2024 Federal Regulatory Preview

January 10, 2024 – ASAM Advocacy is kicking off 2024 with a preview of the biggest regulatory developments we expect to track this year. Keep in mind that this preview is not a definitive list of everything we may see come out of the Biden Administration this year, but rather an early look at the big-ticket items.

DEA Telemedicine Rule

2024 starts with the expectation that we will see a revised proposed rule on the use of telemedicine to treat patients with opioid use disorder (OUD). Keep in mind that the Drug Enforcement Administration (DEA) proposed a rule on this topic in March 2023. ASAM submitted comments on those proposals, highlighting that ASAM opposed the DEA's rule to the extent it devolved into the regulation of the practice of addiction medicine without a strong public health justification, represented a poorly-tailored control against diversion, and constituted actions that threaten public health and safety.

After receiving nearly 38,000 public comments on the proposal, DEA paused the promulgation of this regulation, heard comments through town hall forums, and subsequently extended the COVID-19 era flexibilities twice. The current extension is set to expire in November 2024, so we would expect to see a proposed rule from DEA on this by summer 2024 at the latest to ensure there's a policy in place once the current extension ends.

This one is not yet on the Office of Management and Budget's (OMB) regulatory review dashboard, so we will keep watching for this one.

Confidentiality of Patient Records

We expect to see a finalized rule from the Department of Health and Human Services (HHS) soon (the rule just arrived at the final clearance hurdle at OMB on December 21, 2023) regarding the confidentiality of patient records for patients treated for substance use disorder (SUD). Keep in mind that under 42 CFR Part 2, there are strict standards for clinician's ability to share records of patients seeking treatment for SUD with other clinicians and part of the healthcare ecosystem. Namely, patient consent is required in most instances. On the other hand, under the Health Insurance Portability and Accountability Act (HIPPA), patient consent is not required to share records with other treating clinicians.

Congress made some changes to 42 CFR Part 2 in 2020 by permitting disclosure for treatment, payment, and healthcare operations. The 2020 Congressional action also restricted the use of patient records in legal proceedings.

ASAM made several recommendations to HHS in response to the rule, including a recommendation that HHS conduct a study of the impact of full alignment with HIPAA on the access, availability,

and quality of SUD services, coupled with strengthened HIPAA protections against uses, disclosures, or redisclosures of SUD and other medical records outside the healthcare system. ASAM cautioned that the final rule make it clear, on a consistent basis, that Part 2 records may not be used, disclosed, or redisclosed for civil, criminal, administrative, or legislative proceedings against the patient in the absence of a court order or a specific, written patient consent for that purpose. You can read more of ASAM's response here.

Changes to Federal Methadone Rules

2024 also brings an expected final rule from the Substance Abuse and Mental Health Services Administration (SAMHSA) that revises certain treatment standards for the use of methadone in opioid treatment programs (OTPs). Among other proposals in the proposed rule, SAMHSA proposed to:

- Make permanent the pandemic-era take home allowances of methadone;
- Use telehealth to initiate treatment with buprenorphine;
- Expand the definition of practitioner to include advance nurse practitioners, physician assistants, etc.;
- Review accreditation standards; and
- Remove the requirement that patients be diagnosed with an OUD at least one year before admission to an OTP.

ASAM applauded many of the new rule's proposals, including those that continue and enhance regulatory flexibilities beyond the COVID-19 public health emergency, expand access to and improve the quality of care at OTPs, and promote a patient-practitioner relationship in an integrated system of collaborative care. ASAM also recommended requiring OTP medical directors to have a minimum amount of experience in addiction treatment to ensure benefits and minimize harms to patients at OTPs, adjusting the interim methadone treatment period from 180 to 360 days, and finalizing the definition of long-term care facilities with modifications to include local jails, and state and federal prisons, with further modifications to expand the reach of these facilities.

You can find ASAM's comment letter on the proposal here. We'll be anxiously awaiting SAMHSA's final rule. It appears the rule just cleared the last hurdle of review at OMB, so expect to see something on this relatively soon.

Food and Drug Administration (FDA)

The FDA really kicked into high gear last year and we should expect that trend to continue moving into 2024. Here's a look at two major policy issues emanating from the FDA in the coming year.

Rules to Prohibit Menthol and Ban Flavors in Cigars

Notably, the FDA proposed sweeping rules to prohibit menthol as a characterizing flavor in cigarettes and to prohibit all characterizing flavors in cigars following a commitment by the Biden Administration, which ASAM applauded at the time.

However, those rules have yet to be finalized and are still sitting at OMB for clearance. Reportedly, The White House is undecided on whether or not to finalize the rules.

Use of Buprenorphine at Doses above 24 mg

In December of last year, the FDA held a public meeting on the topic of emerging data and barriers to accessing high dose buprenorphine in the context of high potency synthetic opioid exposure. The goal of the meeting was to gather both quantitative and qualitative data on the need for, effectiveness, and safety of high-dose buprenorphine (24mg+) in the treatment of OUD, particularly in the emerging context of fentanyl exposure and inform federal guidelines and policies with the latest evidence and practical experiences.

Any action on this from the FDA would have major potential for insurers, clinicians, and patients since the current FDA label is restricted to a 24 mg daily dosage and many utilization management policies are designed to reflect that. Be sure to watch this one as the year moves along and we will be sure to keep you in the know if we learn more.

Coverage of Over the Counter (OTC) Products for Tobacco Cessation/Use Disorder (TUD)

Late last year, HHS issued a request for information (RFI) regarding coverage of OTC products, including for tobacco cessation/use disorder without patient cost-sharing. HHS appeared to be of the thought that federal statute would allow this change. ASAM submitted comments to HHS supporting the removal of barriers to smoking cessation products with a goal to provide more people access to these tools. ASAM also urged HHS to consider the important role of clinicians in screening for and treating TUD, noting that efforts to expand access to OTC products should not subvert the critical patient-clinician relationship.

Keep an eye on HHS to see if the Department issues a proposed rule to change regulations to permit coverage and no sharing for certain OTC products.

Contingency Management

There could also be major action on reducing barriers to effective contingency management (CM) this year. Currently, it is unlawful to provide CM to patients who are enrolled in health plans funded by federal dollars. These incentives can be considered kickbacks when they exceed a certain amount (currently $75).

As part of the Consolidated Appropriations Act, the HHS Office of the Inspector General (OIG) was required to produce this report to Congress and consider proposing a safe harbor for

evidence-based CM incentives, which would include any parameters for such a safe harbor. It looks like we could be seeing a proposed rule on this in August of this year.

Medicare Physician Fee Schedule (MPFS)

Every year the Centers for Medicare and Medicaid Services (CMS) issues a proposed rule usually in July governing policies and valuation of services under the fee schedule that determines payment for individual clinicians. Since 2019, we have seen major proposed actions from CMS almost every year.

In last year's rulemaking, CMS welcomed comments from stakeholders on different aspects of treatment of mental health (MH) disorders and SUD and potential rulemaking that the agency could consider. The agency also did this regarding digital therapeutics. In a follow-up to the agency's action to finally establish payment for intensive outpatient services last year, we could also see proposals from CMS on digital therapeutics and other aspects of MH and SUD.

Not to mention, many policies around telehealth are due to expire at the end of 2024. CMS has continuously extended these deadlines in the wake of Congressional action. Absent Congressional action this year, we may see some of these policies expire at the end of the year. This will be an area to watch, as well.

Medicaid Waivers

Last year, we saw CMS approve California's Section 1115 demonstration that covered certain reentry services for incarcerated individuals 90 days prior to release. This was the first approval to include a partial waiver to the Medicaid inmate exclusion policy that prohibits Medicaid payment of services provided during incarceration. CMS followed that approval by releasing guidance to states to encourage them to follow suit. There are several other states that have submitted similar proposals, and we expect to see CMS action on those this year, as well.

These are just some of the issues that ASAM will be watching on the regulatory docket this year, and we are sure to see others pop up that we are not expecting. Subscribe to ASAM's Advocate so you can stay in the know!