency. Thus, since the January 31, 2020 declaration of a public health emergency due to the COVID-19 epidemic, eligible providers have been able to prescribe controlled substances, without a prior in-person visit with a patient, provided:

- The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice;
- The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system; and
- The practitioner is acting in accordance with applicable Federal and State laws.

The public health emergency is scheduled to end on May 11, 2023.

Read the client alert **here**.

The Office of the National Coordinator for Health Information Technology Interoperability and Information Blocking

Final Regulation: Key Concerns for Health Information Technology Companies and Developers

As of April 5, 2021, **health information technology companies and developers are required to comply with the information blocking provisions** of the Centers for Medicare and Medicaid Services' (CMS) and the Office of the National Coordinator for Health Information Technology's (ONC) Information Blocking Final Regulation ("Final Rule"), implementing specific provisions of the **21st Century Cures Act** (the "Cures Act"). The objective of the Final Rule is to (i) promote interoperability and support the access, exchange, and use of electronic health information; and (ii) reduce burdens and costs related to accessing electronic health information and to reduce occurrences of information blocking.

While compliance with the Final Rule is required, enforcement mechanisms are still evolving and are not yet final. This affords health information technology ("Health IT") companies and developers the time and opportunity to familiarize themselves with the Final Rule and the **exceptions** outlined by the ONC.

What does the Final Rule require or prohibit?

The Final Rule prohibits so-called "Actors" from engaging in information blocking practices—such as *interfering, preventing, or substantially discouraging the use, access, and exchange of electronic health information*. An "Actor" is any individual or entity that is a (i) health care provider, (ii) developer of Health IT, (iii) health information network, and/or (iv) health information exchange. There is no duty to proactively make electronic health information available, but these entities must not engage in information blocking practices in response to a legal request for electronic health information.

What is information blocking and why is it discouraged? What are examples of information blocking?

The Final Rule was promulgated by the ONC because Congress expressed concern that Health IT companies were knowingly interfering with the free exchange of information. Information blocking is such a practice, and involves any efforts that are likely to materially discourage the access, use, and/or exchange of electronic information when the entity knows that the practice is likely to do so.

The types of behavior that would be considered information blocking include (i) refusing to provide electronic health information or ignoring reasonable requests; (ii) imposing any unreasonable limitations on the use or requests for access to share electronic health information; (iii) establishing contracts, business associate agreements, licensing terms, and/or policies that would unnecessarily restrict the sharing of electronic health information; and (iv) configuring technology in a way to limit

interoperability.

Put another way, if an electronic health record platform were to restrict its software such that a user is able to export electronic health information for its own use without a fee, but any request to transfer or exchange electronic health information to a competitor's platform would require a fee, the company's activity would likely be considered inappropriate information blocking under the Final Rule.

What constitutes electronic health information?

"Electronic health information" includes electronic protected health information ("ePHI") as defined under HIPAA, if such ePHI is maintained in a HIPAA designated record set ("DRS"). However, unlike HIPAA the new information blocking regulations do not apply to hand written or verbal health data. Additionally, it is important to note that records do not have to be used or maintained by or for a HIPAA covered entity to fall within the definition of electronic health information.

What agency is responsible for enforcement of the Final Rule?

The Cures Act authorizes the Office of Inspector General ("OIG") to investigate any allegations of information blocking. Health IT companies and developers could face up to $1,000,000 in civil monetary penalties per violation. If an OIG's investigation and determines that an Actor has engaged in information blocking activities, the OIG will refer the provider to the appropriate agency to address the alleged violation (e.g. a HIPAA privacy violation would be referred to the Office for Civil Rights to address the violation). The OIG has issued a proposed rule for enforcement outlining enforcement priorities and has requested input on the proposed rule. Any conduct prior to the effective date of the OIG's rule will not be subject to civil monetary penalties.

How does the Final Rule impact the health information sharing community and Health IT companies and businesses?

Companies should ensure current privacy policies and practices with respect to sharing electronic health information comply with the Final Rule. Companies' vendors and Health IT systems should also ensure that the information infrastructure simultaneously protects the transfer electronic health information and facilitates the flow of electronic health information between Health IT systems. Companies should also review current business associate agreements and consider any updates that may be necessary to comply with the new information blocking regulations.

Additionally, companies may also want to consider implementing a policy and procedure that covers the review of all proposed transactions and arrangements, which involve the transfer of electronic health information, to ensure compliance with the Final Rule. This is especially important for Health IT companies to consider as developers and managers of software solutions for providers and other customers.

As regulators continue to push for accountability in the Health IT industry and ultimately the improvement of overall patient care, Health IT developers and businesses must welcome and embrace software and technologies that facilitate compliant sharing of electronic health information.

*Follow our **blog** to receive additional updates and alerts on the Final Rule and the OIG's proposed final rule. Our health care regulatory team intends to publish more in-depth guidance on the nuances of these regulations for Health IT companies and developers.*