AMA
AMERICAN MEDICAL ASSOCIATION

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February 23, 2021

The Honorable Michael Conway
Insurance Commissioner
Colorado Division of Insurance
1560 Broadway, Suite 850
Denver, CO 80202

Comments sent via email to: DORA_Ins_RulesandRecords@state.co.us

Re: American Medical Association support and suggested revisions for Proposed New Regulation 4-2-7X, "Concerning Requirements for Reporting Medication-Assisted Treatment Coverage."

Dear Commissioner Conway:

On behalf of the American Medical Association (AMA) and our physician and medical student members, I am writing to submit comments on Proposed New Regulation 4-2-7X, "Concerning Requirements for Reporting Medication-Assisted Treatment Coverage." The AMA joined the Colorado Medical Society and many others in supporting CO SB 20-007 to help ensure access to evidence-based care for patients with an opioid use disorder (OUD) or other substance use disorder (SUD), as well as identify the challenges faced by patients in finding such care. The AMA strongly supports this proposed regulation, which demonstrates the leadership that the Colorado Division of Insurance (CDI) is taking to meaningfully help end the state's drug overdose epidemic.

This regulation would provide essential support for Colorado's efforts to increase access to evidence-based treatment in that it, "applies to all carriers marketing and issuing or renewing health benefit plans in the individual, small group and large group markets in Colorado, including non-grandfathered plans, short-term limited duration health insurance policies, and student health insurance coverage" as of June 1, 2021. This is one of the most ambitious and far-reaching regulations any state has taken to help patients and end the drug overdose epidemic in Colorado.

The AMA has consistently advocated for this type of action due to the fact that patients routinely report an inability to access evidence-based care for an OUD or other SUDs. The reasons include wide disparities in access to in-network care; prior authorization and other utilization management hurdles both for providers and medication; difficulties in determining which in-network providers are accepting new patients; and cost-sharing decisions that may place some medications or other treatments out of reach. While this regulation will not, by itself, solve every problem, it will provide essential information to provide the CDI a foundation on which to understand precisely where problems exist. It will also provide information to CDI on how it can continue its efforts to bridge gaps between what services and benefits health plans are required to provide for patients, and what they actually deliver.

Overall, the AMA strongly supports each section of the proposed regulation, as well as the proposed appendix. The comments offered below are meant to provide additional clarification and detail about areas (such as differences between access and utilization management protocols broken down by type of medication for OUD) that directly affect patient care. And while it may be beyond the scope of the regulation, the AMA points out that for a health plan, third-party administrator (TPA) or their designees to place utilization management and other restrictions on treatment for OUD or other SUDs, in the midst of an epidemic, is entirely counterproductive to saving lives.

The AMA anticipates that health plans may object to being required to provide this level of detail, but we point out that this information should already be in the health plans' possession if they are to be truly able to build and maintain an adequate network of physicians and other health care professionals to treat SUDs. The nuances matter. We also anticipate that health plans will lodge complaints about there not being enough SUD providers in Colorado. This may be the case for some areas in Colorado, but that makes this proposed regulation even more important because it will help uncover where treatment gaps are most prevalent—and the processes and procedures by which the health plans will address them for enrollees with an OUD or other SUDs.

The AMA's comments below are provided by section:

Section 5

The AMA strongly supports the annual reporting requirements of coverage for medications to treat opioid use disorder (MOUD) and the broad range of network and other data elements that are needed to truly understand access to treatment for OUD. As described below, the comprehensive nature of the data and other elements to be reported by health plans will not only help the CDI better understand where gaps in treatment exist, but also provide a clear picture of how the CDI, health plans, and medical and health care community can work together to resolve those gaps.

Section 6

The AMA strongly supports the CDI's proposal to have health plans report on the different types of providers and SUD and opioid treatment programs (OTPs) in the state on a county-by-county basis. We recommend a simple revision to ensure that this section gathers data showing whether physicians are prescribing methadone for the treatment of opioid use disorder as follows:.

> B. 4. The number of providers who are authorized to ~~can~~ prescribe methadone for the treatment of opioid use disorder;

Similarly, we are acutely aware of the fact that many Colorado physicians and other health care professionals may be certified by the state and federal government to prescribe buprenorphine for office-based OUD, but that they do not actively treat patients with OUD. The appendices in the proposed regulation clearly understand this fact, which is why we recommend having specific reference in Section 6, as well. Therefore, we recommend the addition of the following provision in Section 6:

> B. [ ]. The number of providers with a federal waiver to prescribe buprenorphine for the treatment of opioid use disorder.

This addition will allow CDI to capture the total universe of authorized buprenorphine providers both in OTPs and in the community.

The AMA also strongly supports each provision contained in Part F that is designed to, "provide to the Division a detailed description of its efforts to ensure sufficient capacity for and access to MAT for SUD." This information will be invaluable for the CDI's efforts to protect patients. We offer the following suggestions to further clarify how each of the provisions within Part F could provide additional direction to health plans:

1. Policies and procedures to ensure enrollee access to OTPs, including any policies and procedures to assist with transportation, telehealth services, take-home dosing, and complementary behavioral health services;

2. The methodology or other formal process(es) used by the carrier and TPA, if applicable, to determine network sufficiency to ensure access to MAT for SUD and OUD, and process(es) undertaken if the carrier or TPA has found insufficiencies;

3. Policies and procedures regarding prior authorization requirements for MAT for SUD and OUD, including requirements for pregnant and parenting women as well as minors;

4. Coverage and utilization management for MAT prescriptions, including differences in coverage and utilization management provisions for different FDA-approved medications for the treatment of OUD;

5. Processes to recruit and retain providers to prescribe MAT for SUD and OUD, including both care received in an OTP and office-based buprenorphine, to enrollees; and

6. The evidentiary or other standards and practices used to determine eligibility of providers to prescribe MAT for SUD and OUD to join the network.

With respect to the Appendix, the AMA greatly appreciates the level of detail and understanding that has gone into the tables and accompanying direction. We offer the following comments and suggestions for your consideration:

Item 1

The AMA strongly supports the inclusion of a table to have health plans and their TPA, if applicable, to identify the availability of providers for SUD and OUD care. We point out, however, that federal restrictions for providing OUD care are largely limited to methadone in an OTP and buprenorphine in-office. This is an important distinction because while these medications have a proven evidence-base for the treatment of OUD, a health plan may classify a provider as an SUD or OUD provider, but that provider may not have the requisite authority to prescribe MOUD.

Therefore, we suggest the following revision:

1. The number of in-network providers that are federally-licensed to provide MAT for SUD and OUD at the beginning of the calendar year and end of the calendar year."

In furtherance of the proposed regulation's intent, to better identify who, in-network, offers MOUD, we suggest the addition of a third column to the chart below. We also recommend the addition of an additional provider type to identify all those who the health plan or TPA might include in the network as

an SUD or OUD provider, but who does not have the authority to prescribe MOUD. We recommend this change for both the beginning and end of the calendar year.

Provider Type	SUD	OUD	MOUD
Physician, MD or DO			
Nurse Practitioner			
Physician Assistant			
Clinical Nurse Specialist			
Certified Registered Nurse Anesthetist			
Certified Nurse Midwife			
Other			

Item 2

Similar, to Item 1, the AMA recommends the following revision to enable CDI to better understand distinctions in types of MOUD, if any, offered by SUD treatment programs in the network. The addition of a new column to identify the type(s) of MOUD offered is important to understand whether the three main classes of FDA-approved medication—methadone, buprenorphine, and naltrexone—are offered or not, including which formulations of each medication. This is important because, for example, if a patient is stable on a particular medication for an OUD or other SUD, the patient needs to know that the treatment program will offer that therapy. Just because a treatment program holds itself out as one that treats SUDs, it is not a guarantee that it includes MOUD as part of its protocols—or which MOUD is offered. Therefore, the AMA recommends asking for additional clarity as-follows:

Type of program	Number	Type(s) of MOUD offered
SUD treatment program		
Opioid Treatment Program		

Item 3

Similar to the comments provided for Item 2, the AMA recommends the addition of a third, distinct column to identify whether providers in each, specified county have the requisite authority to offer MOUD. This is not to suggest that every county needs a certain number of providers, or that every county necessarily needs an MOUD provider, but it is essential to know whether such coverage exists. Just because a health plan says a physician can provide care for an OUD or other SUD, it is not a guarantee that the physician offers MOUD. Without copying each county, the proposed revision would look as follows:

County	SUD	OUD	MOUD
Adams			
Alamosa			

Item 4

The AMA supports the CDI in calling on health plans to identify, "the number of providers who can prescribe methadone at the beginning and end of the calendar year in the network." This is similar to the

information sought in Item 3 in that OTPs will be identified in both Items 3 and 4. We are not sure, however, whether the CDI is counting an OTP as a distinct "provider" or whether the intent is to identify the total number of physicians who provide care, including the provision of methadone for the treatment of OUD, within an OTP. The AMA suggests that it is important to identify both the total number of physicians who can provide methadone for the treatment of OUD and the total number of OTPs available in an enrollee's network. Combined with Item 3, this will allow the CDI to determine whether there is sufficient OTP access regionally in Colorado.

Item 5

With the revisions recommended by the AMA to bolster the information in Items 2-4, the AMA strongly supports this item in that it requires health plans to, "Describe the policies in place and strategies utilized to ensure enrollee access to OTPs." Without the information in Items 2-4, health plans would not be able to provide the information in Item 5. This is an excellent example of the type of information that health plans already should have and be readily able to provide to the CDI to demonstrate network sufficiency for OTPs.

Item 6

The AMA strongly supports the information sought in Item 6. One suggestion to add clarity is to inquire about the specific buprenorphine limit with individual columns as follows:

Provider Type Waiver Limit

	Waiver limit		
Provider Type	30 patients	100 patients	275 patients
Physician, MD or DO			
Nurse Practitioner			
Physician Assistant			
Clinical Nurse Specialist			
Certified Registered Nurse Anesthetist			
Certified Nurse Midwife			

Items 7-10

The AMA strongly supports the intent and direction for Items 7-10 to identify the specific number of patients treated for an OUD or SUD by Colorado's health plans. This is essential information to further understand the scope of the epidemic in Colorado. It will help the CDI understand where treatment capacity is needed most. When matched up against other data required by the proposed rule, it also will allow the CDI to better understand whether existing networks are sufficient for that treatment capacity. Having this information by county also would further support the CDI's work with other stakeholders to identify additional policies, including the availability of naloxone, to help build a more comprehensive approach to saving lives from opioid-related overdose. While we appreciate that naloxone may be beyond the scope of this regulation, it is an important part of harm reduction services that has saved tens of thousands of lives throughout the nation.

With the above concepts in mind, the AMA recommends a slight revision to Item 9 to distinguish between patients being seen for OUD, SUD, and those actually receiving MOUD. This is not to suggest

that every patient must receive MOUD, but if a health plan or TPA has a very low proportion of OUD patients receiving MOUD, that raises important questions for further discussion with the health plan. For example, this could reveal a high proportion of prior authorization barriers, too few waivered physicians, PAs or NPs, geographic disparities, or other challenges in access. It also could reveal that patients do not have access to proven medication therapies or qualified health care professionals to provide such care. This would further complicate Colorado's efforts to end the state's considerable drug overdose epidemic.

Therefore, we recommend the following revision to Item 9:

Provider Type	Number of Patients - SUD	Number of Patients - OUD	Number of Patients receiving MOUD
Physician, MD or DO			
Nurse Practitioner			
Physician Assistant			
Clinical Nurse Specialist			
Certified Registered Nurse Anesthetist			
Certified Nurse Midwife			
Other			

Item 11

The AMA strongly supports the information sought in Item 11 to determine the prevalence and policies for administrative barriers to SUD and OUD care, including medications for SUDs. We point out, however, that there are multiple different formulations of buprenorphine—each of which might have different utilization management and cost-sharing policies imposed by the health plan or TPA. This also is an area where the utilization management and cost-sharing policies might be imposed by a pharmacy benefit manager (PBM) acting to administer the pharmacy benefit. If a health plan, PBM, or TPA has any utilization management restrictions on any of the FDA-approved medications, the health plan, PBM, or TPA should be required to identify the specific utilization management policies, how they are implemented, in addition to identifying the cost-sharing and tiering policies that are provided by the health plan, PBM, or TPA. Having this comprehensive information will be essential to helping the CDI carry out the intent of the proposed regulation.

Thus, in the first two questions, while it is important to identify whether prior authorization is required for MAT, OUD, and SUD for "federally-licensed providers," the AMA recommends revisions to account for the broader experiences of patients, physicians and other health care professionals, who are part of the care team. In addition, we recommend focusing the "federally-licensed" qualifier to the prescribing of methadone used in OTPs for the treatment of OUD, and buprenorphine in-office for the treatment of OUD. Similarly, because prior authorization may be imposed on the provider or patient, we recommend a more open-ended question. In addition, naltrexone, which may be used for the treatment of OUD, does not require any special federal requirement to prescribe it as do buprenorphine and methadone. Finally, to the extent that future medications may be identified for the treatment of OUD or other SUDs, the revisions suggested below will capture those medication therapies.

We are sensitive to carriers' likely objections to having to answer a few additional questions, but we believe the additional questions will provide CDI necessary information and will not impose any significant burden on the health plan given that the intent of the regulation is to be comprehensive.

Therefore, we recommend revisions to the first two questions under Item 11 and additional clarifying questions as follows:

Yes/No	Is prior authorization, step therapy, or other utilization management policies required for any FDA-approved medications used as part of the treatment of SUD? ~~MAT for SUD care provided by federally-licensed providers~~?
Yes/No	Is prior authorization required, step therapy, or other utilization management policies for any FDA-approved medications used as part of MAT for OUD care? ~~provided by federally-licensed providers~~?
Yes/No	Does the formulary used place any of the medications used for OUD or SUD on the lowest-cost tier of the formulary?
Yes/No	Does the formulary contain all FDA-approved medications for the treatment of OUD and SUD?
Yes/No	In addition to the medications listed above, what other medications for the treatment of OUD or other SUDs are included on the formulary?
Yes/No	Is Buprenorphine covered? (Please list each formulation that is covered)
Yes/No	Is Methadone covered? (Please list each formulation that is covered)

Items 12-14

The AMA further recommends revisions to the following questions to complement the comments provided above:

12. If prior authorization is required for MAT for SUD or OUD, provide an overview of the carrier's, TPA's or PBM's policies and procedures regarding requiring prior authorization, including the appeals process when a medication is denied. This should include, at a minimum, the education and professional qualifications of the reviewer who is responsible for making the determination at each level of the appeals process.

13. Provide an overview of any other ~~the~~ utilization management protocols in place for each covered medication.

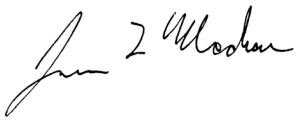
[New question] For the medications identified in the list above, provide which cost-sharing tier each medication is placed, including an overview of the carrier's, TPA's or PBM's policies for placing such medication on the specific tier.

14. Provide a detailed description of the carrier's and TPA's, if applicable, processes to recruit and retain providers ~~that are federally licensed~~ to prescribe MAT for SUD and OUD, including methadone and buprenorphine, to enrollees.

In conclusion, the AMA greatly appreciates the thoughtfulness and comprehensive nature of the proposed regulation. This regulation will help create much-needed transparency to the barriers faced by patients, physicians, and other health care professionals in accessing evidence-based care for OUD and other SUDs in Colorado. Such transparency, moreover, will help the CDI identify where action is needed to meaningfully enforce network adequacy laws, mental health, and substance use disorder parity laws. This level of transparency will also serve to bring key stakeholders together to find solutions to complex issues, such as the provision of evidence-based care in rural and underserved areas in Colorado. The CDI's continued leadership in these areas serves as a marker for the entire nation and we applaud you for your efforts.

If you have any questions about the comments in this letter, please contact Daniel Blaney-Koen, JD, Senior Legislative Attorney, AMA Advocacy Resource Center, at daniel.blaney-koen@ama-assn.org.

Sincerely,



James L. Madara, MD

cc: Colorado Medical Society