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May 31, 2016

Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
Attn: Jinhee Lee, PharmD, SAMHSA
5600 Fishers Lane
Room 13E21C
Rockville, MD 20857

RE: RIN 0930-AA22: Proposed Rule for Medicated-Assisted Treatment for Opioid Use Disorders

Dear Dr. Lee:

The Pew Charitable Trusts is pleased to offer comments to the Substance Abuse and Mental Health Services Administration (SAMHSA) on the proposed rule to increase the patient limit for qualifying physicians to treat opioid use disorders under Section 303(g)(2) of the Controlled Substances Act. Pew is an independent, nonpartisan research and policy organization dedicated to serving the public. Our work to address substance use disorders focuses on developing and supporting policies that 1) reduce the inappropriate use of prescription drugs while ensuring that patients have access to effective pain management and 2) expand access to effective treatment for substance use disorders including through increased use of medication-assisted treatment (MAT).

There is an urgent need to expand access to treatment for substance use disorders. Drug overdose rates hit record levels in 2014, the most recent year for which data are available. This increase was driven by opioids, such as heroin and prescription pain relievers, which were involved in more than 28,000 overdose deaths.[i] This number, while large, does not reflect the full impact of the opioid epidemic, which has left countless individuals, their families, and communities struggling with the health, quality of life, and cost implications of this disease.

Numerous studies have shown that the most effective treatment for substance use disorder is MAT, which pairs medications approved by the Food and Drug Administration with behavioral therapy. Yet, the number of Americans with an opioid use disorder far exceeds existing capacity to provide these individuals with MAT.[ii] **We support the intent of the proposed rule to address this treatment gap and propose the following changes to meet the urgent need to expand access to treatment: further increases to the proposed patient cap for qualifying buprenorphine prescribers and the use of evidence-based reporting requirements for practitioners approved for a patient limit increase.** In addition, while we recognize that legislation is necessary, we strongly support expansion of buprenorphine prescribing authority to nurse practitioners and physician assistants**.** The importance of these changes is described in detail in this letter.

FURTHER INCREASES TO PROPOSED PATIENT CAP FOR QUALIFYING BUPRENORPHINE PRESCRIBERS

Pew supports the intent of the proposed regulation to expand treatment access by increasing the patient cap from 100 to 200 for those physicians with specialty certification or practicing in qualified practice settings. However, **Pew recommends that the threshold should be set higher for these practitioners and that the initial limit on the number of patients a waivered practitioner may treat in the first year should also be increased.** These recommendations are based on wide consensus that the current limits are not evidence-based and serve as a barrier to treatment access. The sponsor of the original DATA 2000 legislation, Senator Hatch, and twelve other senators stated in a 2015 letter to Department of Health and Human Services Secretary Burwell that, "This law arbitrarily capped the number of addicted patients a physician can treat at any one time to 30 through the first year and, if requested and certified, permits expansion to 100 patients thereafter."[iii] With the exception of buprenorphine, there are no federal limits on the number of patients a practitioner may treat using any other office-based medication, including the narcotic analgesics most often involved in drug overdoses. Further, the accumulation of real-world evidence demonstrates that buprenorphine is safe and effective when used properly.

Pew recognizes that concerns have been raised by some stakeholders about eliminating the caps entirely, including concerns that it could result in suboptimal care for some patients. Health care practice sites vary widely in their capacity to treat patients with opioid use disorder. For example, a specialized clinic with a long history of treating opioid use disorder and a significant number of support staff can provide high quality care to many more patients than a solo primary care provider. Given this variation, there is no reliable way to arrive at a single number for how many patients all practices are capable of appropriately managing when providing buprenorphine treatment. It is critical that practitioners treating patients with buprenorphine be able to refer them to counseling and other appropriate ancillary services, which is required in current law. Further, Pew supports adherence to clinical guidelines, requirements for referral services in the current statute, and additional prescriber training as sufficient mechanisms to ensure that patients receive appropriate care. **In light of these factors, instead of removing the caps entirely, we recommend that the limit for buprenorphine prescribers with specialty certification or practicing in qualified practice settings should be raised to 500 patients, and that the initial limit on the number of patients a practitioner can treat in the first year be raised from 30 to 100.** These higher thresholds and their related requirements will ensure that only practitioners with the most expertise and capacity are able to treat an increased number of patients while providing safeguards to promote quality care and prevent diversion. Further, we recommend that SAMHSA monitor the impact of these changes to inform the need for future modifications to these regulations.

As written, the proposed rule greatly diminishes the intent to expand treatment availability to more patients because it allows only those physicians with a subspecialty certification in addiction psychiatry from the American Board of Psychiatry and Neurology or the American Osteopathic Association to qualify for the increased patient limit. This approach would exclude the majority of clinicians who are qualified to provide this care—physicians who have attained board certification from the American Board of Addiction Medicine. Therefore, **Pew recommends that the proposed rule be revised to strike from the list of proposed qualifications the term "subspecialty" to eliminate any ambiguity as to which specialists may be eligible to apply for the increased patient limit.**

EVIDENCE-BASED REPORTING REQUIREMENTS FOR PRACTITIONERS APPROVED FOR A PATIENT LIMIT INCREASE

The proposed rule states that reporting requirements for prescribers approved for a patient limit increase may include, among other metrics, average monthly caseload, percent of patient population with a change in clinical status, and the number of patients no longer receiving therapy. It is unclear whether these measure clinically important patient outcomes. Further, these data may be difficult to extract from medical records. **Pew recommends that SAMHSA refine the proposed metrics so that the final requirements support the provision of high-quality care without serving as a barrier to provider uptake.** Broad stakeholder input, including that of practicing addiction specialists, will ensure that the reporting requirements are consistent with recognized evidenced-based treatment guidelines and do not pose an undue burden that would serve as a disincentive to expanding treatment access.

EXPANSION OF BUPRENORPHINE PRESCRIBING AUTHORITY TO NURSE PRACTITIONERS AND PHYSICIAN ASSISTANTS

Pew strongly supports extending buprenorphine prescribing authority to nurse practitioners and physician assistants as a critical step to expanding access to MAT for the treatment of opioid use disorders. We recognize that legislation is necessary to effect this change. However, we want to use this opportunity to reinforce the importance of expanding prescribing authority as a mechanism to address unmet treatment needs, especially in rural and other underserved areas. A study published in 2015 found that the majority of U.S. counties had no physician who had obtained a waiver to prescribe buprenorphine, resulting in more than 30 million people living in counties without access to this treatment.[iv] It is important to note that nurse practitioners and physician assistants in nearly every state can already prescribe prescription opioids, including DEA schedule II narcotics. They may also prescribe buprenorphine for pain, but not for treatment of opioid dependence.

Thank you for the opportunity to comment on the proposed rule for Medication-Assisted Treatment for Opioid Use Disorders. Should you have any questions or if we can be of assistance with your work, please contact me by phone at 202-540-6916 or via email at creilly@pewtrusts.org.

Sincerely,

Cynthia Reilly, MS, BS Pharm
Substance Use Prevention and Treatment Initiative
The Pew Charitable Trusts

[i] Centers for Disease Control and Prevention (2016). Increases in drug and opioid overdose deaths — United States, 2000–2014. *Morbidity and Mortality Weekly Report,* 62(50),1378-82

[ii] Jones CM, Campopiano M, Baldwin G, & McCance-Katz E (2015). National and state treatment need and capacity for opioid agonist medication-assisted treatment. *American Journal of Public Health*, *105*(8), e55-e63

[iii] Hatch OG, et al (2015). Correspondence to Health and Human Services Secretary Sylvia Burwell, accessed May 18, 2016, http://www.kirk.senate.gov/pdfs/HeroinLetter.pdf

[iv] Rosenblatt RA, Andrilla CHA, Catlin M, & Larson EH (2015). Geographic and specialty distribution of US physicians trained to treat opioid use disorder. *The Annals of Family Medicine*, 13(1), 23-6