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RE: Medication Assisted Treatment for Opioid Use Disorders Reporting Requirements Regulatory Information Number (RIN) 0930-AA22

Dear Ms. Lee,

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 in response to the Supplemental Notice of Proposed Rulemaking regarding Medication-Assisted Treatment for Opioid Use Disorders Reporting Requirements. I offer these comments based on the collective expertise of more than 4,000 ASAM members and hope they will inform clinically meaningful and administratively efficient reporting requirements for those practitioners approved to treat up to 275 patients under 42 CFR part 8, subpart F.

Firstly, ASAM would like to commend HHS for the recently released Final Rule raising the DATA 2000 patient limit for certain qualified physicians to 275. We believe this is an important step in the right direction to expand access to evidence-based treatment for addiction involving opioid use, and we look forward to continuing to partner with HHS as it implements the rule and works to ensure all those who need treatment are able to access it.

As part of this collaborative effort, we appreciate the opportunity to provide further comment on the proposed reporting requirements for physicians treating up to 275

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patients. The supplemental notice of proposed rulemaking states:

“Reporting is an integral component of HHS’s approach to increase access to MAT while helping to ensure that patients receive the full array of services that comprise evidence-based MAT and minimize the risk that the medications provided for treatment are misused or diverted.”

As stated in our initial comment letter, **ASAM does not believe the currently proposed reporting requirements would encourage or ensure the delivery of high-quality care, would not be meaningful markers of “evidence-based MAT,” and would not indicate whether physicians are taking steps to minimize the risk of diversion**. ASAM urges SAMHSA to revise the draft version of the collection template to request more meaningful data as recommended below. Further, while we understand HHS’s eagerness to implement reporting requirements to ensure compliance with the final rule, **we recommend HHS convene an expert panel of addiction specialists to review and re-evaluate the reporting requirements after the first reporting period** to ensure they are capturing clinically meaningful data in the most administratively efficient way, and not unnecessarily burdening physicians or dissuading qualified physicians from treating more patients.

Our specific comments and recommendations are summarized below and detailed responses are included for each question for comment.

SUMMARY

ASAM recommends the reporting requirements should be revised as follows:

a. The average monthly caseload of patients receiving buprenorphine-based MAT, per year.
b. The number of patients in treatment for each month of the reporting period that:
    i. were provided psychosocial or case management services at the same location as the practitioner, and how frequently those patients utilized the services;
    ii. the practitioner referred for psychosocial or case management services at a different location.
c. Percentage of patients who had a quarterly prescription drug monitoring program (PDMP) query during the reporting year.
d. The percentage of patients who have been subject to the following diversion control strategies during the reporting year:
    i. Urine drug screen
    ii. Call-back for a pill count

ASAM also recommends HHS convene a panel of addiction experts to review and re-evaluate the reporting requirements after the first reporting period to ensure they are capturing clinically meaningful information in the most efficient way possible.

QUESTIONS FOR COMMENT

1. **Are there different or additional elements that should be reported in order to assist HHS in ensuring compliance with the final rule?**

Yes. The question regarding psychosocial or case management services should be revised as recommended above. The proposed breakdown between treatment initiation or change in clinical status 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. Moreover, it is unclear what HHS means by "change in clinical status."

ASAM believes it would be less burdensome and more meaningful for physicians to report the number of patients in treatment who were provided psychosocial or case management services onsite, and how frequently patients participated in such services, and the number of patients the physicians referred to psychosocial or case management services at another location.

The fourth question should also be struck in its entirety or significantly revised for the reasons listed above. The number of patients leaving or ending treatment provides no insight into the quality of care received or the risk of diversion. See the response to Question 5 below for additional detail.

The requirement to report on the percentage of patients who had a PDMP query in the past month is straightforward and makes clinical sense. However, we recommend this requirement be revised as recommended above to ask for the percentage of patients who had a quarterly PDMP query during the reporting year. Such a revision would better reflect ongoing high-quality care and prevent the practice of "back loading" PMDP checks for all patients to the month prior to the reporting deadline.

The fourth question regarding the number of patients who have completed a course of treatment or are otherwise no longer receiving buprenorphine should be struck in its entirety. It is not only clinically meaningless, but it betrays a gross misunderstanding of the disease of addiction and how it should be treated. 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 disease is chronic and the appropriate course of such treatment is ongoing. It's akin to asking if a diabetic has completed his course of insulin. Moreover, it incorrectly implies that medication-assisted treatment and recovery are mutually exclusive states. They are not only compatible, but for many patients, ongoing medication therapy is what enables them to achieve and sustain recovery. The other three reasons for why a patient may no longer be under a physician's care are reasonable (although many physicians will continue to see their patients even when referred to a more or less intensive level of care), but it is unclear how reporting these numbers will assist HHS in ensuring compliance with the final rule.

Instead, ASAM recommends HHS request data on the percentage of active patients who were subject to diversion control strategies (e.g. urine drug screens, pill counts and observed dosing) to assess whether recommended diversion control measures are being used.

2. **Are there ways in which some elements can be combined that will lessen the burden for reporting practitioners while maintaining the important function of collecting information that ensure compliance with the final rule?**

ASAM does not recommend combining any of the proposed elements.

3. **Are there other ways that HHS can collect the necessary information to ensure compliance with the final rule?**

Yes. HHS should create an online portal with radio buttons, drop-down lists, and electronic signature capability so that physicians can quickly and expediently submit their required reports. Additionally, ASAM urges HHS to support the development of a standard form that could be incorporated into electronic medical records (EMR) to streamline the reporting process by enabling physicians to report the required data elements electronically and directly from their EMR.

4. **Would it be less burdensome to report on the number of patients in treatment for each month of the reporting period that:**
   (i) Were provided counseling services at the same location as the practitioner, and how frequently those patients utilized the counseling services;
   (ii) the practitioner referred for counseling services at a different location?

Yes, as mentioned above, ASAM believes this would be less burdensome and more appropriate to report than the number of patients who received psychosocial or case management services due to treatment initiation or change in clinical status. However, we urge HHS to revise the language to omit the word "counseling" and instead refer to "psychosocial or case management services" as originally proposed.

5. **Would it be less burdensome to report on the number of patients at the end of the reporting year who had terminated utilization of covered medications?**

It is unclear what HHS means by “terminated utilization.” If the proposal is for physicians to report the number of patients who had an active prescription at one point during the reporting year but no longer have an active prescription at the time of reporting, that may not be burdensome for physicians with an electronic medical record, but could be for those who don’t. More importantly, it does not shed any light on the quality of care patients received during the reporting year or align with the scientific understanding of addiction as a chronic, relapsing brain disease.

For example, has a patient “terminated utilization” one day after his or her prescription ends? One week? One month? Since addiction is a chronic and relapsing disease, we expect to see some patients “terminate utilization” of medication for brief periods of time, only to re-engage with treatment and resume their medication shortly thereafter. These patients haven’t definitively terminated treatment, but may have temporarily done so (or been forced to do so due to involvement with the criminal justice system, housing instability, or other exogenous factor).

6. **Are there other suggested changes that would be less burdensome while maintaining the important function of collecting information that ensure compliance with the final rule?**

No, all of our recommendations have been included in our responses above.

Thank you for the opportunity to submit additional comments on the development of these reporting requirements. We look forward to continuing to work with HHS as it implements the final rule to expand access to medication-assisted treatment and works to ensure patients are receiving evidence-based treatment.

Sincerely,

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President, American Society of Addiction Medicine