



# About us

## About the AMA

The American Medical Association is the powerful ally of and unifying voice for America's physicians, the patients they serve, and the promise of a healthier nation. The AMA attacks the dysfunction in health care by removing obstacles and burdens that interfere with patient care. It reimagines medical education, training, and lifelong learning for the digital age to help physicians grow at every stage of their careers, and it improves the health of the nation by confronting the increasing chronic disease burden.

For more information, visit [ama-assn.org](http://ama-assn.org).

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# I. Introduction

The American Medical Association (AMA) and Manatt Health released a national roadmap in September 2019 to guide policymakers in taking action to help end the nation's opioid epidemic.<sup>1</sup> Based largely on in-depth analyses of the responses to the opioid epidemic in Colorado, Mississippi, North Carolina, and Pennsylvania, the 2019 roadmap identified numerous promising strategies as well as areas where more work and innovation clearly were required.

This expanded 2020 roadmap starts with our 2019 policy recommendations and an assessment of progress made. The results are mixed, with the COVID-19 pandemic creating new challenges but also opening up new opportunities. For example, the important national focus on addressing racial inequities in care has exposed huge disparities in how different populations fare with respect to substance use disorders (SUDs), but also generated new support for addressing those disparities. The 2020 roadmap is organized around the same six essential policy goals as the 2019 version, but goes into far greater detail, provides extensive tangible action items, and details best practices in more than two dozen states.

## Exhibit 1. Progress update on AMA–Manatt Health 2019 policy recommendations

- **Evidence-based treatment for opioid use disorder.** Provide the full continuum of care, including medications to help treat opioid use disorder (MOUD) that are provided equitably across the health care system.
  - **Results are mixed.** The COVID-19 pandemic has brought new challenges and increased mortality from illicit fentanyl, methamphetamine and cocaine. More states have enacted laws prohibiting health insurers from using prior authorization for MOUD, but more than half of the nation's states still allow it.
- **Parity enforcement.** Increase oversight and enforcement of mental health and substance use disorder parity laws, including prospective evaluation of payer compliance.
  - **Results are mixed.** Some states have enacted meaningful laws, and 30 states have joined a new National Association of Insurance Commissioners (NAIC) work group to refine regulatory tools that can hold insurers accountable. Yet state and federal oversight remains limited, as exemplified by the regular parity violations that are found when states conduct compliance exams.

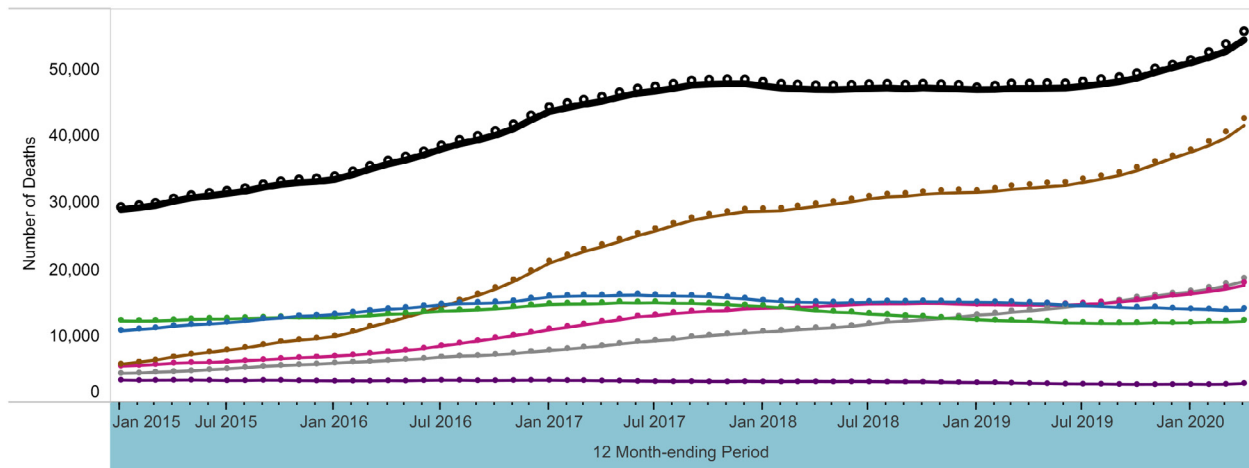
- **Network adequacy/workforce enhancement.** Ensure adequate networks that allow for timely access to addiction medicine, psychiatry and other physicians trained to treat addiction and mental illness; support payment reforms, collaborative care models, and other efforts to bolster and support the nation's substance use disorder treatment workforce.
  - **Much more work remains.** Innovative payment models continue to be explored, and some states are working hard to increase access to care, but millions of Americans with an SUD and/or mental illness remain without treatment.
- **Pain management.** Enhance access to comprehensive, multidisciplinary, multimodal pain care, including nonopioid and nonpharmacologic pain care options; remove arbitrary restrictions on opioid therapy for patients with pain.
  - **Much more work remains.** While policymakers continue to rely on arbitrary restrictions for opioid analgesics, states and insurers have done relatively little to increase access to evidence-based alternatives to opioids and other medications and treatments that have proved cost effective in treating pain.
- **Harm reduction.** Reduce harm by expanding access to naloxone, supporting sterile needle and syringe exchange programs, and coordinating care for patients in crisis.
  - **Progress continues.** If not for naloxone, it is likely that tens of thousands more Americans would have died in 2019-2020. Some states have taken steps to increase access to sterile needles and syringes, and emergency departments are showing great promise in helping coordinate care for patients who experience an overdose event.
- **Data surveillance and evaluation.** Support standardized data collection and surveillance efforts, and evaluate policies and outcomes to identify effective policies and clinical interventions so as to build on the most successful efforts, and also to identify policies and programs that may need to be revised or rescinded.
  - **Much more work remains.** States are taking action to gather more information, but they need to take the next step to turn that data into effective overdose prevention, treatment, and targeted interventions. Few states have evaluated whether current policies are increasing access to care or reducing opioid- and drug-related harms. There remains a lack of standardized data collection efforts across states, and data collection to address racial, ethnic, and gender-related inequities also is limited at best.

The goal of our 2020 roadmap is to highlight the areas where there is opportunity for improvement, as well as to build on the progress that has been made by providing tangible recommendations and best practices to increase access to evidence-based care for SUDs, support multidisciplinary, multimodal treatment for patients with pain, and expand the use of proven and promising harm reduction strategies. With respect to COVID-19, which has contributed to the again-rising overdose death rate (see Exhibit 2), the roadmap highlights the accelerated use of telehealth and other policy changes that could become part of short- and long-term strategies to improve access to overdose prevention and treatment strategies. Removing the stigma for those who receive treatment for an SUD, for patients with pain, and for people who use drugs remains a long-overdue need across all domains.



**Exhibit 2. 12 month-ending provisional counts of drug overdose deaths by drug or drug class, United States, 2015–2020**

Data last updated November 4, 2020.



Legend for Drug or Drug Class

- Opioids (T40.0-T40.4, T40.6)
- Methadone (T40.3)
- Heroin (T40.1)
- Synthetic opioids, excl. methadone (T40.4)
- Natural & semi-synthetic opioids (T40.2)
- Cocaine (T40.5)
- Psychostimulants with abuse potential (T43.6)

---- Reported Value

○ Predicted Value

Source: [www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm](http://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm).

### Exhibit 3. The opioid epidemic continues to evolve into a broader polysubstance use and more deadly drug overdose epidemic

The opioid epidemic continues to evolve into a more deadly and broader drug overdose epidemic, with more people dying from illicit fentanyl, heroin, cocaine, and stimulants even as the country experiences a dramatic drop in the use of prescription opioids. According to the US Centers for Disease Control and Prevention (CDC), from the beginning of 2015 to the end of 2019:<sup>2</sup>

- Deaths involving illicitly manufactured fentanyl and fentanyl analogs increased from 5,766 to 36,705.
- Deaths involving stimulants (eg, methamphetamine) increased from 4,402 to 16,353.
- Deaths involving cocaine increased from 5,496 to 16,055.
- Deaths involving heroin increased from 10,788 to 14,151.
- At the same time, deaths involving prescription opioids decreased from 12,269 to 11,973. (Deaths involving prescription opioids reached their highest point in July 2017, at 15,003.)

The 2020 roadmap also highlights the need to more directly address long-standing inequities in access to SUD treatment for Black and Hispanic Americans and other racial and ethnic groups, including an emphasis on ensuring that policy and clinical interventions directly confront those inequities. This analysis must acknowledge that the opioid epidemic continues to evolve into a more deadly and complicated polypharmacy and illicit drug overdose epidemic, creating an even greater need to treat it as part of a larger substance use disorder epidemic and for policymakers to continually evaluate the effectiveness of their policies and pivot when needed.



#### Exhibit 4. Sharp racial inequities persist in access to SUD treatment and pain care

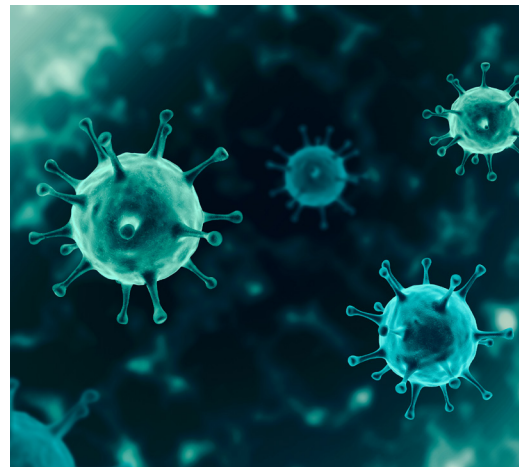
Despite experiencing rates of SUD similar to those of White Americans, Black Americans and other historically minoritized and marginalized groups experience sharp disparities in access to SUD treatment due to a range of factors, including:

- Double stigma among Black Americans who have an SUD due to stereotypes that have mislabeled them as more likely to use illicit substances and to feel less pain
- Fear of legal consequences and significant mistrust of the health care, social services, and justice systems given Blacks' long history of disproportionately lengthy sentencing and incarceration
- Shortage of providers who are Black or are from other minoritized communities and, in particular, shortages in opioid treatment programs (OTPs), as well as in physicians and other health care professionals serving Black, Hispanic and other communities.<sup>3</sup>

Taken together, these and other factors contribute to harsh disparities in access to treatment. One study found that for every appointment where a Black American received a prescription for buprenorphine, White patients had 35 such appointments.<sup>4</sup> These inequities translate directly into differing mortality rates across racial and ethnic groups. In 2018, when the nation was beginning to see a decline in overdose deaths, it was due entirely to gains among White Americans. The rate of drug-induced deaths for American Indians, Asians, Black Americans, and Latinos actually increased and appears to have continued to increase in 2019 at a rate higher than among White Americans.

#### A. Address the implications of COVID-19 for the drug overdose epidemic

COVID-19 has exacerbated the nation's drug overdose epidemic, impacting people with substance use disorders and the physicians and other health care professionals who serve them.<sup>5</sup> National, state, and local media reports indicate that these strains are sharply pushing up overdose rates.<sup>6</sup> Although not enough to overcome rising overdose rates, providers and government agencies moved quickly to enable new flexibilities to provide care options for patients with an SUD and for patients with pain.





**Drivers of increases in overdose.** The COVID-19 pandemic has created a challenging environment for many, including patients with pain and patients with an SUD/ODU due to:

- **More financial instability, stress, and anxiety.** The stress of contracting COVID-19 or facing the loss of family members and friends, coupled with job loss and job insecurity, has contributed to high levels of stress and anxiety. Between March and June 2020, the CDC found that stress and anxiety were up across the board, with adults and, in particular, young adults reporting alarmingly high rates of thoughts about suicide.<sup>7</sup>
- **Social isolation.** The COVID-19 pandemic has increased social isolation, a particular challenge for people with an SUD who rely on social connections as part of their treatment and recovery. While some peer recovery services and groups moved online, these online forums do not always work as well for many people with an SUD. COVID-19 has also caused individuals to use drugs alone, which increases the chance of fatal overdoses because there is no one who can help respond to the overdose.<sup>8</sup>
- **Disruptions in access to treatment options and harm reduction services.** Physicians and other health care professionals who provide addiction medicine and behavioral health care are being further squeezed as states face budget shortfalls, prompting shutdowns or reductions in service options. Potential patients may also face more limited in-person options, requirements to pass COVID-19 tests prior to securing treatment, and changes in where and when they can secure help. While the shift to telehealth has opened up important options in MOUD access, lack of technology access among some people with SUD has disrupted treatment. Harm reduction services that provide primary overdose prevention or sterile needle and syringe services may have become more limited, altered hours, or more difficult to reach during COVID-19.

Elyse Powell, PhD State Opioid Coordinator, North Carolina Department of Health and Human Services, summarized the implications of COVID as follows: “This pandemic has exacerbated many gaps and inequities that were already present in our systems to support people with substance use disorders. The national spike in overdoses seen during COVID is further evidence that harm reduction services, treatment services, and behavioral health services are essential services.”

**Policy innovations.** In response to the COVID-19 pandemic, certain flexibilities were enabled to ensure providers and patients with an OUD or pain had continued access to necessary care and treatment options. These include:

- **Expanded use of telehealth.** In March 2020, the federal government offered increased flexibility to allow for the initiation of buprenorphine via telehealth, including through telephone-only services, which has proved particularly critical for many people with an SUD and/or pain.<sup>9</sup> For example, emergency rules in Texas were extended to help ensure patients with chronic pain have continued access to necessary pain care. The extension allows for “telephone refill(s) of a valid prescription for treatment of chronic pain by a physician with an established chronic pain patient.”<sup>10</sup> An AMA survey of pain medicine physicians found that 80 percent of physician respondents said that the flexibilities provided by the DEA during the COVID-19 pandemic have been either very helpful or somewhat helpful for treating patients with pain.<sup>11</sup> The AMA strongly supports these flexibilities, including the authority “to allow DEA-registered practitioners to begin issuing prescriptions for controlled substances to patients for whom they have not conducted an in-person medical evaluation.”<sup>12</sup>
- **Easing access to medications.** The federal government gave states the flexibility to allow opioid treatment programs (OTPs) to support take-home doses of methadone for up to 28 days at a provider’s clinical discretion. States also offered extended supplies of medications and, in some instances, eliminated prior authorization requirements, as recommended by last year’s AMA-Manatt roadmap, for MOUD.<sup>13</sup> For example, in Minnesota, a new law was passed in April 2020 in response to COVID-19 that protects patients with chronic pain, OUD, and other medical diseases by increasing access to critical medications through relaxed refill limits on controlled substances. The law permits Schedule II-V substances to be dispensed for more than 30 days, and it removed existing refill limitations to encourage patients who rely on these medications to continue appropriate treatments while staying safe.<sup>14</sup>
- **Easing counseling requirements.** Even prior to COVID-19, organizations such as the National Academy of Sciences and the American Society for Addiction Medicine (ASAM) were recommending that government agencies and providers allow people to receive MOUD even if they cannot or do not opt to participate in recommended counseling and therapy. In response to COVID-19, states such as West Virginia temporarily suspended counseling requirements for the duration of the public health emergency, making it easier for people to secure MOUD.<sup>15</sup>

Going forward, it will be important to evaluate and retain those changes in telehealth, counseling, and access to MOUD that have helped sustain individuals with chronic pain and/or an SUD engaging in treatment during the pandemic.

## B. Fix the broader structural and systemic barriers to treatment

Beyond the specific challenges raised by COVID-19, access to evidence-based care remains a barrier to many seeking treatment for an SUD due to ongoing structural and systemic challenges. We once again emphasize:

- **States must be willing to use their oversight and enforcement authority.** State regulators have differing degrees of authority to pursue policies and changes that can have a significant impact on reducing barriers and improving patient care, but the extent to which they use these tools to increase access to evidence-based treatment or hold payers and others accountable for delayed and denied access varies considerably.
- **Medicaid often leads the way.** Medicaid is a major payer for SUD treatment, serving four in ten individuals with an OUD in the United States. It often provides more comprehensive SUD care than the commercial insurance market and, in all states, has been a driving force for greater use of MOUD.<sup>16</sup> During the COVID-19 pandemic, many states have used their Medicaid flexibility to provide additional funding to SUD providers facing declining revenue and new COVID-19–related costs, as well as to dramatically expand use of telehealth for SUD treatment.<sup>17</sup>
- **Grants are helpful, but long-term implementation needs long-term, sustainable funding.** Many best practices that are helping save lives are currently grant funded and need long-term, sustainable funding to continue benefiting individuals with an SUD. Without reliable funding streams, programs that help save lives may simply stop. This issue has become even more important with the large influx of federal dollars during the COVID-19 pandemic and the potential that termination of these emergency funds will leave gaping holes that will be exceptionally hard to fill for states facing significant budget pressures.

### Exhibit 5. Effectiveness of federal funding should be evaluated

According to the Bipartisan Policy Center, \$15 billion was spent in 2019–2020 to help end the epidemic, three-quarters of which went to treatment, recovery, and prevention. We agree with the center’s recommendation that, “[g]iven the size of this investment, publicly available evidence-based evaluations of each of the streams of federal opioid funding must be conducted. These evaluations should include information on whether the grant is meeting the needs of at-risk populations as well as health equity goals. In addition, evaluations should assess whether federal resources are going to implement evidence-based interventions.”

- **Evaluation must include both policy outcomes and surveillance data to address prevention.** Few states have undertaken efforts to evaluate current laws, policies, and programs to determine whether those policies, programs, and laws are working to increase access to evidence-based care and reduce harm. If they have not had their intended outcomes, it is imperative to critically examine why and address policy shortcomings. Similarly, state-level surveillance efforts

must develop and grow in multiple ways. Not only must data collection and surveillance efforts include nonfatal overdose as well as mortality to ensure resources are used to support overdose prevention and treatment, but increased emphasis must be placed on data collection and surveillance that is disaggregated to highlight differences by race, ethnicity, age, gender, and other factors critical to confronting health inequities. In designing evaluation studies, it will be critical to go beyond narrow cost-benefit analyses to measure outcomes in broad social terms.

**“The COVID-19 pandemic has created new challenges and exposed existing cracks in our nation’s treatment system. The nation’s overdose epidemic grows worse. Policymakers must decide that the status quo is unacceptable and remove all barriers to evidence-based care. Unless and until this occurs, more Americans will die.”**

Patrice A. Harris, MD, MA, Immediate Past President, American Medical Association; Chair, AMA Opioid Task Force

#### **Exhibit 6. State officials recognize the need to increase access to evidence-based treatment**

“Access to mental health, behavioral health and substance use disorder treatment is even more important now due to the current COVID-19 public health emergency. Rates of anxiety, depression, and grief related to social isolation have increased, and these conditions are further exacerbated for certain communities of color and communities that face structural barriers to accessing care. These issues are not new, but current events do heighten the urgency to ensure compliance with state and federal parity laws.”<sup>18</sup>

—Michael Conway, Colorado commissioner of insurance

“Maine’s comprehensive Opioid Response Strategic Action Plan focuses on Prevention, Treatment, Harm-Reduction and Recovery Support. We need to be successful in all of these critical areas if we hope to successfully respond to this epidemic. Our work is now challenged by the global pandemic. Both the epidemic and the pandemic pose dangerous risks to public health and both deserve the immediate attention of every citizen.”

—Gordon H. Smith, Esq., Maine director of opioid response

## II. Increase access to evidence-based treatments to help patients with a substance use disorder

As with any condition, it is critical that people with a substance use disorder have access to medically appropriate care, taking into account their individual needs and circumstances. More than eight in ten people with a substance use disorder (82.6%) who need treatment do not receive it.<sup>19</sup> Moreover, among those with an opioid use disorder, many still do not receive MOUD even though evidence is clear that MOUD helps save lives and has numerous benefits; the US surgeon general continues to emphasize that MOUD is the “gold standard” of treatment for OUD.<sup>20</sup> Patients who use MOUD remain in therapy longer and are less likely to use illicit opioids. The result is that SUD treatment helps decrease overdose deaths, reduces the transmission of infectious diseases, including HIV and hepatitis C,<sup>21</sup> and leads to reduced recidivism and other benefits to society, including lower rates of crime.<sup>22,23</sup>

Despite the evidence base for MOUD, barriers to it persist, including inconsistent coverage of all US Food and Drug Administration (FDA)-approved forms of MOUD,<sup>24</sup> inadequate provider networks, stigma that keeps some individuals and providers from using MOUD, lack of provider education and comfort with providing MOUD, high cost sharing for MOUD, and prior authorization requirements. These barriers can make the difference between a person being willing to pursue treatment or continuing to misuse opioids and risking death by overdose.

State responses have been mixed: 21 states and the District of Columbia have enacted laws that limit public and/or private insurers from imposing prior authorization requirements on an SUD service or medication, but the remaining states have not yet done so.<sup>25</sup> The AMA helped support passage of more than a dozen of those laws in 2019 and 2020. Unfortunately, health insurers are often opponents of these laws, despite the fact that many health plans have trumpeted their voluntary pledges to reduce administrative barriers to MOUD.<sup>26</sup> There is no evidence that premiums have increased in states that have removed prior authorization for MOUD, an observation that may be of importance to policymakers navigating this debate.

Beyond MOUD, individuals with an SUD require access to the full SUD treatment and withdrawal management continuum of care. Investing in SUD treatment has demonstrated economic and societal benefits. For example, studies have found that every dollar spent on SUD treatment saves \$4 in health care costs and \$7 in law enforcement and other criminal justice costs.<sup>27</sup> As established by the ASAM, this includes early, preventive interventions, outpatient services, residential services, and medically managed inpatient services.<sup>28</sup> The

appropriate level of care depends on the nature of the person’s substance use disorder, as well as their physical health, emotional health, willingness to enter treatment, living and family circumstances, and earlier treatment experiences. Individuals with an SUD often are directed to the level of care provided by the organization conducting their intake, rather than the level of care that is most appropriate for them based on a thorough assessment and an informed decision made in consultation with their physician or other health care professional.

### Exhibit 7. Facing addiction in America

“We all ask the same question: How can I contribute to ending the opioid crisis and helping those suffering with addiction? The first step is understanding that opioid use disorder is a chronic but treatable brain disease, and not a moral failing or character flaw. Like many other chronic medical conditions, opioid use disorder is both treatable and, in many cases, preventable. It is also a disease that must be addressed with compassion.”<sup>29</sup>

—Jerome M Adams, MD, MPH, surgeon general

## A. Eliminate all barriers to MOUD in Medicaid

Following persistent public education and advocacy campaigns, Medicaid programs are now more likely to cover MOUD, but significant barriers remain. These include some gaps in coverage but, more often, utilization management strategies that delay or deter access—preferred status, prior authorization requirements, quantity limits, step-therapy requirements, and counseling requirements. In addition, stigma around MOUD remains, posing challenges for patient access. There must also be additional efforts to prohibit policies that someone must have failed withdrawal attempts, or failed at abstinence-based treatment, as a condition of MOUD.

A recent review by the Medicaid and CHIP Payment and Access Commission (MACPAC) found that the majority of state Medicaid programs (30 in 2018) still require prior authorization for at least one MOUD medication. Although the SUPPORT (Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment) Act requires Medicaid to cover all forms of MOUD as of October 1, 2020, it remains possible that some states will cover some formulations but not others. For example, they might cover an oral formulation of buprenorphine but not an injectable or implantable formulation, despite the recommendations of the patient’s physician that one formulation is preferred. For example, if patient adherence is an issue, a long-acting formulation might be more beneficial than a formulation requiring daily administration.

Of particular note, many Medicaid beneficiaries face steep barriers when it comes to securing methadone despite four decades of evidence demonstrating it is an effective method to reduce cravings, use of opioids, and mortality.<sup>30</sup> As of 2019, multiple states did not cover methadone under Medicaid for purposes of MOUD, including Idaho, Kansas, Kentucky, Louisiana, Nebraska, Tennessee, and Wyoming.<sup>31</sup> However, even when methadone is covered, other barriers remain; methadone can only be provided by specially licensed OTPs that are tightly and jointly regulated by the Drug Enforcement Agency and SAMHSA and also are subject to varying state requirements, including restrictive zoning, leading to wide variation in the availability of OTPs across states. For example, Wyoming began covering methadone through Medicaid as of October 1, 2020,<sup>32</sup> but there are no methadone clinics operating in the state, which means that the medication likely remains unavailable despite the stated coverage policy.<sup>33</sup>

**As of 2019, multiple states did not cover methadone under Medicaid for purposes of MOUD, including Idaho, Kansas, Kentucky, Louisiana, Nebraska, Tennessee, and Wyoming.**

Stigma remains a key challenge to expanding access to MOUD. Stigma hampers recognition that SUD is a medical illness and should be treated with appropriate medication like other medical conditions. Because buprenorphine and methadone are opioids, the erroneous belief that individuals who receive MOUD are substituting one drug for another is widespread.<sup>34</sup> This thinking amplifies abstinence-only approaches as the only method to achieve recovery, and can lead many residential and recovery housing programs to refuse care for individuals who receive MOUD.

In 2019 and the first part of 2020, some states took steps to expand their coverage of MOUD and eliminate unnecessary prior authorization and utilization management strategies. For example, according to Kaiser Family Foundation, three states added coverage of Vivitrol, a long-acting injectable form of naltrexone, in fiscal year 2019 and fiscal year 2020, while 21 states reported changes in their prior authorization requirements to improve access to MOUD.<sup>35</sup>

In sum, it is critical to cover all forms and formulations of MOUD, including methadone, but also to go beyond coverage to eliminate prior authorization and other utilization management strategies that deter the use of medications. There simply is no medical or policy need that justifies delaying or denying access to MOUD—particularly during an epidemic.

**There simply is no medical or policy need that justifies delaying or denying access to MOUD—particularly during an epidemic.**

**RECOMMENDATION:** State Medicaid officials should continue to expand Medicaid coverage of MOUD of all types and all formulations, eliminate prior authorization and utilization management barriers, and revisit state requirements that deny the availability of methadone and OTP access for patients seeking care.

## **B. Reduce MOUD barriers in commercial insurance**

State insurance regulators often lack the authority to order commercial insurers to cover MOUD, which has led to a variety of strategies, from insurance regulators and attorneys general negotiating agreements with insurers to legislation in 17 states prohibiting state-regulated commercial insurers from imposing prior authorization requirements on SUD medication. Most of these laws have been enacted in the past two years, and they vary in comprehensiveness. While most of these laws remove prior authorization for “at least one modality” of MOUD without specifying additional requirements, only a few cover a more comprehensive set of MOUD or include language that encompasses all FDA-approved SUD medications with enough specificity to ensure comprehensive coverage. For example:<sup>36</sup>

- In New York, regulations are comprehensive and robust, stating that a plan may not impose prior authorization for an initial or renewal prescription for all buprenorphine products, methadone, or long-acting injectable naltrexone for either detoxification or maintenance treatment of an SUD.
- Missouri regulations are also relatively comprehensive, specifying that commercial health plans must cover buprenorphine tablets, methadone, extended-release injectable naltrexone, and buprenorphine/naloxone combination (and those dispensed through an opioid treatment program) without prior authorization.
- In Arkansas, regulations are less comprehensive, stating that insurers cannot impose prior authorization requirements for buprenorphine, naltrexone, and methadone without specifying whether they apply to all modalities of each MOUD type.

While these laws represent progress, it remains important for insurance regulators to monitor and ensure compliance. In some states, such as Pennsylvania, the Insurance Department was able to secure voluntary agreements among leading carriers to eliminate prior authorization for MOUD and take additional steps, such as requiring that MOUD cost sharing be minimal. As with many laws, there are important provisions, such as which medications are covered



and what cost sharing is allowed, that require regulatory attention. For the laws to function as intended, insurance regulators will need to work with payers, the medical community, and patient advocates to ensure that MOUD is routinely available in daily practice.

**RECOMMENDATION: States should require commercial insurers to eliminate prior authorization requirements and other burdensome utilization management practices for MOUD. MOUD should be placed on the lowest cost-sharing tier of health insurer/pharmacy benefit manager (PBM) formularies to help increase access to affordable MOUD options. In states that have taken these steps, state insurance regulators and attorneys general should conduct meaningful review to ensure that health insurers and PBMs are complying with the law and fulfilling plan benefits.**

### **C. Promote access to the full continuum of care**

While MOUD is critical for many with an opioid use disorder, a much broader range of services is needed to meet patient needs, including evidence-based mental and behavioral health care. To ensure that people can secure the most effective treatment for their individual circumstances, it is important for Medicaid and commercial insurers to cover the full continuum of care recommended by the ASAM, the American Academy of Addiction Psychiatry (AAAP), and other professional medical associations. In addition, people with an SUD should undergo an evidence-based assessment with their physician or other health care professional to identify the appropriate level of care.

Increasingly, state Medicaid programs are requiring use of an evidence-based assessment and access to the full continuum of care, in some cases because they are required to do so as part of their 1115 SUD waiver. The complete continuum of care for SUD services includes early intervention services, outpatient and intermediate outpatient services, residential and other inpatient services, and withdrawal management services. A complete continuum of care ensures that individuals with specialized needs, including those with co-occurring mental health disorders, cognitive impairments (eg, traumatic brain injury), and developmental disabilities, have access to tailored programs that are appropriate for their circumstances. Additionally, what constitutes the complete continuum of care differs for adolescents, adults, and older adults, whose needs vary.

State Medicaid programs like those in North Carolina, Pennsylvania, Virginia, and West Virginia are working toward expanding their SUD treatment services to encompass the complete ASAM

continuum of SUD treatment. These states require providers to use the ASAM criteria to assess and place Medicaid enrollees in the appropriate level of care.

Similar requirements do not generally exist for commercial insurers, though California is a notable exception. California recently adopted legislation that requires insurers as part of the Mental Health Parity Act to provide parity of coverage for all mental health and SUD conditions within the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM), including at “intermediate levels of care,” which includes (but is not limited to) residential treatment, partial hospitalization, and intensive outpatient services. The law also bans limitations on coverage for mental health and SUD to “short-term or acute treatment.”<sup>37</sup>

**RECOMMENDATION: States should require all public and commercial payers to cover the full continuum of care as recommended by professional medical associations for SUD treatment and withdrawal management. This should include services that meet the needs of a diverse patient population as appropriate for their individual patient needs and circumstances.**

#### **D. Address inequities in treatment options**

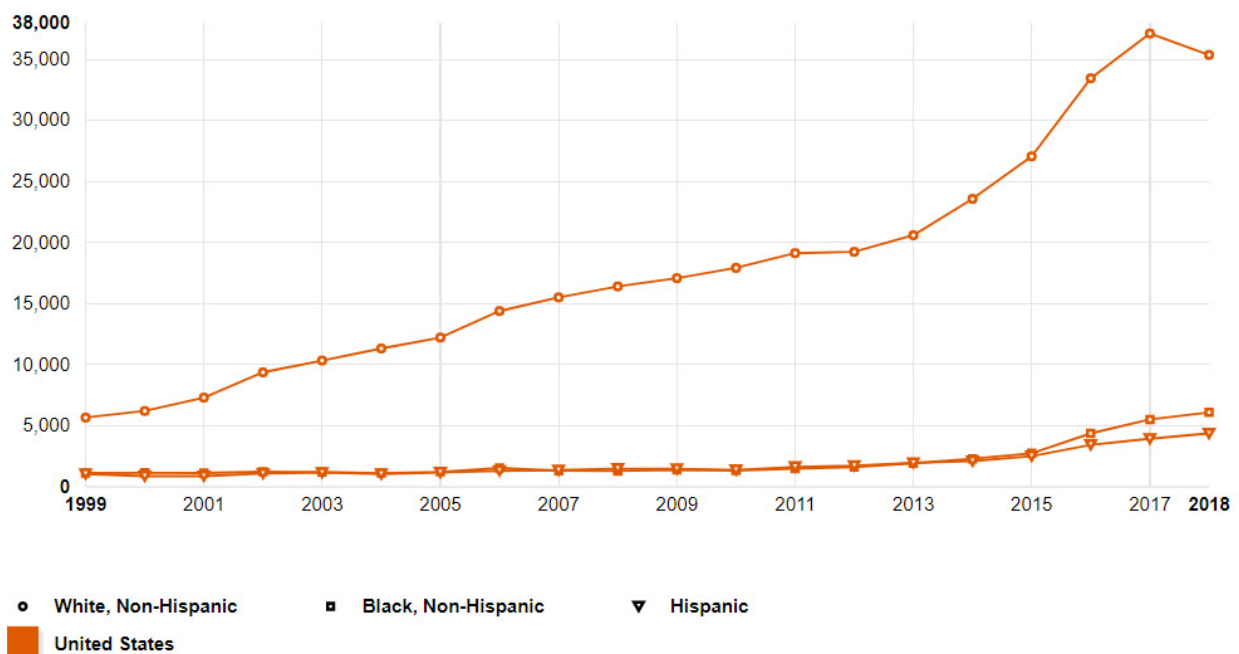
The opioid epidemic—and the larger drug overdose epidemic—has affected all racial groups. It is essential that we have the data to ensure that public health interventions are specifically tailored to ensure affordable, equitable access for historically minoritized and marginalized populations. The AMA is very concerned by increasing numbers overall, and consistent with efforts to ensure access and promote health equity, highlights the recent increasing percentages of opioid-related mortality among Black, Latinx, American Indian, Native Alaskan, and other minoritized populations. While people who self-identify as White remain far more likely to die of a drug overdose than people who identify themselves as Black, African American, Hispanic, American Indian, Native Alaskan, and other minoritized populations this emerging trend must be addressed.

Racial and ethnic differences in access to evidence-based treatment need to be considered and confronted. We must remove any and all systemic barriers to treatment by race, gender, or ethnicity. We must further not associate rates of use without discussing and recognizing how those systemic barriers may be exacerbated by social/structural/political determinants and other factors. Researching, understanding and confronting upstream causes and downstream effects of these factors are complicated, but essential components to breaking down systemic health inequities. Data can reveal certain trends in use and mortality by race, gender and

ethnicity, but one of the keys is to use that data to implement equitable solutions to increase access to prevention and treatment, which will necessarily need to address primary, secondary and tertiary levels of prevention.

According to the CDC, while prescription opioid-involved death rates decreased by 13.5% from 2017 to 2018, these gains are attributable largely to decreases in overdose deaths by non-Hispanic Whites (see Exhibit 8).<sup>38</sup> Even though non-Hispanic Blacks and Hispanics (as defined by CDC) remain far less likely than Whites to die of opioid overdoses, these latest data warrant close attention (Whites had an opioid-related overdose death rate of 19.4 per 100,000 in 2017, compared to 15.7 for American Indian/Alaska Natives, 12.9 for Blacks, and 6.8 for Hispanics in the same year).<sup>39</sup> In the same time frame, death rates involving synthetic opioids (eg, illicitly manufactured fentanyl and fentanyl analogs) increased from 9.0 per 100,000 population in 2017 to 9.9 in 2018 and accounted for 67% of opioid-involved deaths in 2018. The recent increase in death rates involving synthetic opioids is driven in part by an increase in mortality among minority groups; according to the US Agency for Healthcare Research and Quality,<sup>40</sup> from 2013 to 2017, non-Hispanic Blacks had an 18-fold increase in mortality due to synthetic opioids other than methadone, Hispanics had a 12.3-fold increase, and non-Hispanic Whites had a 9.2-fold increase.

#### Exhibit 8. Opioid overdose deaths by race/ethnicity, 1999–2018, Kaiser Family Foundation



Source: [www.kff.org/other/state-indicator/opioid-overdose-deaths-by-raceethnicity/?activeTab=graph&currentTimeframe=0&startTimeframe=19&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D](http://www.kff.org/other/state-indicator/opioid-overdose-deaths-by-raceethnicity/?activeTab=graph&currentTimeframe=0&startTimeframe=19&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D).

SAMHSA's 2020 report, "The Opioid Crisis and the Hispanic/Latino Population: An Urgent Issue,"<sup>41,42</sup> represents an important direction in working to provide, specific to the Hispanic/Latino population in the United States: (1) "recent data on the prevalence of opioid misuse and opioid overdose death rates"; (2) "contextual factors that impact the opioid epidemic in these communities"; (3) "innovative outreach and engagement strategies that have the potential to connect individuals with evidence-based prevention, treatment, and recovery"; and (4) "the importance of ongoing community voice and leadership in the development and implementation of solutions."

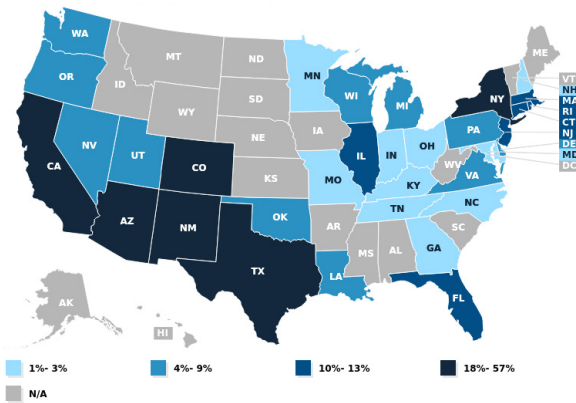
Data that reveal differences and disparities in equitable prevention and treatment initiatives and outcomes are critical for targeting policy interventions to ensure the greatest impact for prevention and treatment. For example, according to a recent study of all US counties,<sup>43</sup> where Black/African American and Hispanic Americans live plays a strong role in the type of medication that they may be offered, creating inequities in medication access and treatment availability in key communities that have been disproportionately impacted by the epidemic. SAMHSA describes the United States system as "a two-tiered treatment system ... where buprenorphine is accessed by Whites, high-income, and privately insured, methadone is accessed by people of color, low-income, and publicly insured."<sup>44</sup> Given the critical importance of providing people with treatment options consistent with their individual circumstances, it is deeply problematic that some forms of MOUD are not equally available to many minoritized and marginalized populations.

To address equity issues, states and commercial insurers have a number of options, including:

- Supporting physicians and other health care professionals who serve a relatively high number of Black, Latinx, American Indian and Native Alaskan people, in securing their Drug Addiction Treatment Act (DATA) waiver (accompanied by appropriate reimbursement)
- Providing training on offering culturally appropriate care
- Gathering, monitoring, and acting on treatment data disaggregated by race, ethnicity, gender, and age in a timely manner
- Involving communities in developing and implementing policy change

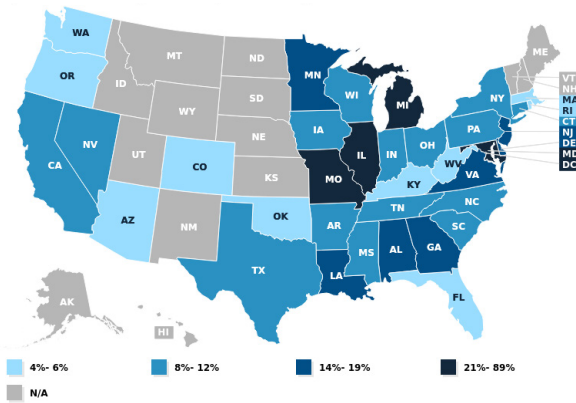
For example, as highlighted by SAMHSA in its recent report, "The Opioid Crisis and the Black/African-American Population: An Urgent Issue," organizations such as the Detroit Recovery Project work in partnership with local hospitals, clinics, and other health care providers to offer a wide array of recovery services tailored to Black/African Americans. The Detroit Recovery Project has developed memorandums of understanding with local federally qualified health centers to offer recovery coaches and facilitates regular town hall meetings to address the impact of the opioid epidemic on Detroit's Black/African American communities.<sup>45</sup>

**Exhibit 9. Opioid overdose deaths by race/ethnicity, percentage Hispanic, 2018, Kaiser Family Foundation**



Source: [www.kff.org/other/state-indicator/opioid-overdose-deaths-by-raceethnicity/?dataView=1&activeTab=map&currentTimeframe=0&selectedDistributions=hispanic&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D](http://www.kff.org/other/state-indicator/opioid-overdose-deaths-by-raceethnicity/?dataView=1&activeTab=map&currentTimeframe=0&selectedDistributions=hispanic&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D).

**Exhibit 10. Opioid overdose deaths by race/ethnicity, percentage Black, Non-Hispanic, 2018, Kaiser Family Foundation**



Source: [www.kff.org/other/state-indicator/opioid-overdose-deaths-by-raceethnicity/?dataView=1&activeTab=map&currentTimeframe=0&selectedDistributions=black%2Dnon%2Dhispanic&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D](http://www.kff.org/other/state-indicator/opioid-overdose-deaths-by-raceethnicity/?dataView=1&activeTab=map&currentTimeframe=0&selectedDistributions=black%2Dnon%2Dhispanic&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D).

The maps indicate that there also are significant regional differences in how the drug overdose epidemic impacts minority populations. Data on opioid overdose deaths show that states with larger Hispanic/Latino populations observe higher rates of opioid overdose among Hispanic/Latino adults, including California, Texas, New Mexico, and states with larger Black populations observe a similar trend for opioid overdose deaths among Black adults, including as Illinois, Missouri, and Michigan (see Exhibits 9 and 10). However, it's important to note that these data are not inclusive of the COVID-19 pandemic time frame. This is one reason the AMA has urged national and state public health officials to increase efforts to provide more timely and actionable data—data that are disaggregated by race, ethnicity, gender, and age. To have the greatest positive impact on reducing overdose mortality, it's essential to have more timely data to guide public health interventions.

**RECOMMENDATION:** States should ensure that public and commercial payers collect, analyze, and make public provider and treatment utilization data disaggregated by race and ethnicity, ensure that racial and ethnic disparities are meaningfully addressed in providing equitable access to and utilization of SUD treatment and support, and take an active role in engaging the community and advocating for policy changes that advance equity and access to culturally appropriate care.

## E. Eliminate treatment barriers for pregnant, parenting, and postpartum women and justice-involved populations

Some particularly vulnerable groups face distinct barriers to coverage. These include individuals incarcerated in jail or prison, many of whom may be incarcerated in part due to their SUD or a related mental health issue. Since the landmark case of *Estelle v Gamble* in 1976, the Supreme Court has held that all incarcerated individuals have the right to adequate medical care, and officials who show a “deliberate indifference” to someone’s serious medical needs are in violation of the cruel and unusual punishment clause of the Eighth Amendment. Even so, it remains common for jail and prison officials to deny SUD treatment, including MOUD, to justice-involved individuals. Increasingly, this practice is being legally challenged and courts are clarifying that a failure to provide SUD treatment represents a violation of the Americans with Disabilities Act and the Eighth Amendment.

### Exhibit 11. Courts increasingly are ruling that MOUD must be provided to incarcerated individuals

In a few recent lawsuits, courts have ruled that failure to provide physician-prescribed medications for opioid use disorder to people in jail or prison violates the Eighth Amendment’s ban on cruel and unusual punishment and the Americans with Disabilities Act, which prohibits discrimination on the basis of disability, including against people in recovery for OUD.

- ***Pesce v Coppinger***.<sup>46</sup> Mr Pesce was a middle-aged man who had been in active recovery for two years on methadone. In 2018, he was sent to jail for 60 days for driving without a license while on his way to pick up his methadone dose, but the jail to which he was assigned would not agree to continue his methadone treatment. After he sued, the court ruled that the jail must continue his methadone treatment, citing in part his doctor’s opinion that involuntary withdrawal of treatment would cause Mr Pesce “severe and needless suffering [that would] jeopardize his long-term recovery and is inconsistent with sound medical practice.”
- ***Smith v Aroostook County***.<sup>47</sup> Brenda Smith was in recovery for a period of about ten years when she was sentenced to 40 days in jail for theft. She ultimately secured the right to continue suboxone while serving her sentence on the grounds that denial of MOUD (buprenorphine, in this case) would cause serious and irreparable harm and violate the Americans with Disabilities Act. While jails and prisons sometimes maintain they cannot safely dispense MOUD due to diversion risk, Ms Smith’s lawyers pointed out that the jail was able to treat pregnant women. In a significant win for patients with OUD, the US Court of Appeals for the First Circuit upheld the district court’s ruling for Ms Smith.

One example of a promising state-led initiative is in North Carolina, which has implemented several new programs to expand MOUD to justice involved individuals. The state Department of Health and Human Services (NCDHHS) is committing over \$16 million to fund jail-based medication assisted treatment programs that induct or continue treatment while people are incarcerated, community-based pre- and post-arrest programs to divert people with substance use disorders from jail to appropriate treatment options as well as create re-entry programs that help connect people to care upon release from incarceration. In a partnership between NCDHHS and the Department of Public Safety, North Carolina is also piloting MOUD induction in three prison re-entry facilities so that people exiting incarceration are connected to MOUD as part of their re-entry process. According to state data, “formerly incarcerated individuals are 40 times more likely than other North Carolinians to die of an overdose in the first two weeks of re-entering the community.”<sup>48</sup>

Pregnant women also often face barriers to treatment, which is particularly problematic given that lack of treatment increases the risk of poor birth outcomes along with risk to the mother’s health. Using a “secret shopper” approach across ten states, the authors of a recent study found that “callers representing pregnant women were less likely than callers representing nonpregnant women to be granted an appointment with an opioid use disorder treatment clinician.” More than 28,000 calls were made during the study period. The authors compared access to buprenorphine-waivered clinicians and opioid treatment programs for women with private insurance or Medicaid.

Among the findings:<sup>49</sup>

- “With both buprenorphine-waivered prescribers and OTPs, insurance was associated with appointment access.”
- “Nonpregnant callers with Medicaid were less likely than nonpregnant callers with private insurance to be granted an appointment with buprenorphine-waivered prescribers.”
- For 26% of buprenorphine-waivered prescribers and 32% of OTPs, appointments were offered only when the caller said she could pay cash.

There also are systemic, stigmatizing barriers faced by pregnant women, including that if they seek care during MOUD treatment or while using drugs, they may be subject to criminal penalties—creating a deterrent to care that could harm the woman and fetus. For example, 23 states and the District of Columbia still consider substance use during pregnancy to be child abuse under civil child-welfare statutes, and three consider it grounds for civil commitment. Moreover, 25 states and the District of Columbia require health care professionals to report

suspected prenatal drug use, and eight states require them to test for prenatal drug exposure if they suspect drug use.<sup>50</sup>

Of particular note, as described in **Exhibit 12**, incarcerated pregnant women with an SUD often do not receive appropriate medical care or receive it only until they deliver, at which point they are taken off physician-prescribed medications.

### Exhibit 12. Treatment for incarcerated pregnant women is limited and often stopped after delivery

New research from Johns Hopkins University highlights that a substantial share of pregnant women who are incarcerated have an opioid use disorder—26% of women admitted to prisons and 14% of women admitted to jails. Most jails and prisons will not initiate MOUD for a pregnant woman who is incarcerated, although they are more likely to maintain it for the duration of the pregnancy if she enters on MOUD. Among those institutions that do provide MOUD, two-thirds of prisons and three-quarters of jails discontinue it after delivery. As the authors conclude, “[p]regnant incarcerated women with opioid use disorder in the United States frequently appear to be denied essential medications and receive substandard medical care.”<sup>51</sup>

In response to these barriers, several states have begun conducting active outreach to obstetrician-gynecologists (OB-GYNs) to educate them about the importance of identifying and treating SUD in women and support them in securing DATA waivers. Other states are revisiting laws that criminalize women with an SUD who are seeking treatment. For example:

- Health care professionals in West Virginia who provide treatment for SUDs and accept Medicaid must give pregnant women priority in accessing services.<sup>52</sup>
- Wisconsin provides priority access to pregnant women in both general and private programs.<sup>53</sup>
- Indiana law prohibits a medical provider from releasing information about a pregnant woman’s drug or alcohol test without her consent.<sup>54</sup>

**RECOMMENDATION: States should provide evidence-based medical care to incarcerated populations, including continuing, initiating and ensuring access to MOUD. States should remove criminal and other penalties for pregnant, postpartum, and parenting women for whom MOUD is part of their treatment for an opioid use disorder.**



## **F. Ensure continued access to MOUD**

Individuals with an SUD are diverse in their treatment needs and circumstances, and best practices continue to point to the need to provide as many therapies, treatments, and options as possible for providers and patients while mitigating unnecessary barriers or conditions to receiving care.

### **Prevent counseling/psychosocial supports from creating a barrier to receiving MOUD.**

Counseling and psychosocial supports have been shown to be beneficial to individuals in SUD treatment, but the National Academy of Sciences and others have concluded that if it is not possible for people to participate in these services, it remains valuable to provide them with medication alone. Increasingly, states are eliminating “hard” requirements that Medicaid beneficiaries engage in counseling as a condition of receiving MOUD and, instead, are focusing on how to promote and expand use of counseling.<sup>55</sup> This shift reflects guidance from ASAM that an individual’s inability or decision not to engage in counseling “should not preclude or delay pharmacological treatment of opioid use disorder, with appropriate medication management.”<sup>56</sup>

For example, states such as New York now explicitly prohibit providers from excluding clients from receiving MOUD if they do not engage in psychosocial treatment.<sup>57</sup> Instead, providers are encouraged to engage clients in any services deemed necessary, including by using peer services, rather than by making their access to MOUD contingent on engagement in psychosocial services. Similarly, Virginia has moved to providing full clinical discretion to providers to determine the circumstances under which access to MOUD should be linked to participation in counseling.<sup>58</sup>

### **Ensure that polysubstance use (including the use of benzodiazepines) is not a reason to discontinue an individual’s treatment with MOUD.**

With the opioid epidemic evolving more fully into a polysubstance use epidemic, the issue increasingly arises as to whether someone who is using drugs for non-medical purposes (eg, prescription opioids, cocaine, methamphetamine, heroin) should be allowed to continue on MOUD. Historically, it has been common practice to require that individuals not use any substances, as measured by periodic urine screens, as a condition of receiving MOUD. Now, however, there is compelling evidence that it is safer and leads to better long-term outcomes, including decreased mortality, if clients remain on MOUD even if they still are using other substances.

For example, New York’s guidance to providers on how to handle continued substance and polydrug use reflects this approach. It explains that MOUD should not be discontinued and clients should not be administratively discharged from treatment *solely* on the basis of continued substance use and/or polydrug use. Also, policies that summarily exclude individuals from being admitted because of polysubstance use are not permitted. Rather, providers are expected to work with clients over time to engage them in addressing their ongoing substance use, using harm reduction principles and motivational interventions, including using their clinical judgment to withhold individual doses of full opioid agonist medications if someone is intoxicated or appears sedated.<sup>59</sup> North Carolina provides similar guidance.<sup>60</sup>

Similarly, the US Food and Drug Administration recently clarified that it is better practice and safer for clients to start and/or continue MOUD even if they are using benzodiazepines or similar drugs rather than leave the substance use disorder untreated, because “the harm caused by untreated opioid addiction can outweigh these risks.”<sup>61</sup>

### **Ensure that individuals entering residential treatment have access to MOUD.**

ASAM clinical practice guidelines recommend that individuals in treatment for SUD have access to MOUD at all levels of care, including residential levels of care. To facilitate access to MOUD, residential facilities can either provide MOUD directly or establish linkages to MOUD providers. Residential treatment without MOUD for individuals with an SUD places them at greater risk of overdose following their departure from treatment. Despite the evidence,<sup>62</sup> many residential treatment facilities do not offer any MOUD; in 2017, 60% of residential treatment facilities did not offer any MOUD, and only 1.3% offered all forms of MOUD.<sup>63</sup> Additionally, residential treatment facilities may bar admission to individuals with an SUD who are on MOUD, which forces them to choose between continuing on MOUD or entering residential treatment.

**In 2017, 60% of residential treatment facilities did not offer any MOUD, and only 1.3% offered all forms of MOUD.**

States can take steps to ensure that individuals entering residential treatment have access to MOUD. For example, states can follow Missouri’s example and require residential treatment facilities to offer or arrange for MOUD as a condition of certification and Medicaid contracting.<sup>64</sup> California law bars residential treatment providers from denying admission based on an individual’s ongoing use of MOUD, and its Medicaid program requires all residential treatment facilities, in order to obtain licensure and certification, to offer or arrange for access to MOUD.

**RECOMMENDATION:** States should ensure that public and commercial payers eliminate treatment policies that impede access to MOUD, such as policies that condition access on participating in counseling or abstaining from use of other drugs. Residential treatment facilities should be required to ensure access to MOUD for new and current patients as a condition of receiving public funding.

## **G. Maintain COVID-19-driven changes that expand access to evidence-based treatment**

During the COVID-19 public health emergency (PHE), the federal government and some states have provided increased flexibility to enable individuals with an SUD to access MOUD and other treatment options, providing increased flexibility to initiate and continue treatment for an SUD. These changes include giving states discretion to allow OTPs to provide a 28-day take-home supply of methadone to stable patients and a 14-day supply to those who are less stable but still able to safely handle take-home doses, subject to the treating physician's clinical determination. The federal government and states also have acted to promote telehealth, with the federal government allowing initiation of buprenorphine for the first time via telehealth and telephone, and states adopting a broad array of policies to promote and pay for care delivered via telehealth. Of particular note, 26 states currently allow audio-only behavioral health calls during the COVID-19 PHE to be reimbursed under Medicaid, a particularly important policy for low-income people with an SUD who may otherwise lack the capacity to participate in telehealth.<sup>65,66</sup>

Early evaluations suggest that the policies have helped to maintain or even expand access to treatment without ill effects on clients. For example, Rhode Island has worked with clients and law enforcement to determine that increased take-home dosing has not resulted in higher rates of adverse events such as diversion and opioid-related deaths.<sup>67</sup> Similarly, Massachusetts has gathered data on take-home doses and found minimal incidents of diversion, even though nearly all patients now are receiving a 28-day supply of methadone.<sup>68</sup> While some providers and clients continue to prefer in-person treatment, early reviews suggest that the easing of access restrictions on MOUD and greater use of telehealth have helped mitigate some of the impact of COVID-19 on treatment for SUD.<sup>69</sup> Going forward, it will be important to continue to monitor the impact of these policies and, if proved effective and safe, to maintain them in the post-COVID-19 era.

**RECOMMENDATION:** States should evaluate policies adopted during the COVID-19 public health emergency and make permanent those that have proven effective in enhancing access to MOUD.

### III. Enforce mental health and substance use disorder parity laws

Parity is still a work in progress, but 2020 saw several important developments indicating that additional state legislatures and regulatory agencies are committed to achieving equal access to mental health and SUD treatment:

- Six more states passed parity laws in 2020, including states as politically diverse as Arizona, Indiana, Maryland, and Oklahoma. Those states join eight others that have passed parity laws since 2018. The trend is likely to continue, with another eight states considering parity bills in 2020 that likely will be taken up again in 2021.
- A growing number of state insurance regulators are using oversight tools, ranging from data calls to attestation requirements to market conduct exams, to monitor compliance. While full-scale exams are a proven method for assessing compliance, they require considerable resources and involve retrospective reviews, causing some states to look at more nimble approaches such as New York's requirement that insurers self-assess and report on their compliance prospectively.
- The NAIC established a new standing work group on parity<sup>70</sup> to provide an ongoing forum for state regulators to share information and develop common strategies for enforcing parity. Thirty states joined the work group, and despite the pandemic, the group has held four meetings since March and is expected to continue moving toward providing strong guidance to states.

#### A. Make parity laws more comprehensive

##### Exhibit 13. Pennsylvania adopts tougher parity laws

Pennsylvania Governor Tom Wolf signed two new mental health and SUD parity laws on October 30, 2020 that he said would “strengthen our already robust efforts.” The new laws require insurers to fully document their compliance with parity standards and make that documentation available to the Pennsylvania Insurance Department (PID) upon request.

“Our exams and investigations, as well as analysis of consumer complaints, indicate that mental health parity noncompliance persists. We appreciate the legislative leaders that worked with PID, insurers, and consumer advocates to help strengthen Pennsylvania’s parity framework through this legislation. The legislation will result in greater compliance across insurance companies and improve consumer access to understandable coverage information.”

—Pennsylvania Insurance Commissioner Jessica Altman commenting on new parity laws

Recently enacted state parity laws, many of which build on less prescriptive parity laws enacted a decade ago, focus on both insurer reporting requirements and regulatory oversight procedures. The recent parity laws set out more stringent standards for insurers to self-assess their compliance and for regulators to exercise more oversight. While the laws require market conduct exams and other forms of retrospective review, recent laws increasingly emphasize prospective action by insurers to identify and correct unequal treatment rather than wait to penalize parity violations after the fact. The shift from “back-end” reviews to “front-end” assessments recognizes that finding and correcting violations several years after the fact is less effective and more expensive than proactively requiring insurers to demonstrate their compliance through annual reports or when seeking rate and form approval for new products.



**Insurer annual reports.** In March 2020, Indiana legislators passed HB 1092, which requires insurers to annually submit a report and analysis to the Indiana Department of Insurance that demonstrates compliance with parity laws, including descriptions of the processes used to develop medical necessity criteria and nonquantitative treatment limitations (NQTs)<sup>71</sup> for mental health and SUD benefits as compared with the processes used for medical and surgical benefits.<sup>72</sup>

Oklahoma passed a similar law in May 2020, requiring health plans to submit an annual report with the following elements:<sup>73</sup>

- A description of the processes used to develop or select medical necessity criteria for mental health/substance use disorder (MH/SUD) benefits and the corresponding processes for medical and surgical benefits
- Identification of all NQTs applied to mental health/substance use disorder (MH/SUD) and medical/surgical benefits
- A comparative analysis that demonstrates that the medical necessity criteria and NQTL limits are comparable for MH/SUD and medical/surgical benefits
- An indication that the insurer is compliant with Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) requirements

“This is kind of where cancer was a lot of years ago when the coverage wasn’t happening. Today, it’s just standard coverage. I think it’s very important that we do this to help those that truly are dealing with mental health. I think it’s one of those that could actually save lives.”  
—Oklahoma Sen. John Haste, R-Broken Arrow, the Senate co-author of SB 1718

**Comparative analysis of NQTLs.** Many of the new laws draw from a model law developed by the American Psychiatric Association (APA) that includes detailed provisions related to NQTLs, which present more difficult challenges when trying to compare standards for medical/surgical coverage to standards for MH/SUD coverage. NQTLs include utilization management techniques, such as prior authorization and step therapy, but also network participation and reimbursement policies for providers. As states wrestle with developing templates and other tools for insurers to use in documenting their own compliance, many Departments of Insurance (DOIs) are turning to the NAIC work group, which is building out those templates to ensure that insurer compliance reviews look at policies and procedures as well as the application of those policies and procedures.

Maryland enacted parity legislation in May 2020 requiring insurers to conduct parity analyses on their highest-selling products, and also directing the Maryland insurance commissioner to use the NAIC’s data collection tool for NQTL comparative analysis as the basis for a standard insurer reporting form.<sup>74</sup>

**Regulatory oversight procedures.** The new laws typically charge state insurance regulators with enforcing federal parity laws and regulations and using the full continuum of regulatory tools to ensure parity. Among the regulatory duties enumerated are developing standard insurer reporting forms, actively reviewing insurer reports and addressing deficiencies, responding to and evaluating consumer complaints, reviewing parity compliance during the rate and form approval process, performing market conduct examinations, and reporting back to the legislature on compliance and enforcement efforts.

Arizona amended its parity law in March 2020 to require detailed insurer reporting on NQTLs and other comparative analyses, and directs the Arizona Department of Insurance (DOI) to review insurer reporting and, among other things, develop a webpage that explains insurer

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obligations and how consumers can file complaints about alleged insurer violations.<sup>75</sup> The webpage must include a DOI summary of its analysis of insurer reporting, “including any conclusions regarding industry compliance.” The statute also includes protections for proprietary information and has specific provisions applicable to multitiered networks and prescription drug benefits.

**Medical standards.** California enacted a sweeping new parity law in September 2020 that expands coverage and requires insurers to rely on medical experts when making coverage decisions. The new law expands the state’s preexisting parity law to cover medically necessary treatment for all mental health and substance use disorders listed in the most recent edition of the Diagnostic and Statistical Manual of Mental Health Disorders (DSM), and tightens requirements as to the use of generally accepted medical standards for developing and applying “medical necessity” criteria to make coverage decisions.<sup>76</sup> More specifically, the law requires insurers to use evidence-based and expert-recognized criteria for medical necessity to ensure that treatment decisions are based on medical expertise rather than insurer-designed standards.<sup>77</sup> The new law addresses some key deficiencies identified in a recent report<sup>78</sup> on California’s parity challenges, but the report also suggests that California’s health insurance regulators should strengthen their oversight of insurers’ utilization management practices, including network participation requirements. The report pointed to lower reimbursement rates for behavioral health providers,<sup>79</sup> as well as onerous payment procedures and burdensome contracting terms, as reasons why behavioral health networks are not necessarily in parity with medical/surgical networks.

“SB 855 is vital legislation in the face of a worsening mental health and addiction crisis exacerbated by the current COVID-19 pandemic,” said Ricardo Lara, California insurance commissioner, on June 10, 2020.<sup>80</sup> “SB 855 will put in place reasonable and necessary reforms to guarantee that Californians have access to life-saving mental health/substance use disorder (MH/SUD) services.” Commissioner

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Lara also emphasized that “SB 855 would create minor costs to the California Department of Insurance: \$3,000 in financial year 2020-21, associated with the slight increase in reviewing form filling.”

According to California Sen. Scott Wiener, the prime sponsor of SB 855: “Mental health care is essential to a person’s overall health, and today, we reaffirmed that people must have access to care for mental health and addiction challenges. California’s mental health parity law has huge loopholes—which the insurance industry has used to deny critically important care—and today that loophole was closed. SB 855 sends a powerful message to the nation that California prioritizes the mental health of its residents.”

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the prime sponsor of SB 855

**RECOMMENDATION:** States should strengthen their mental health and substance use disorder parity laws based on proven models, including California’s Senate Bill 855 and models supported by key stakeholders such as the American Psychiatric Association and the Kennedy Forum.

## B. Use the full continuum of regulatory tools

States are using a variety of approaches to assess and enforce compliance, many of which go beyond the requirements contained in the new parity laws.

**Attestation.** The New York Department of Financial Services (DFS) is developing a comprehensive regulatory strategy with insurer self-assessment and attestation as the foundation for prospective enforcement efforts. The regulations, which became final on October 1, 2020, require insurer compliance programs to establish corporate governance for parity compliance, identify discrepancies in coverage of services for the treatment of mental health conditions and substance use disorder, and ensure appropriate identification



and remediation of improper practices. To expedite enforcement, the regulations require insurers to attest to their compliance on an annual basis and, further, to make their compliance documentation readily available to DFS upon request.<sup>81</sup>

The Pennsylvania Insurance Department proposed a similar attestation requirement in early 2020 and recently completed a public comment period on the regulation, which would establish mental health and SUD parity compliance program requirements similar to those for New York's program. The proposed regulation requires that such compliance programs establish corporate governance for parity compliance, identify discrepancies in coverage of services for the treatment of mental health conditions and SUD, and ensure appropriate identification and remediation of improper practices.<sup>82</sup>

**Data calls.** Washington's Office of the Insurance Commissioner used federal grant funds to collect data from insurers and have it analyzed by clinicians at the University of Washington (UW). In a December 2019 report, the UW clinicians reviewed and analyzed the development, substance, and application of Washington commercial health plans' prior authorization and



utilization management policies and procedures. The report noted that this particular study may be "one of the most in-depth and comprehensive evaluations of parity to date," and found that based on market scan data, many of the carriers that participated made sincere efforts to implement parity between medical/surgical and MH/SUDs, especially through the specific policies outlined to ensure parity for individuals with OUDs and policies implemented to ensure access to potentially life-saving treatments. However, overall, information collected on the real-world operationalization of policies and procedures was limited through this first analysis, with some of the information provided being inconsistent, incomplete, or vague. The report calls for further data collection and analysis using claims data to assess key quantitative treatment limitations (QTLs) and NQTLs, and further study of the actual rates and use of MH/SUD benefits across different insurance plans and products.

While conducting a data call and analyzing the findings can be an extensive and involved process, the findings from this report demonstrate, in a way that other assessments are unable to identify, the value of detailed data calls as a tool for assessing the implementation and operationalization of parity in the commercial insurer space, with the ability to examine existing parity gaps at a more granular level while also understanding the specific challenges insurers face in implementing parity.

**Ombudsman offices.** In 2019, Colorado established the Office of the Ombudsman for Behavioral Health Access, which released its first annual report in September 2020. This independent office helps Coloradans resolve behavioral health access and coverage issues, including helping consumers with parity complaints and reporting on parity enforcement.



In its first year, the Office of the Ombudsman focused on developing formal practices and processes for consumer complaints and new cases. The report emphasizes that, as the office began opening new case calls, many of the cases were complex and time-consuming and required the engagement of multiple stakeholders to resolve reported issues, which extended beyond basic behavioral health access and coverage and engaged areas of housing, justice, and child welfare. The office also worked to establish connections with liaisons in various state and federal agencies, including the state's Division of Insurance, Department of Health Care Policy and Financing, and the state's Office of Behavioral Health, to identify, report, and prioritize behavioral health parity and coverage issues. Behavioral and mental health ombudsman programs and offices are growing in number across the country<sup>83</sup> and are likely to continue to play a role across states in advocating and ensuring parity and compliance for patients with MH/SUD needs.

**Rate and form reviews.** As states consider the most efficient ways to ensure parity compliance, many are focusing on the annual rate and form review process that has become more standardized in the 47 states that have been certified by the Center for Consumer Information and Insurance Oversight (CCIIO) to conduct rate reviews for products to be sold through the ACA Marketplaces. Since rate review (how much the insurer proposes to charge for a given product) is integrally related to form review (what benefits are covered by each given product), many states use their annual ACA process to require insurers to demonstrate that the benefits they cover in their ACA and non-ACA products comply with parity requirements, including NQTLs.

North Carolina issued a new and more comprehensive parity checklist in May 2020 that requires insurers to engage in detailed comparative analysis of MH/SUD and medical/surgical benefits to demonstrate parity. The new North Carolina requirements also include a new attestation form. North Carolina is an active state for market conduct exams as well, but the more rigorous rate and form reviews should allow for early detection of problems and allow the DOI to target examination resources more effectively.<sup>84,85</sup>

The type of “enhanced attestation” required by the North Carolina Department of Insurance is the basis for a recommendation by the AMA, ASAM, and the American Psychiatric Association (APA) for all DOIs to require health insurers to demonstrate compliance with the law at the time of rate and form filing. The AMA, APA, and ASAM believe that the obligation of demonstrating compliance with the law is something payers can and should do. Because the MHPAEA is a comparative law, payers should do the comparisons to analyze whether they are in compliance with the law. Requiring prior comparative analysis can help streamline oversight, can help payers identify gaps, and, most important, may help ensure patients have the coverage required by the law.<sup>86</sup>

**Market conduct exams.** A December 2019 US Government Accountability Office (GAO) report found that market conduct examinations are a leading regulatory strategy, and examination findings are frequently featured on DOI websites as leading indicators of noncompliance with parity requirements. Pennsylvania has been conducting parity examinations for several years, and much of what Pennsylvania regulators learned through those exams has helped shape the agenda for the NAIC’s parity working group.

The AMA, APA, and ASAM believe that the obligation of demonstrating compliance with the law is something payers can and should do.

At the same time, exams have their limitations, including time lags, with exams often looking back two or more years, and procedural requirements, such as time-consuming negotiations over corrective action plans. Indeed, a common thread in the exams described below is that exams started several years ago are still in process. These drawbacks help explain why the NAIC’s market conduct committee has been expanding its continuum of regulatory tools over the past 15 years, and why the NAIC parity working group has focused much of its attention on prospective reporting tools.

With these caveats, exam activity was an important feature of the parity landscape in 2020. In February 2020, the New Hampshire Insurance Department published market conduct exams on the state’s three largest insurers, based on reviewing insurer practices in 2016 and 2017. In the exam report, the state concluded that there was parity noncompliance in the areas of benefit design, network design, grievances and appeals processes, claims handling, provider reimbursement, step therapy, and prior authorization for MOUD/SUD medications. The exams further concluded that Anthem and Harvard Pilgrim did not provide sufficient information to demonstrate that they meet the comparability requirement and would be required to develop compliance assurance plans with the state and to undergo a two-year monitoring and reporting period to ensure implementation of initiatives aimed at improving MH/SUD provider

networks and address other areas of noncompliance. After the two-year monitoring period, if the plans are determined to be compliant, the department will issue an updated report; if noncompliant, the department will begin a follow-up examination.

The Rhode Island Office of the Health Insurance Commissioner (OHIC) published three exam reports in 2020 covering UnitedHealthcare (UHC),<sup>87</sup> Neighborhood Health Plan (NHPRI),<sup>88</sup> and Tufts.<sup>89</sup> In the exams, which were commenced in early 2015, the state concluded that there were parity violations in clinically inappropriate or inadequate utilization review criteria and practices, coercive utilization review practices, denials based on subjective conclusions, notices of adverse benefit determination, noncompliance with decision and appeal time frames, inappropriate denials of coverage, and more. For all three plans, the commissioner ordered the plan to submit a proposed plan of correction to address the recommendations to OHIC for review and approval. For NHPRI and Tufts, in lieu of a penalty payment, the commissioner ordered the plans to make contributions to a fund created by the OHIC at the Rhode Island Foundation to support behavioral health prevention services and early intervention programs in the state, totaling \$330,000 over the next three years for NHPRI and a one-time contribution of \$150,000 for Tufts. For UHC, the commissioner ordered both a penalty payment of \$350,000 by April 15, 2020, and a contribution of \$2.85 million to the Rhode Island Foundation to improve the behavioral health system infrastructure in the state. Previously, OHIC had required the Rhode Island Blue plan to make a \$5 million community contribution in lieu of a penalty in 2018 for similar violations as determined by the state.



Illinois announced in July 2020 more than \$2 million in fines against insurers for parity violations found during market conduct exams from 2015-2017. Penalties were levied against CIGNA, UnitedHealthcare, HCSC (parent company of Blue Cross Blue Shield) and Celtic. The state said its \$582,000 penalty against CIGNA Healthcare was “for failing to use medical necessity guidelines required by statute and the American Society of Addiction Medicine (ASAM), and not allowing providers to request an exception to the company’s step therapy requirement for prescriptions.” The state said its penalty against UnitedHealthcare was for its failure “to use ASAM guidelines, requiring prior authorization from the company before a provider can prescribe the patient buprenorphine to help fight substance use disorder, and requiring prior authorization for prescribing certain ADHD medications.”<sup>90</sup>

The 2019 roadmap noted that the Colorado insurance commissioner had rejected market conduct examinations conducted by contracted examiners because he was not satisfied that the examiners had asked the right question on parity. In a 2020 report, the Colorado DOI reported that it had initiated a new round of exams, though the process will remain confidential until the exams are completed.<sup>91</sup>

#### **Exhibit 14. Pennsylvania: UnitedHealthcare’s exam findings**

In 2019, Pennsylvania released the findings of a market conduct examination that covered January 2015 through March 2016 data and concluded that UnitedHealthcare was in “extensive noncompliance with mental health parity and prompt pay laws, as well as concerns regarding the company’s coverage for services relating to autism spectrum disorders and substance use disorders,” resulting in a civil penalty of \$1 million to the insurer, in addition to an \$800,000 commitment for public outreach activities and restitution payments to its consumers who had claims wrongly denied, had overpaid in out-of-pocket expenses, or had accrued interest on delayed claims.<sup>92</sup>

While state DOIs play the largest role in regulating health insurance carriers, state attorneys general also can play a powerful role in enforcing parity laws. For example, New York Attorney General Letitia James published a report focused on investigations into health plans’ compliance with federal and state parity that resulted in \$3 million in fines and \$2 million for patient reimbursement. The report focused on Anthem, Beacon Health Options, Cigna, EmblemHealth, Excellus, HealthNow, and MVP.<sup>93</sup> In Massachusetts, Attorney General Maura Healey determined that there were parity and other violations by Harvard Pilgrim Health Care and United Behavioral Health d/b/a Optum; Fallon Community Health Plan and Beacon Health Strategies; AllWays Health Partners; Blue Cross Blue Shield of Massachusetts (BCBS); and Tufts Health Plan.<sup>94</sup> We encourage other state attorneys general to consider making parity enforcement a priority for their offices.

**Exhibit 15. GAO report finds parity activity in nearly all states<sup>95</sup>**

Nearly all states reported to the GAO that they review insurer documentation for MH/SUD parity requirements and compliance before approving the sale of plans to consumers in these states, particularly by looking at financial requirements, QTLs, and NQTLs; however, state oversight of insurers after consumers enroll in plans is varied, with 27 states reporting that they have conducted some type of review related to MH/SUD parity after consumers enroll. The types of reviews states conduct vary and include:

- **Targeted reviews based on consumer complaints or other information.** According to GAO's survey, in 2017 and 2018, 38 states tracked MH/SUD parity complaints (which can be submitted by consumers, providers, or advocates), and 12 states conducted targeted reviews that focused on specific issuers or particular parity concerns, largely initiated by consumer complaints. States expressed that targeted reviews are more frequently used than more comprehensive market conduct examinations because they are focused on a specific issue, rely on more recent data, and are generally less time consuming to conduct.
- **Broader market conduct examinations.** Nearly all states perform market conduct examinations, but states have not routinely included a review for MH/SUD parity compliance as part of the examinations. Of 18 states that reported to GAO that they perform routine market conduct examinations (every three to five years), only nine reported that they always include a review of MH/SUD parity compliance. However, the NAIC has developed guidance on MH/SUD parity for its Market Regulation Handbook to encourage more states to include these parity reviews in their market conduct examinations.
- **Statewide comprehensive reviews of all issuers.** Some states reported that they have conducted reviews of all issuers in their states as part of their MH/SUD parity oversight and compliance efforts after consumers enroll in plans. Some states are doing this through legislative requests, and others are conducting such reviews through grant funding.

**RECOMMENDATION:** State insurance regulators should pursue a full continuum of actions for assessing and enforcing mental health and substance use disorder parity, including requiring insurers to prospectively analyze and attest to their compliance, analyzing consumer complaints, conducting rate and form reviews, issuing data calls, and performing market conduct exams. Legislatures should ensure that state parity laws are based on the strongest models, and DOIs and Attorneys General can each play a role in enforcing state laws.

### C. Share resources through the NAIC parity working group

The NAIC officially launched the MHPAEA Working Group on March 9, 2020, charging it with making “recommendations regarding NAIC strategy and policy” with respect to developments related to federal parity law and coordination with the states and federal agencies.

The working group is also charged with providing “supplemental resources to support documentation and reporting” for market regulation purposes. Thirty states have joined the working group, which is led by Pennsylvania and Washington and has met four times.

The working group has already been instrumental in supporting states that are in the process of implementing new state parity laws or exercising their market oversight authority to require more detailed reporting by insurers. For example, Texas’ release of a proposed reporting template and Oklahoma’s implementation of a new parity law<sup>96</sup> both benefited from the work of the parity group.

The working group’s focus on reporting templates started with the more straightforward QTLs and moved to NQTLs, with prescription drug coverage and provider reimbursement policies identified as particularly important and challenging areas. The group also has heard from a wide range of stakeholders, including America’s Health Insurance Plans, which encouraged the group to compile a variety of approaches to the templates, and from NAIC consumer representatives, who asked the group “to operationalize NQTL compliance analysis in a way that is accessible to consumers.”



## Exhibit 16. NAIC principles for parity enforcement

The MHPAEA Working Group adopted the following principles:

- MHPAEA regulations are sequential and interrelated.
- At its core, MHPAEA is about addressing discriminatory differences in how plans/ issuers apply limitations to MH/SUD benefits.
- Parity as a concept, and as contemplated in the laws and regulations, requires comparability analyses:
  - For quantitative measures, comparability is measured as a function of expected claims dollar amounts ratios.
  - For nonquantitative measures, comparability is measured as a comparison of the factors and standards used to arrive at the limitations to be applied.
- Analyses must be completed at inception and on an ongoing basis, ie, as written and in operation.

**RECOMMENDATION:** State insurance regulators should participate in the NAIC's MHPAEA Working Group by sharing best practices from their state, using templates and other tools developed by the Working Group, and following best practices from other states.





## IV. Ensure access to addiction medicine, psychiatry, and other trained physicians

Patients in need of OUD treatment should have timely access to addiction medicine physicians and other health care professionals who treat OUD and mental health disorders. This includes primary care physicians trained to provide treatment for an OUD. Medicaid officials and insurance regulators can expand patients' access to care by enforcing network adequacy requirements and taking other actions to support providers, such as increasing payment for behavioral health and SUD providers and ensuring payment parity for BH/SUD providers



compared with medical/surgical providers. These issues are especially important now, given early state and local data suggesting increases in opioid- and drug-related overdose and death during the COVID-19 pandemic,<sup>97</sup> which emphasizes the need to ensure adequate access to and support for critical addiction specialists other physicians and health care professionals.

Prior to the COVID-19 pandemic, states were expanding Medicaid provider networks for the continuum of SUD services as part of their 1115 SUD waivers. As states think more systematically about network standards that address the various types of outpatient and inpatient care needed to treat SUDs, questions about ensuring quality of care must be addressed. The challenges are most acute with residential treatment, which is much more expensive than office-based treatment, and can attract low-quality or even fraudulent providers if not closely monitored.

Other important developments in 2020 include the rapid expansion of telehealth in response to COVID-19 and stronger parity laws that require behavioral health and SUD providers to be reimbursed in parity with medical/surgical providers.

### A. Measure and monitor provider network capacity

States should strengthen their ongoing efforts to assess network adequacy through annual network reviews and ongoing monitoring of consumer complaints and other indicators of

impeded access to providers. A robust network adequacy program starts with strong and objective statutory and regulatory requirements and “front-end” network reviews as part of approving insurer product filings, to ensure that consumers are being offered plans that have adequate numbers of accessible addiction medicine physicians, psychiatrists, and other mental and behavioral health care professionals accepting new patients. A full network adequacy program also includes “back-end” compliance audits or market conduct exams to regularly review adequacy and access, as well as established processes for collecting and responding to consumer complaints regarding access challenges. While many states use some combination of front- and back-end network adequacy reviews, all states have an opportunity to do more in this area.

**While many states use some combination of front- and back-end network adequacy reviews, all states have an opportunity to do more in this area.**

**Quantifiable standards are important.** As pointed out by health policy experts at Georgetown University, “meeting network adequacy requirements does not automatically guarantee that a plan provides enrollees with access to in-network MH/SUD providers comparable to other medical providers.”<sup>98</sup> A critical first step to ensuring access is to evaluate the current capacity of provider networks to treat enrollees with OUD. To this end, insurance regulators and Medicaid officials should require insurers to identify how many physicians and physician extenders are currently able to provide buprenorphine (a common form of MOUD) in-office for the treatment of OUD, how many patients those physicians can treat, and how many patients they currently are treating. Otherwise, there is a risk that a plan may have a network that appears adequate on paper when, in fact, patients do not have access to participating providers with a DATA 2000 “x-waiver” to the extent promised by the health insurer. Insurers could apply a similar approach to measuring the sufficiency of OTPs for methadone dispensing, residential treatment providers, and other SUD providers so that insurers understand the capacity of network providers.



Exhibit 17 shows an aggregate increase of 32% in the number of physicians able to provide buprenorphine from May 2019 to October 2020. While this represents significant progress, it is likely that states that perform the suggested analysis in this section will find substantial shortages in some geographical areas. In addition, it is critically important that provider networks are culturally relevant and diverse in order to reflect the communities they serve. Addressing the shortages of Black/African American x-waivered physicians across states can help address the significant disparities in access to buprenorphine for Black/African American individuals with an SUD.

### Exhibit 17. SAMHSA national data on waived health care professionals, May 2019 to November 2020

Figure A. SAMHSA buprenorphine practitioner and program data, May 2019<sup>99</sup>

#### Practitioner and Program Data

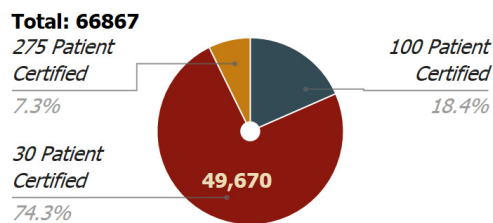
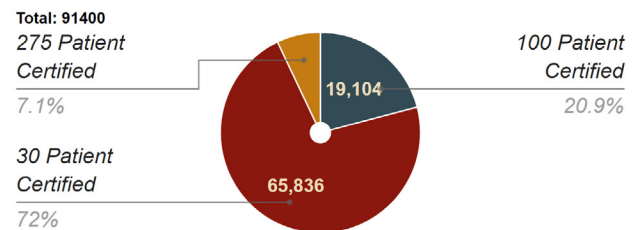


Figure B. SAMHSA buprenorphine practitioner and program data, November 2020<sup>100</sup>

#### Practitioner and Program Data



### Exhibit 18. Colorado regulators intensify focus on network adequacy in response to new state law

The Colorado Division of Insurance published a report on June 1, 2020 that detailed the Division's comprehensive efforts to enforce new parity laws, including stronger network adequacy standards designed to correct deficiencies in network coverage for behavioral health highlighted in a November 2019 Milliman report. Among other findings, the Milliman study found that enrollees were 7.95 times more likely to use an out-of-network behavioral facility than an out-of-network medical/surgical facility.

"It is worth noting that the Division does not typically involve itself with provider-carrier relations, but it has done so given the intricacy of provider relations to parity compliance in areas such as credentialing processes, network adequacy standards, and reimbursement rates."

—Excerpt from a Mental Health Parity Implementation and Enforcement Report by the Colorado Division of Insurance to the Colorado Legislature, June 2020<sup>101</sup>

In response to a 2019 state law, the Colorado DOI amended its network adequacy regulations to include new standards for evaluating the adequacy of mental health, behavioral health, and SUD networks. The requirements were part of a larger package that strengthened the DOI's parity oversight across the board. The DOI cited a 2019 Milliman report that found Colorado consumers eight times more likely to use out-of-network facilities for behavioral health than for medical/surgical treatment.<sup>102</sup>

**RECOMMENDATION: State insurance regulators and Medicaid officials should require all health carriers to publicly disclose the following:**

- The number of physicians and other health care professionals in each network who have an x-waiver to provide buprenorphine in-office for the treatment of opioid use disorder
- The number of patients those waived providers are able to see (ie, the patient limit allowed by the waiver)
- The number of patients currently being treated with buprenorphine

**RECOMMENDATION: States should address the shortage of Black, Hispanic, American Indian, and other minoritized populations of x-waivered physicians across states to ensure network adequacy in areas that are disproportionately impacted by SUD.**

## **B. Build critical infrastructure**

Physicians and other critical MOUD providers who care for patients with an SUD must be equipped with the appropriate support in order to meet the needs of the SUD population. A “hub-and-spoke” model, first developed in Vermont to help address the need for patients to have access to a wide range of medical and social and other behavioral care services, offers providers technical assistance and expert guidance, as well as a mechanism for referring particularly complex patients. The hub-and-spoke model has now been adopted or modified by several other states, including Pennsylvania, North Carolina, and others.

**Enhancing access through hub-and-spoke models.** Pennsylvania’s hub-and-spoke model centers on an addiction specialist, who serves as the “hub,” providing expertise and guidance to primary care physicians, or the “spokes,” who practice in rural and underserved

communities across the state. These primary care providers provide direct patient care and prescribe MOUD where appropriate, and link patients to drug and alcohol counseling in their communities. Having the addiction specialist “on hand” to support primary care providers in the community ensures that primary care providers are equipped with the supports needed to ensure necessary treatment is available to residents seeking care and treatment. The network includes 45 Centers of Excellence (COEs), which have served 32,500 people with an OUD through Medicaid since 2016. There also are 14 Pennsylvania Coordinated Medication Assisted Treatment (PacMAT) programs participating in the hub-and-spoke model to provide evidence-based treatment to people where they live, and since 2018, these centers have helped over 6,000 people receive MOUD<sup>103</sup>; in 2019, the state committed \$26 million to the centers and has provided support to a number of other initiatives and programs to continue addressing the opioid crisis in Pennsylvania. This year, Pennsylvania’s Secretary of Health, Dr Rachel Levine, announced two new health systems intended to build MOUD programs for individuals with SUD who are uninsured, underinsured, or privately insured.<sup>104</sup>

In North Carolina, a collaboration between the University of North Carolina at Chapel Hill School of Medicine and the Mountain Area Health Education Center aims to establish referral relationships with community health centers and health departments in western North Carolina to develop the hub-and-spoke relationships needed to expand access to MOUD for low-income individuals and connect them to other supports and services.<sup>105</sup>



Having providers that are waived and trained, particularly in rural areas, are critical to implementing these models. North Carolina has taken steps to integrate addiction training, including getting the federal DATA waiver to prescribe buprenorphine, as part of standard medical education. The North Carolina Department of Health and Human services funded a residency training program, which has trained more than 800 current providers and residents, as well as incorporated waiver training into more than 30 residency programs in North Carolina. Through an initiative led by the N.C. Governor’s Institute, four out of five North Carolina medical schools now incorporate waiver training as part of their standard curriculum.

**Linking those who experience an opioid-related overdose to treatment.** The risk of fatal overdose is greatly increased when there is a prior, nonfatal overdose.<sup>106,107</sup> Opportunities for engagement, therefore, often occur in the emergency department (ED). When a patient arrives in a University of Colorado Health System emergency department and is identified as having

OULD, a social worker intervenes to conduct an in-depth screening. If clinically indicated and if a patient is willing, providers prescribe buprenorphine. A grant from the Colorado Office of Behavioral Health assisted in the development of resources to provide “warm handoffs” to community providers, according to Denver emergency medicine physician Jason Hoppe, DO. In a published study of the program,<sup>108</sup> “[f]rom June 1, 2018, through August 31, 2019, 120 patients opted for ED buprenorphine induction. 61% presented to initial outpatient intake appointment and 39% remained engaged in treatment after 30 days.” In a subsequent interview, Dr Hoppe said that after two years, of 302 patients identified as needing treatment for a substance use disorder, 268 (88%) agreed to initiate treatment, 56% showed up for their first appointment, and almost half (45%) were still in treatment at 30 days. “It’s hard work,” said Dr Hoppe, “but we’re making progress.”

What worked in Denver, moreover, has been shown to work elsewhere—albeit part of the “hard work” involves systemic changes such as ensuring appropriate ED workflow, staffing, potential changes in electronic health records, education, and identifying “a network of local community ‘fast-track’ providers able to accept patients for next-day appointments,” according to a study of buprenorphine induction in the South.<sup>109</sup> It took 14 months to put the programs together across three different locations, and researchers ultimately reported that, “[o]f the 727 positive screened patients for non-medical opioid use, 70% were determined potentially eligible to receive buprenorphine initiation,” and 231 began treatment with buprenorphine. Of that cohort, 77% went to their next-day appointment, and 60% were in treatment at 30 days.

**RECOMMENDATION:** States should coordinate efforts in communities among emergency departments (EDs), health insurance companies, and physicians who treat opioid use disorder to ensure that ED health care professionals and staff have the education and resources to conduct Screening, Brief Intervention and Referral to Treatment (SBIRT) or similar screening, initiate buprenorphine, and make appropriate referrals, and that there are in-network physicians ready to accept next-day appointments for those willing to continue treatment.

**Leveraging Medicaid managed care requirements and other state tools to expand the provider network.** States can hold their managed care organizations (MCOs) accountable for rigorous and specific network adequacy requirements in their Medicaid managed care contracts, and require that plans reimburse providers at specified rates if necessary, to ensure that plan networks are sufficient to meet the needs of Medicaid members with an SUD. For

example, Ohio requires its Medicaid MCOs to contract with a minimum number of MOUD providers per county and all willing OTPs.<sup>110</sup>

In addition, states have used Medicaid Delivery System Reform Incentive Payments (DSRIP) and SAMHSA grants to increase network capacity for SUD services, including for OTPs and other MOUD providers. For example, Washington has leveraged its DSRIP program to support capacity and infrastructure investments for SUD treatment providers, including OTPs.<sup>111</sup> SAMHSA's State Opioid Response (SOR) grants awarded to state and tribal entities are intended to support the expansion of evidence-based prevention, treatment, and recovery services for OUD and stimulant use. While most of these funds must be used to support direct care services, up to 5% can be used to support infrastructure development for providers, including training and workforce and IT investments.<sup>112</sup> SOR recipients are also required to ensure that all eligible providers obtain waivers to prescribe buprenorphine.

**RECOMMENDATION: States should meaningfully support community hub-and-spoke model programs that expand provider capacity and link patients—including Medicaid, commercially insured, and uninsured populations—to multidisciplinary care.**

**RECOMMENDATION: State Medicaid officials should leverage Medicaid managed care contracting as a tool to enforce robust network adequacy requirements and support the inclusion of racially, ethnically and culturally diverse physicians and other health care professionals in those networks.**

### **C. Enforce parity standards to enhance access to in-network care**

As discussed in the parity section of this roadmap, parity enforcement will promote stronger provider networks. A 2019 study by Milliman found broad inequities in 2017 reimbursement rates between MH/SUD providers and medical/surgical providers for office-based services.<sup>113</sup> These inequities have worsened since 2015, with primary care reimbursements found to be 23.8% higher than behavioral health reimbursements, up from 20.8% higher reimbursements for primary care versus behavioral health in 2015. Eleven states<sup>114</sup> were found to have reimbursement rates for primary care office visits that were over 50% higher than reimbursement rates for behavioral office visits. By contrast, only four states (Hawaii, Indiana,

Mississippi, and Nevada) had provider reimbursements that were more favorable for behavioral health office visits than for primary care office visits.

In addition, wide disparities in out-of-network use for behavioral health care compared to medical/surgical care were identified,<sup>115</sup> with particularly wide disparities for substance use disorder care, finding that out-of-network utilization rates for SUD office visits were 5.7 times those of primary care visits in 2013, and increased in 2017 to 9.5 times those of primary care visits. To be clear, unjustified differences in reimbursement rates and unequal efforts to incentivize network participation are potential MHPAEA parity violations and should be addressed and remediated to promote adequate networks and access for patients with MH/SUD to in-network care.

The NAIC work group is looking at provider payment as a critical parity issue since lack of parity makes it harder for behavioral health providers to participate in insurer networks, which in turn forces patients to find out-of-network providers and incur higher cost sharing.

**RECOMMENDATION:** State regulators should recognize a lack of parity between MH/SUD and medical/surgical provider payments as a parity violation and ensure that behavioral health and SUD providers are being paid at parity under federal and state mental health and SUD parity laws.





## D. Provide federal, state, and local support to SUD providers struggling in wake of COVID-19

Exhibit 19. June 2020 National Council for Behavioral Health survey of community behavioral health organizations

- **71%** have had to *cancel, reschedule, or turn away patients* in the past three months.
- **More than half** do not have enough or are unsure whether they have *enough PPE* for the next two months.
- **44%** think they *can survive six months or less* in the current environment.
- On average, organizations have lost **24.3% of their revenue** during the COVID-19 pandemic.

Even prior to COVID-19, there were significant gaps in the number of providers available to treat SUD, with only one in ten people with SUD receiving treatment. In 39% (1,228) of counties—representing 18 million residents—there was not a single waived buprenorphine provider in 2019.

COVID-19 has made things worse, with both decreased revenue for SUD providers and increased costs in areas such as providing personal protective equipment (PPE), reconfiguring office space, and acquiring telehealth equipment. At the same time, state Medicaid programs are looking at massive cuts unless they receive more federal support. The result could be reduced payment rates for SUD providers,

which would further jeopardize access to SUD treatment. Commercial insurers have helped fill gaps in some states where they have benefited from deferred care, but state efforts to broker extra-contractual support for providers has been rare and ad hoc.

**State activities supporting SUD providers amid the COVID-19 pandemic.** COVID-19 has posed new challenges for SUD providers, and it is critical that they receive funding during the pandemic to prevent closures and other actions that set back efforts to build and expand capacity. To that end, states and, to a more limited extent, commercial insurers are taking steps to provide funding and technical expertise.

States are providing information and technical assistance to providers so that they can take advantage of high-priority federal funding opportunities and understand what programs they qualify for and how they can apply for funding support. Montana, for example, sent its providers a simplified chart that summarizes when and how they can apply for support out of the \$175 billion Provider Relief Fund.<sup>116</sup> Other states are directly increasing Medicaid payments to SUD providers to support them throughout the COVID-19 pandemic. West Virginia increased reimbursement rates for certain SUD providers by 20%.<sup>117</sup> California encouraged its Medicaid

managed care plans charged with providing behavioral health benefits to issue monthly payments to SUD providers based on what they received last year, even as visit volume declined due to COVID-19.<sup>118</sup> Finally, Washington instructed its MCOs to release funds to assist at-risk behavioral health providers through strategies such as advance payments, capitated contracts, and other options.<sup>119</sup>

Additionally, state insurance regulators can facilitate insurer support for providers whose business volume is down by reducing administrative barriers, such as prior authorization, and by directly supporting insurers whose revenues are down during the pandemic. For example, New York required insurers to develop plans for supporting providers with the savings insurers accrued from deferred services.

With the pressure on providers generated by COVID-19, some states took quick action to step up their monitoring of SUD provider capacity. For example, Virginia established an internal dashboard to gather data on where SUD providers (and other key/vulnerable provider types) were shutting down sites or clinics and when they intended to come back online or whether they intended to close, providing actionable data that has enabled the state to respond accordingly.

**RECOMMENDATION: States, Medicaid managed care organizations, and commercial insurers should provide technical assistance and, where feasible, advance payments to SUD providers to sustain SUD networks during the COVID-19 pandemic.**

## **E. Leverage telehealth to improve access**

The rapid expansion of telehealth during the COVID-19 pandemic offers another opportunity to expand access on a permanent basis, particularly for providers who treat patients with OUD and SUD. A recent AAAP survey<sup>120</sup> found that 80% of waived physicians, physician assistants, and nurse practitioners who treat patients with OUD want virtual visits and other telehealth options to continue after the COVID-19 PHE ends, and 76% of providers perceived that their patients were satisfied with virtual visits to maintain medications for OUD. While telehealth access should not be viewed as a substitute for having an adequate in-person provider network, the changes made by the Drug Enforcement Administration (DEA) and SAMHSA to help individuals maintain access to critical services while adhering to social distancing recommendations and stay-at-home orders should be continued.

Both Medicaid officials and insurance regulators expanded access to services through telehealth across multiple domains:

- **Treatment and recovery services.** Most states have issued Medicaid guidance related to MOUD telehealth services. Virginia’s Department of Medical Assistance Services allowed the counseling component of MOUD to be provided via telehealth or telephone communication.<sup>121</sup> In addition, Florida required managed care plans to reimburse behavioral health providers for certain services (including MOUD) when provided via telemedicine (live, two-way communication).<sup>122</sup>
- **Location.** In response to the Public Health Emergency (PHE), most states<sup>123</sup> are allowing both fee-for-service and managed care Medicaid beneficiaries to access services from their home, permitting the home to be an “originating site” for patients, rather than requiring that patients be within a provider’s office, hospital, or other health care facility to receive teleservices. For example, in Iowa, OTPs providing buprenorphine treatment are permitted to render services in the member’s home via telecommunication, telehealth, smartphone videoconference, or other electronic means.<sup>124</sup>
- **Payment parity.** New Hampshire explicitly provided payment parity for telehealth visits via HB 1623,<sup>125</sup> and Oregon permitted providers to be reimbursed at the in-person rate for using telephone communications when barriers to equipment and access exist.<sup>126</sup> The Centers for Medicare & Medicaid Services (CMS) issued guidance<sup>127</sup> clarifying that “no federal approval is needed for state Medicaid programs to reimburse providers for telehealth services in the same manner or at the same rate that states pay for face-to-face services.”
- **Technology platforms**
  - Common video technologies such as FaceTime, Skype, and Zoom. The Office for Civil Rights (OCR) waived<sup>128</sup> all provisions of the Health Insurance Portability And Accountability Act (HIPAA) privacy, security, and breach notification rules if a telehealth provider acted in good faith in attempting to comply with the guidance during the PHE. This has meant, for example, that a provider need not use a communications technology that complies with the HIPAA security rule, but instead can use other technologies—such as Zoom, FaceTime, or Skype—that might not meet all HIPAA requirements but are nevertheless designed to be non-public facing.
  - **Audio-only telehealth.** Many state Medicaid agencies followed Medicare’s lead to expand telehealth coverage to audio-only. This includes states that are either adding coverage for telephonic evaluation and management codes or allowing providers to

bill the usual service codes when the services are delivered via telephone (with certain parameters in place).<sup>129</sup> As of October 1, all 50 state Medicaid agencies and Washington DC had issued guidance to allow for a form of audio-only telehealth services.

**Enhancing provider capacity through telehealth training.** Telehealth/telephone flexibilities are also a critical tool for maximizing existing specialty behavioral health and office-based opioid treatment workforces. For example, New Mexico's TeleECHO (Extension for Community Healthcare

Outcomes)<sup>130</sup> programs are guided-practice models that use a hub-and-spoke knowledge-sharing approach to improve provider capacity in rural and underserved areas. Programs encompass a wide range of trainings, including programs that aim to expand MOUD



prescribing in primary care settings through virtual clinic training. The curriculum covers key aspects of prescribing (eg, overview of OUD and MOUD, induction, specifics of dosing, MOUD and co-occurring disorders, MOUD with special populations, etc), psychosocial supports (motivational interviewing, harm reduction, co-occurring disorders, etc), and clinic-level resources/skills (screening, monitoring, workforce staffing, billing, etc).

**RECOMMENDATION:** States should work with physician and other health care providers to evaluate the impact of telehealth expansions on patient access to MH/SUD treatment, and further support those expansions that prove effective beyond the pandemic. Such evaluations should emphasize the importance of continuity of care for MH/SUD patients by ensuring that all network providers have the option of providing telehealth services to their patients, and patients are not directed or incented to seek care from a separate telehealth network.

## V. Improve access to multidisciplinary, multimodal care for patients with pain

Administrative practices and payment structures put in place by payers create some of the most significant barriers for physicians seeking to provide comprehensive, multidisciplinary, multimodal pain care. Prior authorization requirements by payers are particularly burdensome for physicians and their staff. In fact, 92% of pain specialists surveyed in 2019 by the American Board of Pain Medicine reported that they were required to submit a prior authorization for non-opioid pain care, which delayed patient treatment, and 66% hired additional staff to process the greater administrative workload.<sup>131</sup> Treatments shown to provide benefit for chronic pain but commonly



subject to prior authorization include manual manipulation (ie, occupational or physical therapy), non-opioid prescription pain medications or treatments, and pain creams and patches.<sup>132</sup> Another barrier is “fail first,” whereby payers cover the least costly medication or treatment first instead of what was recommended by the patient’s clinician. Variation in benefit plans means that pain services and medications are covered for some but not others.<sup>133</sup>

Payer coverage models vary widely and increase the complexity of prescribing treatment and the difficulty of accessing care. For example, there is clear evidence that integrated, multidisciplinary, and multimodal care results in better overall outcomes for chronic pain and is more cost effective in the long term than opioid therapy alone.<sup>134,135</sup> Nevertheless, coverage of and payment for this type of pain care are inadequate. Benefit plans that don’t support multidisciplinary, multimodal, and collaborative care for pain are out of step with many clinical practices, current and emerging evidence, and the needs of patients with complex pain. The AMA endorses the US Department of Health and Human Services (HHS) Pain Management Best Practices Inter-Agency Task Force recommendations that payers remove barriers of inadequate coverage and inadequate reimbursement of treatments for chronic pain.

## A. Promote multimodal and multidisciplinary approaches to acute and chronic pain care to shift the paradigm for pain care

Multimodal pain care means the use of multiple types of treatments to treat the physical and psychological aspects of pain. Attitudes and assumptions on the appropriate response for treatment of pain has focused on pharmaceutical options to the detriment of other treatments for far too long. This understanding must change in order to support both patients and physicians in creating pain management plans and treatment regimens that produce better outcomes for patients. Physicians and other health care professionals are challenged to provide this individualized care due to large gaps in coverage for pain management treatments, from acupuncture and massage to non-opioid pharmaceuticals used for pain relief. This is not in alignment with recommendations from HHS' Pain Management Best Practices Inter-Agency Task Force, which state that patient-centered and individualized plans of care are central to effective pain management.<sup>136</sup>

The AMA Opioid Task Force and the AMA Pain Care Task Force support increased research and access to multimodal, evidence-based treatment, including:

- Medication, including non-opioid pain relievers, anticonvulsants, antidepressants, musculoskeletal agents, anxiolytics, and opioid analgesics, when appropriate
- Restorative therapies, which include physical therapy, occupational therapy, physiotherapy, therapeutic exercise, osteopathic manipulative therapy (OMT), and other modalities such as massage and therapeutic ultrasound
- Interventional procedures, such as neuromodulation, radiofrequency ablation, peripheral nerve stimulation, central and peripheral nerve ablation, spine surgery, and steroid injections, and other emerging interventional therapies as part of the multimodal pain care plan

Several pain medicine physicians at top academic medical centers across the nation recently published "Pain Management Best Practices from Multispecialty Organizations during the COVID-19 Pandemic and Public Health Crises" to provide a framework for supporting pain management services, and noted that "systems-wide and individual decisions [on pain management] must take into account clinical considerations, regional health conditions, government and hospital directives, resource availability, [and] the welfare of health care providers."<sup>137</sup>



Physicians should be given access to all of the above as tools to create patient-centered, multimodal pain care plans that are not hindered by administrative or coverage barriers, ensuring that patients with acute or chronic pain have a wide range of options so that providers can personalize and tailor appropriate treatment plans to address their patients' unique needs.

**Multimodal care for acute pain.** Multimodal pain care should be considered for acute pain (including postoperative pain) in place of relying on opioids or non-opioid pharmaceuticals alone. The evidence on which treatments are most effective by type of pain varies, but there is some promising evidence for treatment of musculoskeletal pain. The Agency for Healthcare Research and Quality (AHRQ) has assessed nonpharmacologic interventions for low back pain, and results indicate that interventions such as exercise therapy for acute and chronic pain caused by musculoskeletal conditions may offer relief while avoiding the risks of opioid therapy.<sup>138</sup> However, coverage of rehabilitative therapies typically costs patients more (comparing the copay per physical therapy session versus the one-time copayment for a prescription drug), and such therapies are not always covered.



**Medical efficacy of nonpharmacological pain therapies.** Evidence supports the use of nonpharmacological restorative therapies, including physical therapy, occupational therapy, and acupuncture, as effective treatments for patients with pain.

- Physical therapy is commonly used to treat functional and/or musculoskeletal pain and aims to increase mobility, decrease pain, and improve functional and psychological status. A 2018 study that examined nearly 89,000 patients who visited a health care provider for either back, knee, shoulder, or neck pain found that those with knee pain who received early physical therapy were 66% less likely to fill a long-term opioid prescription (for 120 days or more), and patients with low back pain (LBP) who received early physical therapy were 34% less likely to become long-term opioid users.<sup>139</sup> Physical therapy provides the patient a minimally invasive option as part of a treatment plan.<sup>140</sup> These components are critical in treating biomechanical and structural causes of pain and in addressing the psychological and behavioral components of pain through lower-risk options than prescription opioids. Numerous studies highlight physical therapy as an important component to sustained

recovery for patients with LBP and other musculoskeletal pain diagnoses, and extensive literature reviews show that “physical therapy only or added to usual care implies improved health in almost all studies.”<sup>141</sup>

- Because of their training in psychosocial interventions, occupational therapists help provide evidence-based, nonpharmacological interventions for treating acute and chronic pain.<sup>142</sup> Similar to physical therapy, occupational therapy is recognized as being efficacious for patients with pain because of patients’ active participation and ownership of the treatment (by continuing the therapy outside of regularly scheduled sessions). In addition, pain care from multiple alternative sources may work together to lessen pain in a way that no one type of therapy or medication can effectively address alone.
- Acupuncture is an evidence-based, cost-effective, and low-risk treatment option for numerous pain conditions, including chronic LBP, headache, chemotherapy-induced nausea and vomiting, knee osteoarthritis, migraines, postoperative nausea and vomiting, and postoperative pain.<sup>143</sup>

**Multidisciplinary care for chronic pain.** A multidisciplinary approach, involving providers such as pain management specialists, behavioral health interventionists, physical and occupational therapists, and primary care physicians (PCPs) is appropriate for individuals living with chronic pain. Treatment of chronic pain is a complex “sensory and emotional experience,” and it should include behavioral approaches to address the psychological, cognitive, emotional, behavioral, and social aspects of chronic pain. Focusing on appropriately meeting the behavioral health needs of chronic pain patients can have a significant impact on treatment outcomes.

**Interdisciplinary pain management programs.** Pain management specialists suggest that the best approach to functional improvement for people with significant, high-impact pain or multiple health conditions is an interdisciplinary, coordinated pain management program that teaches patients how to (1) improve their physical function, (2) address stress and trauma that may lie at the root of the pain experience,





and (3) access services that may provide temporary pain relief. The goal of treatment is not to eliminate all pain, but to make pain manageable and to improve quality of life and the patient's ability to conduct activities of daily living. Several examples of robust, interdisciplinary pain management programs include:

- **The Swedish Hospital System's Structured Functional Restoration Program (SFRP).**

This program, out of the Swedish Hospital System in Seattle, Washington, refers to itself as a "pain boot camp" and involves the coordination of care by a number of pain specialists and providers. The interdisciplinary team model has patients participating in four to five hour-long sessions, two to three times per week. During each session, patients visit with multiple pain providers and educators, sometimes individually and other times in groups.<sup>144</sup>



- **Veterans Affairs' Interdisciplinary Pain Rehabilitation Program.** The VA's Interdisciplinary Pain Rehabilitation Program focuses on restoring function and improving symptom self-management and quality of life. The main goal is to improve physical functioning with some, though less, emphasis on reducing pain severity. Individuals participate in the program for up to three months, attending weekly four hour-long sessions with a core team that includes themselves, family members or a support person (if appropriate), a pain physician, a pain psychologist, a physical therapist or rehabilitation specialist, and other professionals according to the individual's needs.<sup>145</sup>

While these programs are good models for chronic pain management, most patients cannot access interdisciplinary, coordinated pain management programs because they are not widely available.

**RECOMMENDATION:** States should partner with universities, MCOs, health systems, and other stakeholders to identify, promote and meaningfully support increased access to evidence-based interdisciplinary pain management delivery models.

## B. Operationalize the multimodal approach to provide coverage through formularies and medical benefits

A more detailed regulatory review of formulary and benefit design by payers and PBMs is necessary to ensure that patients have affordable, timely access to evidence-based non-opioid alternatives, including both pharmacologic and nonpharmacologic options. In conducting such reviews, policymakers are urged to work closely with physicians to ensure appropriate clinical input.

Medicaid coverage for nonpharmacologic pain management modalities is mixed. While most states cover physical and occupational therapy, 20% of states do not; even when these therapies are covered, there are frequently limits on services. Chiropractic care is covered in only half of the states (see Exhibit 20 below).<sup>146,147</sup>

### Exhibit 20. Coverage of nonpharmacologic therapies reported by state Medicaid agencies

**TABLE 2.** Coverage of nonpharmacologic therapies reported by state Medicaid agencies

|   | Covered benefit | Copay required | Limit on services |
|---|-----------------|----------------|-------------------|
| Chiropractic services   | 24              | 13             | 18                |
| Physical therapy  | 41              | 13             | 25                |
| Occupational therapy  | 40              | 13             | 24                |
| Rehabilitation services (specialty mental health and substance use) | 42              | 7              | 22                |

Source: Kaiser Family Foundation. (n.d.). Medicaid & CHIP indicators. <https://www.kff.org/state-category/medicaid-chip/medicaid-benefits>

**Colorado law could become a national model.** The Colorado Legislature approved a promising pain care bill in June 2020 that could become the foundation for a national model offering patients and their providers more options for dealing with pain than are typically available under health insurance benefit plans. HB 20-1085, which enjoyed broad bipartisan support, would have required insurers to cover up to six visits annually for physical therapy, occupational therapy, chiropractic services, and acupuncture, as well as reduce cost sharing and utilization management barriers to atypical opioids, which often are unaffordable for patients with pain despite compelling reasons to favor non-opioid alternatives when treating pain. The AMA joined the Colorado Medical Society, Colorado Consortium Against Prescription Drug Abuse, and dozens of stakeholders in support of the bill before Colorado Governor Jared Polis vetoed the bill, citing cost concerns.

Providing such coverage to patients in Colorado, including increased alternatives to opioids (ALTO) as part of a full continuum of treatment options, would have helped save money and improve patient care, according to a report and actuarial analysis<sup>148</sup> submitted to the Colorado

Division of Insurance by the AMA, Colorado Medical Society, Colorado Pain Society, and Manatt Health. The report was in response to a DOI request for information to address Governor Polis's concerns about whether another bill similar to HB 20-1085<sup>149</sup> could be shown to provide access to cost-effective, evidence-based ALTOs for patients with pain.

The organizations consulted with pain medicine specialists in Colorado to show that ALTOs provide clear health benefits, and worked with Oliver Wyman Actuarial Consulting, Inc, on a preliminary set of actuarial analyses that show ALTOs also would save money on certain other health services. The analysis reinforces the need for a multimodal approach to treatment of pain that requires a critical review of administrative and other health insurance benefit barriers, exclusions, and exceptions to coverage that both inhibit the use of ALTOs and fail to address the needs of patients with acute or chronic pain, including populations that may benefit from opioid therapy when indicated. Key findings include:

- Oliver Wyman found that 13% of patients treated for pain incurred more than \$2,500 per person in pain-related claims in 2018, and that these individuals had total health care costs roughly eight times the total health care costs of all remaining insured members.
- While opioid prescriptions have been significantly reduced in Colorado,<sup>150</sup> the standard health insurance benefit plan continues to feature opioids as the most affordable treatment option for patients, while imposing barriers to ALTOs.
- Oliver Wyman's analysis found that among patients with more than \$2,500 in pain-related claims in 2018, certain other services, such as emergency department utilization, imaging, injections, and other procedures, were used less by patients who received the ALTOs proposed by HB 20-1085 compared with those who did not.
- Cost sharing and utilization management protocols required by health insurers for ALTOs were considerably more burdensome and more prevalent than those for opioid analgesics.



The analysis also highlighted that while physical therapy, occupational therapy, and chiropractic services are currently covered for non-grandfathered individual and small groups in some form under the current Essential Health Benefit (EHB) benchmark plan in Colorado, they come with a number of significant exclusions/exceptions to coverage that do not address the needs of patients with acute or chronic pain. In



addition, acupuncture, another low-risk and cost-effective therapy for a multitude of patients with pain, is not required to be covered for any health conditions under the Colorado EHB. Providing coverage for the proposed coverage benefits outlined in HB 20-1085 would expand cost-beneficial, effective treatment options to help patients with pain in Colorado.

The report also identifies other barriers that cannot be quantified in an actuarial analysis but are very real for patients. These barriers involve the social determinants of health, as well as potential inequities in how pain care has been provided—for example, a patient who would prefer to receive one of the ALTO nonpharmacologic options but is not able to take time off work, or a patient who cannot see a provider before or after work because of child care responsibilities or transportation limitations. These realities point to the complexity of situations faced by patients and necessitate the availability of a wide range of treatments and therapies for patients with pain.

**RECOMMENDATION:** State insurance regulators should review formulary and benefit design options from health insurers to ensure that the treatments pain medicine physicians recommend are included on a formulary's lowest cost-sharing tier with low or no cost sharing.

**RECOMMENDATION:** States should ensure that policies seeking to increase the use of alternatives to opioids (ALTOs) take into account both coverage for ALTO treatments and meaningful access to those treatments, especially in cases where lack of housing or other social determinants of health create additional obstacles.

## C. Revisit policies that simply restrict opioid prescriptions

The federal government and states took aggressive action against the over-prescribing of opioids between 2016 and 2018, adopting 527 federal and state opioid-related policies (statutes, rules/regulations, and guidelines).<sup>151</sup> Of these policies, 246 focused on Prescription Drug Monitoring Programs (PDMPs), and “170 specifically imposed limits on opioid prescribing and an additional 35 specifically referred to, or incorporated, the CDC opioid prescribing guideline.” Nearly every state also “mandated some amount of pain or opioid prescribing” continuing medical education (CME).

These laws have predictably reduced opioid prescriptions, but there is no indication that they have improved patients’ pain outcomes. For example, a 2020 AMA report found:<sup>152</sup>

- **Opioid prescribing decreased for the sixth year in a row.** Between 2013 and 2019, the number of opioid prescriptions decreased by more than 90 million—a **37.1% decrease nationally**.<sup>153</sup>
- **PDMP registrations and use continue to increase.** In 2019, health care professionals nationwide accessed state PDMPs **more than 739 million times**—a 64.4% increase from 2018 and an increase of more than 1,100% from 2014. More than 1.8 million physicians and other health care professionals are registered to use state PDMPs.<sup>154</sup>

Furthermore, these laws have had unintended consequences that need to be evaluated so that public policy can be recalibrated to ensure effective pain care. For example, these laws have led to a plethora of nonlegislative and nonregulatory actions that have treated CDC guidelines as a hard policy threshold when that is not their intent:

- Walmart’s policy includes a 50 MME or seven-day hard threshold for opioid prescribing.<sup>155</sup>
- CVS Caremark’s policy has multiple restrictions, including a seven-day hard threshold for opioid prescribing.<sup>156</sup>
- OptumRx’s policy is aligned with 2016 guidelines.<sup>157</sup>
- Walgreen’s Good Faith Dispensing Policy does not list specific thresholds, but the AMA has received numerous complaints about pharmacists refusing to fill a prescription because of “corporate policy.”<sup>158</sup>
- Blue Cross Blue Shield Association imposes a seven-day hard threshold.<sup>159</sup>
- UnitedHealthcare has a seven-day, 90 MME hard threshold.<sup>160</sup>

## Exhibit 21. CDC addresses Guideline's misuse

The CDC has highlighted<sup>161</sup> four specific ways in which 2016 Guideline for Prescribing Opioids for Chronic Pain has been misapplied:

- **Misapplication of recommendations to populations outside of the Guideline's scope.** The Guideline is intended for primary care clinicians treating chronic pain for patients ages 18 and older. Examples of misapplication include applying the Guideline to patients in active cancer treatment, patients experiencing acute sickle cell crises, or patients experiencing postsurgical pain.
- **Misapplication of the Guideline's dosage recommendation that results in hard limits or "cutting off" of opioids.** The Guideline states, "*When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should ... avoid increasing dosage to  $\geq 90$  MME/day or carefully justify a decision to titrate dosage to  $\geq 90$  MME/day.*" The recommendation statement does not suggest discontinuation of opioids already prescribed at higher dosages.
- **The Guideline does not support abrupt tapering or sudden discontinuation of opioids.** These practices can result in severe opioid withdrawal symptoms, including pain and psychological distress, and some patients might seek other sources of opioids. In addition, policies that mandate hard limits conflict with the Guideline's emphasis on individualized assessment of the benefits and risks of opioids given the specific circumstances and unique needs of each patient.
- **Misapplication of the Guideline's dosage recommendation with respect to patients receiving or starting medication-assisted treatment for opioid use disorder.** The Guideline's recommendation about dosage applies to use of opioids in the management of chronic pain, not to the use of medication-assisted treatment for opioid use disorder. The Guideline strongly recommends offering medication-assisted treatment for patients with OUD.

In addition, these laws have not been counterbalanced by any meaningful increase in access to ALTOs or reductions in administrative barriers. Health insurance companies continue to delay and deny access to non-opioid pain care and evidence-based treatment for opioid use disorder, while pharmacy chains, pharmacy benefit managers, and state laws continue to inappropriately use arbitrary guidelines to restrict access to legitimate medication that some patients need to help manage their pain.

### Exhibit 22. Pain specialists face treatment barriers

- 92% of pain medicine specialists said that they have been required to submit a prior authorization request for non-opioid pain care. Physicians and their staff spend hours per day on such requests.
- 72% of pain medicine specialists said that they—or their patients—have been required to reduce the quantity or dosage of medication prescribed.<sup>162</sup>

In sum, the data show that physicians have taken considerable steps—before and after policy mandates—to reduce opioid prescriptions and to use PDMPs. Yet it is not clear that these restrictive laws have led to reduced drug-related mortality or improved access to evidence-based pain care. There is, however, growing evidence that arbitrary opioid restriction policies—including the CDC’s failure to clarify that its 2016 Guideline should not be used as a hard threshold—have harmed many patients.<sup>163,164</sup>

**RECOMMENDATION:** States with prescription opioid restriction policies, PDMP requirements, or CME mandates should undertake a retrospective review, including qualitative interviews with physicians and patients with pain to determine the impact of these policies, including patient outcomes. If policies based on the 2016 CDC Guideline are not found to have improved patient outcomes, the policies should be revised or rescinded.



## VI. Expand harm reduction efforts to reduce death and disease

Harm reduction seeks to minimize the negative impacts associated with drug use and is an essential component of addressing the drug overdose epidemic. In 2019, a nationwide network of harm reduction organizations distributed more than 1 million doses of naloxone.<sup>165</sup> Without the widespread availability and distribution of naloxone from community-based harm reduction organizations, hundreds of thousands of overdose events likely would have ended in death. Given the importance and efficacy of naloxone, it's critical to ensure people who use drugs, those with an OUD and their family members and loved ones have sufficient access to naloxone. This section examines the challenge of providing that access and looks at broader harm-reduction policies, such as syringe service programs (SSPs) and targeted messaging, that states are increasingly implementing to prevent overdoses, especially during the COVID-19 pandemic.

A cornerstone of states' approaches to harm reduction is the availability of naloxone, the opioid overdose-reversal agent. According to the American Society of Addiction Medicine, "[n]aloxone is a remarkably effective, inexpensive, and safe medication. It acts quickly, and has no addictive potential."<sup>166</sup> The US surgeon general has also emphasized the importance of naloxone to save lives from opioid-related overdose.<sup>167</sup> Equally important is the availability of SSPs.

Harm reduction should also include broader efforts to prevent harm, such as syringe services programs (SSPs). In addition to providing sterile needles and syringes to help reduce blood-borne infections, SSPs distributed more than 700,000 doses of naloxone, including refills, during a 12-month study period that captured the responses of 263 SSPs nationwide.<sup>168</sup> The study also found that more than 25% of respondent SSPs distributed naloxone to more than 1,000 persons in the past 12 months, and 29% of SSPs "ran out of naloxone or needed to ration their naloxone in the preceding 3 months." Naloxone distribution varied by region.

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## A. Continue to expand access to naloxone programs

All 50 states and the District of Columbia have enacted laws to support broad, unrestricted access to naloxone. This includes provisions to enable people to obtain naloxone directly from a pharmacist without a patient-specific prescription—referred to as a “standing order” authorization. In response to COVID-19, a number of states have taken even more steps to get naloxone into the hands of individuals at risk of overdose, their family members, and first responders. The AMA Opioid Task Force also recommends the provision of naloxone in a wide range of settings, including primary care settings, specialty care settings, and emergency departments to patients at risk of overdose.

**Prescribing naloxone to those at risk of overdose.** The AMA Opioid Task Force recommends that the decision to prescribe naloxone should remain within the purview of the patient and the physician. According to HHS, through increased prescribing and standing orders, naloxone prescriptions increased from 136,395 to nearly 600,000 between 2016 and 2018;<sup>169</sup> however, national data on patients to whom clinicians should consider prescribing naloxone show that less than 1% of these patients actually receive a naloxone prescription.<sup>170</sup> Data for 2019 shows more than 1 million naloxone prescriptions were dispensed.<sup>171</sup>

**Increasing access also requires removing barriers.** Barriers persist to ensuring patients who would benefit from naloxone can receive it. While pharmacies in nearly every state have the authority to dispense naloxone to patients without a patient-specific prescription, pharmacists report many barriers to doing so. This includes lack of time to educate patients, insufficient support from corporate managers, and a lack of pharmacist education and training.<sup>172</sup> Thus, while some national pharmacy chains have signaled strong support for naloxone education and distribution,<sup>173,174</sup> more work needs to be done to ensure that patients and others can readily access naloxone from their pharmacy.

Another key barrier is cost. A CDC study<sup>175</sup> found that in 2018, only 42% of naloxone prescriptions dispensed at a pharmacy “did not require out-of-pocket costs.” For the remaining naloxone prescriptions:

- 24.5% required out-of-pocket (OOP) costs of less than \$10
- 21.9% required OOP costs between \$10.01 and \$50
- 5.8% required OOP costs of more than \$50



The CDC found that Medicare required OOP costs for 71% of naloxone prescriptions, and Medicaid and commercial insurance required OOP costs 44% and 41% of the time, respectively. It is not clear how often these OOP costs prevented individuals from obtaining naloxone.

Several states have implemented low- or no-cost naloxone availability programs to increase patient access, especially during the COVID-19 pandemic. These include:

- An ongoing policy in New York<sup>176</sup> that provides naloxone at no cost through registered opioid overdose prevention programs and state copayment assistance of up to \$40 for naloxone
- Programs by the New Jersey Harm Reduction Coalition,<sup>177</sup> including a program that prioritizes free naloxone distribution for people who use drugs, people who have recently stopped using drugs, people returning home after incarceration, people leaving treatment, and their families, partners, friends, and roommates; and a program that enables individuals to receive naloxone through the mail after completing a brief online training and a request form
- Programs by the Ohio Harm Reduction Coalition,<sup>178</sup> including a mail-based Narcan and naloxone distribution program that provides free Narcan to Ohio residents who think they may be in a position to reverse an overdose during the COVID-19 pandemic; and Project DAWN (Deaths Avoided With Naloxone), Ohio's network of opioid education and naloxone distribution programs, which provides program participants with a take-home naloxone kit and educational training
- In Massachusetts, an initiative by the Winthrop Police Department<sup>179</sup> to offer survival kits to prevent overdoses and connect individuals to recovery resources during the COVID-19 pandemic that include naloxone; local resources to facilitate referrals to detoxification services, harm reduction services, MOUD, and recovery supports; COVID-19 safety information; and fentanyl safety information and, in some cases, testing strips
- Statewide naloxone distribution days in Pennsylvania,<sup>180</sup> which provided free naloxone at 95 locations (including state health centers and county/municipal health departments) to any Pennsylvanian who wanted it as part of the administration's ongoing effort to reduce opioid overdoses and get residents into treatment
- In Maine, shortly following her inauguration, Governor Janet T. Mills signed Executive Order #2 which authorized purchase and distribution of 35,000 doses of naloxone. Distributed through the Maine Naloxone Distribution Initiative, the medication was made available to any individual requesting it, although insured patients were encouraged to obtain a

prescription in order to obtain third party payment. Medicaid also covers naloxone without prior authorization. Over a fifteen-month period, the state purchased naloxone has been tracked and was responsible for 935 successful reversals.

In terms of cost, legislation can address cost-sharing barriers, and regulators can ensure that naloxone is not placed on prohibitively high cost-sharing tiers of health insurers' pharmacy benefits. Additionally, policymakers can and should ensure that other payer-imposed administrative barriers, such as prior authorization, are not delaying patients' access to naloxone and deterring individuals from filling prescriptions at the pharmacy counter. For example, states such as Colorado provide access to naloxone without prior authorization under Medicaid. This practice should be extended to commercial payers and adopted in every state.

Finally, life insurers may be adding to the barriers imposed by health insurers by inquiring about naloxone use in life insurance applications. The Colorado Division of Insurance issued a bulletin on January 31, 2020, explicitly prohibiting an insurer from denying insurance on the basis of an applicant's naloxone use:<sup>181</sup> "[A]n insurer cannot utilize information regarding the purchase of naloxone as part of evaluation of an application for insurance." We recommend all states issue similarly clear guidelines.

**RECOMMENDATION: States should increase access to naloxone by removing cost-sharing and administrative barriers for individuals seeking a prescription for naloxone for themselves or a family member or loved one; promoting and encouraging health care professionals to prescribe naloxone to patients who may be at risk of overdose—or their family members or friends; and supporting community-based harm reduction organizations in distributing no-cost naloxone in the community.**

## **B. Pursue comprehensive harm reduction efforts**

Life-saving harm reduction efforts extend far beyond the prescribing of naloxone. Especially in the midst of the COVID-19 pandemic, in which access to outpatient and inpatient rehabilitation and treatment centers has become notably more difficult<sup>182</sup> and feelings of isolation are on the rise, extending comprehensive harm reduction efforts across states is essential to ensuring care continuity and support at a time that is especially challenging for individuals with a substance use disorder. Broader harm reduction strategies include syringe services programs, pharmacy distribution of clean syringes, and new ways to target communication about safe practices.

**Syringe services programs.** Syringe services programs are community-based prevention programs that provide access to and disposal of sterile syringes and injection equipment. The CDC points out the numerous benefits of SSPs,<sup>183</sup> including reducing the risk of blood-borne infection, preventing outbreaks, and preventing viral hepatitis, HIV, endocarditis, and other serious health issues. These programs are increasingly being recognized as effective and safe harm reduction strategies to support individuals with an SUD.

SSPs are beneficial not only because they protect the public and first responders by facilitating the safe disposal of used needles and syringes, but effective SSPs also reduce stigma and provide critical bridges for individuals with an SUD to other important health services, including hepatitis C and HIV diagnosis and treatment, as well as MOUD. According to the CDC, “people who inject drugs who regularly use an SSP are more than five times as likely to enter treatment for a substance use disorder, and nearly three times as likely to report reducing or discontinuing injection as those who have never used an SSP.”<sup>184</sup> In addition, SSPs are uniquely positioned to provide culturally relevant services and provide outreach to persons at high risk for experiencing or observing an opioid overdose, and provide access to naloxone and educational information about treatment for SUDs. According to a 2020 study from the CDC, in 2019, 94% (n=247) of SSPs had implemented evidence-based overdose education and naloxone distribution programs, providing critical supports and services for individuals who visit SSPs.<sup>185</sup>

The COVID-19 pandemic has highlighted how SSPs are facing challenges in continuing operations, which puts individuals who rely on SSPs at risk. As part of its state recommendations concerning harm reduction,<sup>186</sup> the AMA recommends that states ensure continuity of syringe services programs, including provision of PPE. This includes expanding PPE priority to include harm

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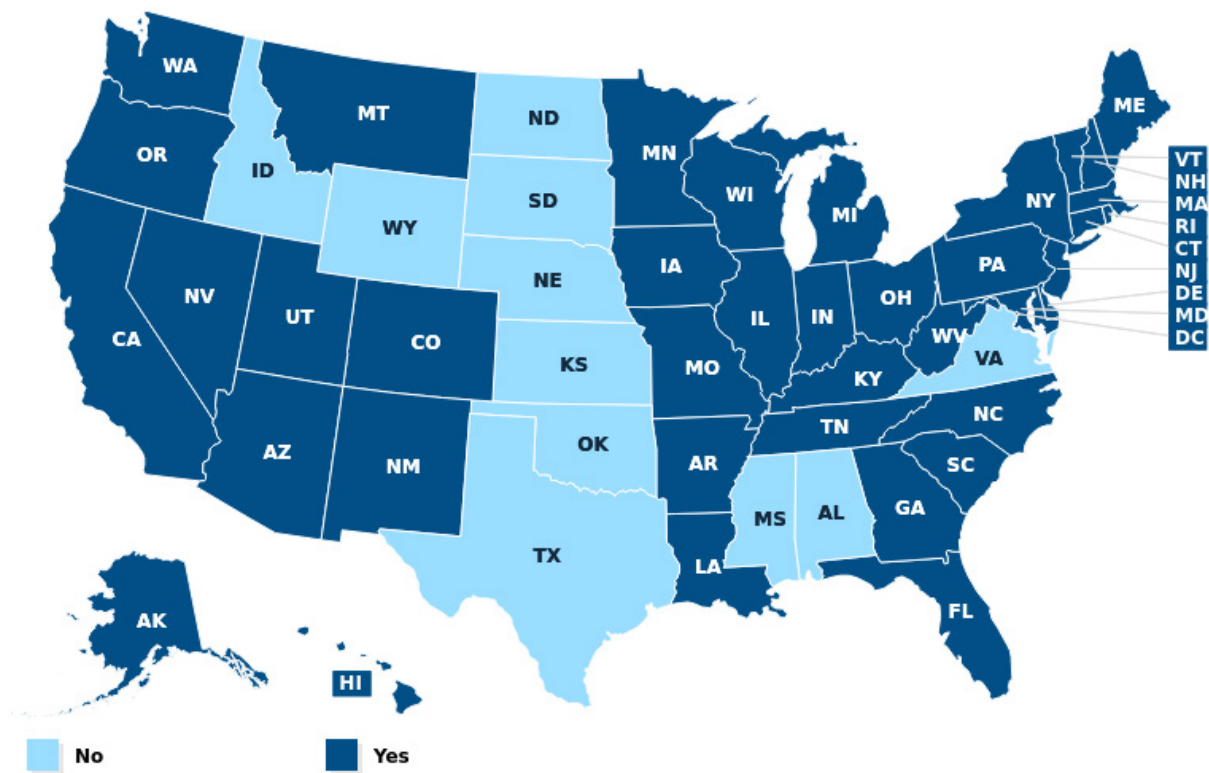
The AMA recommends that states ensure continuity of syringe services programs, including provision of PPE. This includes expanding PPE priority to include harm reduction organizations and other community-based organizations that provide services to people who inject drugs, to help protect against the spread of infectious disease.

reduction organizations and other community-based organizations that provide services to people who inject drugs, to help protect against the spread of infectious disease.

The AMA also recommends that states implement, as part of an executive order or other initiative, specific policies to increase access to sterile needle and syringe exchange services. An executive order issued by Maine Governor Janet Mills as part of her pandemic response removed restrictions in the state on sterile needle and exchange services to help reduce harms among people who inject drugs and protect against the spread of infectious disease. Under Executive Order 27, the state will no longer require during the national COVID-19 PHE a 1:1 exchange—allowing individuals to receive multiple sterile needles and exchanges.<sup>187</sup> The Order also allows for the mailing of SSP supplies in order to minimize the need for social distancing at the SSP locations.

While Maine provides a good example, 11 states still do not have any formal SSP.<sup>188</sup>

### Exhibit 23. Sterile syringe exchange programs, 2018. Kaiser Family Foundation



Source: [www.kff.org/hiv/aids/state%2Dindicator/syringe%2Dexchange%2Dprograms/?activeTab=map&currentTimeframe=0&selectedDistributions=has%2Dsyringe%2Dexchange%2Dprogram&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D](http://www.kff.org/hiv/aids/state%2Dindicator/syringe%2Dexchange%2Dprograms/?activeTab=map&currentTimeframe=0&selectedDistributions=has%2Dsyringe%2Dexchange%2Dprogram&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D).

There also is a long-term need to ensure that individuals who work in SSPs, as well as those who obtain supplies from SSPs, are not subject to arrest or prosecution for providing sterile needle and syringe supplies. This includes providing or possessing sterile or used needles, hypodermic syringes, or other injection supplies obtained from or returned to a program, including testing supplies for illicit substances. It also includes residual amounts of a controlled substance contained in a used needle, used hypodermic syringe, or used injection supplies obtained from or returned to a program.<sup>189</sup>

#### Exhibit 24. California's Pharmacy Access Bill

In late September, California Governor Newsom signed the Pharmacy Access Bill (AB 2077)<sup>190</sup> into law until January 1, 2026, which protects both pharmacists' and providers' discretion to provide hypodermic needles and syringes to individuals without a prescription, and an individual's right to possess such syringes for personal use without fear of prosecution.<sup>191</sup>

**Targeted messaging.** During the COVID-19 pandemic, states and SUD treatment providers have released flyers and guidance to people who use drugs on how they can safely use drugs during the pandemic and access harm reduction resources. Rhode Island's instructions include preventing overdose by having a friend check in, using one drug at a time and going slowly; stocking up on supplies such as naloxone, fentanyl testing strips, and clean syringes; trying to maintain social distancing with others; and trying not to share supplies.<sup>192</sup>

**RECOMMENDATION:** States should adopt laws and other policies to remove barriers to sterile needle and syringe exchange programs, including decriminalization of SSP supplies; and to ensure continuity of syringe services programs, including by expanding PPE priority to include harm reduction organizations and other community-based organizations that provide services to people who inject drugs to help protect against the spread of blood-borne infectious disease.

## VII. Improve monitoring and evaluation

Collaboration and sharing of timely data are critical for responding to the overdose epidemic our nation currently faces. According to the Bipartisan Policy Center, the federal government provided \$7.6 billion in funding in 2019 for a variety of opioid-related efforts ranging from treatment, recovery, and prevention to research and law enforcement.<sup>193</sup> This was a 3.2% increase from 2018, but as in previous years, the results of these efforts are unclear. Part of the reason is that there are insufficient data that can be used to help tailor meaningful intervention. With overdose deaths on the rise, we cannot let data collection delay action, but there are multiple areas for state-level improvement in collecting data as expeditiously as possible:

- Gather enhanced, standardized surveillance data of fatal and nonfatal overdose, including evidence of naloxone administration and referral to treatment.
- Increase data gathering to better address delivery of care by race, gender, age, ethnicity, income, and other factors that may point to inequitable distribution of care.
- Begin meaningful review of policies to help determine whether actions taken by state legislatures and state agencies have led to measurable impacts in reducing drug-related harms and improving access to care. Policies that have not helped should be revised or rescinded.



## A. Standardize data reporting

Standardized overdose surveillance data can be used to inform targeted drug-related prevention, treatment, policymaking, and harm reduction strategies. However, implementation of data-sharing programs and subsequent data visualization are complex and suffer from a lack of data standardization and quality standards, disparate overdose surveillance case definitions, and lengthy delays in data acquisition. Currently, national surveillance efforts include fatal overdose data; however, relying on fatality data alone can result in an incomplete picture of the ongoing and evolving overdose epidemic.<sup>194</sup> It is important to have data that show the evolution of the epidemic—from one driven primarily by nonmedical use of prescription opioids to one now fueled by illicitly manufactured fentanyl, fentanyl analogs, heroin, cocaine, and methamphetamine.<sup>195</sup> While these data tell us that policy interventions must shift, the data do not tell us where to target comprehensive prevention and treatment efforts. Timely, nationally representative data related to nonfatal overdoses currently do not exist. Effectively implementing optimal policies, prevention strategies, and interventions will require coordination of stakeholders and accurate, timely, and actionable information on both fatal and nonfatal drug-related overdoses and interventions.



**Need for consistency in nonfatal overdose reporting to inform public health interventions.** All 50 states have a system for mandatory case reporting to health departments in a timely manner, allowing state health departments to track potential outbreaks and rising epidemics. However, most states do not have laws or policies that require timely reporting of drug overdoses or that recognize adverse drug reactions and overdoses as reportable conditions. What gets reported with respect to nonfatal overdoses varies considerably with respect to who is required to report, what information gets reported, to whom the information must be reported, and the time interval for reporting.<sup>196</sup> Public health researchers have emphasized that “the provision of rapid, targeted interventions to overdose survivors as well as to that person’s friends and family members and highly affected areas may



be one of the best uses of scarce public health outreach resources. These interventions can be delivered by trained public health nurses, social workers, and peers in recovery as part of the health agency's ongoing programming or as a rapid response team specifically created to address the overdose crisis.<sup>197</sup> The CDC similarly recommends that "[t]imely data help improve coordination among health departments, community members, healthcare providers, public health, law enforcement, and government agencies and promote readiness for regional or multiple state overdose increases."<sup>198</sup> Maine's recently announced OPTIONS (Overdose Prevention Through Intensive Outreach, Naloxone and Safety) provides a behavioral health professional in each county to outreach to overdose survivors.

It also is critical to understand that the epidemic's effects vary by race, gender, age, ethnicity, income, and other factors. Just as clinical treatment regimens must be informed by the unique characteristics of each individual, so too must policies be tailored and targeted to ensure equitable interventions. For example, policy interventions to address nonmedical use of prescription opioids by youth likely are going to be different than policies to increase access to treatment for those in their 40s or 50s who use illicit fentanyl. As a first step, it is essential to capture the data for fatal and nonfatal overdose by race, ethnicity, age, gender, geography, and income. It is further essential to understand those groups' insurance status and whether they have sought and received treatment, including how much it has cost and whether the individuals have been subject to any utilization management protocols or other barriers, such as prior authorization or step therapy.

**RECOMMENDATION:** States should implement standardized systems to accurately monitor and evaluate overdose and mortality trends to provide equitable public health interventions that include comprehensive, disaggregated racial and ethnic data collection related to testing, hospitalization, and mortality associated with opioids and other substances.

**RECOMMENDATION:** States should require health insurance companies to report deidentified data on enrollees who have received treatment, length and type and cost of care (eg, residential, intensive outpatient, other outpatient), and whether those individuals have been required to go through any utilization management protocols as a condition of receiving treatment.

## B. Increase data surveillance and reporting

The CDC has implemented a new funding agreement, Overdose Data to Action (OD2A), that supports recipients in collecting in-depth data on drug overdoses, and in using those data to inform prevention and public health response efforts.<sup>199</sup> Funded recipients include state, territorial, county, and city health departments. OD2A builds on previous programs, including the “Enhanced State Opioid Overdose Surveillance (ESOOS),” which CDC notes are to “provide more timely and comprehensive data on fatal and nonfatal opioid overdoses and risk factors associated with fatal overdoses.” ESOOS grants have helped create State Unintentional Drug Overdose Reporting Surveillance (SUDORS) systems in several states.<sup>200</sup>

Multiple states were awarded federal grants for their ESOOS and created SUDORS programs. Rhode Island, for example, enhanced its reporting on the factors identified above,<sup>201</sup> but it is not clear how the comprehensive data are being widely used. Information from Iowa, Massachusetts, and Illinois suggest that the data are used across multiple agencies.<sup>202,203,204</sup> Promising efforts in Georgia and Ohio suggest that data showing spikes in overdose are transmitted to public health authorities to target interventions, but the extent to which these efforts have been statewide or led to long-term treatment is not clear.<sup>205</sup> CDC staff has presented on multiple areas of promise for SUDORS-type programs, but it is similarly unclear how states will sustain them due to their reliance on federal funding.

Another example of a program where data are being used to target interventions is RxSafe Marin,<sup>206</sup> a county-level, data-driven overdose prevention and education network that relies on data sharing and community-based engagement to bring together physicians, pharmacists, educators, law enforcement, and others in a broad-based effort. One example of its work



includes data-sharing agreements to help emergency medical technicians record when naloxone was administered to reverse an opioid overdose. The program effort led to weekly reports identifying where overdoses occurred and alerts if there were three or more overdoses in a day. The data-sharing agreements and county policies allow for follow-up contact with every patient who overdoses to link them with behavioral health services and treatment.

Another area of action has been the creation of dashboards to provide a snapshot of how the epidemic has impacted the state. Dashboards have been developed at regional, state, county, and community levels. Reviewing different dashboards, however, reveals wide differences in the types of data included, the types of data sources, frequency of data updates, and the data visualization methods used.<sup>207</sup> Some states, such as Colorado,<sup>208</sup> Florida,<sup>209</sup> Maryland,<sup>210</sup> and Vermont,<sup>211</sup> and even more regional jurisdictions<sup>212</sup> provide a wide range of information in their reports. For example, Colorado includes emergency department admissions, Florida highlights the use of PDMPs, and Vermont takes a scorecard-type approach. Each effort has merit and is likely the result of considerable resources, but on the surface, it is not clear how the different efforts positively affect timely surveillance or are linked to the broader health care and public health communities. The Georgia Department of Public Health, for example, has done an exemplary job of using syndromic surveillance to detail opioid-related harms throughout the state, including providing statewide updates during the COVID pandemic.<sup>213</sup>

**RECOMMENDATION:** States receiving federal grants to implement overdose-related action plans should be required to publicly report on the programs' progress, including whether and how they have partnered with medical societies and other stakeholders to ensure that the data obtained are provided to health care and public health professionals. Programs also should be required to publicly report how the data have been used to implement overdose prevention, treatment, and recovery-related efforts in the state.

### C. Monitor and evaluate policy

States must actively monitor and evaluate their policy and program initiatives to ensure that resources are being used efficiently and that interventions are effective in meeting their goals. Monitoring should include review of information on an immediate and ongoing basis to determine how an intervention is unfolding and whether policies should be adjusted to address unintended consequences. In some cases, midcourse corrections will be needed.

Evaluation should be done at set intervals, often at the midpoint and end of a demonstration program, or yearly for other types of interventions. Evaluation can help determine whether hypotheses about impacts are accurate and whether the related impacts can be attributed to the intervention after controlling for other independent factors, such as the COVID-19 pandemic that has changed the landscape in many unexpected ways.<sup>214</sup> While it appears that few states have initiated the kind of comprehensive policy reviews warranted by this epidemic, some state Medicaid agencies are monitoring and evaluating changes that have been implemented. COVID-19 has been an unexpected source of innovation, creating opportunities for states to assess and evaluate the impact of policies they adopted during the pandemic, to determine whether maintaining them in the long term is warranted.

- **West Virginia.** West Virginia has embedded in the Medicaid agency statisticians/data staff from West Virginia University who are helping to track the impact of policy changes adopted during the pandemic.
- **Virginia.** Virginia maintains a contract with Virginia Commonwealth University to evaluate the state's approach to SUD treatment, including through qualitative research such as focus groups on the impact of moving to telehealth during the COVID-19 pandemic, and ongoing data analysis.
- **Medicaid Outcomes Distributed Research Network (MODRN).** Through MODRN, a group of state Medicaid agencies and partner universities adopt a common data model, contribute to a common analytic plan, and conduct analyses locally on their own Medicaid data using standardized code developed by a data coordinating center. Finally, the state-university partners provide aggregate results, not data, to the data coordinating center, which synthesizes the aggregate findings from multiple states for reporting. MODRN's first project assessed OUD treatment quality and outcomes in Medicaid, working with nine states (Kentucky, Maryland, Michigan, North Carolina, Ohio, Pennsylvania, Virginia, West Virginia, and Wisconsin) to inform policy decisions on coverage of OUD treatments in Medicaid. MODRN analyzed 20 access, quality, and outcomes measures and found significant variation in the access to and quality of treatment for OUD across Medicaid programs.<sup>215</sup>

**RECOMMENDATION:** States should use federal and state data to assess the results of their SUD, pain, and harm-reduction policies to identify and expand successful programs and to make appropriate midcourse corrections where needed.

## VIII. Conclusion

**This roadmap covers a lot of terrain and offers many recommendations for further action:**

**Policy enactment has been extensive.** Policymakers and regulators across the country and in Washington, DC, have spent considerable time, energy and resources on ending the nation's drug overdose epidemic. This epidemic has led to the passage of hundreds of new laws, regulations, clinical guidelines, and national recommendations. Some are evidence-based, such as increasing access to MOUD, enforcing mental health and substance use disorder parity laws and enhancing access to harm reduction services, including continued emphasis on access to naloxone to help save lives from opioid-related overdose.

**Policy implementation remains elusive.**

Even as access to evidence-based treatment for OUD has been a major focus, much more work remains to *ensure* access to treatment for OUD. Putting policies into action requires additional steps, which is why the bulk of recommendations in this report focus on tangibly removing barriers to evidence-based treatment for OUD and enforcing state and federal parity laws. Health insurance companies and other payers must change their practices or patients will continue to be harmed.



Moreover, while some policymakers have recognized the need to increase access to alternatives to opioids, few actions have occurred to make access to ALTOs a reality. In addition, while naloxone has saved the lives of tens of thousands of Americans, comprehensive harm reduction efforts also must include increased access to sterile needle and syringe services programs.

**Policies must be examined.** This report highlights the need for thorough evaluation and commitment by states to further policies that work and to revise or rescind policies that are harmful to patients. This includes ensuring that policy evaluation and data collection directly address long-standing health inequities. Specifically, policies must be carefully examined to

determine whether they help improve patient outcomes and reduce mortality. If they don't accomplish these goals, they need attention.

**There are many examples to learn from.** The AMA–Manatt analyses reveal multiple areas in which there have been positive outcomes and promising results. This includes the development of hub-and-spoke models of care, community-based naloxone access efforts, and reforms in state Medicaid agencies to improve access to multidisciplinary, multimodal pain care. The 2020 roadmap identifies many initiatives that all states can learn from and potentially adopt. This includes providing MOUD to those in justice-involved settings, removing stigma for OUD and pain, and using data to meaningfully reduce longstanding health inequities.

**Demonstrating program success is a work in progress.** This report identifies many areas in which additional work can be done to further increase access to evidence-based care, including pilot projects being done by emergency departments to assess and refer patients to treatment for OUD. Because many successful pilot programs are dependent on grant funding, we urge greater attention to program evaluation to help illuminate which pilot programs that may be helping hundreds of people today can be scaled up as national models that could help hundreds of thousands tomorrow.

**All stakeholders can take action.** This national roadmap provides recommendations that may not be easy to implement, but they are necessary to help end the epidemic. There are recommendations that can be applied by governors, state legislators, attorneys general, insurance commissioners, Medicaid officials and other policymakers. Many of the recommendations also could be implemented voluntarily by health insurance companies, PBMs and other stakeholders if they were so inclined or encouraged to do so. Patients with an SUD and patients with pain need help. The overdose epidemic is more deadly than ever. Physicians and other health care professionals must continue to take action, and the AMA stands ready to work with all stakeholders to implement these recommendations and help America's patients.



## Endnotes

- <sup>1</sup> This report discusses in detail the need to change terminology from “opioid epidemic” to “drug overdose epidemic.” There are several reasons for doing so, including the fact that what may have begun a decade ago as an epidemic of opioid misuse, overdose, and death related to prescription opioids has now become a much more complicated and deadly epidemic due to illicitly manufactured fentanyl, methamphetamine, cocaine, and heroin. Harm related to prescriptions has decreased slightly but remains far too high. The terminology is critical to ensure that policy interventions focus on the larger epidemic rather than primarily *prescription* “opioids.”
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