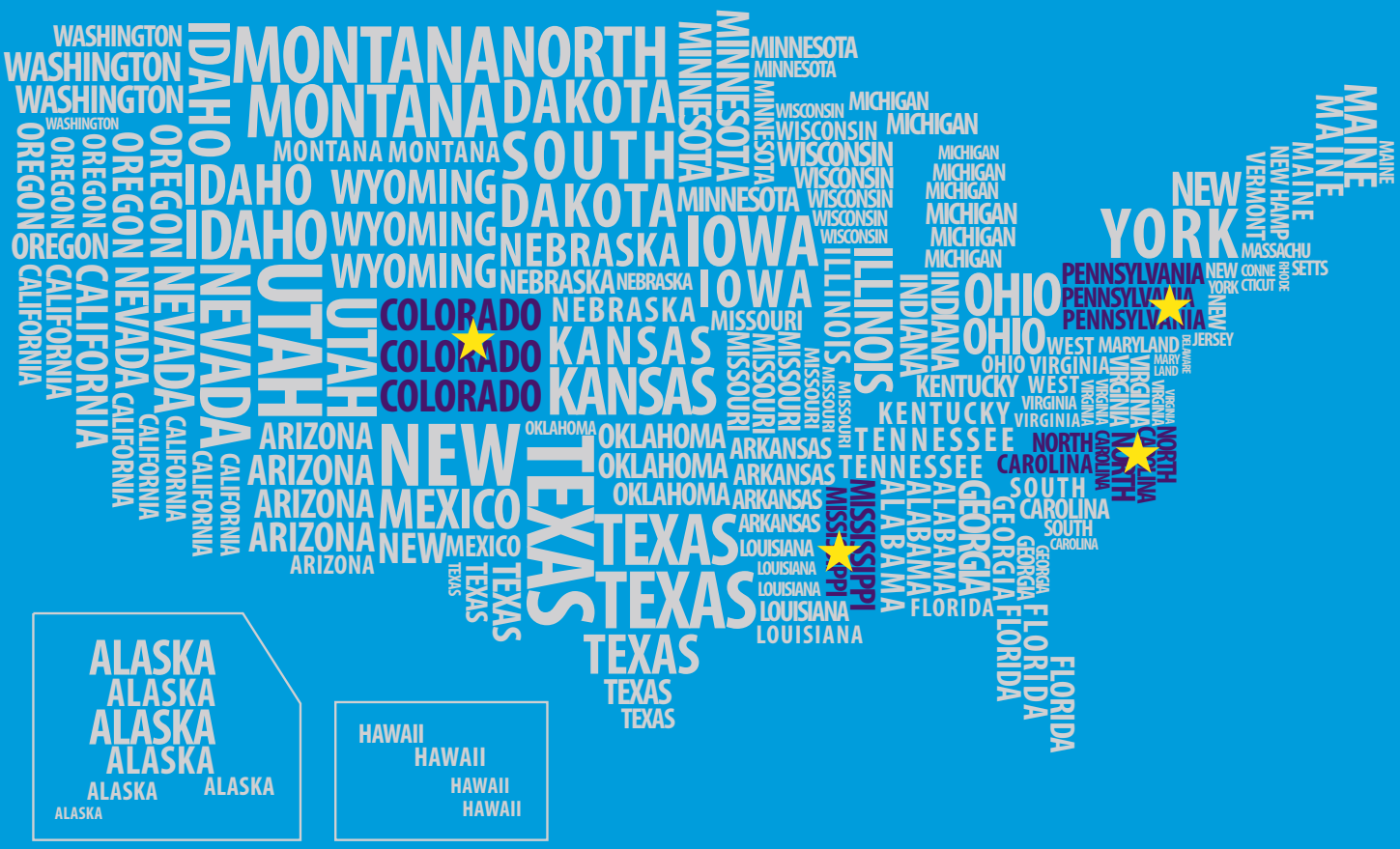

National Roadmap on State-Level Efforts to End the Opioid Epidemic

Leading-edge Practices and Next Steps

SEPTEMBER 2019

AMA AMERICAN MEDICAL ASSOCIATION

manatt

About Us

About the AMA

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I. Introduction

The American Medical Association (AMA) and Manatt Health recently undertook an in-depth analysis of the response to the opioid epidemic by 4 states: Colorado, Mississippi, North Carolina, and Pennsylvania. The analysis focuses on state efforts in 6 key areas to identify best practices and provide a roadmap for all states to follow in order to increase access to high-quality, evidence-based treatment for persons with a substance use disorder (SUD) or who need comprehensive, multidisciplinary, multimodal pain care, and to increase access to naloxone to save lives from overdose. The analysis also highlights the need to evaluate state-level data and state policies in order to determine what is working while amending actions and policies that may be having unintended consequences.

Before turning to the 6 key areas where states can act, we highlight 4 key themes that emerged from our work:

- **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 impeded access varies considerably.

- **Medicaid is leading the way.** Medicaid is on the front lines and often provides more comprehensive care for substance use disorders than the commercial insurance market does; there may be opportunities to extend Medicaid successes to commercial coverage. Expanding Medicaid would help even more patients.

- **Grants are helpful, but long-term implementation needs long-term, sustainable funding.** Many best practices that are helping save lives are grant-funded and need long-term, sustainable funding to continue benefiting patients. Without reliable funding streams, programs that help save lives will simply go away.

- **The process of evaluating what works is just starting.** Some states have undertaken efforts to evaluate current policies and programs to determine what is actually working; most of these evaluations are just beginning. Comprehensive analysis is essential in order to focus resources on successful interventions—and to revise or rescind policies that are having unintended consequences.

The 4 state spotlights highlight lessons learned from Medicaid directors, insurance commissioners, and other state officials, but many of those lessons are relevant for governors, state regulators, attorneys general, federal policymakers, and other public- and private-sector leaders who drive states' responses to the epidemic. We also should note that many of our findings are most relevant for patients with either Medicaid or state-regulated commercial insurance coverage. Individuals without affordable coverage are very unlikely to receive sustained treatment. This means that states that have expanded Medicaid coverage to low-income adults are, at baseline level, far ahead of those that have not expanded in terms of addressing this epidemic. **We urge all states to expand their Medicaid programs as allowed under the Affordable Care Act (ACA) as a key step in addressing the epidemic.**

"We are at a crossroads in our nation's efforts to end the opioid epidemic. It is time to end delays and barriers to medication-assisted treatment (MAT)—evidence-based care proven to save lives; time for payers, PBMs and pharmacy chains to reevaluate and revise policies that restrict opioid therapy to patients based on arbitrary thresholds; and time to commit to helping all patients access evidence-based care for pain and substance use disorders. Physicians must continue to demonstrate leadership, but unless and until these actions occur, the progress we are making will not stop patients from dying."

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

Exhibit 1. State Officials Recognize the Need to Increase Access to Treatment

"If even one person is delayed access to the treatment they need, it is one person too many."

Pennsylvania Governor Tom Wolf

"Addressing this epidemic will require an ongoing, sustained effort comprised of multiple strategies and with coordination and partnership across a wide range of stakeholders including law enforcement, education, health care, policymakers, philanthropy, advocates, and the business community. While we have made progress in addressing this crisis, we have much more work to do."

Mandy K Cohen, MD, MPH, and Susan M Kansagra, MD, MBA, North Carolina Department of Health and Human Services

"Far too many Mississippi families and communities have suffered the devastating effects of opioid and heroin use disorder. . . . We hope to inspire Mississippians to work together to build healthier communities by understanding the dangers of opioids, learning the signs and symptoms of addiction, and finding out about treatment for themselves or people they know who may be suffering."

Diana Mikula, executive director, Mississippi Department of Mental Health

"Right now, we have a 90% treatment gap for patients with substance use disorders. Theoretically, this situation would be similar to a cancer patient going to a treatment center and being told, 'Sorry, we can only give treatment to 1 out of 10 people.'"

Rob Valuck, director, the Colorado Consortium for Prescription Drug Abuse and Prevention

This national roadmap highlights 6 key areas where regulators, policymakers, and other key stakeholders can take action.

- **Access to evidence-based treatment for opioid use disorder.** Remove prior authorization and other barriers to medication-assisted treatment (MAT) for opioid use disorder—and ensure MAT is affordable.
- **Parity enforcement.** Increase oversight and enforcement of mental health and substance use disorder parity laws.
- **Network adequacy/workforce enhancement.** Ensure adequate networks that allow for timely access to addiction medicine physicians and other health care professionals; this includes payment reforms, collaborative care models, and other efforts to bolster and support the nation's opioid use disorder treatment workforce.
- **Pain management.** Enhance access to comprehensive, multidisciplinary, multimodal pain care, including non-opioid and non-pharmacologic pain care options.
- **Access to naloxone.** Reduce harm by expanding access to naloxone and coordinating care for patients in crisis.
- **Evaluation.** Evaluate policies and outcomes to identify what is working, so as to build on the most successful efforts, and also to identify policies and programs that may need to be revised or rescinded.

II. Expand Access to MAT by Removing Barriers to MAT and Enhancing Affordability

Health care experts and researchers agree that medication-assisted treatment (MAT) is proven to help maintain recovery and prevent death in patients with opioid use disorder (OUD). The surgeon general's "Spotlight on Opioids" report calls MAT the "gold standard" of treatment for OUD.[1] Patients who use MAT to treat their opioid use disorder remain in therapy longer than people who do not, and they are also less likely to use illicit opioids. MAT helps decrease overdose deaths and reduce the transmission of infectious diseases, including HIV and hepatitis C. FDA-approved MAT for OUD includes buprenorphine, buprenorphine-naloxone combination products, naltrexone, and methadone.

Despite strong evidence that MAT is the most effective treatment option for many individuals with OUD, barriers to MAT persist, including inadequate provider networks, stigma that keeps some patients and providers from utilizing MAT, high cost-sharing for MAT, and prior authorization requirements.

When a patient is ready to begin MAT, barriers such as prior authorization should not delay or prevent care. Such administrative delays could make the difference between recovery and continuation of opioid-related harm or even death by overdose. There is no medical or policy need that justifies delaying or denying access to MAT—particularly during an epidemic.

Exhibit 2. 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."[2]

Jerome M Adams, MD, MPH, vice admiral, US Public Health Service surgeon general

Reducing MAT barriers in Medicaid. All states should take notice of the growing practice among Medicaid agencies of reducing prior authorization requirements for MAT. Three of the four spotlight states have reduced prior authorization requirements. For example, North Carolina and Pennsylvania Medicaid have eliminated prior authorization for leading forms of MAT and used federal grants to provide training and support to providers who offer MAT services to patients.

Reducing MAT barriers in commercial insurance. State insurance commissioners and other state leaders have been working directly with payers to remove administrative barriers to MAT in some states, notably Pennsylvania. While many payers in other states maintain that they have removed prior authorization for MAT, questions of accountability remain. We urge insurance regulators not only to secure public commitments from payers in their state, but to work with the medical community and patient advocates to evaluate whether the payers' promises are reflected in daily practice.

- **Forging voluntary agreements.** On October 12, 2018, Pennsylvania announced[3] that all major commercial insurers in the Commonwealth would eliminate prior authorization requirements for most forms of MAT and cover it on the lowest patient cost-sharing tier of the pharmacy benefit, building on a practice that had previously been adopted in the Commonwealth's Medicaid program. This agreement between the governor and the 7 largest payers serves as a national model for other states, illustrating that payers can voluntarily agree to end a practice that only serves to prolong the epidemic. At the same time, evaluating payer compliance is essential.

- **Committing to specific policies.** In November 2018, Blue Cross Blue Shield of North Carolina (BCBSNC) announced[4] that it was eliminating prior authorization for all of its preferred buprenorphine products, representing 96% of all buprenorphine-based MAT products. The announcement stemmed from BCBSNC's involvement in a state-based payers' organization, which has reported more broadly that "most insurers in North Carolina" are "streamlining or eliminating prior authorization," though other insurers have not been as specific about their policies.

Expanding the role of attorneys general and state legislatures in reducing MAT barriers. Attorneys general can play an important role in using their offices to remove barriers to care. For example, the New York attorney general reached settlement agreements in New York with Anthem, Cigna, and Empire Blue Cross Blue Shield to end prior authorization for MAT.[5] And the California attorney general is urging all California payers to eliminate prior authorization for MAT.[6] It likely will take the ongoing engagement of insurance regulators to ensure compliance.

Legislative initiatives to remove barriers to MAT. A few leading states also have taken steps to remove prior authorization for MAT in the commercial market through legislative initiatives, including by Maryland in 2017; Arizona and Illinois in 2018; and Arkansas, Colorado, and Washington in 2019. Other states have taken an initial step but could go further. For example, in May 2018, Colorado adopted a package of laws to address the epidemic, including beginning to reduce prior authorization barriers to MAT; allocating funds to expand the workforce of physicians and other health care professionals in rural and underserved areas; and planning to open up Medicaid coverage of substance use disorder (SUD) treatment in residential settings. In 2019, multiple state legislative efforts are underway to remove prior authorization for MAT, and at least 10 states have successfully done so. Some states have enacted comprehensive legislation that removes prior authorization for MAT and also ensures that MAT options are on the lowest cost-sharing tier.[7] Other states have limited efforts to Medicaid.[8] In all, more than a dozen states have pursued legislation and other policy initiatives to remove barriers to treatment for OUD.[9] Yet, 2019 also saw multiple efforts fail as a result of opposition by insurers.[10]

III. Enforce Mental Health and Substance Use Disorder Parity Laws

Meaningful oversight and enforcement of mental health and substance use disorder parity are critical to reversing the opioid epidemic. SUD treatment is an essential health benefit (EHB) under the Affordable Care Act (ACA) for individual and small-group coverage. Moreover, the Mental Health Parity and Addiction Equity Act (MHPAEA) requires that when mental health or SUD benefits are covered, they be covered equally with physical health services. Unfortunately, mental health and SUD parity compliance is clearly still a work in progress across all public coverage programs as well as commercial insurance—despite the MHPAEA having been enacted in 2008.

Enforcing parity through active oversight and market conduct examinations. Many state insurance regulators are undertaking market conduct examinations to supplement other regulatory tools used to assess parity compliance in the commercial market. Market conduct examinations typically involve review of policies, procedures, and claims-handling to determine if insurers are meeting their obligations in all 3 areas. Market conduct exams can support enforcement of parity laws and protect consumers—and regulators can take such action using their current oversight authority. In those states where regulators are using market conduct exams to evaluate parity compliance, the results so far suggest that parity violations are common. Steps that states are taking to oversee and enforce parity requirements include:

- **Developing new tools to examine insurer conduct.** The Pennsylvania Insurance Department (PID) is developing new templates and tools to make parity standards as transparent as possible and to identify cases where appropriate standards are not being applied in a compliant manner.

- **Publishing the exam findings.** PID recently published a market conduct examination that detailed one insurer's multiple parity violations with respect to SUD medical and pharmacy claims. This included findings that the health insurer imposed treatment limitations not in parity with medical/surgical benefits, including "limiting the scope and duration of treatment" of mental health and SUD claims "more stringently than medical/surgical benefits."

- **Requiring corrective action.** The PID exam report required the company to "review and revise internal control procedures to ensure compliance with the mental health and

substance use disorder parity compliance requirements of [federal and state law]." The next step in the typical market conduct exam process is for the company to agree on a corrective action plan and, in some cases, pay a civil penalty.

- **Continuing to monitor compliance.** Reexaminations are also a common tool to ensure corrective action has been taken. As the PID and other state DOIs move forward to complete market conduct examinations of a state's leading insurers, it is essential to refine DOI analytical tools and examination procedures to provide examples for other states exploring strong evaluation and enforcement actions.

- **Ensuring thorough examinations.** The Colorado Division of Insurance (DOI) was not satisfied with the proposed findings on parity in market conduct examinations submitted by its contracted examiners. The Colorado insurance commissioner rejected the proposed findings and has indicated that further examinations and other follow-up will be necessary to ensure that the DOI is asking all the right questions in assessing parity compliance.

- **Enhancing the public's ability to report violations.** Colorado enacted a 2018 law establishing an office of the ombudsman to assist state residents in accessing behavioral health care and requiring the DOI to report on compliance with mental health and substance use disorder parity laws. Colorado is providing an excellent example of doing what is necessary to thoroughly evaluate and enforce mental health and SUD parity.

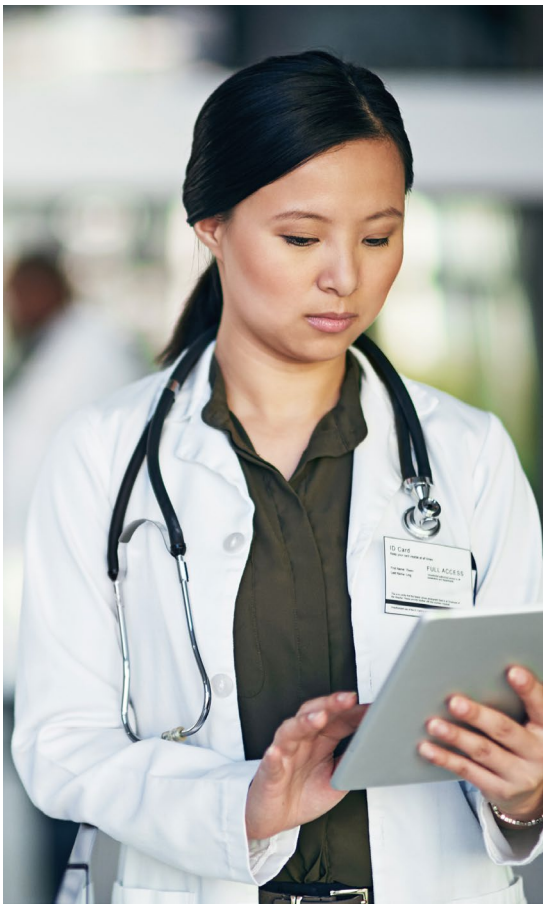
Exhibit 3. Center on Addiction Finds Compliance With the MHPAEA Is Lacking[11]

- Over half the states offered ACA plans in 2017 that did not comply with the ACA's requirements for coverage of SUD benefits. This is a slight improvement from the 2017 EHB Benchmark Plans, over two-thirds of which were determined to be noncompliant.

- Twenty percent of the states offered ACA plans in 2017 that violated parity requirements. Compliance with parity was virtually unchanged, as 18% of the 2017 EHB Benchmark Plans contain parity violations.

- Plan documents continue to lack transparency and specificity about covered SUD benefits. Ninety percent of the 2017 EHB Benchmark Plans were identified as lacking sufficient information about SUD benefit coverage; 92% of states also offered ACA plans in 2017 that were lacking in this information.

Strengthening review procedures. In several of the states that have not initiated market conduct examinations, state insurance departments have obtained federal grants to conduct a thorough review of their rate and form review processes with respect to mental health parity. The Mississippi Insurance Department (MID) is conducting a comprehensive review of its procedures for reviewing health insurance issuer policy forms, summary plan descriptions, certificates of coverage, and other plan documents to assess their compliance with the MHPAEA. While the MID's efforts are not complete, its work offers a roadmap for comprehensive analysis and review to measure parity compliance. It also illustrates how federal grants can provide the foundation for further regulatory work, which typically requires a combination of state resources and insurer reimbursements for examination costs.



The North Carolina Department of Insurance is engaged in a similar process, while other states, including Washington,[12] have issued comprehensive data calls to carriers on their parity practices. Finally, the National Association of Insurance Commissioners' Market Conduct Handbook is being updated to provide better guidance to states on assessing parity compliance.

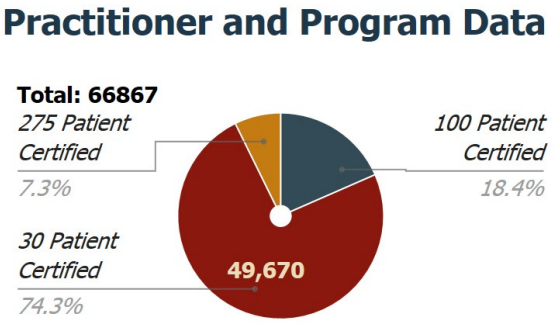
Enforcing parity under Medicaid. Some Medicaid agencies also are ramping up enforcement of parity requirements. New Hampshire, for example, has adopted a multipronged strategy to assess, monitor, and strengthen parity, including by requiring plans to submit information about limitations imposed for each behavioral health, substance use disorder, and medical/surgical service, as well as narrative responses to questions designed to ensure procedures are in place to achieve parity. The state reviewed the responses and actively worked with plans to address any gaps, requiring and recommending subsequent clarifications and changes to policy. To ensure that patients and providers could provide input into the review, the state held public meetings on the topic of parity and established a dedicated email account to which people could send parity concerns. Notably, New Hampshire views its parity work as "far from over" and has a specific plan for ongoing compliance and review activities.

IV. Enforce Network Adequacy Requirements to Ensure Timely Access to Care

In addition to enforcing mental health and SUD parity requirements, Medicaid officials and insurance regulators can support efforts to increase capacity and to establish and enforce measurable network adequacy requirements to ensure that patients in need of OUD treatment have timely access to addiction medicine physicians and other health care professionals who treat OUD and mental disorders.

Measuring network capacity. A critical first step in ensuring timely access to qualified providers is to determine the current capacity of provider networks to treat enrollees with OUD. To help determine the total number of potential OUD patients who could be cared for in a network, insurance regulators could require insurers to identify how many physicians are currently able to provide buprenorphine (a common form of MAT) in-office for the treatment of OUD, how many patients those physicians can treat, and how many patients they currently are treating. That is, a network may appear adequate on the surface, but if the providers are not accepting new patients, then additional work is needed to ensure patients have access to an addiction medicine professional.

Exhibit 4. SAMHSA National Data on Waivered Health Care Professionals[13]



The federal waivers physicians must obtain to prescribe buprenorphine in-office for the treatment of OUD specify whether the physician (or physician assistant or nurse practitioner, in some cases) can treat 30, 100, or 275 patients, making it easier to assess the total number of patients who potentially could be served by the waivered physicians in a network. Regulators then can work with insurers to learn precisely how many of those MAT providers are actively seeing patients with OUD, and at what level. Furthermore, it is important to know how many providers can treat patients with methadone for opioid use disorder. Methadone treatment for OUD is available only in federally certified Opioid Treatment Programs.

A Formula to Begin the Analysis of a Network's Capacity to Treat Patients With OUD

For example: Health Insurance Company A has 30 addiction medicine physicians in its network. Only 25 provide MAT, including buprenorphine. Of those 25 providers, 15 are certified to provide care for up to 30 patients, 5 are certified to treat up to 100 patients, and 5 are certified to treat up to 275 patients. The network capacity of Health Insurance Company A, therefore, theoretically would be to treat up to 2,325 patients with MAT.

The analysis of the network is not complete, however, because the regulator could ask Health Insurance Company A to specify how many patients those providers are actually seeing—and how many new patients they are willing to treat. These numbers may or may not add up to 2,325.

Supporting collaborative efforts to increase network capacity. The analysis above will provide regulators—and insurers—with a breakdown of how many patients can be seen in each insurance company product. If the analysis shows that a network does not have sufficient capacity, the regulator can work with the insurer on a corrective action and access plan. If the analysis shows that the network is sufficient, but that physicians are not accepting new patients, regulators and insurers can and should work with physician organizations to identify the specific reasons why physicians are not treating up to the top of their waiver—and how those barriers can be overcome.

Combine front-end rate and form reviews with back-end market conduct examinations. A robust network adequacy program starts with "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. 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.

Building infrastructure to support MAT providers. At the same time, a common problem that states may face with regard to capacity and workforce is a lack of adequate infrastructure to support physicians and other MAT providers as they attempt to shift elements of their practices in order to be able to care for patients with an SUD. To support physicians and other providers who offer MAT and encourage them to treat to the top of their capacity, many states have adopted systematic statewide approaches to ensuring that frontline providers have the resources they need through the **"hub and spoke" model** or similar models. The hub-and-spoke model was 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. Several other states now have adopted or modified the model. For example:

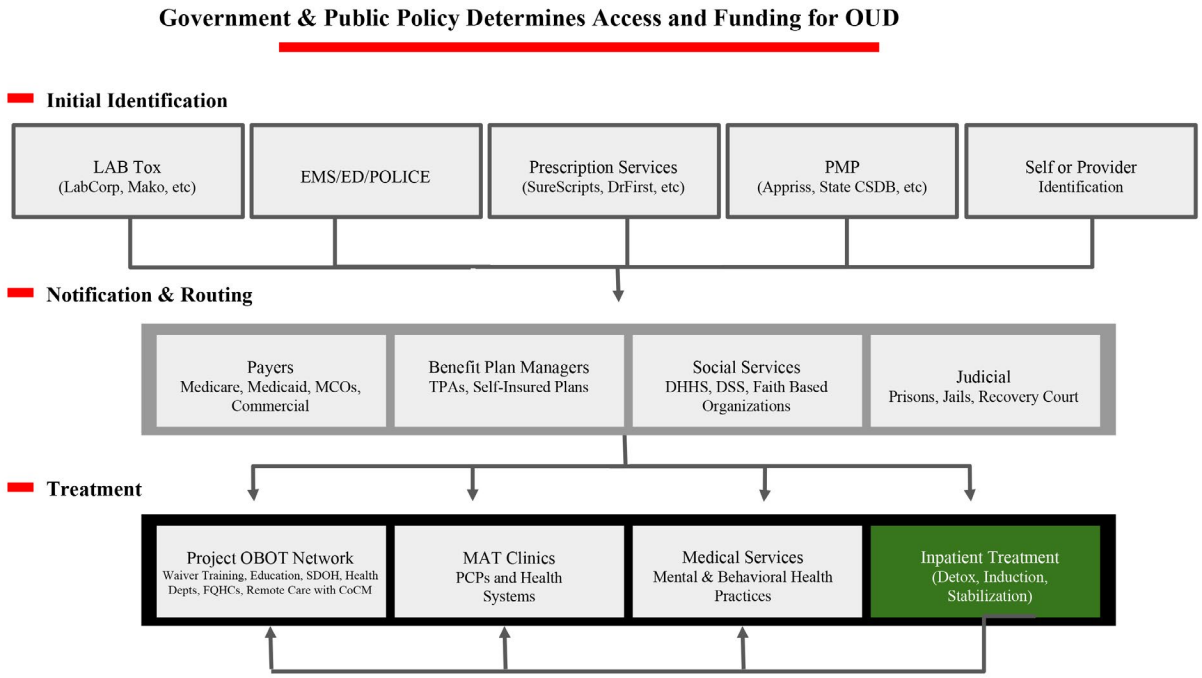
- **Centers of Excellence in Pennsylvania.** Pennsylvania used state behavioral health and Medicaid funding in 2015 to launch 45 Centers of Excellence (COEs) on OUD treatment. They are used to reduce gaps in services and better support frontline providers in treating patients—regardless of the patients' source of coverage or whether they are insured—with OUD. The COEs provide integrated behavioral and primary care services, including MAT, emphasizing a whole-person approach to care. Using a hub-and-spoke model, each COE includes a designated health center (the hub) charged with providing MAT and care coordination via a team of health care providers, certified recovery peer specialists, and navigators. The hub also offers support to primary care physicians and other community-based providers (the "spokes") treating people with OUD.

Exhibit 5. Pennsylvania Centers of Excellence Improve Treatment Results

In 2017, the 45 COEs in Pennsylvania were able to engage 71% of the beneficiaries whom they saw in treatment, and 62% remained in treatment for at least 30 days. Comparatively, in 2014, Medicaid data indicate that only 48% of individuals with SUDs received treatment, and only 33% of them were engaged in care beyond 30 days.[14]

- **Project OBOT in North Carolina.** The North Carolina Medical Society has developed a collaborative community-based model that is similar to the hub-and-spoke model. Project OBOT brought together a coalition of organizations including the Governor's Institute, the North Carolina Association of Local Health Directors, LabCorp, The Recovery Platform, the UNC Gillings School of Global Public Health, Project Echo, Appriss, and Mountain Area Health Education Center. They promote collaborative care coordination by working with physicians and other providers to ensure treatment plans include information from all providers, as well as by leveraging technology to increase access to care.[15] Project OBOT also is working with recovery courts to include them in the collaborative care model. Project OBOT is one of the first state medical society efforts to directly coordinate collaborative community-based care with local physicians serving as the hub, and the medical society helping build partnerships to develop the "spokes."

Exhibit 6. Government & Public Policy Determines Access and Funding for OUD



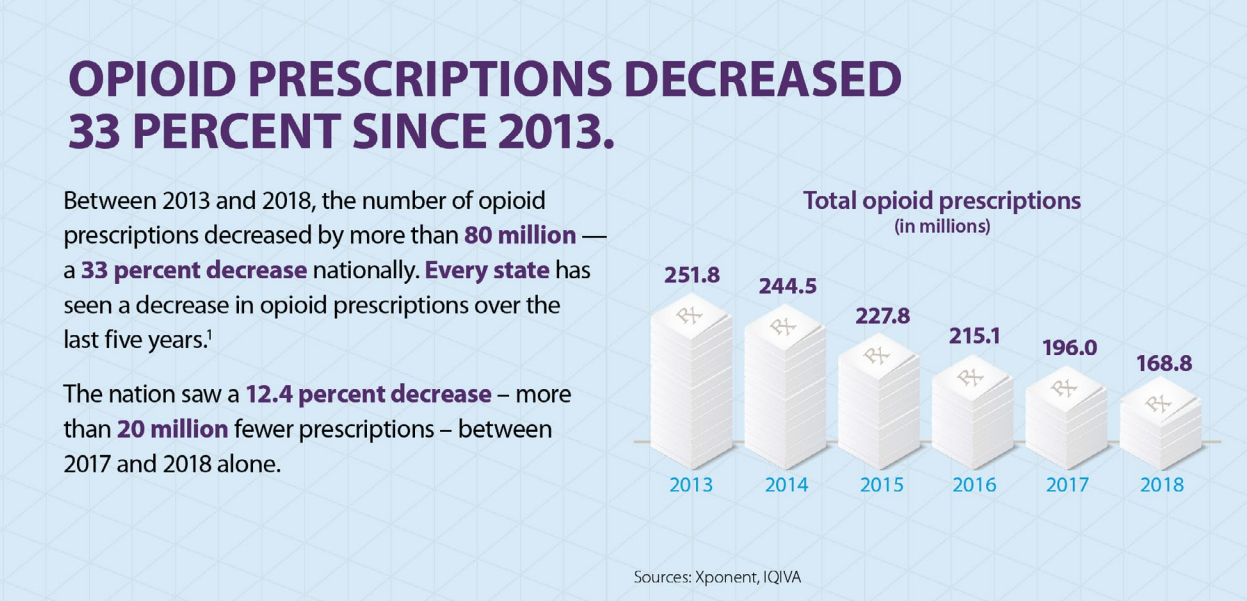
Expanding access to treatment in Medicaid. To expand access to treatment under Medicaid, 21 states have obtained federal Medicaid waivers of an otherwise applicable federal ban on using Medicaid funds to cover mental health and SUD residential treatment services in facilities with more than 16 beds.[16] For example, under a recently approved 1115 SUD waiver, North Carolina can now use Medicaid funds to finance stays delivered in institutions of mental disease (IMDs) for more than 15 days in a month, which expands access to residential treatment services for Medicaid beneficiaries. The federal waivers also include requirements to expand other services to cover the full continuum of needed services. From October 2019 to September 2023, states also will be able to cover SUD treatment services provided in an IMD for up to 30 days a year using a more streamlined federal approval process under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. Notably, both the waiver and the streamlined "State Plan" options require residential facilities to provide or offer access to MAT.

V. Improve Access to Comprehensive Pain Care

As physicians and patients work to reduce opioid-related misuse, millions of Americans still have chronic pain and require help. In 2016, the latest year for which data are available, the Centers for Disease Control and Prevention (CDC) estimates that 20.4% (50.0 million) of US adults had chronic pain and 8.0% of US adults (19.6 million) had high-impact chronic pain.[17] As policymakers and prescribers continue to decrease access to opioid analgesics to treat pain, it is vital to expand access to non-opioid pain management strategies, including non-opioid prescription medications and behavioral, cognitive, restorative, and interventional therapies.

Tailoring pain treatment to patients' needs. Even prior to the nation's extensive policymaking to restrict the prescription of opioid analgesics, physicians and other health care professionals were making more judicious prescribing decisions, leading to a 33% decrease in the prescription of opioid analgesics between 2013 and 2018.

Exhibit 7. Nation's Opioid Supply Began to Decrease Prior to Policy Interventions



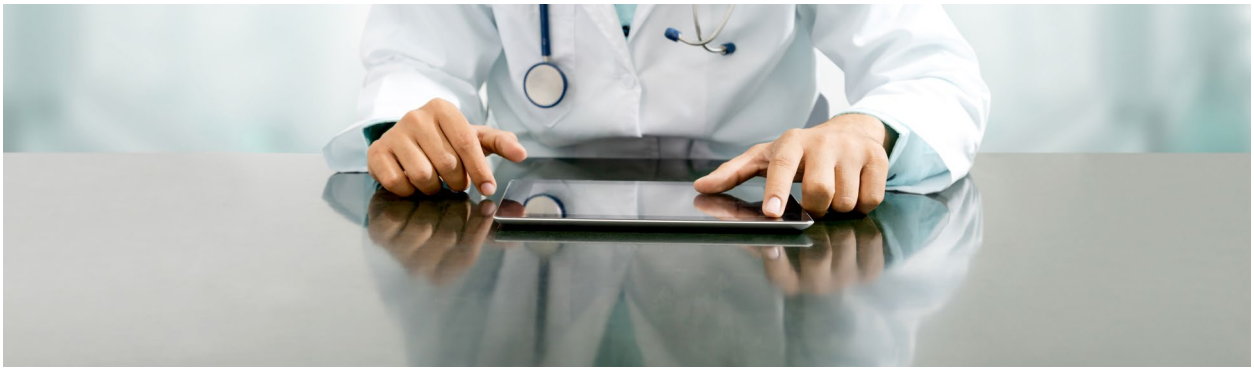
State laws and national guidelines, in combination with payer, pharmacy, and pharmacy benefit manager (PBM) restriction policies, have contributed to further reductions. For example, in 2016 the CDC issued guidelines on opioid prescribing that suggested dosage and duration thresholds, as well as limits on and tapering of drug dosage.[18] While the guidelines were meant to be voluntary and advisory, many policymakers and insurers incorporated them into laws, regulations, and policies.[19] Unfortunately, however, there is growing evidence that the abrupt termination of a patient's prescription opioid medication, or nonconsensual tapering, can have unintended consequences, including increased pain, use of illicit opioids, or even in some instances patient suicide.

As a result of both growing reports of patient harms and ongoing physician advocacy, on April 9, 2019, the FDA issued a special safety announcement emphasizing the potential harm to patients who are receiving opioid therapy for pain and forced to taper or discontinue that therapy.[20] The CDC followed the next day with a letter clarifying that "[t]he Guideline does not endorse mandated or abrupt dose reduction or discontinuation, as these actions can result in patient harm."[21] Shortly thereafter, the CDC published a much more formal clarification in the *New England Journal of Medicine*.[22]

The guidelines have been misapplied so widely, however, that it will be a challenge to undo the damage, which has also included nonconsensual tapering and patients being denied their prescriptions. There is a pressing need for regulators and policymakers to reevaluate current policies' effects on patients and ensure that formularies and benefit designs support comprehensive, multimodal, multidisciplinary pain care. The AMA is urging a detailed regulatory review of formulary and benefit design by payers and PBMs to ensure that patients have affordable, timely access to medically appropriate treatment—pharmacologic and non-pharmacologic.

Exhibit 8. CDC Calls Out Misapplications of Its Guidelines That Could Put Patients at Risk[23]

- **Misapplication of recommendations to populations outside the Guideline's scope.** The Guideline is intended for primary care clinicians treating chronic pain in patients 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" opioids.** The Guideline states, "*When opioids are started*, clinicians should prescribe the lowest effective dosage. Clinicians should . . . avoid *increasing* dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day." The recommendation statement does not suggest discontinuation of opioids already prescribed at higher dosages.
- **Misapplication of the Guideline to 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 to patients receiving or starting MAT 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 MAT for OUD. The Guideline strongly recommends offering MAT for patients with OUD.



Expanding access to non-opioid pain management under Medicaid. In several states, Medicaid programs are improving access to non-opioid pain management options in their benefit designs and preferred drugs lists. By doing so they offer potential models for departments of insurance and other regulators to consider how commercial payers should structure their formularies and benefits. For example:

- **Colorado's expansion of treatment options.** Under Colorado's Medicaid program, non-opioid options include local anesthetics, such as steroidal lidocaine patches or injections; physical therapy (PT), occupational therapy, and cognitive behavioral therapy; and other medical, physical, and mental health services. Colorado Medicaid covers non-opioid pain relievers, such as anti-epileptics (e.g., Lyrica and Neurontin), without prior authorization, and the antidepressant duloxetine (e.g., Cymbalta) without prior authorization when it is used for fibromyalgia, neuropathic pain, or chronic musculoskeletal pain. Colorado Medicaid also increased payment rates for PT. The increase led to a larger number of PT providers participating in Medicaid, and to the provision of more PT services.

- **Pennsylvania's clinical oversight.** Pennsylvania's Medicaid program uses in-house clinical staff to review the Medicaid coverage policies of each Medicaid managed care organization (MCO) in the state, including whether it covers non-opioid pain treatments. Notably, Pennsylvania Medicaid evaluates whether an MCO's utilization management strategies are inhibiting access to non-opioid pain management strategies. In addition, all Medicaid MCOs in the state, as well as the state's fee-for-service program, cover physical therapy, occupational therapy, cognitive behavioral therapy, and a number of other services.

Improving access in commercial insurance. Insurance regulators could make similar progress by using their authority to review both insurer formularies and benefit designs to ensure that non-opioid alternatives, including non-pharmacological treatment options, are available and affordable. It is critical to review not just whether such alternative treatment options are included as covered benefits but also whether there are barriers to accessing that care, such as higher cost-sharing, prior authorization, step therapy requirements or treatment limits.

For example, the Colorado DOI recently promulgated a regulation stating that it will consider placement of 50% or more of all drugs to treat a specific condition on the highest-cost tiers of a formulary to be a benefit design discrimination against individuals who have chronic conditions requiring treatment with those drugs.

Insurance regulators can also enhance transparency by working with insurers to ensure that formularies are posted online and regularly updated so that patients can clearly see whether their benefit plan covers non-opioid options and what the cost-sharing requirements are.

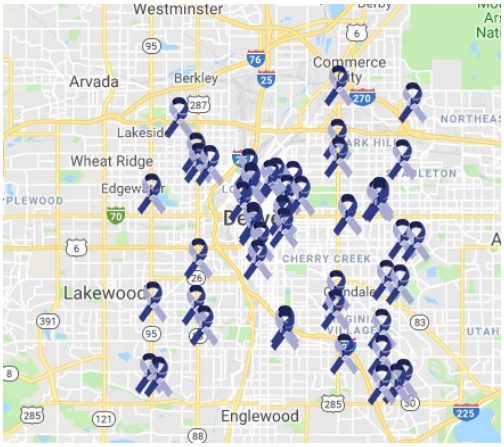
Expanding pilot projects and private sector initiatives. More broadly, states can look at successful pilot projects and private sector initiatives and assess their potential to be expanded statewide. For example, the Colorado Opioid Safety Pilot, run by the Colorado Hospital Association, was a 6-month pilot in 8 Colorado hospital emergency departments (EDs) and 2 freestanding EDs to reduce the administration of opioids by ED clinicians. The initiative used guidelines developed by the Colorado chapter of the American College of Emergency Physicians that recommend the use of alternatives to opioids (ALTOs) as a first-line treatment for pain. The EDs achieved a 36% reduction in opioid administrations during the pilot period, compared to the prior year. The initiative introduced new procedures, such as using non-opioid patches for pain and using ultrasound to "look into the body" and help guide targeted injections of non-opioid pain medicines. Doctors also used non-opioid interventions including ketamine and lidocaine, an anesthetic commonly used by dentists. Lidocaine's use in the project's EDs rose 451%. Ketamine use was up 144%. Based on the success of the pilot, the Colorado Hospital Association is working to implement the program in EDs statewide, and the AMA urges other states to consider whether ALTOs might be pursued in additional hospitals, clinics and hospital systems.

VI. Access to Naloxone Can Help Save Lives From Overdose

Naloxone, the opioid-reversal agent, has likely saved hundreds of thousands of lives in the past decade. 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. Moving forward, there are additional areas in which states can take action to ensure the continued success of naloxone in saving lives from overdose, and some states are showing leadership in these areas.

Promoting and encouraging health care professionals to co-prescribe naloxone to patients at risk of overdose. The uptake of naloxone has been a public health success, but there is more that can be done. Through co-prescribing and standing orders, naloxone prescriptions have increased from 136,395 to nearly 600,000 between 2016 and 2018.[24] The AMA Opioid Task Force recommends co-prescribing naloxone to patients at risk of overdose and has developed a handout for physicians and other health care professionals that provides guidance to co-prescribe naloxone when clinically appropriate—a decision to be made between the patient and physician. Regulators and others could use this information as the basis of public education efforts.[25] Colorado's "Stop the Clock" campaign has developed an interactive map to help people identify pharmacies that carry naloxone.[26] This type of public awareness effort could be broadened to include the entire state so that when a person needs to fill a prescription or wants to obtain naloxone through a standing order, he or she can quickly identify a pharmacy that stocks the medication.

Exhibit 9. Stop the Clock Colorado: Pharmacies Carrying Naloxone in the Denver Metro Area



Evaluating whether current programs have been successful and broadening those that have. States and communities are creating innovative programs and policies to promote access to naloxone, and policymakers cannot afford to overlook the scalable innovations that are resulting in measurable success. For example, North Carolina purchased nearly 40,000 units of nasal naloxone to make the overdose reversal drug more widely available and distributed the medication to partners across the state, including opioid treatment providers (OTPs), EMS agencies, and Oxford House, and other community partners.[27] Additionally, the NC Harm Reduction Coalition has distributed over 60,000 naloxone rescue kits across the state since August 2013, and the coalition tracks the number of opioid reversals done by community members using those kits (not including reversals by first responders, presented separately below). There were more than 2,000 community naloxone reversals in the first 6 months of 2018 alone.

Linking those who experience an opioid-related overdose to treatment. When a patient arrives in a University of Colorado Health System emergency department and is identified as having OUD, a social worker intervenes to conduct an in-depth screening. When a patient is willing, providers prescribe buprenorphine. A grant from the Colorado Office of Behavioral Health has increased resources to provide "warm handoffs" to community providers. "Early findings have been that of 40 patients identified for needing treatment for a substance use disorder, all but one showed up for their first appointment, and more than half were still in treatment at 30 days," said Denver emergency medicine physician Jason Hoppe, DO. "It's hard work, but we're making progress."

Identify and remove remaining barriers that may impede greater access to naloxone. Several of the nation's pharmacies, including CVS and Walgreens, have broadly supported access to naloxone, but there still are reports of pharmacies that do not carry naloxone, and the mistaken belief that naloxone encourages risky behavior still exists.[28] While this is not an area where state regulators and other policymakers typically engage, there is an opportunity for regulators and others to work with the medical and public health community to provide accurate information to consumers. One area where regulators do have jurisdiction is in ensuring that naloxone is not placed on prohibitively high cost-sharing tiers of health insurance company pharmacy benefits. Furthermore, regulators can help identify whether naloxone is subject to prior authorization requirements that would delay or deny access to the medication. Colorado Medicaid provides access to naloxone without prior authorization, which is another practice that could be extended to commercial insurers.

VII. Improve Evaluation

As states implement policies aimed at savings lives, improving patients' pain outcomes, and reducing opioid-related harm, it is imperative that states conduct timely, practical evaluations to ensure that resources are being used efficiently. Evaluation should determine what is working to improve patient care and reduce opioid-related harms, and should help the state understand relationships between current policies and clinical outcomes so it can further successful efforts and amend those that may be having unintended consequences.

While it appears that few states have initiated the kind of comprehensive policy evaluation warranted by this epidemic, some states are taking initial steps that help lay the groundwork for broader evaluation.

- **The North Carolina Division of Public Health** regularly tracks and monitors opioid overdose data and issues monthly surveillance reports of ED visits, deaths, and naloxone distribution. In addition, the division manages an opioid data dashboard, created in 2017, to track the multiple data metrics developed to measure the state's progress against its Opioid Action Plan. Metrics are divided into 5 strategy areas and are updated on a quarterly basis.

- **Pennsylvania** has established a state-level dashboard that provides information at the state and county levels on newborns who are on Medicaid and are born with neonatal abstinence syndrome; the number of successful naloxone reversals; individuals covered by Medicaid expansion who have OUD; individuals covered by Medicaid who receive MAT; and individuals covered by Medicaid who have OUD.

- **Colorado** has made several efforts to gather and report data on the size and scope of the epidemic, some driven by provider organizations or private/public partnerships. For example, the Colorado Consortium for Prescription Drug Abuse Prevention has developed one of the nation's most comprehensive dashboards, which provides data on mortality, ED visits, hospital discharges, opioid prescriptions, treatment admissions, and nonmedical use of pain relievers.[29] The Consortium reports that these data can be used to help direct state and local resources to areas of greatest need. At the same time, Colorado, like nearly all states, has not developed a statewide, systematic way to track the effectiveness of its interventions, whether legislative and regulatory or implemented on a pilot project basis. This is clearly an area of tremendous opportunity.

VIII. Conclusion

Policymakers and regulators across the country and in Washington, DC, have made ending the epidemic their highest priority. 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 MAT, removing barriers to comprehensive pain care, and enhancing availability of naloxone to help prevent overdose deaths. Other policies, such as arbitrary prescribing limits and prior authorization for MAT continue to hurt efforts to improve patient outcomes. There must be a thorough evaluation and commitment by states to further policies that work and revise or rescind policies that are demonstrating harm to patients.

The AMA–Manatt analyses also revealed 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 non-opioid pain care. These efforts represent areas where all states can learn from and potentially adopt. This also will require state regulators to commit to meaningful oversight and enforcement of mental health and substance use disorder parity laws and take bold steps to identify and help resolve gaps in treatment networks.

The analyses also identified several areas in which additional work can be done to further increase access to evidence-based care. This includes work being done by emergency departments to assess and refer patients to treatment for OUD, but many successful pilot programs are dependent on grant funding. Further success of these pilots will require states to commit considerable resources to ensure long-term benefits.

This national roadmap provides recommendations that may not be easy to implement, but they are necessary to help end the epidemic. The AMA stands ready to work with all stakeholders to implement the recommendations in this national roadmap.

Endnotes

1 US Department of Health and Human Services (HHS), Office of the Surgeon General, Facing Addiction in America: The Surgeon General's Spotlight on Opioids. Washington, DC: HHS, September 2018. Available at https://addiction.surgeongeneral.gov/sites/default/files/Spotlight-on-Opioids_09192018.pdf.

2 US Department of Health and Human Services (HHS), Office of the Surgeon General, Facing Addiction in America: The Surgeon General's Spotlight on Opioids. Washington, DC: HHS, September 2018. Available at https://addiction.surgeongeneral.gov/sites/default/files/Spotlight-on-Opioids_09192018.pdf.

3 Wolf Administration Announces Agreement with Insurers to Eliminate Barriers to Medication-Assisted Treatment, October 12, 2018. Available at https://www.media.pa.gov/Pages/Insurance-Details.aspx?newsid=344.

4 Greene, Estay. "THE OPIOID EPIDEMIC: ACCESS EXPANDS FOR MEDICATION-ASSISTED TREATMENT." November 12, 2018. Available at https://blog.bcbsnc.com/2018/11/opioid-epidemic-access-expands-medication-assisted-treatment/.

5 https://ag.ny.gov/sites/default/files/final_letter_agreement_anthem-empire_mat_010117.pdf.

6 https://oag.ca.gov/system/files/attachments/press-docs/matletter.pdf.

7 Arkansas Act 964 requires all health insurers and the Arkansas Medicaid program to remove prior authorization to FDA-approved medications that have been shown to support recovery, reduce health care costs and save lives, including buprenorphine, methadone and naltrexone. See http://www.arkleg.state.ar.us/assembly/2019/2019R/Acts/Act964.pdf.

8 Iowa House File 623 removes prior authorization under Medicaid fee-for-service and managed care administration for at least one form of MAT: methadone, buprenorphine, naloxone, buprenorphine-naloxone combination products and naltrexone. See https://www.legis.iowa.gov/legislation/BillBook?ga=88&ba=HF623.

9 As of June 2019, more than one dozen states introduced bills or took other action to remove barriers to MAT, including using AMA model legislation. States that have taken action to remove barriers, including prior authorization in the commercial and/or Medicaid markets (both traditional and managed care) include AR, CA, CO, DC, KY, LA, ME, MO, MT, NJ, NY, VA, VT, TX and WA. Efforts were ultimately unsuccessful in CA, KY and MT.

10 Bills in California, Kentucky and Montana to remove barriers to MAT were defeated, in part, due to opposition from health plans. In California, opposition came from the California Association of Health Plans, the Association of California Life and Health Insurance Companies, and America's Health Insurance Plans. Kentucky's bill was opposed by the Kentucky Association of Health Plans; and Montana's bill was opposed by several health plans in the state, including Blue Cross Blue Shield.

11 Center on Addiction. "UNCOVERING COVERAGE GAPS II - A Review and Comparison of Addiction Benefits in ACA Plans." March 2019. Available at https://www.centeronaddiction.org/download/file/fid/2238.

[12] Market conduct activities, including data calls, are typically confidential until the state publishes its results. While the Washington data call has been discussed in public meetings, the data call itself is likely to remain confidential until aggregate results are published.

[13] US Substance Abuse and Mental Health Services Administration. Practitioner and program data. Accessed May 23, 2019. https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/practitioner-program-data.

[14] Governor Wolf Announces Year-One Successes of Centers of Excellence, February 28, 2018. Available at https://www.governor.pa.gov/governor-wolf-announces-year-one-successes-centers-excellence/.

[15] https://projectobot.com.

[16] 42 USC § 1396d (a)(29)(B).

[17] CDC: Morbidity and Mortality Weekly Report, September 14, 2018, https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6736a2-H.pdf.

[18] CDC Guideline for Prescribing Opioids for Chronic Pain Fact Sheet. Available at https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf.

[19] More than 30 states now have a specific opioid prescribing statutory threshold for acute pain, ranging from limits on the number of days' supply to the maximum dose strength or both. While most state laws include exceptions for cancer and hospice or palliative care, the policies are not evenly applied. Moreover, many state and national pharmacy chains, PBMs, and health insurance companies also have implemented their own thresholds based on the CDC guidelines.

[20] US Food and Drug Administration. April 9, 2019, Safety Announcement. "FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering." Available at https://www.fda.gov/Drugs/DrugSafety/ucm635038.htm.

[21] See letter from CDC Director Robert Redfield, MD, to Daniel Alford, MD. April 10, 2019. Available at https://img1.wsimg.com/blobby/go/3d70257f-a143-4a5b-b9df-f7d265df0d3d/downloads/Alford%20Final%20.pdf?ver=1554957603807.

[22] Despite the CDC's acknowledgment that the guidelines have been misapplied, it will be a challenge to undo the damage caused by patients being refused opioid therapy or non-consensually tapered down from beneficial opioid doses. The AMA is urging a detailed regulatory review of formulary and benefit design by payers and PBMs to ensure that patients have affordable, timely access to medically appropriate treatment, pharmacologic and non-pharmacologic. The full CDC clarification is available here: https://www.nejm.org/doi/full/10.1056/NEJMp1904190.

[23] CDC Advises Against Misapplication of the Guideline for Prescribing Opioids for Chronic Pain. April 24, 2019. Available at https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html.

[24] Combined Audit from February 2013 to January 2019; IQVIA-FIA Audit from February 2013 to January 2019.

[25] Factors that may be helpful in determining whether to co-prescribe naloxone to a patient, or to a family member or close friend of the patient, include:

- Does the patient history or prescription drug monitoring program (PDMP) show that the patient is on a high opioid dose?
- Is the patient on a concomitant benzodiazepine prescription?
- Does the patient have a history of substance use disorder?
- Does the patient have an underlying mental health condition that might make him or her more susceptible to overdose?
- Does the patient have a medical condition, such as a respiratory disease, sleep apnea, or other comorbidities, that might make him or her susceptible to opioid toxicity, respiratory distress, or overdose?
- Might the patient be in a position to aid someone who is at risk of opioid overdose?

[26] See, for example, http://stoptheclockcolorado.org/map/.

[27] See, for example, https://governor.nc.gov/news/cooper-announces-state-distribution-40000-doses-life-saving-naloxone-fight-opioid-epidemic.

[28] "Saving Lives Is Not a Moral Hazard," by Dr Tom McLellan. March 13, 2018. Available at https://www.shatterproof.org/blog/saving-lives-not-moral-hazard.

[29] Colorado Consortium for Prescription Drug Abuse Prevention. Available at http://www.corxconsortium.org/resources/#1519773299597-6b65637b-522f.