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March 28, 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,

Talkiatry welcomes the opportunity to provide comments on the Drug Enforcement Administration (DEA) proposed rule on telemedicine prescribing of controlled substances. Talkiatry is a national, physician-led, group telepsychiatry practice that provides in-network care. With a human-centered philosophy and technology to strengthen relationships, Talkiatry provides patients with the care they need—creates mental health care access where it did not exist, and allows psychiatrists to focus on why they got into medicine.

As you know, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 was passed to stop illegitimate internet pharmacies that proliferated in the 1990s from selling controlled substances online. Additionally, the law limited the use of telemedicine by requiring prior in-person evaluation in order to prescribe a controlled substance. However, when passing that law Congress explicitly recognized the important and growing opportunity for telemedicine to enable patient care and allowed for legitimate patient care to be excluded from these restrictions. The law and subsequent amendment by the SUPPORT Act, empowers (and directs) the Administrator of the DEA, in conjunction with the Secretary of HHS, authority to create a special registration process under which practitioners may prescribe controlled medications, without an in-person medical evaluation, through telemedicine.

We deeply appreciate this Congressional foresight, as the foreseen era of telemedicine has now emerged – and Talkiatry embodies that opportunity. With 400+ employed psychiatrists across 49 markets, Talkiatry has already brought access to mental health treatment to more than 125,000 patients. Many of these individuals reside in areas where there is no option for in-person psychiatric care – and we are concerned that, not only will they lose access to Talkiatry doctors, but they will lose access to mental health care entirely.

We understand and respect the DEA's concerns about the risk of diversion of controlled substances, but we believe this risk must be balanced by the pressing national need for access to mental health across

every community in America – access that can realistically only be met by leveraging telemedicine and a geographically diverse network of providers.

We have, therefore, responded to the major provisions in the rule and then offered some minor modifications to the proposal that we believe would have a dramatic impact in protecting patient access to mental health services while continuing to offer significant protections against inappropriate prescribing of controlled substances. Specifically, we will recommend additional flexibility for the treatment of a mental health condition by a medical doctor or Psychiatric Mental Health Nurse Practitioner, including the use of stimulants as part of that treatment plan.

The Mental Health Challenge

As a prelude to discussion of the rule provisions, we believe it is important to consider the public health context under which these decisions are being made – specifically the mental health needs of Americans. Forty percent of American adults report symptoms of anxiety and depression.[1] Unfortunately, the broader behavioral health workforce is stretched, with more than half of all U.S. counties lacking a psychiatrist.[2]

There has been a thirty percent rise in the percent of children and adolescents with anxiety and depression.[3] The situation is so dire that the American Academy of Pediatrics (AAP), the American Academy of Child and Adolescent Psychiatry (AACAP) and the Children's Hospital Association (CHA) have declared a National State of Emergency in Children's Mental Health under which they call on regulators to "*address regulatory challenges and improve access to technology to assure continued availability of telemedicine to provide mental health care to all populations.*"[4]

While DEA has bifurcated telemedicine and the buprenorphine access for the purposes of its rulemaking, America's mental health needs and substance use disorder challenges cannot be separated, as 65 percent of all patients who had a substance use disorder or overdose diagnosis in 2021 had a preexisting mental health condition.[5] Treatment for these conditions is necessary to prevent a worsening of the substance use disorder crisis.

We appreciate that President Biden has recognized the challenge before us and put forth a plan to expand access to mental health treatment in which he calls for expanded access to tele-and virtual mental health care options, noting that they have been proven both safe and effective while reducing barriers to care. [6] Unfortunately, a requirement for an in-person visit prior to the prescribing of a Schedule II non-narcotic controlled substance or for a prescription of Schedule III-V controlled substance following a 30 day supply through telemedicine threatens to derail much of the Biden Administration's progress on mental health access and leave hundreds of thousands of Americans without access to treatments upon which they currently rely.

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

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

[3] 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

[4] https://www.aap.org/en/advocacy/child-and-adolescent-healthy-mental-development/aap-aacap-cha-declaration-of-a-national-emergency-in-child-and-adolescent-mental-health/

[5] 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

[6] 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/

As you may know, Americans continue to rely heavily on telehealth for access to treatment for these mental health conditions, with it representing 62.5 percent of all telemedicine treatment in December 2022.[7] Viewed another way, 50 percent of all psychiatry visits in the United States were offered through telemedicine in 2021.[8] Given this radical transformation in the way care is delivered, its extremely unlikely that we would be able to continue existing access to care without this flexibility continued.

Omission of Schedule IIN Non-Narcotic Controlled Substances from the Proposed Rule

As mental health providers who regularly rely on Schedule IIN treatments for mental health issues, we are concerned by the omission of any Schedule IIN substances from the proposed rule. These treatments have meaningful clinical benefits that significantly outweigh any risks when prescribed by a trained mental health professional who can accurately diagnose and monitor ongoing treatment. Treatment of a condition like ADHD with a controlled substance does not increase the risk of developing a substance use disorder[9] and this proper treatment of a mental health condition can even lead to lower likelihood of a future substance use disorder. In fact, 23 percent of U.S. adults who seek treatment for substance use disorder have co-occuring ADHD.[10] In child populations, those with ADHD are three times more likely to develop a substance use disorder[11], but treatment can reduce that risk by more than 30 percent.[12] Among adolescents and young adults, 15 percent of those with ADHD also have a substance use disorder. [13] Untreated ADHD can lead to significant psychiatric, social, and academic problems that have potential to lifelong consequences. In childhood, it can cause insurmountable deficits in education and learning potential leading to underperforming despite academic acumen. It leads to strained family relationships because of perceived primary behavioral problems. This focus on behavioral problems instead of attentional deficits can lead to misdiagnosis and treatment that does not address the true underlying issue. This is especially prevalent in Black and Latino patients and can lead to overprescribing of medications, especially antipsychotics, for behavioral disturbances. This under recognition of ADHD and appropriate treatment[14] coupled with overprescribing of antipsychotics has contributed to the inequities in healthcare which medicine is working very hard to eliminate.

Limitations on Prescribing to 30-days

While we understand that DEA intent in allowing a 30-day prescribing allowance may have been to ensure patients could get access to treatment while seeking an in-person alternative, this proposal is problematic on several fronts.

First, limitations on treatment venture well beyond the DEA's authority for diversion control and well into treatment decisions that should be up to a patient and their provider.

Second (and partially because it oversteps into treatment decisions) the rule does not accommodate the wide variations in type of health care offered and needs for controlled substances that are restricted by the rule. While there may be some conditions for which a 30-day supply is an appropriate treatment regimen that should be revaluated after a month – this does not resemble an appropriate mental health treatment plan. Mental health treatments are generally part of a long-term patient-provider relationship, and mood-altering drugs should not be started and stopped inconsistently.

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[7] https://www.fairhealth.org/states-by-the-numbers/telehealth

[8] https://www.mckinsey.com/industries/healthcare/our-insights/telehealth-a-quarter-trillion-dollar-post-covid-19-reality

[9] https://www.uclahealth.org/news/are-children-who-take-ritalin-for-adhd-at-greater-risk-of-future-drug-abuse

[10] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4414493/

Finally – and building on the second point – because of unpredictability of care after 30-days, no responsible psychiatrist with a long-term patient relationship would prescribe a serious mental health medication without reasonable certainty that the patient would not be cut off from access and placed at a higher risk of subsequent harm.

This timeline will also create pressure for a doctor to choose between prescribing immediately when they see a patient (and creating the longest window for the subsequent referral) and spending time to really get to know a patient as appropriate, prescribe, and then terminate a healthy doctor patient relationship.

This means that the rule as written could have the opposite effect of what was intended. Less scrupulous healthcare providers will not be prevented from offering 30 days of a schedule III-V substance to a patient without concern for what comes after. Responsible doctors with meaningful patient-provider relationships will be faced with risking a patient's health by providing care they cannot promise will continue.

In-Person Referral Requirement and Process

Telemedicine has been pivotal in unlocking access to mental health care. One analysis found that telemedicine use has increased 38 times from the pre-COVID-19 baseline, with the largest share in psychiatry and substance use disorder (SUD) treatment claims.[11] Its notable that patients like this care, with less than 5 percent of all mental health patients choosing to switch from virtual, to in-person care after a telemedicine visit – this is a much lower percentage than other conditions, which more frequently mix in-person and virtual care.[12] Patients continue to prefer telemedicine to access mental health services.

Additionally, an in-person evaluation is not the standard of care for mental health treatment. The Centers for Medicare and Medicaid Services (CMS) released guidelines which state that, for many mental health services, visualization between the patient and clinician may be less critical to provision of service.[13] While a physical health evaluation may sometimes be appropriate prior to the prescribing of a controlled substance, this determination should be based on the clinical judgment of the psychiatrist and primary care provider.

A referral process would be challenging to operationalize. Approximately 36 percent of Americans in their 30's don't have a primary care provider.[14] Requiring an in-person referral adds another step in an already complicated care journey. The average wait time for an in-person primary care visit is 24 days[15] and may be greater depending on transportation ability and other barriers. Patients will bear the burden of additional costs and logistics of an in-person visit requirement. If the patient were to establish a relationship with a primary care provider, there would still be difficulties for the primary care provider to find a specific psychiatrist to send a referral to, or one that completed extensive documentation. This would threaten the ability to deliver care to the patient. Additionally, the requirement by the DEA for a

[11] https://www.mckinsey.com/industries/healthcare/our-insights/telehealth-a-quarter-trillion-dollar-post-covid-19-reality
[12] https://www.zocdoc.com/blog/zocdoc-reports-the-healthcare-experience-2022/
[13] https://www.federalregister.gov/documents/2023/03/01/2023-04248/telemedicine-prescribing-of-controlled-substances-when-the-practitioner-and-the-patient-have-not-had#citation-27-p12878
[14] https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2757495
[15] https://www.fshealth.com/blog/how-much-time-does-doctor-visit-really-take

copy of the medical record to be provided by the qualifying referral practitioner prior to the telemedicine practitioner prescribing a controlled substance could lead to additional delays associated with the transfer of medical records.

Another issue is the widespread difficulty in providing a referral directly from one provider NPI to another. Health care organizations typically provide referral options, or refer to a provider group, but limitations to a specific individual are difficult to operationalize. It is difficult to confirm availability, if the clinician is taking new patients, and creates significant complexity. Finally, the patient may prefer a different clinician, but would not have that option once a referral was made.

Our patients are at risk of losing access to care as a result of the proposed rule. Over 15,000 Talkiatry patients are on controlled substances today- which is less than 20 percent of our patients. The majority of our patients couldn't see their current doctor in person, with 89 percent living in a different city than their doctor. These patients also lack alternative treatment options, with 82 percent of patients living in a county with a shortage of mental health care providers.

Other Provisions

We appreciate the DEA's efforts to mitigate the impact of its drastic removal of telemedicine access by offering a 180-day flexibility for patients with an ongoing patient-provider relationship. Unfortunately, as noted above, this solution will not prevent patients from losing access to care. In many cases, it will still disrupt meaningful patient-provider relationships and clinically appropriate treatment regimens causing significant harm to patients with mental health needs. This disruption of patient-provider relationships may also result in patients seeking medications or illicit drugs from other, non-clinical sources , which would increase their risk of an overdose and their risk of exposure to more dangerous substances.

We request a clarification of DEA intent on provisions around DEA license requirements. As written, these provisions seem to indicate that there could be a need to obtain a DEA license in any state a practitioner may practice in, which would meaningfully increase cost and administrative time while reducing access for patients. We request that DEA clarify that a provider only needs one DEA license, in any state, to prescribe controlled substances, so long as the provider is licensed to practice medicine in the state the prescription is written in and follows all state laws.

POLICY RECOMMENDATIONS

While we support efforts at diversion, we remain very concerned about the adverse impacts the proposed rule will have on patients receiving mental health care.

The flexibilities afforded during the public health emergency demonstrated both the opportunity and risks associated with waiving portions of the Ryan Haight Act. While it significantly expanded access, we recognize that it enabled some unscrupulous actors. In order to facilitate a balanced approach that will protect consumers while maintaining access to care, we have developed a proposal for the careful, measured implementation of rules around the prescribing of controlled substances through telehealth. We propose the below narrow exception as a starting point for DEA to consider as it crafts a narrow rule.

Mental Health Treatment Plan Exception

We recommend the creation of a limited mental health treatment plan to allow for longer-term relationship-based telemedicine care between a patient and their provider.

First, we propose the following limits on the use of this exception –

- The prescribing practitioner must have completed dedicated medical training on the prescribing of a controlled substance through either a medical residency degree or an active Psychiatric-Mental Health Nurse Practitioner Certification.
- The prescribing practitioner must have performed a clinically appropriate assessment of medical health through a telemedicine encounter of not less than 45 minutes that meets APA guidelines for the assessment of medical health.[16]
- Similarly, the prescribing practitioner could be limited to actively prescribing controlled substances for no more than 275 patients at a time in order to prevent creative business models around prescribing.
- The mental health treatment plan exception must be limited to controlled substances clinically indicated for mental health treatment.

Second, we recommend two flexibilities under this exception –

- The prescribing practitioner may prescribe schedule IIN non-narcotic controlled substances as part of a mental health treatment plan.
- The 30-day supply limitation shall not apply to prescriptions issued by a practitioner as part of an ongoing mental health treatment plan.

We believe this narrow, tailored flexibility strikes the right balance for meeting the needs of hundreds of thousands of Americans while presenting the least risk of diversion.

Recognizing that there are other clinically valid use cases for the prescribing of controlled substances, we would also like to emphasize that we believe this starting point can be a proof-of concept for other conditions or provider types as the DEA works to find the right balance between patient access and diversion in regulating health care.

Please find a redline of this regulatory proposal attached as Appendix I.

Other Policy Recommendations

In addition to the mental health exception above, we believe that DEA would be well served by updating its definition of a qualifying telemedicine referral by expending from a clinician national provider identifier to include the definition of a health care provider in the Public Health Service Act.[17] This definition of health care provider would allow for a referral from a primary care provider to a medical group or other health care entity that may employ multiple psychiatrists – allowing greater access to the patient, and the optionality of choosing from several clinicians. Without this flexibility, many patients will receive a referral to a psychiatrist, but be unable to see that doctor within a reasonable timeframe due to significant national behavioral health workforce limitations.

Finally, while we do not believe additional diversion steps are needed in order to protect Americans from the inappropriate prescribing of controlled substances through telehealth, we are aware of many

[16] https://psychiatryonline.org/guidelines
[17] https://www.law.cornell.edu/uscode/text/42/300jj#3

options that would be both more effective and more targeted than the options presented by DEA in the proposed rule.

Please find additional options that could replace guardrails proposed by DEA attached as Appendix II.

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Thank you for the opportunity to provide comments on this important issue. We hope you will consider this recommendation as you examine ways continue access for clinically appropriate mental health treatments. If you have any additional questions, please do not hesitate to contact myself or Dr. Gaveras at robert.krayn@talkiatry.com or Georgia.gaveras@talkiatry.com.

Sincerely,

Robert Krayn
Co-Founder & CEO

Georgia Gaveras, DO
Co-Founder & Chief Medical Officer

APPENDIX I – REGULATORY RECOMMENDATION REDLINE

PART 1300—DEFINITIONS

§ 1300.04

(k) A *qualifying telemedicine referral* means a referral to a practitioner that is predicated on a medical relationship that exists between a referring practitioner and a patient where the referring practitioner has conducted at least one medical evaluation in the physical presence of the patient, without regard to whether portions of the evaluation are conducted by other practitioners, and has made the referral for a legitimate medical purpose in the ordinary course of their professional practice. A qualifying telemedicine referral must note the name and National Provider Identifier of the practitioner or health care provider as defined in 42 USC § 300jj(3) to whom the patient is being referred.

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PART 1306—PRESCRIPTIONS

§ 1306.31

Circumstances under which the practice of telemedicine may be conducted pursuant to 21 U.S.C. 802(54)(G).

(a) An individual practitioner may issue telemedicine prescriptions if all of the following conditions are met:

(1) The telemedicine prescription is pursuant to a telemedicine encounter and is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.

(2) At the time of the telemedicine encounter that gives rise to the issuance of the telemedicine prescription, the practitioner is located in a State, Territory, or possession of the United States; the District of Columbia; or the Commonwealth of Puerto Rico.

(3) The practitioner is:

(i) Authorized under their registration under 21 CFR 1301.13(e)(1)(iv) to prescribe the basic class of controlled substance specified on the prescription; or

(ii) Exempt from obtaining a registration to dispense controlled substances under 21 U.S.C. 822(d).

(4) The prescription includes the information required by § 1306.05.

(b) In addition to the conditions outlined in paragraph (a), practitioners are also subject to the limitations in paragraphs (c), (d), (e), and (f) of this section when prescribing controlled substances pursuant to this section.

(c) Characteristics of telemedicine prescriptions:

(1) A telemedicine prescription may only be for a:

(i) A schedule III, IV, or V non-narcotic controlled substance; or

(ii) A schedule IIN non-narcotic controlled substance prescribed as part of a mental health treatment plan, provided that the following criteria are met:

(A) The prescribing practitioner has;

i. Completed an Accreditation Council for Graduate Medical Education (ACGME) certified medical residency program.

ii. An active American Nurses Credentialing Center certified Psychiatric-Mental Health Nurse Practitioner Certification.

(B) The prescribing practitioner has performed a clinically appropriate assessment of medical health through an initial telemedicine encounter of not less than 45 minutes.

(~~ii~~ iii) Any controlled substance that the practitioner is otherwise authorized to prescribe, provided that one or more of the following criteria are met:

(A) The prescribing practitioner has received a qualifying telemedicine referral as defined in § 1300.04(k) for that patient from a referring practitioner who has conducted a medical evaluation as described in paragraph (d)(3) of this section;

(B) The prescribing practitioner is employed by the Department of Veterans Affairs and the prescription is issued for a patient of the Department of Veterans Affairs health system who has received an in-person medical evaluation from a practitioner who, at the time of the examination was employed by the Department of Veterans Affairs; or

(C) The prescribing practitioner has a telemedicine relationship established during the COVID-19 public health emergency with the patient, as defined in § 1300.04(o).

(2) The prescribing practitioner may issue multiple prescriptions for the patient, provided, however, that the prescriptions do not authorize the dispensing of more than a total quantity of a 30 day supply of the controlled substance.

(i)This 30-day limitation shall not apply to prescriptions issued by a practitioner who has a telemedicine relationship established during the COVID-19 public health emergency with the patient, as defined in § 1300.04(o), or to a practitioner employed by the Department of Veterans Affairs when prescribing to a patient of the Department of Veterans Affairs health system who has received an in-person medical evaluation from a practitioner who, at the time of the examination, was employed by the Department of Veterans Affairs. The prescribing practitioner may prescribe a supply in addition to the 30 day supply if a medical evaluation is conducted pursuant to paragraph (d)(1), (2), or (3) of this section.

(ii) This 30-day limitation shall not apply to prescriptions issued by a practitioner as part of an ongoing mental health treatment plan, provided that the following criteria are met:

(A) The prescribing practitioner has;

i. Completed an Accreditation Council for Graduate Medical Education (ACGME) certified medical residency program.

ii. An active American Nurses Credentialing Center certified Psychiatric-Mental Health Nurse Practitioner Certification.

(B) The prescribing practitioner has performed a clinically appropriate assessment of medical health through a telemedicine encounter of not less than 45 minutes.

(C) The prescription is limited to those permitted under schedule IIN or IV

(d) Such a medical evaluation for the purposes of this section may be one of the following:

(1) An evaluation during which the patient is treated by, and in the physical presence of, the prescribing practitioner;

(2) An evaluation during which:

(i) The patient is treated by, and in the physical presence of, a DEA-registered practitioner (other than the prescribing practitioner);

(ii) This practitioner in the physical presence of the patient is acting in the usual course of professional practice;

(iii) The evaluation is conducted in accordance with applicable State law; and

(iv) The remote prescribing practitioner, the patient, and the DEA-registered practitioner on site with the patient participate in a real-time, audio-video conference in which both the practitioners and the patient communicate simultaneously.

(3) An evaluation during which the patient is treated by, and in the physical presence of, an individual DEA registered practitioner, or individual practitioner exempt from registration under 21 U.S.C. 822(d), who:

(i) Issued a written qualifying telemedicine referral as defined in § 1300.04(k) for the patient to the prescribing practitioner or health care provider as defined in 42 USC § 300jj(3);

(ii) Communicated the results of the evaluation by sharing the relevant information in the medical record which includes, at a minimum, the diagnosis, evaluation, and treatment of the patient prior to the prescribing practitioner issuing the prescription; and

(iii) Has issued the written referral based on the diagnosis, evaluation, or treatment that occurred as a result of the medical evaluation.

(e)(1) Prior to issuing the prescription, the practitioner, including a practitioner employed by the Department of Veterans Affairs, must review and consider the prescription drug monitoring program in the State where the patient is located (if the State has such a program) for data regarding any controlled substance prescriptions issued to the patient in the last year, or, if less than one year of data is available, in the entire available period. The practitioner, if employed by the Department of Veterans Affairs, must also review the Department of Veterans Affairs internal prescription database for data regarding any controlled substance prescriptions issued to the patient in the last year, or, if less than a year of data is available, in the entire available period.

APPENDIX II – ADDITIONAL OPTIONS DEA COULD CONSIDER INSTEAD OF AN IN-PERSON VISIT

Ensure that the most dangerous substances continue to require an in-person clinician relationship by limiting prescribing through telemedicine without an in-person exam to mental health treatments (schedule IV and IIN) substances. Other substances, such as substance use disorder treatments, should also be included on a case-by-case basis.

Prevent bad actors from inappropriately using the registration by prohibiting the use of any of these substances for off-label uses. Substances must be FDA-approved in adults to treat the condition they are prescribed for.

Ensure meaningful patient-provider relationships prior to the prescribing of controlled substances through telemedicine and prevent inappropriately high patient volumes for these practitioners. In order to properly maintain a patient-provider relationship through telehealth, the patient being prescribed a controlled substance could be required to have a follow-up visit a minimum of once every 3 months. Virtual care should also be supplemented by a urine toxicology examination, as determined by the clinician, but no less frequently than annually.

Prevent the use of apps or other asynchronous telemedicine tools for the prescribing of controlled substances by limiting prescribing to real-time and interactive audio-video visits connected to a certified electronic health record.

Ensure clinicians are fully committed to the care of patients by limiting the prescribing to the primary practice location under which the registration is requested. Many clinicians serve in multiple roles – this requirement would be intended to limit the use of the registration outside their primary practice roles. To ensure providers are providing meaningful care through the registration process, require practitioners (except solo practitioners unaffiliated with an MSO) to be a w-2 recognized employee working at least one day per week at the practice where they are utilizing the registration to prescribe.

Ensure providers prescribing through telemedicine demonstrate an ability to meet regulatory requirements placed on other health care organizations by requiring clinicians to participate in Medicare or another federal payment program. Enrollment in a federal payment program will create another, secondary tool to monitor and regulate clinicians while supporting access for patients that rely on federal programs.

DEA could also create a practice-level registration process that could serve as an additional guardrail for higher risk entities with characteristics similar to those currently under investigation by the Department of Justice. Academic institutions, hospitals, or federally qualified health centers should not trigger these additional requirements. This could include similar criteria, such as:

- At least 90 percent of prescribing providers should be W-2 employed doctors and all providers within the practice who prescribe controlled substances must be able to meet the criteria for the individual provider level exemption.
- The practice must be enrolled in Medicare or another federal payment program and the practice, its affiliated MSO (if applicable), and none of its prescribing clinicians, may have been excluded from federal healthcare programs.
- Practice and its affiliated MSO (if applicable) must not offer a subscription-based payment model that includes the cost of medical care/the cost of prescriptions, that could create a

payment incentive for continued care beyond the patient's needs. (Broader primary care-based subscription models would not apply).

- Practice and its affiliated MSO (if applicable) must not dispense medication (either directly or in conjunction with an outsourced pharmacy vendor) or have a financial relationship with a pharmacy.