January 26, 2023

The Honorable Xavier Becerra

Secretary

U.S. Department of Health and Human Services

Comments in response to RIN 0930-AA39: Medications for the Treatment of Opioid Use Disorder

Dear Secretary Becerra,

Medications for Opioid Use Disorder (MOUD) are first-line treatments for opioid use disorder with established safety and effectiveness over a broad range of populations.[1-7] At the same time, opioid agonist MOUD such as methadone and buprenorphine involve some risks to patients as well as to other individuals to whom they may be diverted. A certain amount of monitoring of the provision of opioid agonist MOUD is thus desirable. The challenge for regulators is to find the "sweet spot" between an overly restrictive system that is hard for patients to access and an overly lax system that results in harms to patients and to the community. Broadly speaking, the U.S. has regulated opioid agonist MOUD strictly relative both to other countries and to what makes for an accessible treatment system. Thus**, *we believe that the fundamental impulse behind the NPRM to relax monitoring is the right one***. The challenge now is to proceed cautiously and to continue evaluating whether the optimal point has been achieved or whether significant new harms emerge in the coming years due to regulatory relaxation. This is particularly a concern for methadone, a full opioid agonist which merits careful monitoring, but is also important for buprenorphine.

In the comments that follow, we note that the NPRM does not take account of the risks to health and well-being observed from European experiences in regulatory reform for methadone. The NPRM also interprets patterns of methadone utilization and risks following the pandemic-related flexibilities in a fashion that makes the verdict on risks from regulatory reform appear more settled than is likely the case. In addition, the NPRM proposes to make accreditation by existing bodies (e.g., CARF and JCAHO) central to promoting appropriate treatment and minimization of risks. Given the sometimes-inadequate performance of these bodies in achieving such goals, we are concerned that important changes to existing arrangements with these organizations

must be put in place if the strategy in the NPRM is to be pursued. Finally, we address the telehealth provisions proposed and comment on the regulatory impact analysis.

The European Experience

The concern about risks from regulatory reform is not hypothetical. The experience of other nations is instructive for understanding optimal regulation of these treatments. When the Danish methadone maintenance system expanded take-home dosing and reduced requirements for in person visits, supervised dosing, and urine drug testing, the number of heroin overdoses in the country decreased as methadone became more available. But the number of methadone overdoses both among individuals prescribed and not prescribed increased. The growth in methadone overdoses was equal to the decline in heroin overdoses, offsetting any public health or safety benefit of the new regulations.[8] Relaxation of regulations have been followed by increased MOUD-related deaths in other nations as well, including Sweden[9] and the United Kingdom[10-11].

Interpreting the U.S. Experience with Regulatory Flexibility

The U.S. experience with relaxed MOUD regulations during COVID-19 should also not be oversimplified and over generalized. The NPRM reviews studies showing benefits to patients without apparent harms. Add the fact that the street price of diverted buprenorphine and methadone during COVID did not fall, which would have happened if MOUD diversion occurred on a large scale.[12] But clearly relaxed regulations make diversion easier, and at least one study[13] found that the proportion of current MOUD patients testing negative for their opioid agonist therapy medication significantly increased after monitoring was relaxed.

Also, importantly, the stock of patients enrolled in MOUD is far larger than the number who enter care each year. American experience thus far with regulatory flexibilities is primarily that of established and generally stable patients being shifted to lower levels of monitoring, and the results from this group cannot be assumed to apply to patients with whom providers have no pre-existing relationship or knowledge. It should also be recognized that the goal of regulatory modifications during the COVID pandemic was to make care more accessible, but enrollment in treatment dropped at the national level during this period. This is important because the evidence cited in the NPRM focuses on the percentage of overdoses that were due to methadone. However, the more relevant risk analysis is to consider the rate of overdoses among people actually using methadone. Direct evidence on that risk is absent.[14] The implication is that recognizing the unique nature of the circumstance caused by the pandemic

should create caution about overgeneralizing from health outcomes that occurred in that context. That in turn increases the value of conducting a formal reassessment of the impact of regulatory change after the pandemic has abated.

Recommendations: The Government Accountability Office or equally credible evaluator should be tasked with performing an extended evaluation of the impact of the new regulations articulated in the NPRM. This evaluation should examine impact on accessibility of MOUD care, retention in MOUD care, medication diversion, and overdose deaths among individuals prescribed and not prescribed MOUD. The evaluation should also include a process study of a representative sample of care providers to determine how they are determining which patients are subject to what level of monitoring (the term “stable patients” is open to a wide range of interpretation).

Accreditation as the Safety Protections

A related concern is the plan proposed in the NPRM puts great reliance on accreditation processes that are intended to establish and govern treatment and safety standards. The track records, with respect to oversight of appropriate treatment for opioid use disorder, of the two main accrediting bodies (JCAHO and CARF) are, at best, mixed. For example, results from a secret shopper study of residential treatment programs showed that some JCAHO and CARF accredited programs used aggressive recruitment methods, often without any clinical evaluations, and some certified facilities refused to use MOUD and refused to admit people being treated with buprenorphine.[15] Those prior failures make clear the serious limitations of current accreditation arrangements to curb undesirable practices. In addition, accreditation processes fail to check methods that exploit people with substance use disorders through brokering activities (payments for recruitment of patients) that have been highlighted in Congressional hearings.[16] That is, residential programs enlisting brokering services that recruit patients without a clear clinical determination that residential treatment is the most appropriate level of treatment. The NPRM calls for more information sharing between accrediting bodies and SAMHSA and for more elaborate training of accreditation personnel. We are concerned that these alone may not be sufficient to promote safe, high-quality care.

Recommendation: Given the potential for increased risks to consumers and potential for stinting by opioid treatment programs, the role of accrediting bodies takes on increased importance. Because the track records of these organizations in related areas is spotty, we recommend that SAMHSA establish and specify in the rule performance metrics for use by and for assessment

of accrediting bodies and an explicit process for tracking and review of performance. In addition, SAMHSA should also conduct direct monitoring of the performance of OTPs. Moreover, consequences for substandard performance for both accreditors and OTPs should be codified.

Proposed Telehealth Changes

During the pandemic, telehealth has provided an important way to access MOUD and related OUD services and likely contributed to ensuring patients stayed on MOUD during the early months of the pandemic.[17] The proposed rule would make permanent some pandemic era flexibilities around OTPs' use of telehealth for buprenorphine initiation, allowing initiation via either audio-visual or audio-only telehealth technology if an OTP or other authorized clinician determines that telehealth will allow an adequate evaluation of the patient before prescribing. Given the need to expand access to MOUD, and the available evidence on telehealth use for buprenorphine initiation, such a policy change seems prudent.

OUD clinicians appear to have taken a measured approach to the use of telehealth for buprenorphine initiation as evidenced by their greater likelihood of using telehealth for follow-up visits than for initiation of care and the consideration of clinical and other characteristics of patients in making decisions about the use of telehealth. For example, in a national survey of clinicians who prescribe MOUD, a much larger proportion of clinicians (88.9%) reported that they were comfortable using telehealth to care for established patients who were clinically stable in their recovery relative to using telehealth for new patients with OUD (38%).[18] In studies of Medicare and private insurance data, approximately 15% of buprenorphine initiations were conducted via telehealth during the first year of the pandemic.[19,20] Even at its peak in April 2020, the proportion of buprenorphine initiations delivered via telehealth (approximately one-third or fewer) were lower than the rates of telemedicine use for other behavioral health conditions (40-56%). [19-22]

Much less is known about clinician practices and perspectives regarding methadone initiation via telehealth. Due to the additional safety concerns with methadone relative to buprenorphine noted in the NPRM, we support the more measured approach to relaxation of the regulations in the case of methadone – i.e., permanent relaxation of telehealth restrictions only for audio-visual telehealth and not audio-only as proposed in the NPRM.

However, given widespread concerns about the digital divide, it is critical that the new rule promotes equity in telehealth access, ensuring that all patients regardless of race, ethnicity, disability status, or income can access video visits (even while allowing audio-only telehealth

initiation of buprenorphine).[23] Although we do not know of any research that specifically compares audio-only vs. video visits in quality of OUD care, most OUD clinicians perceive that video visits result in better care.[18, 23] We must also be mindful of the difficulties for patients to obtain access to video services that are safe and confidential if they do not have secure access to the relevant devices.

Patient factors and the digital divide are a key reason that many patients cannot access video visits. But we are also conscious that many clinicians do not provide video visits at all or only selectively provide video visits. Addressing these clinician barriers is also important in improving access.

Recommendation: One way to address these types of barriers is to include one or more performance metrics in the OTP accreditation process related to promoting access to video telehealth. For example, possible metrics could focus on: 1) whether the OTP offers telehealth visits for MOUD initiation; 2) whether the OTP provides certain resources to support patients in overcoming barriers to accessing video visits (e.g., offering real time technical assistance, connecting patients to digital navigators, conducting practice video visits, hosting patients participating in video visits in the clinic or parking lot, or providing devices to those who do not have them); or 3) the percentage of audio-only buprenorphine initiations that receive either an in-person or video telehealth follow up visit as opposed to exclusive use of audio-only telehealth for follow up care.

Regulatory Impact Analysis: The RIA set out in the NPRM is focused primarily on the costs to SAMHSA of administering new provisions described in the NPRM. Although the NPRM discusses general evidence concerning the costs and benefits of opioid use disorder treatment, none of it is specific to the program changes being proposed. This runs entirely counter to the purpose of the RIA, which is to analyze the economic, health, and social consequences of the policy provisions proposed. The NPRM contains a variety of economically meaningful features. These include the following:

- Relaxed entry requirements for treatment in an opioid treatment program
- Expanded telehealth in providing initial evaluations and on-going treatment
- Expanded use of take-home methadone
- Expanded definition of staff that can dispense methadone
- Expanded use of harm reduction

Provisions will affect the demand for MOUD treatments, many of which are paid for by public funds (e.g., Medicaid and Medicare). These provisions include reforms to enrollment, expanded use of telehealth, flexibility regarding take home methadone, and expanded mobile dispensing. Some of these provisions likely affect the costs of producing treatment. For example, an expanded definition of providers that can dispense, expanded use of telehealth, and a relaxed rule regarding take-home methadone may all affect treatment costs. Finally, harm reduction services broaden the scope of services offered that may make claims on public funds. The RIA should be assembling evidence to project how resulting changes in care patterns would change the costs of care and the sources of payment. In addition, provisions that change access to care and how care is delivered will alter the risks and benefits associated with methadone treatment.

Recommendation: The RIA should draw on a broad range of experiences in the U.S. and abroad to consider how this regulatory change would affect people receiving treatment and public budgets that support so much of the care.

We hope these comments are helpful to you as you continue to improve the regulatory landscape for medications for opioid use disorder.

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