May 22, 2016

Kana Enomoto
Acting Director
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Regulatory Information Number (RIN) 0930-AA22

Dear Ms. Enomoto,

On behalf of the American Society of Addiction Medicine (ASAM), the nation's largest medical specialty society representing physicians and allied health professionals who specialize in the treatment of addiction, I am pleased to submit our comments on the proposed rule to increase the highest patient limit for qualified physicians to treat opioid use disorder under section 303(g)(2) of the Controlled Substances Act (CSA) from 100 to 200. ASAM applauds the administration for initiating regulatory action to increase access to life-saving office-based opioid addiction treatment. We offer these comments based on the collective expertise of our more than 3,800 members and hope they will inform an even more robust final rule.

As the proposed rule recognizes, there is an urgent need to increase patient access to opioid addiction treatment with buprenorphine. ASAM commends the proposed rule for recognizing the robust body of literature documenting buprenorphine's effectiveness and cost-effectiveness as a treatment for opioid addiction. Despite this evidence and the worsening epidemic of opioid misuse, addiction and related overdose deaths, buprenorphine is significantly underutilized. Many factors contribute to its underutilization, including hesitancy among non-specialist physicians who feel they do not have adequate training or the ability to offer recommended psychosocial supports, low reimbursement rates for addiction treatment services by Medicaid and commercial insurers, and stigma. While the proposed rule does not seek to address these factors, it seeks to increase access to buprenorphine by increasing the number of patients physicians with subspecialty board certification are able to treat, as well as the number of patients who can be treated by waivered physicians working in qualified practice settings.

ASAM represents thousands of addiction specialist physicians who are acutely aware of the need to increase the patient limit. Many of these

4601 N. Park Avenue, Upper Arcade #101, Chevy Chase, MD 20815
Phone: 301.656.3920 | Fax: 301.656.3815
www.ASAM.org

specialists have reported the limit restricts their ability to treat patients in need of care, even though they have the clinical capacity and expertise to do so. As the opioid epidemic has worsened over the past decade, ASAM members have reported that patients have lost their lives while waiting for treatment due to the DATA 2000 patient cap. As such, ASAM urges SAMHSA to untie ALL addiction specialists' hands – both those physicians with subspecialty board certification in addiction medicine or addiction psychiatry as well as those who have achieved certification through the American Board of Addiction Medicine (ABAM) – and permit them to treat additional patients in an effort to combat this deadly epidemic.

The proposed rule is a step in the right direction, but our comments below, summarized first and then expanded upon according to the questions for comment, detail how it can be strengthened to ensure more highly trained physicians are able and incentivized to offer comprehensive and high-quality addiction treatment with buprenorphine to the millions of patients in need.

SUMMARY

ASAM recommends the following changes be incorporated into the final rule:

- **Include ABAM-certified physicians among those who would qualify for the higher limit based on their medical education and training by striking the term "subspecialty" from §8.610(b)(1).** This change would align the eligibility requirement with the concept of "board certification" as defined in §8.2**,** which includes board certification in addiction medicine from ABAM. As currently written, the proposed rule appears to categorically exclude the vast majority of the addiction specialist physician workforce from the opportunity to treat additional patients and thus would have a very limited impact on access to specialist care.
- **Expand the training pathways to allow non-specialists to qualify for the higher limit by taking additional and ongoing training in addiction medicine**. The addiction treatment gap is so large and the urgency to expand access so great in the face of our current epidemic that it is imperative we leverage the full strength of our primary care workforce. Specialists and those who work in qualified practice settings will not be able to close the treatment gap on their own, and patients are dying as they wait for care. Non-specialists with additional training (as described below) should be able to treat additional patients regardless of their practice setting.
- **Raise the patient cap to 500 for board-certified physicians and those who have completed additional and ongoing training.** To make a meaningful impact on the current epidemic, the proposed rule needs to go further in expanding access to treatment.
- **Clarify the requirements to be a "qualified practice setting."** Additional detail is needed for physicians to understand if their practice meets the requirements of the rule.
- **Convene an expert panel to revise the data collection form**. The template reporting requirement form requests information that is either clinically meaningless, uninformative to determining whether the care being provided is of high quality, difficult to extract from an electronic medical record (EMR), or all of the above. ASAM offers some specific comments below, but recommends SAMHSA convene an expert panel of addiction specialists to revise the form before it is instituted as a reporting requirement.

QUESTIONS FOR COMMENT

1. Optimal Patient Prescribing Limit

ASAM commends HHS for proposing to increase the patient prescribing limit for qualifying practitioners to 200 patients, as any increase is a step in the right direction. However, we believe the increase does not go far enough to make a meaningful impact on the current treatment gap. Moreover, board-certified specialists, including ASAM-certified and ABAM-certified physicians, are more than capable of providing high-quality opioid addiction treatment with buprenorphine to more than 200 patients. **ASAM recommends the patient cap for all board-certified addiction specialists (including ASAM-certified and ABAM-certified physicians) be raised to 250 in the first year, and 500 patients thereafter.**

2. Potential New Formulations

ASAM appreciates the proposed rule's forward-thinking flexibility to give the Secretary authority to count differently patients who are treated in the future with newer buprenorphine formulations that have features to enhance safety or reduce the risk of diversion. The principles which will be the basis for the criteria to determine how new medications or reformulations will be considered – specifically, the relative risk of diversion and time required to monitor patient safety, ensure medication compliance and effectiveness, and deliver or coordinate behavioral health services – are reasonable.

However, the final rule should reflect our current knowledge of products under development rather than delay a decision about treatment options that may be available to patients before the rule is even finalized. Additionally, the final rule should clarify whether physicians who perform only implantations and extractions of implantable buprenorphine and do not coordinate behavioral health services or otherwise treat the disease of addiction (for example, as a dermatologist might) are required to obtain a waiver.

Further, to ensure expeditious consideration by the Secretary and thus patient access to new treatment options not yet in development, ASAM recommends the final rule include a timeframe to which the Secretary would commit to make a determination as to how patients being treated by new medications or formulations would count toward the prescribing limit. Specifically, **ASAM recommends the Secretary commit to making a determination about new products within 6 months of approval by the Food and Drug Administration to ensure patients can be treated with newer, safer and less divertible products as soon as possible after approval.**

3. Practitioner Training

ASAM recommends in the strongest terms possible that the opportunity to qualify for a higher patient limit be broadened to include those addiction specialists with ABAM certification by striking the term "subspecialty" from §8.610(b)(1). This change would align the eligibility requirement with the concept of "board certification" as defined in §8.2**,** which includes board certification in addiction medicine from ABAM. As written, the eligibility requirement is unclear; "subspecialty board certification" is not defined anywhere in the proposed rule but implies that only physicians with subspecialty board certification in addiction psychiatry from the American Board of Psychiatry and Neurology (ABPN) or subspecialty board certification in addiction medicine from the American Osteopathic Association (AOA) would qualify for the higher patient

limit based on their medical education and training. If that is indeed the case, the proposed rule is forfeiting a valuable opportunity to expand access to high-quality addiction treatment.

There are currently 3,644 U.S. physicians certified by ABAM, but only 1,088 physicians with an addiction psychiatry subspecialty certification from ABPN, and 7 physicians with a subspecialty board certification in addiction medicine from AOA. **As currently written, the proposed rule appears to categorically exclude the vast majority of the addiction specialist physician workforce from the opportunity to treat additional patients.** These are physicians who have demonstrated advanced expertise in addiction medicine through a rigorous board examination and have dedicated their medical careers to treating patients with the disease of addiction. Excluding these physicians would surely and severely limit the impact of the proposed rule and perpetuate the current addiction treatment gap.

While addiction medicine was recently recognized as a multi-specialty subspecialty by the American Board of Medical Specialties (ABMS) under the American Board of Preventive Medicine (ABPM), it will still be several years before any physician will be able to claim "subspecialty" board certification in addiction medicine under ABPM, and many ABAM-certified physicians will never be eligible for subspecialty board certification under ABPM:

- ABPM has yet to announce when it will offer the first ABMS-level addiction medicine exam for subspecialty certification. It will be no sooner than 2017. If no exam is offered in 2017, it will not be until 2019 that some current ABAM diplomates and other physicians who have completed an addiction medicine fellowship could claim ABMS certification.
    - Physicians who passed the 2015 ABAM exam will not be required to recertify under ABPM to claim ABMS board subspecialty certification. However, only 392 of the 539 who passed the exam will be eligible for the ABMS-level certificate and it is unknown when it will be awarded to them (although it's been indicated that it will not be until the first cohort of successful ABMS examinees are awarded their certificates).
- Current ABAM-certified physicians with a primary ABMS board certification who are younger than 65 on July 1, 2016 will have until at least until 2022 to sit for the ABMS addiction medicine exam. (Physicians with a primary ABMS board certification who are 65 or older on July 1, 2016 will not be required to take the ABMS exam and will receive a time-unlimited certificate from ABAM when the transition period ends.)
- Current ABAM-certified physicians without a primary ABMS board certification (940 total physicians including 328 osteopathic physicians) are ineligible for ABMS subspecialty certification in addiction medicine. These physicians will also receive a time-unlimited certificate from ABAM when the transition period ends.

Given that it will be at least one year until *any* physician can claim "subspecialty" board certification in allopathic addiction medicine, and that it may be five years or more until the majority of the ABAM-certified addiction specialists are able to complete the ABMS exam and claim "subspecialty" board certification, and that a large fraction of the addiction specialist workforce will *never* be able to claim "subspecialty" board certification, **ASAM urges SAMHSA to remove the requirement that physicians hold "subspecialty board certification" in §8.610(b)(1)**

and clarify that all physicians with a "board certification" in addiction medicine or addiction psychiatry as defined in §8.2 be eligible to apply for the higher patient limit.

Furthermore, ASAM believes that the addiction treatment gap cannot be closed by addiction specialists alone and the opportunity to qualify should be broadened even further to allow non-board certified physicians with additional training to qualify for a higher patient limit as well. Even if ASAM- and ABAM-certified physicians were included in the final rule and every single specialist increased his or her patient load by 100 patients, there would still be a large addiction treatment gap. According to Jones et al (2015), there was an opioid agonist treatment gap of 1.3 to 1.4 million people in 2012. Assuming 507,700 additional patients are treated by specialists in this best-case scenario, close to a million patients would still need treatment. To close that gap, more prescribers need to be able to treat more patients. Moreover, these estimates say nothing of the geographical alignment between specialist availability and patient need. Rather than assume they are well-matched, it is more realistic to assume that the distribution of specialists does not perfectly align with the distribution of patients needing treatment and that non-board certified physicians would need to increase their patient panels to close the treatment gap fully.

Accordingly, ASAM recommends that non-board certified physicians who complete 40 hours of didactic and skills-based training based in the standards of high-quality care using buprenorphine, as delineated in national medical practice guidelines related to the treatment of opioid addiction with pharmacotherapy (such as ASAM's National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use), should qualify to treat more than 100 patients with buprenorphine. ASAM recommends these physicians also be authorized to treat up to 250 patients in the first year of the waiver expansion and 500 patients thereafter. ASAM communicated the details of this recommendation in a July 31, 2014 letter to Secretary Burwell. Specifically, ASAM recommends the 40-hour training include at least 2 hours each, in the following areas:

1. The chronic disease of addiction
2. The nature of the continuum of care and ASAM Criteria (choosing the correct level of care)
3. The use of the full range of FDA-approved medication options for all addictive disorders with special attention to controlled substances
4. The behavioral interventions required to stabilize and maintain a patient in long term recovery including but not limited to: Mutual help models of recovery, Cognitive Behavioral Therapy, Motivational Enhancement Therapy, Trauma Informed Care, Contingency Management and the team based approach to care with integrated and/or off-site behavioral therapist
5. Development and use of treatment plans
6. Use of and interpretation of drug screens and tests
7. Diversion control: random call backs, drug screens, and medication counts
8. Medical and Psychiatric comorbidities and the coordination of care

9. Use of prescribed or illicit drugs of abuse while in buprenorphine treatment: integrating the roles of PDMPs, care coordination, contingency management, treatment plans, family sessions, and the continuum of care
10. Medico-legal and ethical issues in addiction treatment with buprenorphine

ASAM believes non-specialist physicians who complete this training to qualify to apply for a patient waiver of 200 be required to demonstrate maintenance of their addiction medicine education by completing an additional 36 hours of addiction-related CME every three (3) years.

Additionally, while the proposed rule does include provisions for physicians who practice in "qualified practice settings" to apply to treat up to 200 patients, ASAM does not believe many practices would qualify based on the criteria delineated in the rule (see Question 11 below for additional comments on the definition of "qualified practice setting"). As such, we do not anticipate this allowance will greatly expand access. For those practices that do qualify, however, **ASAM strongly recommends that any non-board certified physicians who apply to treat more than 100 patients be required to complete additional training in addiction medicine** (as outlined above). Simply because a patient receives care at a practice that has emergency coverage, offers case-management services, uses an EMR system, is registered for its state PDMP and accepts third-party payment does *not* ensure the patient will receive high-quality addiction treatment with buprenorphine; the prescribing physician must also have some additional training in addiction medicine beyond the current 8-hour course. As written, the setting alone would qualify any physician who is currently waivered to treat up to 100 patients based on the current waiver pathways to treat up to 200 patients. ASAM believes the current training requirements – specifically, the one-time eight-hour course – is insufficient to prepare a non-board-certified physician to treat a larger panel of patients with addiction.

4. Alternate Pathways

As stated above, ASAM believes that non-board-certified physicians and those who work outside of "qualified practice settings" be eligible to apply for a patient limit increase if they demonstrate completion of an initial 40 hours of addiction-related CME and ongoing completion of 36 hours of CME every three years (also described above).

5. Process to Request a Patient Limit of 200

The proposed rule would require a practitioner to submit a Request for Patient Limit Increase to SAMHSA that includes (a) a completed request for patient limit increase form, (b) a statement certifying that the practitioner will abide by certain requirements such as adherence to nationally recognized evidence-based guidelines and a diversion control plan, and (c) any additional documentation as requested by SAMHSA. ASAM does not have data on the approximate costs of each requirement delineated in part (b) or an estimate of what fraction of practitioners in qualified practice settings would be able to fulfill them. However, ASAM would like to note that **requirements (6) and (7) under part (b) should be the responsibility of the State Opioid Treatment Authority or Single State Agency rather that the responsibility of individual physicians.** These agencies have broad, systemic understanding of state treatment capacity in a way that individual physicians do not, and they should be tasked with ensuring patients' care is

not interrupted if and when a certain physician is incapacitated or his or her waiver to treat more than 100 patients is not renewed.

6. Patient Volume Necessary

The current reimbursement structure for providing addiction treatment is largely insufficient to maintain a viable practice. This is proven not only through an evaluation of in-network contract fee schedules, but also by the fact that a large number of providers are forced to require self-pay to stay operational. This is particularly true when discussing the most vulnerable portion of the addiction patient population whose payer is commonly Medicaid. Therefore, it is unlikely that many providers will choose to pursue board certification or choose to become a "qualified practice setting" in order to expand their patient limits because it will likely be a poor financial decision for them given the constraints. This will likely result in not achieving the desired goal of expansion of access in this critical time of need.

7. Frequency of Renewal Request and 8. Synchronization of Renewal Request with DEA Practitioner Registration Renewal

ASAM believes that requiring renewal for practitioners seeking to treat more than 100 patients every three years is sufficient; it is not necessary to require renewal more frequently given the annual reporting requirements that will indicate the quality of care provided. Moreover, if HHS chooses to broaden the opportunity to qualify to non-specialist physicians who have completed additional training and/or add training requirements for physicians who practice in qualified practice settings, the three-year renewal period would be an appropriate time for these physicians to demonstrate their completion of recommended ongoing CME requirements.

Additionally, ASAM recommends SAMHSA synchronize the 3-year Request for Patient Limit Increase renewal with the renewal of the DEA practitioner registration to reduce practitioner burden. For this rule to have its intended impact of expanding access to addiction treatment with buprenorphine, it is critical that it keep administrative burdens to a minimum so as not to dissuade physicians from seeking an increase in their patient limit.

9. Estimation of Time Required to Seek Approval to Treat up to 200 Patients

ASAM believes SAMHSA's assumptions regarding the time required (1 hour) for a practitioner to complete the request for the higher patient limit are accurate.

However, ASAM would like offer the following comments on the template Request for Patient Limit Increase form:

- Question 7A9 assumes that physician has an "original 100 patients," per se, and then additional patients "above the 100 patient level" who would need to be transferred elsewhere in the event that a physician's renewal request for the higher patient limit is denied. However, it is unrealistic to assume that a physician would be treating the exact same original 100 patients 3 years (or even 1 year) after being approved to treat more than 100 patients under this rule. Please clarify what is meant by "patients above the 100 patient level" as it is not possible to distinguish which patients would be "below" or "above" the 100 patient level. Would a physician simply pick and choose which patients she or he would retain if the request for a higher patient limit is not renewed?

- Question 8 requires physicians to certify that they "will only use Schedule III, IV, or V drugs or combinations of drugs that have been approved by the FDA for use in maintenance or detoxification treatment and that have not been the subject of an adverse determination." What is the purpose of this certification? The intent may be to prevent the use of other, non-FDA-approved opioids for the treatment of opioid use disorder, but it appears to be a significant restriction on a physician's ability to practice medicine and prescribe other medications for her or his patient as needed. By signing this certification, is a physician prohibited from prescribing non-scheduled medications or scheduled medications with other indications to treat co-occurring conditions? Moreover, physicians routinely prescribe medications "off-label" when there is clinical evidence for their safety and effectiveness despite lacking FDA approval for a certain indication. For example, ASAM's *National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use* recommends, based on consensus opinion, the inclusion of clonidine as a practice to support opioid withdrawal. It states, "Clonidine is not US FDA-approved for the treatment of opioid withdrawal, but it has been extensively used off-label for this purpose." Are physicians attesting they will ignore the recommendation of clinical guidelines and not use any medications off-label? The final rule needs to clarify this point.

10. Estimation of the Change in Practitioner Behavior

As stated above, the current reimbursement structure for providing addiction treatment is largely insufficient to maintain a viable practice. This is proven not only through an evaluation of in-network contract fee schedules, but also by the fact that a large number of providers are forced to require self-pay to stay operational. This is particularly true when discussing the most vulnerable portion of the addiction patient population whose payer is commonly Medicaid. Therefore, **it is unlikely that many providers will choose to pursue board certification or choose to become a "qualified practice setting" in order to expand their patient limits because it will likely be a poor financial decision for them** given the constraints. This will likely result in not achieving the desired goal of expansion of access in this critical time of need.

11. Estimation of Eligible Practitioners

If the implication in §8.610(b)(1) that only physicians with "subspecialty" board certification is correct and ASAM- and ABAM-certified physicians are ineligible to apply to treat more than 100 patients based on their training in addiction medicine alone, then **a mere 1,095 subspecialists would be eligible to submit a Request for Patient Limit Increase to treat up to 200 patients**. Even if all applied to treat more patients and increased their patient load to 200, a wide addiction treatment gap would remain.

In addition to the subspecialists, the proposed rule would allow physicians at "qualified practice settings" to submit a Request for Patient Limit Increase to treat up to 200 patients. However, **it is unclear how many practice settings would qualify based on the criteria listed in the proposed rule. ASAM urges SAMHSA to clarify what constitutes a "qualified practice setting."** For example:

- What exactly does the proposed rule mean by "professional coverage for patient medical emergencies during hours when the practitioner's practice is closed? Even practices with

24-hour nurse phone lines and practices which have physicians on call 24 hours a day will direct patients to the nearest emergency department in the case of a true medical emergency. Does SAMHSA believe that practices should have medical professionals available to attend personally to all patient emergencies? If so, this is a tall order which very few if any physician practices could attain.

- What exactly does the proposed rule mean by "provides access" to case-management services? Does is suffice for a practice simply to refer patients to other providers for these services?

Additional clarity on these points are necessary to estimate how many practices might qualify.

12. Estimation of Number of People who will Receive MAT

Given the limited scope of the expansion the proposed rule outlines, ASAM believes that very few additional patients will receive addiction treatment with buprenorphine as a result of the proposed rule. With a mere 1,095 subspecialists eligible to treat an additional 100 patients each, unclear criteria for what constitutes a "qualified practice setting," and continued poor reimbursement for addiction treatment which makes it unlikely any physicians would pursue subspecialty board certification or a change in practice setting to treat an additional 100 patients, the proposed rule as written will have a discouragingly small impact on our nation's current epidemic of opioid addiction and related overdose deaths.

13. Reporting Periods

SAMHSA requested comment on the burden associated with the proposed reporting requirements. ASAM does not believe the proposed requirements would pose a significant burden on physicians. However, **ASAM does not believe the currently proposed reporting requirements would encourage or ensure the delivery of high-quality care.** Rather, reporting would merely be a "check-the-box" exercise that does not achieve the stated goal of improving quality or minimizing diversion. ASAM urges SAMHSA to revise the draft version of the collection template to request more meaningful data as recommended below, or to convene a panel of addiction experts to review and provide input on the data collection instrument prior to adoption.

The proposed rule states:

"The reporting requirements are intended to reinforce recommendations included in clinical practice guidelines on the delivery of high quality, effective, and safe patient care. Specifically, nationally-recognized clinical guidelines on office-based opioid treatment with buprenorphine suggest that optimal care include administration of the medication and the use of psychotherapeutic support services. They also recommend that physicians and practices prescribing buprenorphine for the treatment of opioid use disorder in the outpatient setting take steps to reduce the likelihood of buprenorphine diversion. Each of these tenets is reflected in the proposed reporting requirements."

Further, it asserts that the reporting requirements "would allow the Department to monitor the quality of care being delivered, identify any changes in the rate of diversion, and improvements in health outcomes for opioid-dependent patients."

However, the data requested by the draft version of the collection template would not, in fact, be meaningful markers of high-quality care nor would they indicate whether physicians are taking steps to minimize the risk of diversion.

- The first question asks for the percentage of active buprenorphine patients who received psychosocial or case management services due to treatment initiation or change in clinical status. This breakdown is not clinically relevant or meaningful in ascertaining whether patients are receiving high-quality care. For example, if a physician has a full panel of stable patients, 100% should be receiving psychosocial or case management services, but 0% would receive them due to treatment initiation and 0% would receive them due to a change in clinical status. The breakdown in effect masks good care without reason. It's not important to know whether patients are initiating treatment or changing clinical status; it's important to know they are receiving recommended services.
- The second question regarding PDMP checks is straightforward and sensible. ASAM has no comment except to note that not all states have PDMPs and in some states (such as Pennsylvania), they are only available to law enforcement.
- The third question is not only clinically meaningless, it betrays a gross misunderstanding of the disease of addiction and how it should be treated as the answer to #1 (The number of patients who have "completed an appropriate course of treatment… in order for the patient to achieve and sustain recovery") is always going to be 0. **There is no way to "complete" an appropriate course of treatment for addiction, when the appropriate course of such treatment is ongoing.** It's akin to asking if a diabetic has completed his course of insulin and does not make sense when discussing treatment for a chronic disease. The other three options for why a patient may no longer be under a physicians' care are reasonable (although many physicians will continue to see their patients even when referred to a more or less intensive level of care).

To truly gauge whether high-quality care is being provided and judge whether physicians are taking steps to minimize diversion, ASAM recommends the following revisions to the data collection form:

- The first question should be revised to capture the percentage of patients who receive psychosocial or case management services by type of service (motivational enhancement therapy, behavioral therapy, family therapy, etc.)
- The third question should be struck in its entirety. The number of patients leaving or ending treatment provides no insight into the quality of care received or the risk of diversion. Instead, ASAM recommends SAMHSA request data on the percentage of active patients who were subject to random urine drug screens or random pill counts to assess whether recommended diversion control measures are being used.

14. Balance of Access and Safety

ASAM asserts that the proposed rule does not come close to striking the right balance between ensuring the credentials needed to prescribe buprenorphine are within reach for interested practitioners, programs are practical to implement, and reporting requirements are not perceived to be a barrier.

- As stated repeatedly above, the requirement that practitioners have "subspecialty" board certification in addiction medicine or addiction psychiatry is severely limiting and excludes the majority or the highly-trained and dedicated addiction specialist physician workforce.
- Also as stated above, the criteria for what constitutes a "qualified practice setting" need to be clarified, especially with regards to the requirement for professional emergency coverage. As written, it is impossible to determine if such a program is practical to implement.
- Thirdly, while the reporting requirements may not be a barrier, they will not capture clinically relevant information that would facilitate an assessment of care quality or diversion. To achieve the stated goals of the reporting requirements, the data collection form should be revised as recommended above.

Additionally, as SAMHSA seeks to understand whether this proposed rule will in fact expand access to treatment, it must also consider other barriers to accessing office-based opioid addiction treatment, including the role of pharmacies in filling prescriptions for buprenorphine. ASAM has received many and increasing complaints from its members that pharmacies are refusing to stock buprenorphine and/or fill prescriptions for it. Even if physicians can treat additional patients as a result of this rule, if pharmacies aren't partners in the effort to expand access to treatment and patients can't obtain their prescriptions, the effort will be for naught.

In conclusion, it is imperative that SAMHSA expand the eligibility requirements for the higher patient limit to include the majority of the addiction specialist physician workforce – those physicians who have pursued a specialty career through ASAM and ABAM certification – as well as clarify what constitutes a "qualified practice setting" in order for this rule to have its intended impact of expanding treatment access and saving lives. Moreover, ASAM urges SAMHSA to raise the patient limit even further for board-certified specialists and other physicians who complete additional and ongoing training in addiction medicine to make a real difference in the addiction treatment gap. As written, ASAM believes the proposed rule does not go far enough to expand access to a clinically effective and cost-effective treatment option for patients whose lives are at risk, especially when our nation is battling an epidemic of opioid addiction and overdose deaths.

Thank you for the opportunity to provide comments on this important proposed rule. We look forward to continuing to work with the Administration to ensure that patients with addiction are able to access the highest quality addiction treatment and enter recovery.

Sincerely,

R. Jeffrey Goldsmith, MD, DLFAPA, DFASAM
President, American Society of Addiction Medicine