March 29, 2023

The Honorable Anne Milgram
Administrator
United States Drug Enforcement Administration
800 K Street NW Suite 500
Washington, D.C. 20001

RE: Telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation (RIN:1117-AB40)

Dear Administrator Milgram,

The Alliance for Connected Care ("the Alliance") welcomes the opportunity to provide comments on the Drug Enforcement Administration ("DEA") proposed rule on telemedicine prescribing of controlled substances. We appreciate the DEA's quick response during the COVID-19 public health emergency (PHE), which expanded access to necessary medical treatment via telemedicine. While the Alliance has significant concerns with the structure of the proposed rulemaking – which would drastically reduce that access – we stand ready to work with you on alternate policy approaches to identify and mitigate the risks of diversion in the prescribing of controlled substances through telehealth.

The Alliance is dedicated to improving access to care through the reduction of policy, legal and regulatory barriers to the adoption of telemedicine and remote patient monitoring. Our members are leading health care and technology companies from across the spectrum, representing health systems, health payers, and technology innovators. The Alliance works in partnership with an Advisory Board of nearly 50 patient and provider groups who wish to better utilize the opportunities created by telehealth.

As you know, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 ("Ryan Haight Act") provides authority for the Administrator, in conjunction with the Secretary of Health and Human Services, to promulgate rules that would allow practitioners to treat patients via telemedicine without having had an in-person evaluation in certain circumstances. It also permits the Attorney General to issue a practitioner a special registration to engage in the practice of telemedicine if the practitioner demonstrates a legitimate need for the special registration and meets other DEA requirements.[1] In our below comments, we discuss how the flexibilities put in place during the COVID-19 public health emergency (PHE) by the DEA increased access to care, offer specific feedback on the proposed rule, and offer a specific time-sensitive recommendation for DEA to consider this spring if it needs additional time to incorporate all of our recommendations.

Access to Care During the COVID-19 PHE

With many health care expansions, our biggest challenge is demonstrating the proof of concept, and capturing the data needed to understand the implications of a policy change. Fortunately, we now have several years of experience on which to base permanent telemedicine policy.

[1] https://www.congress.gov/110/plaws/publ425/PLAW-110publ425.pdf

During the COVID-19 PHE, the DEA acted swiftly[2] to ensure that adults and children could continue to access medically necessary controlled substances via telemedicine by waiving the requirement that the patient have a prior in-person visit, regardless of their location, for the duration of the public health emergency. The PHE flexibilities have made clear the importance of increased access to telemedicine services.

The benefits of these changes are widely recognized. The Office of National Drug Control Policy (ONDCP) has recommended that the DEA make permanent the authorization of qualified practitioners to prescribe controlled substances to patients using telemedicine without first conducting an in-person evaluation.[3]

We recognize that there were some highly public instances of these pandemic flexibilities being abused. We believe these public health emergency abuses are similarly instructive – they emphasize the need for a regulation and give the DEA very clear insights into exactly what types of business practices require additional oversight and monitoring. This experience should allow the DEA to craft a nuanced regulation that targets questionable practices while allowing the practice of medicine to continue through telemedicine. The DEA must balance their concerns with a huge number of patients who will lose access to providers who are offering medically necessary care.

Need for the Special Registration to Engage in the Practice of Telemedicine

We are concerned that this rule does not satisfy multiple congressional directives to establish a process for providers to prescribe controlled substances via telemedicine without a prior, in-person medical evaluation. This Notice of Proposed Rulemaking does not outline a registration process allowing the consistent prescribing of controlled substances via telemedicine despite the DEA's legal obligation to do so. After years of requests, multiple congressional directives[4][5][6] and the DEA acknowledging it would "issues a separate rule" consistent with this obligation, the DEA still has not activated the special telemedicine registration, even in this Notice of Proposed Rulemaking (NPRM).[7]

To the contrary, the DEA suggests this NPRM fulfills its obligation to issue a special registration, determining to do so was "deemed potentially burdensome for both prospective telemedicine providers and patients." We respectfully disagree. The Controlled Substance Act, amended pursuant to the Ryan Haight Act, already allows seven exceptions for a practitioner to prescribe a controlled substance via telemedicine without a prior in-person medical evaluation.[8] The special registration for telemedicine is

[2] https://www.deadiversion.usdoj.gov/coronavirus.html
[3] https://www.whitehouse.gov/wp-content/uploads/2022/06/Telehealth-and-Substance-Use-Disorder-Services-in-the-Era-of-COVID-19-FINAL.pdf
[4] The Substance Use Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, signed into law on October 24, 2018, required the DEA to promulgate final regulations related to a Special Registration for Telemedicine.
[5] Senator Warner (D-VA) sent a letter to the DEA requesting a plan to ensure continuity of care for patients being prescribed controlled substances via telemedicine after the end of the PHE.
[6] The Fiscal Year (FY) 2023 Omnibus Appropriations bill directs DEA to promulgate final regulations specifying the circumstances in which a Special Registration for telemedicine may be issued and the procedure for obtaining the registration.
[7] 74 FR 15596, 15603.
[8] 21 U.S.C. §802(54)

one of seven categories (#5) under the practice of telemedicine authority recognized by the CSA, while the NPRM is issued pursuant to exception that allows the DEA to issue rules with HHS.

We have attached to this letter a Foley & Lardner LLP memo discussing the legal authority and statutory obligation of the DEA to promulgate the special registration rule.[9] Notably, statute directs DEA to provide an exception to an in-person medical evaluation requirement where the practitioner is "engaged in the practice of telemedicine".[10] The original statute and subsequent amendment by the SUPPORT Act, empowers (and directs) the DEA to implement a process for telemedicine prescribing of controlled substances, without an in-person medical evaluation, in situations that do not meet any of the other six telemedicine exceptions.

The Alliance urges the DEA to move forward with the development of a special telemedicine registration to ensure access to medically necessary services are available via telemedicine. This registration process should be an opportunity for health care providers or provider organizations to subject themselves to a higher level of scrutiny by DEA, and in exchange have greater flexibility to prescribe without in-person referral requirements, prescribing time-limits, and the ability to prescribe a wider range of substances.

Specific Feedback on Proposals in the Proposed Rule

Broadly, the Alliance for Connected Care is disappointed by the approach taken by DEA in the proposed rule. Rather than working to develop an evidence-based approach to identify and mitigate the risk of diversion, the DEA has created overbroad restrictions on health care access that will have serious and detrimental implications for tens of thousands of Americans who rely on telehealth practitioners for care.

We continue to believe that it is both reasonable and possible for the DEA to protect Americans while differentiating between the higher-risk business practices (that the DEA invested resources into investigating) and the normal provision of medical services through telehealth. We urge DEA to work with stakeholders, the Department of Health and Human Services (HHS), and others to find a more nuanced approach to diversion that allows ongoing, relationship-based care between patients and their virtual providers to continue.

Limit Prescriptions for a Controlled Medication Issued to a Patient to a 30-Day Supply

While we have long known that telehealth can provide clinically equivalent care for many conditions, this has been repeatedly proven over the past several years.[11] Unfortunately, this rule places an arbitrary limit on the care a telehealth provider is able to offer for many conditions, undermining that care in favor of in-person care which may or may not meet the patient's needs or offer the same quality of care.

The proposed rule restricts a patient receiving telehealth care including a controlled medication to a 30-day supply. There are several challenges with this approach in addition to there being no evidence presented that it will be an effective diversion control tactic. First, rules on how clinicians may treat

[9] https://connectwithcare.org/wp-content/uploads/2023/03/DEA-Special-Registration-Rule-Ryan-Haight-Act-White-Paper-Foley-Lardner-March-2023.pdf
[10] Ryan Haight Act (21 U.S.C. 802(54))
[11] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2796668

patients overstep the DEA's important role of preventing diversion, and into medical decisions that should be determined by clinicians and patients, or at the very least by organizations with medical expertise making decisions based on medical outcomes data.

Second, the arbitrary nature of a 30-day supply requirement means its impact is unclear and erratic. There will be some conditions for which an entire treatment regimen is less than 30 days, and other conditions – such as many mental health treatments —for which a 30-day restriction is an absolute barrier to high-quality care. If we think about this restriction in practice – it means that a telehealth clinician will be pressured to prescribe a medication to a patient without clear knowledge of if that patient would be able to complete the full treatment regimen. While they will of course hope that an in-person referral is possible, leading to continued treatment, there will always be a risk of that patient being unable to get an in-person visit within 30 days due to ongoing primary care and other workforce shortages. In many situations, such as mental health or substance use disorder treatment, losing access to a treatment that is working for the patient could be as harmful or even more harmful than the original condition being treated.

As an example, a study published in JAMA Network Open found that patients who initiated medications for opioid use disorder (MOUD) within 14 days were equally likely to have at least one subsequent prescription in the 30 to 90 days after the index visit in the pandemic period. The mean days' supply for patients with at least one fill within 90 days of the index visit was consistent across the pre-pandemic and pandemic period for clinicians in both the low and high telemedicine use groups.[12] Numerous other barriers prevent broader access to medication-based treatment for opioid use disorder including stigma, inadequate professional education and training related to the evidence base for using medication, and challenges in connecting individuals with medication-based treatment. It is widely recognized that the time and money required to travel long distances for frequent office visits may prove challenging, especially for rural patients.[13]

A time-based restriction is simply not a good approach to prevent diversion while causing many disruptions to the practice of medicine. DEA could consider many alternative options that may more directly address the risk of diversion – such as monitoring and audits of providers with unusually high-volumes or unusual treatment patterns when compared to peers in their specialty.

Requirement for an In-Person Medical Evaluation for Additional Prescriptions for a Controlled Medication

Building on widespread concerns around a 30-day limitation on prescribing are concerns around the in-person visit and referral process. Unfortunately, the premise that an in-person visit is a control against diversion is flawed. As we know, there was no telehealth prescribing of controlled substances between 2008 and 2020 – a period during which the national opioid epidemic surged.

[12] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800718
[13] https://tbhcoe.matrc.org/wp-content/uploads/2019/12/implementing-medication-assisted-treatment-opioid-disorder-rural-primary-care-environmental-scan-volume-one-2017.pdf?9d4e56&9d4e56

We do appreciate the DEA's stated intent in creating a referral pathway to allow for greater telehealth treatment, however. We also recognize that there are legitimate clinical situations in which a telehealth practitioner may feel it is appropriate for a patient to have a physical examination. Many telehealth practitioners make clinically appropriate referrals to in-person providers when a physical examination is needed – including important evaluations like urine toxicology to ensure treatments are not being abused. For this reason, we feel a referral from a telehealth provider to an in-person provider for a physical exam to be the more appropriate and clinically indicated step.

The primary challenge with an in-person referral mandate – even when not clinically required – is the limitation on access it creates for the millions of Americans seeking treatment for a condition for which there are significant barriers to access. These can include stigma, provider shortages, long-distances to see providers, and many other barriers. In particular, rural residents and non-elderly adults are more likely to use telehealth for mental health and substance use disorder visits, especially in areas with fewer providers – as noted by SAMHSA in its recent publication "Digital Access: A Super Determinant of Health."[14] There is no reliable guarantee that patients who found access to care through telehealth over the past few years will be able to find and obtain a meeting with an in-person practitioner able to make an examination and referral. Average wait times for a physician appointment across the nation range between 17 and 45.6 days – meaning some areas are likely much higher.[15] Telehealth has created meaningful access for these individuals, and we risk losing that progress.

If DEA were to move forward with a referral structure, it should consider edits to make this process more operationally workable. Requiring a specific clinician-to-clinician referral as required by the language in the proposed rule is operationally challenging, and likely to undermine patient care. There are many reasons why a clinician-to-clinician referral could fail to meet the patient needs – such as the telehealth clinician leaving a practice or medical group or the clinician not having time or bandwidth to accept a referral. DEA should modify its proposal to allow for referrals to a medical group that may consist of many clinicians. This will make it more likely a clinician is available to see the patient, it will allow the patient choice if there is some reason they do not want to see a specific clinician, and it will continue a path to care even if the referred to clinician were to be on leave, retire, etc. Allowing the referring provider to be able to refer to a medical group, health system practice or other health care organization, would better align with how health care referrals work in the real world and make sure there is a path to patient care even if a clinician is overbooked, unavailable, on leave, or even retired.

Simplicity in the referral process is also extremely important for pharmacies nationwide, who need to provide a final line of defense against diversion while also enabling important patient access. Confusing and difficult to evaluate referral rules will lead to many patients being inappropriately denied access to their medications.

Omission of Schedule II and IIN Controlled Medications

Since March 16, 2020, the DEA quickly responded to the COVID-19 PHE and allowed DEA-registered practitioners in all areas of the United States to issue prescriptions for all Schedule II-V controlled

[14] https://www.samhsa.gov/blog/digital-access-super-determinant-health
[15] https://www.merritthawkins.com/trends-and-insights/article/surveys/2022-physician-wait-times-survey

substances to patients for whom they have not conducted an in-person medical evaluation, provided certain conditions were met. The COVID-19 PHE has demonstrated almost three years of evidence for the prescription of Schedule II controlled medications via telemedicine.

We urge the DEA to evaluate Schedule IIN non-narcotic substances separately, evaluating the relative risks of diversion against the patient harm that may be caused by lack of access. In the broader interest of continuing to prevent substance use disorder, we make specific note of the fact that treatment of a condition like ADHD with a controlled substance does not increase the risk of developing a substance use disorder and that proper treatment of a mental health condition can even lead to lower likelihood of a future substance use disorder.[16]

Other Comments

During the PHE, the DEA waived the requirement that a provider have a registration for each state where they prescribe to patients. The NPRM includes no indication as to whether that waiver will continue for 180 days like the rest of the waivers, and instead, signals that providers must be registered both the state where the patient is located and the state where the provider is at the time of the telemedicine visit (even if the provider is physically in a state where they never see patients). Further, though the NPRM recognizes that telemedicine practitioners might be prescribing in a state where they do not have a physical location, the proposed rule does not update registrations procedures for where providers – particularly those in specialties like behavioral health – might have a multistate practice. While the Special Registration framework would be ideal for addressing multistate telemedicine provider registrations, we request the DEA offer additional clarity and streamline how providers with a multi-state practice can meet registration requirements.

We applaud the DEA for its proposal to continue access for patients that have an ongoing telehealth relationship for 180 days. Unfortunately, we continue to believe that many of those patients will have trouble finding an in-person provider and will still lose access to care at that time.

While not directly stated in this rule, there continues to be a misconception among many that telemedicine is separate and different from in-person care – when it is the same care, just provided through a different modality. One relevant substance use disorder example – a 2021 Substance Abuse and Mental Health Services Administration (SAMHSA) report found strong evidence that telemedicine was just as effective as an in-person medication-assisted treatment (MAT).[17] There is no other evidence that currently exists that an in-person visit is more effective than telemedicine visits in improving treatment outcomes or minimizing diversion.[18]

Mitigating the Upcoming COVID-19 PHE Access Cliff

While the Alliance strongly prefers a proactive special registration process which validates clinicians as having a low risk of diversion and empowers them to provide comprehensive medical care

[16] https://www.uclahealth.org/news/are-children-who-take-ritalin-for-adhd-at-greater-risk-of-future-drug-abuse
[17] https://store.samhsa.gov/sites/default/files/pep21-06-02-001.pdf
[18] https://ldi.upenn.edu/our-work/research-updates/lowering-the-barriers-to-medication-treatment-for-people-with-opioid-use-disorder/

through telehealth, we recognize that the time needed for DEA to draft and implement such a regulation is now short. There is immense pressure from all stakeholders to finalize a regulation prior to the end of the public health emergency.

With that in mind, we believe there is a most important action that DEA can take to mitigate the immense patient harm this rule would cause if implemented as currently written. DEA must find a path to allow the continuation of comprehensive mental health (and substance use disorder – which is often overlapping) treatment to patients through telehealth. While we believe there are many appropriate use-cases for telehealth involving controlled substances, such as palliative care, the vast majority of patients who would be harmed by the rule are relying on telehealth for access to mental health care.

The only realistic path to achieving the goals of President Biden's Mental Health Strategy,[19] which seeks to connect more Americans to mental health care, is through the widespread use of telehealth. As you may know, forty percent of American adults report symptoms of anxiety and depression, and there has been an alarming thirty percent rise in the percent of children and adolescents with anxiety and depression.[20][21] Unfortunately, the broader behavioral health workforce is stretched – both in numbers and in distribution. More than half of U.S. counties do not have a psychiatrist[22] and an estimated 122 million Americans, or 37 percent of the population, live in mental health professional shortage areas.[23] This means that the requirement for an in-person referral is a particularly high barrier to access for patients with mental health needs.

It is also important to consider the downstream implications of reduced access on the 57.8 million adults with mental illness.[24] It's reported that 65 percent of all patients who had a substance use disorder or overdose diagnosis in 2021 had a preexisting mental health condition – meaning mental health and substance use disorder cannot be effectively separated without causing harm.[25]

Finally, and importantly for this proposed rule – approximately 36 percent of all mental health and substance use treatment patients are relying on telehealth for access to care.[26] While we cannot project how many Americans would find alternative in-person treatment, these figures suggest that millions of Americans could lose access to their existing mental health treatment provider that is offering care through telehealth. While many of these people will manage without treatment, many others will lose their jobs, disrupt their families, and some may even turn to the use of illicit drugs.

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[19] https://www.whitehouse.gov/briefing-room/statements-releases/2022/03/01/fact-sheet-president-biden-to-announce-strategy-to-address-our-national-mental-health-crisis-as-part-of-unity-agenda-in-his-first-state-of-the-union/

[20] https://www.kff.org/report-section/the-implications-of-covid-19-for-mental-health-and-substance-use-issue-brief/

[21] https://www.hhs.gov/about/news/2022/09/01/back-to-school-hhs-announces-40-point-22-million-in-youth-mental-health-grants-awarded-in-august-plus-47-point-6-million-in-new-grant-funding.html

[22] https://www.aamc.org/news-insights/growing-psychiatrist-shortage-enormous-demand-mental-health-services

[23] https://usafacts.org/articles/over-one-third-of-americans-live-in-areas-lacking-mental-health-professionals/

[24] https://www.nimh.nih.gov/health/statistics/mental-illness

[25] A Comparison of Substance Use Disorders before and during the COVID-19 Pandemic: A Study of Private Healthcare Claims https://www.fairhealth.org/publications/whitepapers

[26] https://www.kff.org/coronavirus-covid-19/issue-brief/telehealth-has-played-an-outsized-role-meeting-mental-health-needs-during-the-covid-19-pandemic/

Conclusion

While the Alliance has significant concerns with the structure of the proposed rulemaking, we stand ready to work with you to identify and mitigate the risks of diversion in the prescribing of controlled substances through telehealth. We strongly urge you to 1) modify the proposed rule to continue patient access to their telehealth providers, 2) ensure mental health and substance use treatment access is not severed for millions of Americans after the public health emergency, and 3) immediately begin work on a special registration process that allows practitioners to meet a higher bar of DEA evaluation and be able to practice medicine without these limitations.

Thank you for your consideration of these comments. If you have any additional questions, please do not hesitate to contact Chris Adamec at cadamec@connectwithcare.org.

Sincerely,

Krista Drobac
Executive Director
Alliance for Connected Care

DEA Special Registration for Controlled Substance Prescribing via Telemedicine without an In-Person Medical Evaluation

March 20, 2023

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MEMORANDUM

FROM: Foley & Lardner LLP

DATE: March 20, 2023

RE: Special Registration for Controlled Substance Prescribing via Telemedicine without In-Person Medical Evaluation

Introduction

This "white paper" discusses the legal authority and statutory obligation of the Drug Enforcement Administration (DEA) to promulgate regulations specifying the circumstances in which a special registration may be issued, and the procedures for obtaining such a special registration, to allow practitioners to prescribe controlled substances via telemedicine without an in-person medical evaluation.

The special registration for telemedicine, which would allow for prescribing controlled substances via telemedicine without an in-person medical evaluation, a feature contemplated in the Ryan Haight Act, is important because it can more readily allow for legitimate direct-to-patient prescribing of medically necessary controlled substances when the patient is located outside a hospital facility (e.g., at home). The special registration was added to federal law in 2008, but the DEA has never promulgated a proposed or final rule allowing clinicians to use it. For nearly 15 years, patients, clinicians, industry stakeholders, and federal elected officials have asked the DEA to activate the rule (even going so far as to enact a new federal law expressly instructing the DEA to publish the rule by 2019). To date, the special registration for telemedicine still has not been released.

The recently released proposed rule does not satisfy DEA's obligation as directed by the Ryan Haight Act and the SUPPORT Act to implement a telemedicine special registration process enabling practitioners to prescribe controlled substances via telemedicine without a prior, in-person medical evaluation.

The DEA has the legal authority and duty to issue rules developing a special registration permitting a practitioner to prescribe controlled substances via telemedicine without conducting an in-person medical evaluation. The DEA should use its authority to fulfill its obligations under federal law.

Ryan Haight Act Background

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008[1] ("Ryan Haight Act") amended the federal Controlled Substances Act by adding a series of new regulatory requirements and criminal provisions designed to combat the proliferation of so-called "rogue Internet sites" that unlawfully dispensed controlled substances by means of the Internet.[2] Congress passed the Act "to prevent the Internet from being exploited to facilitate such unlawful drug activity."[3] The Act was enacted on October 15, 2008 and was effective April 13, 2009. The DEA issued interim final regulations on April 6, 2009, effective April 13, 2009.[4]

The Ryan Haight Act prohibits the distributing, dispensing or delivery of controlled substances via the "Internet" (a broadly-defined term that includes telemedicine) without a valid prescription.[5] The term "valid prescription" means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by: 1) a practitioner who has conducted at least one in-person medical evaluation of the patient; or 2) a covering practitioner.[6] The term "in-person medical evaluation" means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.[7] Once the practitioner has conducted this in-person medical evaluation, the Ryan Haight Act does not set an expiration period or a minimum requirement for subsequent annual exams.

Telemedicine Exceptions

The Ryan Haight Act and its regulations offer seven exceptions to the in-person medical evaluation requirement for when a prescriber is engaged in the "practice of telemedicine."[8] They are as follows:[9]

> (1) **Treatment in a hospital or clinic.** The practice of telemedicine is being conducted while the patient is being treated by, and physically located in, a hospital or clinic registered under section 303(f) of the Act (21 U.S.C. § 823(f)) by a practitioner acting in the usual course of professional practice, who is acting in accordance with applicable State law, and who is registered under section 303(f) of the Act (21 U.S.C. § 823(f)) in the State in which the patient is located, unless the practitioner:

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[1] 21 U.S.C. §829.

[22] The term 'Internet' means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/ Internet Protocol, or any predecessor or successor protocol to such protocol, to communicate information of all kinds by wire or radio. 15 U.S.C. § 802(50).

[3] 74 FR 15596, 15597 (April 6, 2009).

[4] *See* 21 CFR Part 1300, 1301, 1304, *et al.;* 74 FR 15596 (April 6, 2009).

[5] 21 U.S.C. § 829; 21 C.F.R. § 1306.09(a).

[6] 21 C.F.R. § 1300.04(l)(1); 21 U.S.C. § 829(e)(2)(A).

[7] 21 C.F.R. § 1300.04(f); 21 U.S.C. § 829(e)(2)(B).

[8] 21 U.S.C. § 829(e)(3)(A).

[9] 21 C.F.R. § 1300.04(i).

(i) Is exempted from such registration in all States under section 302(d) of the Act (21 U.S.C. § 822(d)); or

(ii) Is an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract, and registered under section 303(f) of the Act (21 U.S.C. § 823(f)) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);

(2) **Treatment in the physical presence of a practitioner.** The practice of telemedicine is being conducted while the patient is being treated by, and in the physical presence of, a practitioner acting in the usual course of professional practice, who is acting in accordance with applicable State law, and who is registered under section 303(f) of the Act (21 U.S.C. § 823(f)) in the State in which the patient is located, unless the practitioner:

(i) Is exempted from such registration in all States under section 302(d) of the Act (21 U.S.C. § 822(d)); or

(ii) Is an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract, and registered under section 303(f) of the Act (21 U.S.C. § 823(f)) in any State or is using the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);

(3) **Indian Health Service or tribal organization.** The practice of telemedicine is being conducted by a practitioner who is an employee or contractor of the Indian Health Service, or is working for an Indian tribe or tribal organization under its contract or compact with the Indian Health Service under the Indian Self-Determination and Education Assistance Act; who is acting within the scope of the employment, contract, or compact; and who is designated as an Internet Eligible Controlled Substances Provider by the Secretary of Health and Human Services under section 311(g)(2) of the Act (21 U.S.C. § 831(g)(2));

(4) **Public health emergency declared by the Secretary of Health and Human Services.** The practice of telemedicine is being conducted during a public health emergency declared by the Secretary of Health and Human Services under section 319 of the Public Health Service Act (42 U.S.C. § 247d), and involves patients located in such areas, and such controlled substances, as the Secretary of Health and Human Services, with the concurrence of the Administrator, designates, provided that such designation shall not be subject to the procedures prescribed by the Administrative Procedure Act (5 U.S.C. §§ 551–59 and 701–06);

(5) **Special registration.** The practice of telemedicine is being conducted by a practitioner who has obtained from the Administrator a special registration under section 311(h) of the Act (21 U.S.C. § 831(h));

(6) **Department of Veterans Affairs medical emergency.** The practice of telemedicine is being conducted:

(i) In a medical emergency situation:

(A) That prevents the patient from being in the physical presence of a practitioner registered under section 303(f) of the Act (21 U.S.C. § 823(f)) who is an employee or contractor of the Veterans Health Administration acting in the usual course of business and employment and within the scope of the official duties or contract of that employee or contractor;

(B) That prevents the patient from being physically present at a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f) of the Act (21 U.S.C. § 823(f));

(C) During which the primary care practitioner of the patient or a practitioner otherwise practicing telemedicine within the meaning of this paragraph is unable to provide care or consultation; and

(D) That requires immediate intervention by a health care practitioner using controlled substances to prevent what the practitioner reasonably believes in good faith will be imminent and serious clinical consequences, such as further injury or death; and

(ii) By a practitioner that:

(A) Is an employee or contractor of the Veterans Health Administration acting within the scope of that employment or contract;

(B) Is registered under section 303(f) of the Act (21 U.S.C. § 823(f)) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f); and

(C) Issues a controlled substance prescription in this emergency context that is limited to a maximum of a five-day supply which may not be extended or refilled; or

(7) **Other circumstances specified by regulation.** The practice of telemedicine is being conducted under any other circumstances that the Administrator and the Secretary of Health and Human Services have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.

Some of the above exceptions are suited to institutional/hospital arrangements, but most have limited utility in contemporary telemedicine services, most notably direct-to-patient care when

the patient is located at home. The main exception designed to accommodate this type of direct-to-patient care is the special registration exception. ("The practice of telemedicine is being conducted by a practitioner who has obtained from the Administrator a special registration").[10]

History and Context of the Special Registration for Telemedicine

The Ryan Haight Act was signed into law in October 2008 and the DEA was instructed to publish regulations. The DEA did not use the standard federal rulemaking process of posting a proposed rule, soliciting public comments, and then publishing the final regulations. Instead, on April 6, 2009, the DEA published an "interim final rule" that took effect April 13, 2009 – a mere nine days after it was published. This process allowed no consideration of public comments nor any revisions to the regulation – an atypical approach.

Typically, the process of making new federal regulations starts with a proposed rule, published and shared with the public. The public is given a period of time, typically 90 days, to read the proposed rule and submit comments to the federal agency. The agency then must read, consider, and respond to every comment. The comments and responses are then published in a final regulation available for the public to review. This procedure is an iterative process, conducted in the open, allowing the public (including patients and practitioners in the telemedicine industry) to comment on and suggest changes to the regulation before it is finalized.

In contrast, with an interim final rule, the agency simply publishes the new regulation and effective date, often without officially considering or responding to any public comments. The risk of an interim final rule is that it might not be aligned with the best interests of patients and practitioners, and there is no opportunity for these stakeholders to share their comments and suggestions for improvement. This interim final rule process is the process DEA used in 2009 for the Ryan Haight Act regulations.

The DEA conceded its interim final rule was drafted and enacted on a rapid basis "in order to implement the Act within the relatively short time period" between the passage of the Ryan Haight Act and its effective date (six months).[11] Moreover, the interim final rule did not activate the special registration exception. The DEA did acknowledge it was required to develop "a special registration relating to the practice of telemedicine," and promised it "will issue a separate rule promulgating regulations consistent with this directive."[12]

That was 2009. Despite years of requests, and more than 10 different federal notices that a special telemedicine registration rule would be published, it was never released.

In October 2015, the American Telemedicine Association ("ATA") sent a letter[13] to the DEA, advocating for changes to the Ryan Haight Act. (Foley & Lardner was a contributing author to the letter.) The letter urged DEA to activate the special registration process allowing

[10] *See* 21 C.F.R. § 1300.04(i)(5).
[11] *See* 74 FR 15596, 15597.
[12] 74 FR 15596, 15603.
[13] A copy of the letter can be accessed at: https://www.foley.com/-/media/files/insights/publications/2017/03/ata-letter-to-dea-re-ryan-haight.pdf?rev=8a66700c968040a6bc2f15a128b3de82.

practitioners to prescribe controlled substances via telemedicine without the need for an in-person medical evaluation. It also suggested an architecture through which the DEA might craft the special registration to meet the needs of contemporary, legitimate telemedicine services.

Four months later, in February 2016, representative from the ATA, Foley & Lardner, and several telemedicine companies and clinicians participated in a half-day meeting at the DEA's Headquarters to discuss the status of the special registration rule development. After the meeting, the DEA published a revised notice of rulemaking, which stated the special telemedicine rule would be published in January 2017. Yet, more than two years after the meeting with DEA, regulations had not been issued.

Eventually, both Congress and the White House agreed the delay was unacceptable, and passed the Special Registration for Telemedicine Act[14] on October 24, 2018. The law, part of the SUPPORT for Patients and Communities Act, instructed the Attorney General, in consultation with the Department of Health and Human Services ("HHS"), to promulgate final regulations specifying the circumstances in which a special registration may be issued and the procedure for obtaining a special registration by October 24, 2019.[15] DEA did not publish the rule by the deadline.

On September 30, 2020, the DEA published the final rule titled "Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008" adopting the interim final rule as final, and including the minor technical changes made by subsequent DEA rules.[16] The Final Rule went into effect on October 30, 2020.

More years passed and, on March 17, 2022, DEA's special registration rule was listed on the Unified Agenda (RIN 1117-AB40).[17]

As of the date of this memo, despite growing public and legislative pressure, the rule has not yet been published.

Special Registration for Telemedicine Allows for Controlled Substance Prescribing Without an In-Person Medical Evaluation

[14] Public Law No. 115-271.

[15] The law was added to Title III, Subtitle B, Chapter 4 of a larger legislation titled the "SUPPORT for Patients and Communities Act" and provides:

> Section 311(h)(2) of the Controlled Substances Act (21 U.S.C. 831(h)(2)) is amended to read as follows:
> (2) REGULATIONS.— Not later than 1 year after the date of enactment of the SUPPORT for Patients and Communities Act, in consultation with the Secretary, the Attorney General shall promulgate final regulations specifying—
> (A) the limited circumstances in which a special registration under this subsection may be issued; and
> (B) the procedure for obtaining a special registration under this subsection.

[16] 85 FR 61594.

[17] Office of Management and Budget (OMB), Unified Agenda: Special Registration to Engage in the Practice of Telemedicine, RIN: 1117-AB40, 2018 (https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201810&RIN=1117-AB40); and OMB, Unified Agenda: Special Registration to Engage in the Practice of Telemedicine, RIN: 1117- AB40, 2019, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201910&RIN=1117-AB40).

The DEA has the legal authority (and legal obligation) to issue a special registration for telemedicine prescribing of controlled substances without a prior, in-person medical evaluation.

Even when the Ryan Haight Act was introduced, the Senate Judiciary Committee expected the DEA to revise the rules as telemedicine evolved, writing:

> "the statute provides that the Attorney General and the Secretary of Health and Human Services may promulgate regulations ***that allow for the full practice of telemedicine consistent with medical practice guidelines***, so long as those regulations continue to effectively control diversion. The Committee anticipates that the Attorney General and the Secretary may update these regulations on an ongoing basis to reflect changes in telemedicine."[18] (emphasis added).

When the Ryan Haight Act actually was passed, Congress contemplated the DEA would, with the concurrence of HHS, "promulgate regulations governing the issuance to practitioners of a special registration relating to the practice of telemedicine."[19]

As indicated above, the statutory architecture of the Ryan Haight Act is such that, in 21 U.S.C. 829(e), the Ryan Haight Act generally requires an in-person medical evaluation prior to the prescription of controlled substances. Section 829(e), however, also provides an exception to this in-person medical evaluation requirement where the practitioner is "engaged in the practice of telemedicine"[20] within the meaning of the Ryan Haight Act (21 U.S.C. 802(54)). The exceptions to the in-person requirement reside in the definition of "the practice of telemedicine." The original statute and subsequent amendment by the SUPPORT Act, empowers (and directs) DEA to implement a process for telemedicine prescribing of controlled substances, without an in-person medical evaluation, in situations that do not meet any of the other six telemedicine exceptions.

Indeed, the preamble to the regulations implementing the Ryan Haight Act specifically contemplated that the special registration for telemedicine would provide a process to allow practitioners to prescribe controlled substances via telemedicine **without an in-person medical evaluation**:

> *"Special registration for telemedicine*—A practitioner who is engaged in the practice of telemedicine within the meaning of the Act ***is not subject to the mandatory in-person medical evaluation requirement of 21 U.S.C. 829(e)*** (although such practitioner remains subject to the requirement that all prescriptions for controlled substances be issued for a legitimate medical purpose) (emphasis added)."[21]

[18] Sen. Rept. 110-521 – Ryan Haight Online Pharmacy Consumer Protection Act of 2007 (https://www.congress.gov/congressional-report/110th-congress/senate-report/521/1).
[19] 74 FR 15595, 15597.
[20] 21 U.S.C. § 829(e)(3)(A).
[21] 74 FR 15595, 15603.

Further, in its recent proposed rule on telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation, the DEA itself recognized that the special registration for telemedicine would not include an in-person medical evaluation requirement. Specifically, the DEA stated:

> "in the foregoing and other circumstances encompassed by the Ryan Haight Act's definition of the 'practice of telemedicine,' the Act contemplates that the practitioner will be permitted to prescribe controlled substances by means of the internet ***despite not having conducted an in-person medical evaluation*** when certain safeguards are in place to ensure that the practitioner who is engaged in the practice of telemedicine is able to conduct or participate in a *bona fide* medical evaluation of the patient at the remote location, and is otherwise prescribing for a legitimate medical purpose while acting in the usual course of professional practice."[22] (emphasis added).

Requiring any in-person medical evaluation by the prescriber as part of the exception would give no meaning to the special registration. Additionally, none of the other six exceptions require the prescriber to conduct an in-person medical evaluation. Thus, the special registration for telemedicine calls for a process that allows for telemedicine prescribing of controlled substances without an in-person medical evaluation.

DEA Proposed Rule Does not Satisfy Obligation to Issue Special Telemedicine Registration

On March 1, 2023, the DEA published proposed rules for prescribing controlled substances via telemedicine after the COVID-19 Public Health Emergency expires.[23]

In a footnote within the rule, DEA asserts the rule fulfills DEA's obligation under the Ryan Haight Act and the SUPPORT Act to promulgate the special registration for telemedicine. Specifically, DEA wrote:

> In the SUPPORT for Patients and Communities Act (SUPPORT Act), signed into law on October 24, 2018, Congress required DEA to promulgate regulations concerning such special registrations. *See id*. 831(h)(2). This instance of rulemaking, which sets forth circumstances under which telemedicine encounters may result in the prescription of controlled substances without an in-person evaluation and also provides safeguards for such prescriptions, is consistent with, and fulfills, DEA's obligations under both the Ryan Haight Act and the SUPPORT Act.[24]

Although DEA asserts the rule fulfills its obligation to issue a special registration for telemedicine, in the same rule, DEA states it considered allowing the practice of telemedicine pursuant to an application and issuance of a special registration but ultimately decided against

[22] 88 FR 12875, 12877.
[23] 88 FR 12875.
[24] 88 FR 12875, 12877.

this option citing such special registration process would be burdensome for both prospective telemedicine providers and patients. Specifically, DEA wrote:

> DEA considered allowing the practice of telemedicine pursuant to an application and issuance of a "special registration" allowing such practice. Upon further consideration, this alternative was deemed potentially burdensome for both prospective telemedicine providers and patients. Therefore, DEA decided against this alternative.

In other words, despite the history of the Ryan Haight Act, nearly 15 years of advocacy efforts and calls for action, and a 2018 federal law (the SUPPORT Act) mandating DEA publish the special registration, DEA decided not to do so on the grounds it "was deemed potentially burdensome for both prospective telemedicine providers and patients." Instead, DEA proposed a rule with a complex architecture of different and new exceptions, confusing terminology, and extensive administrative recordkeeping.

The DEA contends it has somehow fulfilled its legal obligation to publish the special registration rule, despite never actually publishing the special registration rule and providing no legal basis or analysis for its assertion.

Despite DEA's assertion, the recently proposed rule is categorically not the same as the special registration rule. The special registration is exception #5 under the Ryan Haight Act (21 U.S.C. § 802(54)(E)) ("The practice of telemedicine is being conducted by a practitioner who has obtained from the [DEA] Administrator a special registration"). The proposed rule is exception #7 under the Ryan Haight Act (21 U.S.C. § 802(54)(G)) ("The practice of telemedicine is being conducted under any other circumstances that the Administrator and the Secretary of Health and Human Services have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety"). The two exceptions reflect different statutory sections and authority, different processes, and serve to fulfill different, although overlapping, public policy goals.

As such, the recently released proposed rule does not satisfy DEA's obligation as directed by the Ryan Haight Act and the SUPPORT Act to implement a telemedicine special registration process enabling practitioners to prescribe controlled substances via telemedicine without a prior, in-person medical evaluation.