Published on *The National Law Review* https://natlawreview.com

Will Federal Special Registration Exception Preempt More Stringent State Rules on Remote Prescribing of Controlled Substances?

Article By:

Health Care and Life Sciences Practice Group

The Ryan Haight Act Online Pharmacy Consumer Protection Act of 2008 (21 U.S.C. § 802(54)) (the "Ryan Haight Act" or "Act") expanded the federal Controlled Substances Act to define appropriate internet usage in the dispensing and prescribing of schedule drugs, and in doing so effectively banned the issuance of prescriptions via telemedicine services for any controlled substances unless the ordering physician has conducted at least one in-person evaluation of the patient. The Act includes multiple exceptions that permit prescribing of controlled substances without conducting an in-person evaluation, the most relevant to the practice of telemedicine being the mandate that the Drug Enforcement Administration ("DEA") or other federal agency establish rules for a "Special Registration" to be utilized by health care providers. However, despite the statutory mandate, since the 2008 passing of the Act neither the DEA nor any other federal agency has promulgated any regulation or other guidance regarding the development and implementation of such a Special Registration process.

Several previous TechHealth Perspectives blog posts have highlighted the pressures imposed from Congress on the DEA to promulgate the Special Registration process in the wake of the opioid crisis and the recent passage of House Bill 5483, entitled the "Special Registration for Telemedicine Clarification Act of 2018" (the "Bill"), which seeks to address the lack of regulatory guidance regarding the Special Registration exception to the Ryan Haight Act. Ironically, the Bill would require the DEA to promulgate rules that are already required under the Ryan Haight Act to allow health care providers to apply for a Special Registration.

In the interim, state legislatures have started passing their own laws to address the issue of remote prescribing of controlled substances by telemedicine providers. State remote prescribing legislation varies widely among the states that have enacted such provisions, but generally fits into one of three categories:

Category I—Remote Prescribing is Allowed. Many states have not regulated the remote prescribing of controlled substances any differently than how the state has regulated in-person prescribing practices, or states have placed very minimal, added responsibilities on telemedicine providers seeking to do remote prescribing of controlled substances, which primarily are intended to ensure that the standard of care provided in the telemedicine delivery setting sufficiently mirrors the

standard of care provided in the traditional in-person delivery setting. Examples of states that have taken this route include Arizona, Kentucky, Maine, Minnesota, Missouri, Tennessee, and Vermont.

Category II—Remote Prescribing is Prohibited. A handful of states have completely prohibited the remote prescribing of controlled substances or only permit it to occur in rare instances. Connecticut and Georgia (citation available just past verification page) are examples of two states that have adopted this approach.

Category III—Remote Prescribing is Allowed, But Additional Burdens and Barriers Are Placed on Prescribing Providers. Several states, including New Jersey, North Dakota, Oklahoma, and South Carolina, require at least one in-person appointment before a health care provider can remotely prescribe controlled substances or scheduled narcotics / medications to their patients. While these states may allow for the remote prescribing of controlled substances, there may be limits on prescribing activities, including limits on the types of controlled substances that can be remotely prescribed (and expressly prohibiting the prescribing of certain controlled substances entirely, such as opioids and certain schedule narcotics).

Regardless of which category a state may fall into, many of these states' laws would be in direct conflict with the Special Registration exception under the Act, if it is ever formulated. That is, many states either prohibit the remote prescribing of controlled substances without an initial in-person consult, or impose more stringent conditions on remote prescribing than what is mandated under current federal law. The question is whether federal law would preempt any state law that is inconsistent with the Special Registration exception and would prohibit remote prescribing without an in-person examination even if the health care provider holds a Special Registration from the federal government.

Congress expressly retained supremacy and preemption through provisions of the Controlled Substances Act (21 U.S.C. § 903): "[n]o provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together." The legislative intent is clear that upon the passing of the Controlled Substances Act, Congress anticipated federal and state conflicts of law and expressly directed that federal law would control. However, the drafting yields some authority to the states and is somewhat ambiguous on relevant points.

Thus, states may also regulate remote prescribing and many have taken the opportunity to do so. If the DEA or any other federal agency promulgate rules that potentially could affect any of the existing state laws pertaining to remote prescribing, the supremacy provision in the Controlled Substances Act is sufficiently vague such that states could craft creative legal arguments providing that the federal and the state laws can consistently stand together. Currently, no entity (federal or state) has challenged any of the existing state laws as conflicting with the Ryan Haight Act or the exceptions for remote prescribing without an initial in-person examination. However, should such an action be filed, federal preemption could overrule any inconsistent state laws, rules, or regulations.

Recently, we have seen some indicia of federal preemption in the telehealth arena with the Department of Veterans Affairs asserting dominance over any state regulation and oversight of telemedicine services with the promulgation of recent regulation (38 C.F.R. § 17.417) which states in no uncertain terms that the federal rule overrides any conflicting state laws. Moreover, the notice and

comments from the Department of Veterans Affairs strongly invoke federalism in this area.

Ultimately, federal law could preempt the various state laws that completely prohibit telehealth prescribing, as well as those state laws that have put in place barriers to remote prescribing that are inconsistent with the Ryan Haight Act. Upon the promulgation of the Special Registration process, if and when it may occur, each state will have to assess and address any inconsistencies with federal law in the area of remote prescribing. Of course, while the provisions in the Ryan Haight Act addressing Special Registration do not have limitations on what kind of controlled substances could be remotely prescribed without an in-person examination under the exception, the Special Registration could incorporate limitations on the type of controlled substances that can be remotely prescribed without an in-person examination (similar to current requirements in a number of states).

In the end, the DEA (or whatever other federal agency decides to address the issue of remote prescribing) will need to find a balance when developing the Special Registration process, as there are legitimate concerns surrounding how to address the opioid crisis which is at the forefront of ongoing public health discussions. The current federal stance related to the opioid abuse in this country may prompt federal regulators to turn a blind eye to any conflicting state law or, in the alternative, it may prompt the federal regulators to exercise the power to promote access to needed treatment. The federal government may have the right to preempt and enforce against state laws inconsistent with the Ryan Haight Act; however, most state laws are generally aligned with the public policy intent behind the Ryan Haight Act. Below are additional resources which will be helpful in attaining a broader understanding of the current public information on both the state and federal level concerning the Opioid Crisis:

- Opioid Overdose Crisis
- Department of Justice Announces Regulatory Steps to Address Opioid Epidemic
- Combating the Opioid Crisis: Legislation
- Opioid Summaries by State
- U.S. and States Ramp Up Response to Opioid Crisis
- Addressing the Opioid Epidemic in New York State
- DHHR Announces Implementation of New Opioid Prescribing Requirements (WV)

Rebecca Francis, a Summer Associate (not admitted to the practice of law) in the firm's Houston Office, contributed significantly to the preparation of this post.

National Law Review, Volume VIII, Number 227

Source URL:https://natlawreview.com/article/will-federal-special-registration-exception-preempt-more-stringent-state-rules