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

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MEMORANDUM

FROM: Foley & Lardner LLP

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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.