March 18, 2025

The Honorable Derek S. Maltz
Acting Administrator
Drug Enforcement Administration
500 Army Navy Drive
Arlington, VA 22202

Re: Special Registrations for Telemedicine and Limited State Telemedicine Registrations (RIN 1117-AB40)

Dear Acting Administrator Maltz:

The Medical Group Management Association (MGMA) thanks the Drug Enforcement Administration (DEA) for the opportunity to comment on the Special Registration for Telemedicine and Limited State Telemedicine Registrations proposed rule. While we support the DEA's efforts to establish a special registration to improve the efficiency of prescribing controlled medications under the *Ryan Haight Online Pharmacy Consumer Protection Act of 2008* (*Ryan Haight Act*), the proposed process would unnecessarily impede patient access to telehealth care and add burdensome and unworkable requirements, ultimately undermining the intention of the special registration framework.

With a membership of more than 60,000 medical practice administrators, executives, and leaders, MGMA represents more than 15,000 medical group practices ranging from small private medical practices to large national health systems, representing more than 350,000 physicians. MGMA's diverse membership uniquely situates us to offer the following policy recommendations.

We appreciate the DEA's leadership in enforcing controlled substance laws and working over the past few years to expand access to telehealth services. The *Ryan Haight Act* initially required a patient to have an in-person medical evaluation prior to receiving a prescription for a controlled substance. During the COVID-19 Public Health Emergency (PHE), the DEA instituted critical policy flexibilities to allow practitioners to continue treating patients and prescribing medication through telehealth without an in-person visit. This was a demonstrable success, especially for patients in rural areas and locations with provider shortages. Instead of disrupting care following the end of the COVID-19 PHE, the DEA rightly continued these policies through the end of 2025.

While we understand the need for appropriate protections, MGMA cautions the DEA against moving forward with an overly restrictive and administratively complex special registration process. It is essential to build on the progress made over the last five years and not upend the availability of vital telehealth services.

Key Recommendations

- **Withdraw the proposed special registration regulation as currently written or substantially revise the proposal to ensure its workability.** The DEA should withdraw the proposed rule and work with the healthcare community to institute a special registration process that appropriately balances patient protections with facilitating access to care.
- **Permit the use of audio-only telehealth visits when prescribing controlled substances under the special registration process.** Audio-only services can be a lifeline to patients who may not possess the requisite technology for audio-video visits; restricting access to critical prescriptions through audio-only services would hinder patient access to care.
- **Allow for all medical specialties to qualify under the Advanced Telemedicine Prescribing Registration to reflect the clinical care they provide.** The DEA should avoid instituting overly restrictive policies that impede many specialty groups from offering telehealth services.
- **Do not proceed with technically infeasible and burdensome requirements such as having practitioners undertake a nationwide Prescription Drug Monitoring Program check.**
- **Streamline registering and reporting requirements under the special registration framework**. Work with other federal and state partners to ensure regulatory reporting requirements are not duplicated.

Special Registration Process

The DEA proposes establishing a multi-tiered special registration process for practitioners predicated on prescribing certain Schedules of controlled substances and other requirements. The Telemedicine Prescribing Registration would allow clinician practitioners to prescribe Schedule III-V controlled substances without an initial in-person visit. Practitioners would have to show a legitimate need for the registration: physicians, nurse practitioners, and other mid-level practitioners, as defined by the DEA, would show a legitimate need if they are expecting to treat patients where in-person exams would be burdensome.

For Schedule II-V prescriptions, the proposed rule would limit the ability to write Schedule II prescriptions to certain listed clinical practitioners under the Advanced Telemedicine Prescribing Registration. This advanced level of registration would require that the patient and practitioner are in the same state when issuing a Schedule II prescription via a telehealth encounter. It would also limit the special registration of prescriptions of Schedule II controlled substances to less than 50% of the practitioner's total Schedule II prescriptions.

While understanding the DEA has legitimate and important law enforcement mandates, we urge the administration against instituting onerous requirements for practitioners who qualify for the special registration process, thereby undermining the intention of the registration. Any special registration process should come with greater flexibility for practitioners who qualify, not subject them to a more challenging regulatory process that undercuts their ability to offer telehealth care.

Specifically, the proposal to require 50% of Schedule II prescriptions to be in-person would constrain qualified clinician practitioners' ability to provide effective telehealth care. Practitioners should be able to treat patients using the full scope of their licensure and should not be arbitrarily limited in the care they can provide to their communities. The DEA should focus on preventing medication diversion and other

law enforcement efforts and remove the 50% requirement as it potentially interferes with patient continuity of care.

Requiring the patient and practitioner to be in the same state in order to prescribe Schedule II controlled substances under the Advanced Telemedicine Prescribing Registration does not accurately reflect the current landscape of telehealth services in this country. There are numerous clinically valid reasons a patient and practitioner might be in a separate state based on geographic considerations and other factors. Interfering with the patient-practitioner relationship by foreclosing these telehealth services would unnecessarily add barriers to care without a legitimate corresponding law enforcement need. We urge the DEA to rescind this proposal.

Further, the DEA should not place arbitrary restrictions on which specialties can prescribe controlled substances when practicing under their standards of care. The DEA should expand access to the Advanced Telemedicine Prescribing Registration to all medical specialties to accurately account for the telehealth care they provide.

Telemedicine Platform Registration

The proposed rule allows direct-to-consumer (DTC) telehealth companies to issue controlled substance prescriptions and qualify for a special registration as a covered online telemedicine platform under the Telemedicine Platform Registration. The DEA includes specific requirements and fees separate from clinician practitioners applying under the registration processes described above.

With the proliferation of DTC telehealth companies, it is essential to reinforce the importance of the patient-physician relationship, which is central to our healthcare system. We share the DEA's concerns about potential dangers that may result from the actions of these DTC companies, as demonstrated by the Office of Inspector General for the Department of Health and Human Services' special fraud alert in 2022, as well as various lawsuits and settlements that underscore these concerns.[1] The DEA should institute appropriate oversight and guardrails that are necessary to avoid risks to patient safety and program integrity.

Nationwide Prescription Drug Monitoring Program Check

The DEA proposes to require all prescriptions made through the special registration process to be issued through electronic prescribing for controlled substances (EPCS). Practitioners who have obtained a special registration would be required to verify the patient's identity and check the Prescription Drug Monitoring Program (PDMP) for all 50 states and any U.S. district or territory with its own PDMP to review the patient's controlled substance prescription data. This requirement would be effective three years after final publication of the rule.

Prior to the 50-state requirement coming into effect, practitioners would have to check patients' controlled substance prescription data in PDMPs of specific jurisdictions as outlined in the proposal. For all Schedule II-V controlled substances, clinician practitioners would be required to conduct a PDMP check of the state/territory where the patient is located, the state/territory where the clinician practitioner is

[1]Department of Health and Human Services, Office of Inspector General, Special Fraud Alert: OIG Alerts Practitioners to Exercise Caution When Entering Into Arrangements with Purported Telemedicine Companies, July 20, 2022, https://oig.hhs.gov/documents/root/1045/sfa-telefraud.pdf.

located, and any state/territory that has a PDMP reciprocity agreement with the states/territories the patient and clinician practitioner are located.

MGMA urges the DEA to rescind this provision as it is unworkable due to a lack of interoperability required to enable practitioners to undergo a nationwide check of every state's PDMP. The proposed rule acknowledges this lack of connectivity as the reason for instituting the interim policy for the three years before the nationwide PDMP check is required, stating that healthcare providers are unlikely to have access all state PDMPs. State PDMP systems vary widely in their functionality, and significant progress would need to be made regarding the interoperability and functionality of systems before such a process would be feasible.

The DEA should not finalize this nationwide PDMP requirement given the likelihood of it not becoming a reality within the three-year timeline – it is impractical and would cause significant uncertainty. Instead, the DEA should work with states and other federal agencies to modernize PDMPs to move towards a more interconnected system.

Audio-Only Prescriptions

Under the special registration framework, the DEA mandates that clinician practitioners utilize audio and video components of audio-video telecommunications systems to prescribe controlled substances for every encounter, whether an initial visit or follow-up. The DEA allowed for audio-only telemedicine visits during and after the COVID-19 PHE, but believes that this policy should end after evaluating the telehealth landscape.

The DEA acknowledged the benefits of audio-only prescribing by recently allowing it in its Expansion of Buprenorphine Treatment via Telemedicine Encounter final rule. Further, the Centers for Medicare & Medicaid Services (CMS) permanently extended the coverage of audio-only telehealth services in its 2025 Medicare Physician Fee Schedule. The same logic applies to this proposed rule, as audio-only telehealth services are a lifeline for patients who are unable or prefer not to use video technology.

Increasing barriers to care by not allowing the prescription of vital medications to patients using audio-only service would harm patient outcomes, institute confusing audio-only requirements that differ by federal agency, and undermine the value of the special registration process. The DEA should allow for audio-only telehealth visits under the special registration process to support the patient-provider relationship.

Registration, Reporting, Record Keeping, and Other Requirements

The special registration application process would utilize a new proposed application - Form 224S. Applicants would use Form 224S to apply for one of the three kinds of special registration in addition to state telemedicine registrations. There would be a three-year cycle for practitioners to renew their special registration.

Special registrants would be required to annually report data on the number of new patients in each state where they issued at least one prescription for a Schedule II controlled substance or specific Schedule III controlled substances (such as tramadol, benzodiazepines, and ketamine). This data would be aggregated across all states for the DEA to monitor any concerning trends to stop the exploitation of the special registration process. Clinician practitioners would be required to maintain existing recordkeeping and

reporting obligations on top of additional requirements under the special registration framework. Practitioners must maintain photographic records for patient verification, encounter records of the telemedicine encounter, and special registration prescription records at the designated special registered location.

The special registration process should be optimized to reduce the administrative burden for clinician practitioners who qualify, not add more time-consuming and costly tasks. While understanding the need to track the use of controlled substances accurately, the numerous application and reporting requirements in this proposal would add to an ever-increasing administrative load and divert resources and staff time from patient care.

The DEA should simplify and streamline the application and reporting process to avoid instantiating additional burdens and work with other state and federal agencies to harmonize as much as possible. Physician practices are already subject to numerous federal and state requirements — the DEA should ensure that it does not add to this increasing burden and focus on law enforcement activities rather than regulating medical groups.

Conclusion

MGMA appreciates the DEA proposing a special registration process under the *Ryan Haight Act*. We urge the DEA to withdraw this proposal as currently written and work with stakeholders to implement a functional special registration process that avoids instituting administratively burdensome and unworkable requirements that would interfere with patient access to telehealth care. If you have any questions, please contact James Haynes, Associate Director of Government Affairs, at jhaynes@mgma.org or 202-293-3450.

Sincerely,

/s/

Anders Gilberg
Senior Vice President, Government Affairs