



Centers for Medicare & Medicaid Services

CMS Action Plan to Enhance Prevention and Treatment for Opioid Use Disorder

June 15, 2021

Executive Summary

Purpose of this Action Plan

The opioid crisis in the United States is a serious public health emergency affecting many, including individuals directly impacted by opioid use disorder (OUD), those with acute and chronic pain who use or may benefit from the use of opioids, as well as their families and communities. On average, 38 Americans died each day from prescription opioid related overdoses,¹ and an estimated 10.1 million people misused opioids in 2019.² The economic cost of the opioid crisis was estimated to be \$504 billion in 2015, or 2.8 percent of GDP that year.³

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act) was signed into law on October 24, 2018. Section 6032 of the SUPPORT for Patients and Communities Act includes a requirement for the Secretary of the U.S. Department of Health and Human Services (HHS) to develop an “Action Plan on recommendations for changes under Medicare and Medicaid to prevent opioid addictions and enhance access to medication-assisted treatment”⁴ in collaboration with the Pain Management Best Practices Inter-Agency Task Force (PMTF).⁵ This Action Plan will accompany a Report to Congress also required by Section 6032 of SUPPORT for Patients and Communities Act.

As the largest healthcare payer in the United States, the Centers for Medicare & Medicaid Services (CMS) is actively addressing the opioid epidemic. In 2018, CMS developed an agency-wide *CMS Roadmap: Fighting the Opioid Crisis*, including a framework that articulates three key focus areas: prevention, treatment, and data⁶



Figure ES-1. CMS Roadmap: Key Areas of Focus

Leveraging this three-part strategy, CMS actively collaborated across federal agencies, and carefully considered inputs from external sources, to create an action plan to meet the requirements of Section 6032 of the SUPPORT for Patients and Communities Act. These efforts have produced significant policy modifications, detailed in this Action Plan. These inputs along with key themes and actions are summarized below.

Inputs, Key Themes and Actions

The following inputs have informed this Action Plan:

- Analysis of Medicare and Medicaid payment and coverage policies with potential relevance to the opioid crisis.
- Analysis of Medicare and Medicaid beneficiaries' access to care for pain management and treatment of OUD.
- Feedback from the PMTF received at a CMS public meeting on June 26, 2019, during which the PMTF final May 2019 report's recommendations specific to CMS were discussed.
- Feedback from public stakeholders and other members of the public at a CMS public meeting held on September 20, 2019, as required by Section 6032(b) of the SUPPORT for Patients and Communities Act.
- Analysis of public stakeholder feedback obtained from a CMS Request for Information issued on September 11, 2019 (closed on October 11, 2019).
- Analysis of other reports and studies included in other provisions of the SUPPORT for Patients and Communities Act.

The findings from these analyses and stakeholder engagement activities are detailed in Section 4 of the report and key themes are highlighted below.

Key Themes from Public Stakeholder Inputs

- Payment and coverage policies can enable access to timely and effective care for Medicare and Medicaid beneficiaries by supporting providers in executing best practices with respect to **pain management**:
 - Pain management is optimal if it is individualized, multimodal, and multidisciplinary.
 - Patients would like to have access to a variety of options for pain management treatment and be educated about their options for covered treatments.
 - Care is ideally coordinated and integrated across the individual's care providers, particularly for transitional and chronic care.
 - Non-opioids, when clinically appropriate, can be used as first-line therapy in order to reduce unnecessary exposure to opioids. Opioid therapy should be initiated only when the benefits outweigh the risks.
 - Patients would like to have access to opioids when they are clinically indicated.
 - Providers can consider the use of screening and prevention measures to manage risk.
 - Payers can provide another layer of risk screening and management through tools such as drug utilization reviews (DURs), safety edits at the point of sale for opioids, and case management.
 - When high-risk patients are identified, providers can optimize care by including options for treatment referrals to pain, mental health, and other specialists, including addiction medicine physicians.

- Payment and coverage policies can enable access to timely and effective care for Medicare and Medicaid beneficiaries by supporting providers in executing best practices with respect to **treatment of OUD**:
 - Patients would like to have access to a variety of options for treatment of OUD and be educated about their options for covered treatments, including treatment for withdrawal where appropriate indications are met.
 - Care is ideally coordinated and integrated across the individual’s care providers, particularly for transitional and chronic care.
 - Medication-assisted treatment (MAT) would be more widely utilized if offered in a variety of settings, including emergency departments and community settings.
 - Barriers to prescribing medications for MAT may include federal or state restrictions as well as issuer coverage and payment policies, such as prior authorization.
 - Case management, recovery support services, and other community supports can aid in the treatment of OUD.
- **Data** can be leveraged to help aid providers in ensuring appropriate treatment for pain management and OUD:
 - Data can help to identify populations with special needs that may require individualized coverage and payment policies to ensure adequate treatment for pain management or OUD.
 - Standardized collection and sharing of data, such as in prescription drug monitoring programs, can assist providers and payers in identifying at-risk patients and managing risk.

Actions

In consideration of current policies and public stakeholder input, pursuant to Section 6032 of the SUPPORT for Patients and Communities Act, and building on the CMS Opioid Roadmap, the agency will take the following actions to further address the opioid crisis.

Prevention

Manage pain using a safe and effective range of treatment options that rely less on prescription opioids

Medicare

Enhance patient care coordination and multidisciplinary pain care

- Explore the possibility of establishing a new bundled payment under the Medicare Physician Fee Schedule for integrated multimodal pain care furnished by clinicians in an office or outpatient setting. This bundle could include comprehensive assessment, diagnosis, person-centered plan of care, care coordination, care management (including management of multiple chronic conditions), psychotherapy (group, individual, family), counseling, reassessment, patient education and self-management training, medication management, care for patients in crisis, and other aspects of care, including care rendered through remote communication technology. Consider payment and coding stratification that recognizes different levels of patient need and types of practice arrangements,

including care for people who have pain and substance use disorder(s), or other behavioral health conditions.

- Explore the feasibility of leveraging payment policy for pain management to facilitate access in underserved communities through telehealth or other technology-assisted delivery methods.

Identify and support the use of effective, non-opioid treatment options for pain

- Provide additional coding, coverage, and payment guidance and education to support Medicare providers in implementing clinical best practices with respect to pain management and opioid prescribing.
- Review the evidence base to explore the appropriateness of expanding Medicare coverage to include additional treatment options for pain management. An example cited by public stakeholders is high-flow oxygen to treat cluster headaches.
- Evaluate options to expand coverage for the full continuum of care for pain management by providing consistent and timely coverage for evidence-based interventional procedures early in the course of treatment when clinically appropriate.
- Evaluate policies to ensure appropriate payment for complex opioid and non-opioid pain management consistent with the time and resources required for patient education, safe evaluation, risk assessment, re-evaluation, and integration of non-opioid modalities.

Medicaid

Support state Medicaid agencies by identifying and sharing best practices in pain management

- Continue to share best practices and innovative initiatives received from states through DUR surveys.

Promote transparency in the Medicaid program by collecting and sharing information on program activities

- Survey states to assess acute and chronic pain management services, support, payment, and compliance with the SUPPORT for Patients and Communities Act.
- Compile National and State Comparison/Summary Reports on Medicaid fee-for-service (FFS) and managed care Medicaid DUR programs and make available on Medicaid.gov to provide a snapshot of individual state Medicaid FFS and managed care program activities.

Payment and Service Delivery Models

Investigate innovative payment models for multidisciplinary and multimodal pain care

- Examine models that recognize and reimburse holistic, integrated, multimodal pain management and leverage available technologies. Examples cited by public stakeholders include Project ECHO (“Extension for Community Healthcare Outcomes”)-type models, multidisciplinary and multimodal approaches for perioperative pain control in selected patients at higher risk for OUD, and the Enhanced Recovery After Surgery (ERAS) team-based model.

- Incorporate quality measures related to safe and effective use of best practices in pain management in existing bundled payments, such as the Bundled Payments for Care Improvement (BCPI) Advanced Model.

Treatment

Expand access to treatment of opioid use disorder

Medicare

Support Medicare providers to offer a full range of MAT options for OUD

- Broaden bundled payment under the Medicare Physician Fee Schedule for office-based treatment for opioid use disorders. Consider a range of services to include, such as assessment and educational services for people at risk, assessment, diagnosis, person-centered plan of care, care coordination, care management (including management of multiple chronic conditions), psychotherapy (group, individual, family), counseling, occupational therapy, medication-assisted treatment, medication management, laboratory and toxicology services, services for patients in crisis, peer support services, and other aspects of care, including care rendered through remote communication technology. Consider payment and coding stratification that recognizes different levels of patient need and types of practice arrangements, including care for patients in crisis.
- Expand and develop Medicare program incentives for providers and facilities to 1) offer a full range of MAT options (including therapy for withdrawal when appropriate) 2) treat to capacity; and/or 3) initiate MAT and facilitate linkages to OUD treatment in community-based and acute care settings, including emergency departments.

Medicaid

Support state Medicaid agencies to offer a full range of MAT options for OUD by identifying and sharing best practices and providing technical assistance

- Conduct an aggregated evaluation of Social Security Act Section 1115 SUD-related demonstrations through state-reported information to assess the impact of the demonstrations and develop lessons learned.
- Provide technical assistance to states interested in exploring alternative payment methodologies for behavioral health treatment under existing Medicaid authorities.
- Work with and provide technical assistance to state Medicaid agencies that received planning grants under the Demonstration Project to Increase SUD Provider Capacity (authorized by Section 1003 of the SUPPORT for Patients and Communities Act) to conduct comprehensive assessments of SUD provider capacity and develop state capabilities to assess and treat SUD, including OUD.
- Explore opportunities to improve connections to SUD treatment for recently incarcerated individuals who are transitioning back into their communities.

Payment and Service Delivery Models

Implement and disseminate learning from the following models and demonstrations that address OUD treatment:

- Maternal Opioid Misuse (MOM)⁷ Model: seeks to improve coordination and integration of care for pregnant and postpartum Medicaid beneficiaries with OUD.⁸
- Integrated Care for Kids (InCK)⁹ Model: a child-centered local service delivery and state payment model that aims to prevent, treat, and coordinate care for children under 21 years of age covered by Medicaid and the Children’s Health Insurance Program.¹⁰
- OUD Treatment Demonstration (Value in Opioid Use Disorder Treatment):¹¹ creates two new payments for OUD treatment services furnished to applicable Medicare beneficiaries participating in the demonstration programs.

Data**Use data to target prevention and treatment efforts****Leverage data to understand beneficiary needs and the impact of CMS policies**

- Conduct an interagency review using available data to better understand adequacy of payment and coverage for opioid alternatives.
- Systematically review special populations using the CMS Chronic Conditions Data Warehouse to determine populations appropriate for exclusion from certain opioid related payment and coverage policies; review data to understand racial disparities in diagnoses and treatment of pain and OUD.
- Review feasibility of options for tracking opioid use in the hospital setting.

Use quality measurement to understand care patterns and health impacts, and to promote clinical best practices

- Review forthcoming recommendations from the National Quality Forum related to the development and implementation of quality measures related to opioid use and OUD in federal healthcare quality programs.

Fighting the opioid epidemic is a top priority for HHS, and CMS remains committed to ongoing examination of its payment and coverage policies to ensure healthcare providers are enabled to execute best practices with respect to pain management and treatment of OUD. This Action Plan represents an important step in this effort.

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1 Overview

1.1 Purpose

The opioid crisis in the United States is a serious public health issue affecting many, including individuals directly impacted by opioid use disorder (OUD) and those with acute and chronic pain who use or may benefit from the use of opioids, as well as their families and communities. On average, 38 Americans died each day from prescription opioid related overdoses,¹² and an estimated 10.1 million people misused opioids in 2019.¹³ The economic cost of the opioid crisis was estimated at to be \$504 billion in 2015, or 2.8 percent of GDP that year.¹⁴

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act) was signed into law on October 24, 2018. The SUPPORT for Patients and Communities Act includes a requirement for the Secretary of the U.S. Department of Health and Human Services (HHS) to develop an “Action Plan on recommendations for changes under Medicare and Medicaid to prevent opioids addictions and enhance access to medication-assisted treatment,”¹⁵ in collaboration with the Pain Management Best Practices Inter-Agency Task Force (PMTF) convened under Section 101(b) of the Comprehensive Addiction and Recovery Act of 2016.¹⁶ This Action Plan will be followed by a public Report to Congress.

1.2 CMS Role in the Federal Response to the Opioid Crisis

As the largest healthcare payer in the United States,¹⁷ the Centers for Medicare & Medicaid Services (CMS) has a clear stake in addressing the opioid epidemic that has adversely affected many of its beneficiaries. Medicare beneficiaries have among the highest and most rapidly growing prevalence of OUD, with more than 500,000 individuals diagnosed in 2018 and with OUD-related hospitalizations increasing by 10 percent per year.^{18,19} Medicaid is currently the single largest payer of behavioral health services, including substance use disorder (SUD) treatment services, in the United States.²⁰ Almost 12 percent of adult Medicaid enrollees have a SUD,²¹ and among the nearly two million non-elderly adults who suffer from OUD, nearly four in ten are covered by Medicaid.²²

As part of the agency’s response to the opioid epidemic, CMS developed the *CMS Roadmap: Fighting the Opioid Crisis*, including a framework that articulates three key focus areas:

- **Prevention:** Manage pain using a safe and effective range of treatment options that rely less on prescription opioids
- **Treatment:** Increase access to evidence-based treatment for OUD
- **Data:** Use data to target prevention and treatment efforts and to support fraud, waste, and abuse detection.²³

Over the past several years, CMS has taken several actions to help reduce unnecessary opioid exposure and improve coverage for treatment of OUD in both Medicare and Medicaid, which are summarized in Section 4 of this report. This Action Plan represents the next step in CMS’s response to the opioid crisis. CMS has actively collaborated across federal agencies and carefully considered inputs from external sources to create this Action Plan. These efforts have produced

policy modifications and recommendations resulting in planned actions, which are discussed in Section 3.

1.3 Legislative Mandate for this Action Plan

CMS prepared this Action Plan as required by Section 6032 of the SUPPORT for Patients and Communities Act, and used it to determine its priorities for subsequent actions. As required by Section 6032(e), a public Report to Congress will summarize the results of the review and any recommendations under this Action Plan, and identify the Secretary's planned next steps with respect to this Action Plan.²⁴

As required by Section 6032(b), this Action Plan includes the following:

- b) The action plan shall include a review by the Secretary of Medicare and Medicaid payment and coverage policies that may be viewed as potential obstacles to an effective response to the opioid crisis, and recommendations, as determined appropriate by the Secretary, on the following:
 1. A review of payment and coverage policies under the Medicare program under title XVIII of the Social Security Act and the Medicaid program under title XIX of such Act, including a review of coverage and payment under such programs of all medication-assisted treatment approved by the Food and Drug Administration related to the treatment of opioid use disorder and other therapies that manage chronic and acute pain and treat and minimize risk of opioid misuse and abuse, including in such review, payment under the Medicare prospective payment system for inpatient hospital services under section 1886(d) of such Act (42 U.S.C. 1395ww(d)) and the Medicare prospective payment system for hospital outpatient department services under section 1833(t) of such Act (42 U.S.C. 1395I(t)), to determine whether those payment policies resulted in incentives or disincentives that have contributed to the opioid crisis.
 2. Recommendations for payment and service delivery models to be tested as appropriate by the Center for Medicare and Medicaid Innovation and other federally authorized demonstration projects, including value-based models, that may encourage the use of appropriate medication-assisted treatment approved by the Food and Drug Administration for the treatment of opioid use disorder and other therapies that manage chronic and acute pain and treat and minimize risk of opioid misuse and abuse.
 3. Recommendations for data collection that could facilitate research and policy-making regarding prevention of opioid use disorder as well as data that would aid the Secretary in making coverage and payment decisions under the Medicare and Medicaid programs related to the access to appropriate opioid dependence treatments.
 4. A review of Medicare and Medicaid beneficiaries' access to the full range of medication-assisted treatment approved by the Food and Drug Administration for the treatment of opioid use disorder and other therapies that manage chronic and acute pain and treat and minimize risk of opioid misuse and abuse, including access of beneficiaries residing in rural or medically underserved communities.
 5. A review of payment and coverage policies under the Medicare program and the Medicaid program related to medical devices that are non-opioid based treatments approved by the Food and Drug Administration for the management of acute pain and

chronic pain, for monitoring substance use withdrawal and preventing overdoses of controlled substances, and for treating substance use disorder, including barriers to patient access.²⁵

1.4 Inputs into the Action Plan

The following inputs informed this Action Plan:

- Analysis of Medicare and Medicaid payment and coverage policies with potential relevance to the opioid crisis.
- Analysis of Medicare and Medicaid beneficiaries' access to care for pain management and treatment of OUD.
- Feedback from the PMTF via a public meeting on June 26, 2019, during which the PMTF final May 2019 report's recommendations specific to CMS were discussed.
- Public meeting held on September 20, 2019, as required by Section 6032(b), and input in response to the meeting from public stakeholders and other members of the public.
- Request for Information issued on September 11, 2019 (closed on October 11, 2019), and associated responses and recommendations from public stakeholders.
- Other reports and studies identified in other provisions of the SUPPORT for Patients and Communities Act.

1.5 Organization of this Action Plan

Section	Purpose
Section 2: Background	Provides contextual information on pain management and the role of opioids, treatment of opioid use disorder, and the role of CMS in the federal response to the opioid crisis.
Section 3: Actions	Summarizes CMS actions resulting from recommendations developed or received over the course of the development of this Action Plan, including from stakeholder input and analysis of relevant CMS policies.
Section 4: Review of Payment and Coverage Policies, Beneficiary Access to Care, and Public Stakeholder Inputs	Provides an analysis of key Medicare and Medicaid coverage and payment policies of relevance to the opioid crisis, including those related to pain management and treatment of opioid use disorder. Also provides reviews of beneficiary access to care and payment and coverage policies for Food and Drug Administration-approved medical devices. Summarizes activities and inputs from the CMS Public Meeting, Request for Information, and Pain Management Best Practices Inter-Agency Task Force.
Appendices	<p>Appendix A: Pain Management Best Practices Inter-Agency Task Force Recommendations Pertaining to the CMS Action Plan</p> <p>Appendix B: Various Therapies that Manage Chronic and Acute Pain</p> <p>Appendix C: Therapies that Treat Opioid Use Disorder</p> <p>Appendix D: Additional Tables on MAT Access</p>
Acronym List	Defines the acronyms used in this document.
Glossary	Defines the key terms used in this document.

2 Background

This section introduces foundational terms and concepts that will be used throughout this Action Plan, covering pain management and the role of opioids as well as prevention and treatment of OUD. Key terms are also defined in the Glossary at the end of this report.

2.1 Pain Management and the Role of Opioids

Pain is a significant public health issue, with an estimated 50 million Americans suffering from some form of chronic pain, of whom 19.6 million report pain interfering with life or work activities.²⁶ Opioid medications are commonly used to manage acute and chronic pain alike. However, these drugs are associated with significant risks, including OUD and accidental death by overdose. A prevention approach to the opioid crisis emphasizes the management of pain using a safe and effective range of treatment options that rely less on prescription opioids.

A May 2019 HHS PMTF Report described therapies available to manage chronic and acute pain, which include but are not limited to:²⁷

- **Pharmaceutical Therapies** (including opioids and various classes of non-opioid drugs).
- **Restorative Therapies**²⁸ (noted by the PMTF as including physical therapy, occupational therapy, and other movement modalities).
- **Interventional Procedures**²⁹ (e.g., image-guided and minimally invasive procedures).
- **Behavioral Health Approaches**³⁰ (e.g., cognitive behavioral therapy) that address the relationship between pain and psychological health, as well as special considerations for pain management in patients with pain and behavioral health conditions.
- **Complementary and Integrative Health**³¹ (e.g., acupuncture, massage, yoga).

The PMTF noted that different medications can complement one another, and their effects can be synergistic when used in combination. It also concluded that multidisciplinary approaches to pain management, including non-pharmaceutical approaches, address different aspects of chronic pain conditions; further, that the efficacy of coordinated, integrated approaches has been documented to reduce pain severity, improve mood, improve overall quality of life, and increase function.³² For the complete list of PMTF-identified therapies in the above-listed categories, see Appendix B.

When opioids are clinically indicated, multiple clinical practice guidelines (including guidelines from the U.S. Department of Veterans Affairs [VA]/U.S. Department of Defense [DoD],³³ Centers for Disease Control and Prevention [CDC],³⁴ and the American Society of Interventional Pain Physicians)³⁵ indicate the need for risk assessment, close follow-up, and pain re-evaluation as part of the treatment plan prior to and throughout the duration of opioid therapy, in order to help prevent adverse consequences.

HHS has endeavored to support appropriate application of these guidelines, emphasizing “care as a patient-centered experience.” For example, CDC’s 2016 Guideline for Prescribing Opioids for Chronic Pain was designed for primary care practitioners prescribing to adults with chronic pain in outpatient settings and outside of active cancer treatment, palliative care, and end-of-life care. Since its release, some policies and practices derived from the Guideline have been misapplied,

and often go beyond, the recommendations.³⁶ HHS agencies have since developed and disseminated materials, such as the October 2019 *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, to facilitate best practices in the application of the Guideline.³⁷ Section 4 includes further discussion on the CDC Guideline and related materials.

2.2 Screening and Treatment of Opioid Use Disorder

Various screening approaches have been developed and adopted in different clinical settings. One methodology is Screening, Brief Intervention, and Referral to Treatment (SBIRT). SBIRT is an evidence-based early intervention approach that can be used in any healthcare setting to identify individuals with nondependent substance use to provide effective strategies for intervention prior to the need for more extensive or specialized treatment. SBIRT services aim to prevent the unhealthy consequences of drug and alcohol use among individuals who may not reach the diagnostic level of a SUD, and help those with SUD to enter and stay in treatment.³⁸

SBIRT Components

Screening: Screening and/or assessing a patient for risky substance use behaviors using standardized screening tools.

Brief Intervention: Engaging a patient showing risky substance use behaviors in a short conversation, providing feedback and advice.

Referral to Treatment: Providing a referral to brief therapy or additional treatment to patients whose assessment or screening shows a need for additional services.

Medication-assisted treatment (MAT) is “the use of Food and Drug Administration (FDA)-approved medications, in combination with counseling and behavioral therapies, to provide a ‘whole patient’ approach to the treatment of [SUDs]”³⁹. For individuals with OUD, MAT is recognized as the “gold standard” for treatment, and “treatment programs that offer more of these evidence-based components have the greatest likelihood of producing better outcomes.”⁴⁰ MAT has been shown to decrease opioid overdose deaths for people receiving methadone or buprenorphine compared to those not receiving MAT after a nonfatal opioid overdose.⁴¹ MAT has been proven effective in treating OUD, yet in 2017, only 34 percent of adults between the ages of 18 and 64 years with OUD received any treatment.⁴²

Section 6032(f) of the SUPPORT for Patients and Communities Act defines MAT to include “opioid treatment programs, behavioral therapy, and medications to treat substance abuse disorder.” The FDA has approved three drugs for MAT for OUD: buprenorphine, methadone, and naltrexone.⁴³ Each drug is safe and effective when combined with counseling and psychosocial support. The FDA emphasizes that people who need OUD treatment should have the therapeutic option to access each of these three medications, so that providers and patients can identify the option that is best able to meet individual needs⁴⁴. Appendix C provides a summary of the various forms of each drug which has been approved by the FDA.

The drugs used in MAT have different mechanisms of action and carry different restrictions on how they can be prescribed and dispensed, as summarized below:

- **Methadone** is a long-acting synthetic opioid agonist, and a schedule II drug that can only be ordered and dispensed through a Substance Abuse and Mental Health Services Administration (SAMHSA)-certified opioid treatment program (OTP) that has been registered with the Drug Enforcement Administration as a narcotic treatment program.⁴⁵ Counseling services must be available at the primary facility unless the program sponsor has entered into a formal agreement with another entity to provide these services.⁴⁶
- **Buprenorphine** is a synthetic opioid medication that acts as a partial agonist that can be offered in office-based opioid treatment settings by a provider with a Drug Addiction Treatment Act of 2000 waiver—subject to certain requirements and patient limits.⁴⁷
- **Naltrexone**, a long-acting synthetic opioid antagonist, can be prescribed in any setting by any clinician with prescribing authority.⁴⁸

Behavioral therapies used in combination with these medications can also support people with OUD to modify behaviors in ways that enable them to lead healthier lives. These therapies are often offered in individual, group, or family sessions, and can be provided in a variety of settings, including outpatient, inpatient, and residential settings. Appendix C, Table 11 provides a brief description of behavioral therapies, case management approaches, and recovery support services for treating OUD.

Naloxone is an overdose reversal drug that can be used to reverse opioid overdose. The availability of naloxone varies widely due to prescribing and dispensing patterns.⁴⁹ States, commercial pharmacies, and many local communities have made it a priority to expand the use, distribution, and access to naloxone when clinically appropriate.⁵⁰

Coverage and payment policies related to therapies used to manage pain and treat OUD, and Medicare and Medicaid beneficiaries' access to them, are detailed in Section 4.

3 Actions

This section presents actions CMS intends to pursue as part of its strategic initiative to fight the opioid crisis. In order to identify areas for further action, CMS performed a review of Medicare and Medicaid payment and coverage policies, Medicare and Medicaid beneficiary access to care, recommendations from the PMTF, and input received from key stakeholder groups through a September 2019 public meeting and a request for information (RFI) process. The findings and recommendations emerging from this analysis, presented in Section 4, were used to inform the actions summarized below. Actions aim to support beneficiaries to attain a full continuum of care for pain management and OUD treatment, in which they have access to a variety of options for individualized, multimodal and multidisciplinary care, and their treatment is coordinated and integrated across health care settings. Section 4.1 lists key themes identified in the analysis.

In addition to the proposed actions for Medicare and Medicaid, this section also includes planned actions for testing payment and service delivery models to enhance OUD prevention and treatment, and data collection to facilitate research and policymaking, as required by the SUPPORT for Patients and Communities Act (outlined in Section 1.3).⁵¹

The actions proposed by CMS are classified as Prevention, Treatment, and Data to align with the framework in the agency-wide *CMS Roadmap: Fighting the Opioid Crisis*.⁵²

The detailed list of actions is below.

3.1 Prevention



Figure 1. CMS Roadmap: Key Areas of Focus (Prevention)

Medicare

Enhance patient care coordination and multidisciplinary pain care

- Explore the possibility of establishing a new bundled payment under the Medicare Physician Fee Schedule for integrated multimodal pain care furnished by clinicians in an office or outpatient setting. This bundle could include comprehensive assessment, diagnosis, person-centered plan of care, care coordination, care management (including management of multiple chronic conditions), psychotherapy (group, individual, family), counseling, reassessment, patient education and self-management training, medication

management, care for patients in crisis, and other aspects of care, including care rendered through remote communication technology. Consider payment and coding stratification that recognizes different levels of patient need and types of practice arrangements, including care for people who have pain and substance use disorders (SUD), or other behavioral health conditions.

- Explore the feasibility of leveraging payment policy for pain management to facilitate access in underserved communities through telehealth or other technology-assisted delivery methods.

Identify and support the use of effective, non-opioid treatment options for pain

- Provide additional coding, coverage, and payment guidance and education to support Medicare providers in implementing clinical best practices with respect to pain management and opioid prescribing.
- Review the evidence base to explore the appropriateness of expanding Medicare coverage to include additional treatment options for pain management. An example cited by public stakeholders is high-flow oxygen to treat cluster headaches.
- Evaluate options to expand coverage for the full continuum of care for pain management by providing consistent and timely coverage for evidence-based interventional procedures early in the course of treatment when clinically appropriate.
- Evaluate policies to ensure appropriate payment for complex opioid and non-opioid pain management consistent with the time and resources required for patient education, safe evaluation, risk assessment, re-evaluation, and integration of non-opioid modalities.

Medicaid

Support state Medicaid agencies by identifying and sharing best practices in pain management

- Continue to share best practices and innovative initiatives received from states through Drug Utilization Review (DUR) surveys.

Promote transparency in the Medicaid program by collecting and sharing information on program activities

- Survey states to assess acute and chronic pain management services, support, payment and compliance with the SUPPORT for Patients and Communities Act.
- Compile National and State Comparison/Summary Reports on Medicaid fee-for-service (FFS) and managed care programs and make available on Medicaid.gov to provide a snapshot of individual state Medicaid FFS and managed care program activities.

Payment and Service Delivery Models

Investigate innovative payment models for multidisciplinary and multimodal pain care

- Examine models that recognize and reimburse holistic, integrated, multimodal pain management and leverage available technologies. Examples cited by public stakeholders

include Project ECHO (“Extension for Community Healthcare Outcomes”)-type models, multidisciplinary and multimodal approaches for perioperative pain control in selected patients at higher risk for OUD, and the Enhanced Recovery After Surgery (ERAS) team-based model.

- Incorporate quality measures related to safe and effective use of best practices in pain management in existing bundled payments, such as the Bundled Payments for Care Improvement (BCPI) Advanced Model.

3.2 Treatment



Figure 2. CMS Roadmap: Key Areas of Focus (Treatment)

Medicare

Support Medicare providers to offer a full range of MAT options for OUD

- Broaden bundled payment under the Medicare Physician Fee Schedule for office-based treatment for opioid use disorders. Consider a range of services to include, such as assessment and educational services for people at risk, assessment, diagnosis, person-centered plan of care, care coordination, care management (including management of multiple chronic conditions), psychotherapy (group, individual, family), counseling, occupational therapy, medication-assisted treatment, medication management, laboratory and toxicology services, services for patients in crisis, peer support services, and other aspects of care, including care rendered through remote communication technology. Consider payment and coding stratification that recognizes different levels of patient need and types of practice arrangements, including care for patients in crisis.
- Expand and develop Medicare program incentives for providers and facilities to 1) offer a full range of MAT options (including therapy for withdrawal when appropriate) 2) treat to capacity; and/or 3) initiate MAT and facilitate linkages to OUD treatment in community-based and acute care settings, including emergency departments.

Medicaid

Support state Medicaid agencies to offer a full range of MAT options for OUD by identifying and sharing best practices and providing technical assistance

- Conduct an aggregated evaluation of Section 1115 SUD-related demonstrations through state-reported information to assess the impact of the demonstrations and develop lessons learned.
- Provide technical assistance to states interested in exploring alternative payment methodologies for behavioral health treatment under existing Medicaid authorities.
- Work with and provide technical assistance to state Medicaid agencies that received planning grants under the Demonstration Project to Increase SUD Provider Capacity (authorized by Section 1003 of the SUPPORT for Patients and Communities Act) to conduct comprehensive assessments of SUD provider capacity and develop state capabilities to assess and treat SUD, including OUD.
- Explore opportunities to improve connections to SUD treatment for recently incarcerated individuals who are transitioning back into their communities.

Payment and Service Delivery Models

Implement and disseminate learning from the following models and demonstrations that address OUD treatment:

- Maternal Opioid Misuse (MOM)⁵³ Model: seeks to improve coordination and integration of care for pregnant and postpartum Medicaid beneficiaries with OUD.⁵⁴
- Integrated Care for Kids (InCK)⁵⁵ Model: a child-centered local service delivery and state payment model that aims to prevent, treat, and coordinate care for children under 21 years of age covered by Medicaid and the Children’s Health Insurance Program (CHIP).⁵⁶
- OUD Treatment Demonstration (Value in Opioid Use Disorder Treatment):⁵⁷ creates two new payments for OUD treatment services furnished to applicable Medicare beneficiaries participating in the demonstration programs.

3.3 Data



Figure 3. CMS Roadmap: Key Areas of Focus (Data)

Leverage data to understand beneficiary needs and the impact of CMS policies

- Conduct an interagency review using available data to better understand adequacy of payment and coverage for opioid alternatives.

- Systematically review special populations using the CMS Chronic Conditions Data Warehouse to determine populations appropriate for exclusion from certain opioid related payment and coverage policies; review data to understand racial disparities in diagnoses and treatment of pain and OUD.
- Review feasibility of options for tracking opioid use in the hospital setting.

Use quality measurement to understand care patterns and health impacts, and to promote clinical best practices

- Review forthcoming recommendations from the National Quality Forum related to the development and implementation of quality measures related to opioid use and OUD in federal healthcare quality programs.

The aforementioned actions will build on existing efforts underway at CMS that harness key data and analytic tools to understand and address the opioid crisis. These include:

- **The Part D Prescriber Public Use File**, which provides information on all prescription drugs covered by Part D plans. These data are organized by individual prescriber and drug name, so that prescribing patterns of opioids as well as other medications that may interact with opioids may be analyzed.
- **The Medicare Part D and Medicaid Opioid Prescribing Mapping Tools**, which are interactive tools that show geographic comparisons of de-identified Medicare Part D and Medicaid opioid prescriptions filled within the United States. The tool also includes a data table on the individual opioid prescribing rates of healthcare providers that participate in the Medicare Part D program.
- **The Overutilization Monitoring System (OMS)**, which monitors opioid overutilization by examining Prescription Drug Event data, thereby helping identify potential at-risk beneficiaries for Part D drug management programs.
- **Quality Measurement** initiatives at CMS that measure and quantify healthcare processes, outcomes, patient populations, and patient perceptions. CMS has defined Prevention and Treatment of Opioid and Substance Use Disorders as one of its Meaningful Measure Areas in order to better identify gaps in measurement and quality improvement efforts with respect to combating the opioid crisis.⁵⁸ Programs that include measures to address the opioid epidemic include the Quality Payment Program, Hospital Payment Programs, and the Medicaid Adult Core Set (detailed in Section 4).

4 Review of Payment and Coverage Policies, Beneficiary Access to Care, and Public Stakeholder Inputs

Over the past several years, CMS has taken active steps to address the opioid crisis, including many policy and operational changes intended to help reduce unnecessary opioid exposure and improve coverage for treatment of OUD in both Medicare and Medicaid. In order to identify areas for further action, CMS reviewed its policies and analyzed information collected from key stakeholders; the findings from that analysis were used to inform the actions detailed above in Section 3. The inputs CMS used to inform this Action Plan are listed in Section 1.

The findings from these analyses and stakeholder engagement activities are detailed in this section. Key themes are summarized below.

4.1 Key Themes from Public Stakeholder Inputs

- Payment and coverage policies should enable access to timely and effective care for Medicare and Medicaid beneficiaries by supporting providers in executing best practices with respect to **pain management**:
 - Pain management is optimal if it is individualized, multimodal, and multidisciplinary.
 - Patients would like to have access to a variety of options for pain management treatment and be educated about their options for covered treatments.
 - Care is ideally coordinated and integrated across the individual's care providers, particularly for transitional and chronic care.
 - Non-opioids, when clinically appropriate, can be used as first-line therapy in order to reduce unnecessary exposure to opioids. Opioid therapy should be initiated only when the benefits outweigh the risks.
 - Patients would like to have access to opioids when they are clinically indicated.
 - Providers can consider the use of screening and prevention measures to manage risk.
 - Payers can provide another layer of risk screening and management through tools such as drug utilization reviews (DURs), safety edits at the point of sale for opioids, and case management, such as through drug management programs.
 - When high-risk patients are identified, providers can optimize care by including options for treatment referrals to pain, mental health, and other specialists, including addiction medicine-trained physicians.
- Payment and coverage policies should enable access to timely and effective care for Medicare and Medicaid beneficiaries by supporting providers in executing best practices with respect to **treatment of OUD**:
 - Patients would like to have access to a variety of options for treatment of OUD and be educated about their options for covered treatments.
 - Care is ideally coordinated and integrated across the individual's care providers, particularly for transitional and chronic care.

- Medication-assisted treatment (MAT) would be more widely accessible if offered in a variety of settings, including emergency departments and community settings.
- Barriers to prescribing may include federal or state restrictions as well as coverage and payment policies.
- Case management, recovery support services, and other community supports can aid in the treatment of OUD.
- **Data** can be leveraged to help aid providers and payers in ensuring appropriate treatment for pain management and OUD:
 - Data can help to identify populations with special needs that may require individualized coverage and payment policies to ensure adequate treatment for pain management or OUD.
 - Standardized collection and sharing of data, such as in prescription drug monitoring programs, can assist providers and payers in identifying at-risk patients and managing risk

4.2 Medicare Payment and Coverage Policies

In response to Section 6032(b)(1) of the SUPPORT for Patients and Communities Act, this section provides a review of Medicare payment and coverage policies that encompass two general areas: (1) therapies that manage chronic and acute pain; and (2) MAT and other therapies that treat and minimize risk of opioid misuse and abuse.

4.2.1 Background

The Medicare program, under title XVIII of the Social Security Act, includes “traditional” or “original” Medicare benefits administered in Part A (hospital and other inpatient facility services) and Part B (physician and other outpatient facility services, and certain drugs); Part C (Medicare Advantage), in which beneficiaries alternatively elect to receive their Medicare benefits through a private insurance plan; and the optional prescription drug benefit administered by private plans under Part D. Beneficiaries enrolled in Medicare Part A and B may also purchase Supplemental Medicare Insurance policies from private insurance companies.

4.2.2 Therapies that Manage Chronic and Acute Pain

The opioid epidemic highlights the need for a balanced treatment approach to effectively manage chronic and acute pain that offers a range of treatment options to meet individuals’ needs, and prescribes opioids for pain only when clinically indicated. In addition to a review of Medicare payment and coverage policies, this section provides an evaluation of possible incentives or disincentives that may encourage the use of certain pain management approaches. Where applicable, recommendations or issues raised by the PMTF are discussed.

4.2.2.1 Medicare Part A and Part B Policies

4.2.2.1.1 *Evaluation of Incentives and Disincentives Under the Inpatient and Outpatient Prospective Payment Systems*

Medicare generally pays under Part A for covered inpatient hospital services furnished during an inpatient hospital stay based on payment rates set under the inpatient prospective payment system (IPPS).⁵⁹ Under the IPPS, CMS sets bundled payment rates to reflect average costs incurred by hospitals in providing care, generally comprising all items and services supplied by the hospital during the inpatient stay, including any drugs or other therapies provided for the purpose of managing pain. Under the IPPS, CMS annually reviews and assigns discharges to Medicare severity-diagnosis related groups (MS-DRGs), which associate patients with similar clinical conditions who are expected to require similar amounts of hospital resources.

Medicare generally pays under Part B for covered outpatient department services furnished to beneficiaries in hospital outpatient departments at amounts set under the outpatient prospective payment system (OPPS).⁶⁰ Under the OPSS, CMS annually classifies services into ambulatory payment classifications (APCs) on the basis of clinical and cost similarity. All services included in an APC have the same payment rate. Under the OPSS, certain drugs and biologicals are packaged into APCs if their per-day cost is below a certain threshold or if they fit into one of the

categories of drugs that are packaged (such as drugs that function as supplies in surgical or diagnostic procedures). Drugs and biologicals are also packaged if they are billed with a comprehensive APC service. Drugs that are not packaged under the OPPS drug packaging policies are paid separately, generally at average sales price (ASP) +6%.

Section 6032(b)(1) of the SUPPORT for Patients and Communities Act requires a review of OPPS and IPPS to determine whether payment policies have resulted in incentives or disincentives that have contributed to the opioid crisis. For the past several years as part of its annual rulemaking for OPPS and ambulatory surgical centers (ASCs), CMS has evaluated certain services that are packaged into categories for purposes of bundled payments, most recently, its “OPPS/ASC non-opioid pain management packaging policies.”⁶¹ These reviews were largely in response to stakeholder feedback; recommendations from the President’s Commission on Combatting Drug Addiction and the Opioid Crisis⁶² that CMS review and modify rate-setting policies that discourage use of non-opioid treatments, particularly those options for treating immediate post-surgical pain; and Section 6082 of the SUPPORT for Patients and Communities Act, which requires a review of payments under OPPS for opioids and evidence-based “non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives.”⁶³ Based on its review, CMS has not found evidence that its OPPS packaging policies have discouraged the use of such non-opioid alternatives in the hospital outpatient department (HOPD) setting.⁶⁴ However, in the ASC setting, changes in utilization prompted CMS to make separate payment for non-opioid pain management drugs used for post-surgical pain management to remove a potential barrier to their use rather than prescription opioids. Moreover, CMS will continue to work with stakeholders as it considers possible refinements to OPPS and the ASC payment system that will encourage use of medically necessary items and services that have demonstrated efficacy in decreasing opioid prescriptions and/or opioid use or misuse during or after an outpatient visit or procedure.

A Medicare Payment Advisory Commission (MedPAC) 2019 Report to Congress also examined how Medicare pays for opioid and non-opioid pain management drug treatments in the inpatient and outpatient hospital settings, and how current policies under IPPS and OPPS might incentivize prescribing of opioids and non-opioids for pain management, by analyzing the difference in prices between opioid and non-opioid drugs commonly used in the hospital setting.⁶⁵ After evaluating pricing across nine different pain drug groups (opioids, opioid agonists/antagonists, non-steroidal anti-inflammatory drugs (NSAIDs), neurologic, sedative, musculoskeletal therapy, and ophthalmologic agents, as well as local and general anesthetics across several routes of administration and dosage forms), MedPAC determined that opioids and other pain drugs are available at overlapping price ranges, and that there is no indication that Medicare IPPS or OPPS provides systemic payment incentives that promote the use of opioid analgesics over non-opioid analgesics. For instance, seven of the nine pain drug groups featured at least one option of a drug, route of administration, and dosage form combination that costs less than \$1 per dose. MedPAC noted that hospitals that take on additional costs by selecting more expensive non-opioid drugs (e.g., intravenous acetaminophen) for clinical reasons can mitigate those costs by also adopting multimodal approaches (e.g., a combination of non-opioid

medications such as Tylenol, ibuprofen, gabapentin, ketamine, and lidocaine) and best practices that result in reduced length of stay, as well as by shifting patients to less costly options (e.g., commonly used NSAIDs and other non-opioid pain relievers).

4.2.2.1.2 *Non-drug Pain Management Therapies Under the Physician Fee Schedule*

The Medicare Physician Fee Schedule (PFS) governs payment for physician and non-physician practitioner services under Part B. Payments under the PFS are based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service and fall into three categories of resources: work, practice expense, and malpractice expense. CMS also annually incorporates geographic adjustments to reflect variations in the costs of furnishing services in different geographic areas. The conversion factor is a national dollar amount that is multiplied by the total geographically adjusted RVU to determine the Medicare-allowed payment amount for a specific physician service.

Some non-drug therapies⁶⁶ for pain management are covered as clinician services under the PFS. These therapies can be considered singularly or combined with other therapies as part of a multimodal approach to the management of chronic and acute pain, based on individual needs.

Restorative Therapies: Medicare Part B covers outpatient physical and occupational therapy at 80 percent of the Medicare approved amount, which for some beneficiaries may create a disincentive due to higher out-of-pocket costs for the patient as compared to drug costs. Previously, the Medicare statute limited the amount of coverage for outpatient therapy available to beneficiaries in a calendar year, but that cap was removed beginning in 2019.⁶⁷ Although determining the efficacy of some forms of restorative therapy requires additional study, the PMTF report recommends that there should be minimal barriers to accessing modalities for which clear indications of benefits in the treatment of chronic pain exist as part of a recommended multidisciplinary approach.

Interventional Procedures: The PMTF, during its meeting with CMS, encouraged CMS to provide consistent and timely coverage for evidence-informed interventional procedures early in the course of treatment when clinically appropriate.⁶⁸ One PMTF member noted an example of an inconsistent coverage policy: low-risk interventional procedures such as neuromodulation require pre-approval for coverage, whereas more complex procedures such as spinal fusions do not require the same level of prior authorization.⁶⁹

Behavioral Health Approaches: The PMTF recommended that CMS improve reimbursement policies for integrated, multidisciplinary, multimodal treatment approaches that include psychological and behavioral health interventions through a variety of delivery methods (e.g., in-person, telehealth, internet self-management, mobile applications, group sessions, telephone counseling).⁷⁰ Medicare covers annual depression screenings.⁷¹ Medicare Part B pays for outpatient group or individual psychotherapy. In many cases, Medicare may also pay for a health provider's services to manage a behavioral health condition as part of the Psychiatric Collaborative Care Model (which includes a set of integrated behavioral health services that include care management support, such as care planning, medication support, and counseling) or other behavioral health integration services.

Complementary and Integrative Health: While acknowledging that more research is needed to determine the therapeutic value, risks and benefits, and mechanisms of action of various complementary and integrative approaches, the PMTF report urges considering them as part of an integrated approach to chronic pain in Medicare policies.

4.2.2.2 Medicare Part C Policies Related to Pain Management

Medicare Advantage (MA) plans must cover all Part A and B benefits (as well as Part D benefits for Medicare Advantage-Prescription Drug (MAPD) plans); however, payment arrangements between plans and providers vary from plan to plan, and may differ significantly from the benefit structure in traditional Medicare. CMS payment and coverage provisions relevant to Part D plans also apply to MAPD plans.

4.2.2.2.1 Supplemental Benefits for Pain Management Therapies

MA plans are permitted to offer certain additional covered items and services, which are not covered by traditional Medicare and are primarily health related, among other criteria, as supplemental benefits. In the 2019 Call Letter, CMS issued a broad definition of “primarily health related” to allow for the inclusion of certain non-opioid pain treatments as supplemental benefits.⁷² The Bipartisan Budget Act of 2018 (Public Law No. 115-123) further amended this policy, effective in plan year 2019, to allow plans to offer special supplemental benefits for chronically ill enrollees (SSBCIs) that have a reasonable expectation of improving or maintaining the health or overall function of the enrollee including *non-* primarily health-related benefits, and to waive the uniformity requirements so targeted supplemental benefits could be offered to subsets of enrollees based on medical condition and needs. CMS’s 2020 Medicare Advantage and Part D Final Call Letter encouraged MA plans to consider Part C benefit designs for supplemental benefits that address non-opioid pain management and complementary and integrative treatments.⁷³ For example, “peer support services” delivered by qualified individuals may be effective in facilitating recovery and assisting beneficiaries in navigating healthcare resources.

4.2.2.3 Medicare Part D Policies Related to Opioids

CMS has been monitoring overutilization of prescription drugs in the Part D program through prescriptions drug event data and other data since Part D’s inception in 2006,⁷⁴ and has required Part D plan sponsors to operate DUR, quality assurance, and medication therapy management programs. In recent years, CMS has introduced enhanced Medicare Part D opioid overutilization policies with the aim of promoting appropriate stewardship of prescription opioid utilization while still preserving medically necessary access to pain treatment. These policies also incentivize collaboration and care coordination among Medicare drug plans, pharmacies, providers, and patients in order to prevent opioid misuse and promote safer prescribing practices.⁷⁵

4.2.2.3.1 *Overutilization Monitoring System and Drug Management Programs*

With respect to retrospective DUR opioid policy, beginning in calendar year 2013, Part D sponsors were expected to identify potential opioid overutilizers, conduct retrospective reviews, and perform case management with beneficiaries' prescribers aimed at coordinated care.⁷⁶ The OMS was initially implemented in July 2013 to monitor compliance with this policy. Through the OMS, Part D sponsors received quarterly reports on high-risk beneficiaries who met the OMS criteria (using high levels of opioids with potential coordination-of-care issues due to obtaining opioids from multiple prescribers and/or multiple pharmacies). After case management with the opioid prescribers to determine medical necessity of the opioid prescriptions, sponsors subsequently provided CMS with the outcome of their review of each case. The OMS is now a reporting tool that supports the Drug Management Programs.⁷⁷ As noted in the 2019 Part C/D Call Letter, despite increasing Medicare enrollment from 2011 to 2017, from 31.5 to 45.2 million beneficiaries, the percentage of opioid users steadily decreased from about 32 percent to 28 percent. CMS concurrently observed a 76 percent decrease (almost 22,500 beneficiaries) in the number of Part D beneficiaries identified as potential very high-risk opioid users (outliers), with the greatest decrease observed from 2016 to 2017 (40%). Likewise, the percentage of opioid users identified as outliers has steadily decreased from 0.29 to 0.05 percent, a decrease of 81 percent.⁷⁸

CMS issued a final rule in 2018 to implement the Comprehensive Addiction and Recovery Act (CARA) provision that allows Part D sponsors to create Drug Management Programs (DMPs) to help address opioid misuse and abuse⁷⁹. The rule established the framework under which Part D sponsors may adopt DMPs, and codified many aspects of the retrospective Part D opioid DUR Policy and OMS. Under the DMP rule, after case management with the opioid prescribers and notice to the beneficiary, Part D plans may limit access to coverage of opioids and other frequently abused controlled substances for beneficiaries considered to be at risk for abuse and misuse of opioids. Cash transactions for these drugs are not captured in the prescription drug claims data used for the OMS.

After identifying at-risk beneficiaries, plan sponsors send a notification letter to the beneficiaries outlining the coverage limitations the plan has chosen to apply and informing them of the right to appeal. Plan sponsors have three approaches they may use to limit coverage:

- Prescriber coverage limitations, in which beneficiaries are restricted to receiving prescriptions from one or more selected prescribers.
- Pharmacy coverage limitations, in which beneficiaries are restricted to filling their prescriptions at one or more selected pharmacies.
- Beneficiary-specific point-of-sale claim edits, in which the plan sponsor sets a limit for dispensing frequently abused drugs and will not cover prescriptions that go beyond that limit.⁸⁰

Most sponsors implemented DMPs in 2019⁸¹ and a provision of the SUPPORT for Patients and Communities Act will make Part D DMPs mandatory effective January 2022. Another provision of the SUPPORT for Patients and Communities Act will expand DMPs to include beneficiaries

with a history of an opioid related overdose. CMS issued a final rule to implement these provisions in the January 19, 2021 Federal Register.⁸²

Beneficiaries who reside in long-term care facilities, are in hospice or receiving palliative or end-of life care, or are being treated for active cancer-related pain are exempted from DMPs. In the January 2021 final rule, CMS has also extended this exemption to beneficiaries who have sickle cell disease (SCD).⁸³

4.2.2.3.2 *Quality Measures Related to Opioid Prescribing and Use Under Part D*

CMS uses Medicare Part D star ratings (which are made available to beneficiaries selecting plans to help them distinguish between plans) and display measures (which are made publicly available but are not incorporated into the star ratings). CMS added a display measure related to the use of opioid opioids at high dosage and from multiple providers in the 2019, 2020, and 2021 Part D display measures⁸⁴.

4.2.2.4 **Quality Incentive Programs**

CMS has implemented a broad range of performance-based programs to improve the quality and safety of care paid for by Medicare, and CMS can use these quality programs to help address the opioid crisis. For example, CMS introduced the Meaningful Measure initiative, which identifies the highest priorities for quality measurement and improvement. Prevention and Treatment of Substance Use Disorders including Opioid Use Disorders was among those priority areas. Data collected via reporting in this Meaningful Measure area can be used for measurement and quality improvement efforts in combating the opioid crisis.⁸⁵

Additionally, Section 6093 of the SUPPORT for Patients and Communities Act required HHS to establish, or to use the consensus-based entity it contracts with, to establish a technical expert panel for reviewing quality measures relating to opioids and OUDs, identifying gap areas, and making recommendations on quality measures to include in certain Medicare quality incentive programs. This report was completed by the consensus-based entity, the National Quality Forum, in February 2020.⁸⁶

4.2.2.4.1 *Quality Payment Program*

The primary performance-based program for clinicians is the Quality Payment Program, which has two major components: the Merit-based Incentive Payment System (MIPS), in which most clinicians participate; and the Advanced Alternative Payment Model (APM) track, in which clinicians can opt to participate in APMs that meet certain threshold levels of payments or patients instead of participating in MIPS. MIPS provides financial incentives to clinicians through adjustments to their Medicare payments, based on scoring across four performance categories: Quality, Cost, Improvement Activities, and Promoting Interoperability.

In the Quality performance category, clinicians are generally required to submit six quality measures, of which one must be an outcome measure or a high-priority measure. There are currently five measures related to opioids and OUD on which clinicians may choose to report, listed in Table 1, including a measure of the percentage of patients undergoing selected surgical procedures who were managed with multimodal pain management, which was newly added for

the 2020 performance period. To promote the use of these measures, CMS has designated them as high priority.

In the Promoting Interoperability performance category, clinicians have the option to report on one measure related to opioids and OUD. CMS has released an RFI on Potential Opioid Measures for Future Inclusion in the Promoting Interoperability performance category for new potential measures that might be relevant to specific clinical priorities or goals related to addressing OUD prevention and treatment.⁸⁷

In the Improvement Activities performance category, clinicians can select improvement activities relevant to their practice to earn points. There are currently five Improvement Activities clinicians can implement related to OUD prevention and treatment.

Table 1. MIPS Measures Related to Opioids and OUD⁸⁸

Performance Category	Activity/Measure
Promoting Interoperability	Query of the Prescription Drug Monitoring Program
Quality	Multimodal Pain Management
Quality	Continuity of Pharmacotherapy for OUD
Quality	Documentation of Signed Opioid Treatment Agreement
Quality	Evaluation or Interview for Risk of Opioid Misuse
Quality	Opioid Therapy Follow-up Evaluation
Improvement Activities	CDC Training on CDC's Guideline for Prescribing Opioids for Chronic Pain
Improvement Activities	Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support
Improvement Activities	Completion of Training and Receipt of Approved Waiver for Provision of Opioid Medication-Assisted Treatments
Improvement Activities	Consultation of Prescription Drug Monitoring Program
Improvement Activities	Patient Medication Risk Education

4.2.2.4.2 Hospital Quality Programs

In the fiscal year (FY) 2020 IPPS and Long Term Acute Care Hospital Prospective Payment System final rule,⁸⁹ CMS finalized the addition of a new opioid-related electronic clinical quality measure (eCQM), the Safe Use of Opioids – Concurrent Prescribing eCQM, for the Hospital Inpatient Quality Reporting (IQR) Program and the Promoting Interoperability Program eCQM measure sets, from which hospitals select four eCQMs to report, beginning with the calendar year (CY) 2021 reporting period.⁹⁰

4.2.2.4.3 Quality Improvement Organization Program

Another key resource in CMS's effort to improve quality and efficiency of care for Medicare beneficiaries is the Quality Improvement Organization (QIO) program. The mission of this program is to improve the effectiveness, efficiency, economy and quality of services delivered to Medicare beneficiaries. Its core functions are to:⁹¹

- Improve quality of care for beneficiaries;
- Protect the integrity of the Medicare Trust Fund by ensuring that Medicare pays only for services and goods that are reasonable and necessary and that are provided in the most appropriate setting; and
- Protect beneficiaries by expeditiously addressing individual complaints, such as beneficiary complaints; provider-based notice appeals; violations of the Emergency Medical Treatment and Labor Act (EMTALA); and other related responsibilities as articulated in QIO-related law.

The quality improvement interventions of the QIO Program are implemented by area- and task-specific QIO contractors and QIO support contractors who work directly with healthcare providers and practitioners in designated geographic service areas (which generally encompass multiple states, including the District of Columbia, or territories). A QIO comprises health quality experts, clinicians and consumers organized to improve the quality of care delivered to Medicare beneficiaries.⁹² Certain QIOs support providers by facilitating data-driven quality improvement initiatives and disseminating best practices within a target region. The *CMS Roadmap: Fighting the Opioid Crisis* highlighted the QIO Program as one of its four key platforms for fostering innovation and expanding opportunities to support on-the-ground initiatives to combat the opioid crisis.⁹³ In particular, QIOs and support contractors have advanced quality improvement initiatives that provide data, education and technical assistance to help identify and implement local and national best practices to combat the opioid epidemic.⁹⁴

4.2.2.5 Highlights: Medicare Payment and Coverage Policies Related to Pain Management

- Medicare IPPS and OPPS are not designed to incentivize particular treatments. Continued assessment and evaluation of additional data and evidence are warranted.
- The lack of consistent and timely coverage for evidence-informed approaches early in the course of treatment when clinically appropriate has been noted as a barrier to non-opioid pain management.
- CMS has taken steps to address payment and coverage barriers to the use of non-opioid pain management therapies in Part C. CMS has offered new flexibilities under the MA program by allowing plans to offer targeted benefits and cost-sharing reductions for enrollees with chronic pain or SUD.
- CMS has taken a number of steps to enable and incentivize safe and effective prescribing practices for opioid analgesics. In the Medicare Part D program, CMS has developed additional tools and policies to enable plans to monitor utilization of opioids, implement safety edits at the point of dispensing, and put in place limitations on access to opioids in

cases at risk for abuse and misuse. CMS has also leveraged its quality programs to incentivize payers, prescribers and hospitals to use best practices for the safe use of opioids.

4.2.3 Therapies that Treat and Minimize Risk of Opioid Misuse and Abuse

As noted in Section 1, MAT is recognized as the gold standard for treating people with OUD.⁹⁵ Also critical to treating and minimizing the risk of OUD are coverage policies that (1) allow providers to screen for risk before OUD or abuse might occur, and—when screening or treatment fails—(2) improve access to the overdose antidote naloxone. A “whole-patient” approach, which includes the use of FDA-approved medications, described below, in combination with counseling and behavioral therapies, is essential for curbing the opioid crisis.

4.2.3.1 Medication-Assisted Treatment

4.2.3.1.1 Medicare Coverage Policies

There is no distinct Medicare benefit category for SUD treatment. However, items and services used for substance use treatment may fall within Medicare benefit categories and may be covered if reasonable and necessary and if they otherwise meet applicable requirements. For instance, Medicare covers certain physician-administered medications for MAT such as buprenorphine, buprenorphine-naloxone combination products,⁹⁶ and extended-release (ER) injectable naltrexone. As noted previously, Medicare also covers counseling and behavioral therapy services (described in Appendix C, Table 11) that are reasonable and necessary, and that are furnished by eligible Medicare practitioners who can bill and receive payment under Medicare.

In general, Medicare Part B covers drugs in three categories: drugs furnished incident to a physician’s services (drugs that are not usually self-administered); drugs administered by means of a covered item of durable medical equipment (DME); and other drugs specified by statute. Drugs furnished incident to a physician’s service include injectable or infusion drugs that are administered in a non-facility setting or in a hospital outpatient setting (when adopted under OPPS). Buprenorphine (injection), buprenorphine (implant), and naltrexone (injection) are generally covered and paid for under Part B. Medicare Part D covers drugs that are dispensed upon a prescription by a pharmacy (consequently, methadone is not currently considered a Part D drug when used for MAT, since it can be dispensed for purposes of MAT only through an OTP certified by SAMHSA. However, methadone dispensed for pain may be considered a Part D drug). Oral medications, such as oral buprenorphine, currently fall under Part D. To ensure that beneficiaries’ access to MAT is not impacted, CMS expects sponsors to exempt buprenorphine for MAT from opioid safety edits.⁹⁷

Although methadone is one of the three FDA-approved treatment options for MAT, Medicare has historically not covered it for MAT due to the unique method by which it is dispensed and administered. In the CY 2020 PFS final rule, CMS adopted regulations implementing Section 2005 of the SUPPORT for Patients and Communities Act, which establishes a new Part B benefit category for OUD treatment services furnished by an OTP for episodes of care beginning on or after January 1, 2020. The SUPPORT for Patients and Communities Act amends the definition of

“medical and other health services” to provide for coverage of OUD treatment services, and establishes new bundled payments for OTPs for OUD treatment services furnished during an episode of care. Inclusion of OTPs (and more specifically methadone for MAT) in Medicare coverage policies addresses a critical need, as the majority of patients at the 1,700 OTPs across the United States receive methadone for MAT services as opposed to buprenorphine or naltrexone.⁹⁸

4.2.3.1.2 *OTP Medicare Coverage*

In the CY 2020 PFS rule,⁹⁹ CMS established several bundled payment amounts for OUD treatment services which include:

- Drug component (the medications approved by the FDA for use in the treatment of OUD):
 - Oral buprenorphine, injectable buprenorphine, and implantable buprenorphine
 - Naltrexone
 - Methadone
- Non-drug component:
 - The dispensing and administration of such medication
 - Substance-use counseling
 - Individual and group therapy
 - Toxicology testing
 - Intake activities and periodic assessments

Payment for most Part B drugs is based on the drug’s average sales price (ASP) plus a statutorily mandated 6 percent add-on. The payment does not include the cost to administer the drug to the patient. MedPAC notes that the 6 percent add-on may create an incentive for providers to use more expensive drugs because the percentage-based add-on has the unintended consequence of potentially generating increased revenue for more expensive drugs.¹⁰⁰ To avoid creating a perverse incentive for OTPs to favor expensive MAT drugs over more appropriate drugs, CMS has limited payment amounts for MAT medications included in the drug component of OTP bundled payments to the ASP, when the ASP is available, such that there is no 6 percent add-on.

4.2.3.1.3 *Prior Authorization*

Prior authorization is meant to help payers ensure appropriate care while helping to minimize costs and reduce wasteful spending on unnecessary services. Prior authorization helps make treatments available and affordable. But prior authorization can sometimes lead to delayed, or denied care. Medicare Parts A and B do not typically make use of prior authorization for substance abuse or pain management medication, but MA and Medicare Part D plans often require prior authorization for certain drugs.

In April 2018, CMS announced¹⁰¹ that it would not approve Part D formularies that required prior authorization for buprenorphine products more frequently than once per year, citing the FDA labeling change¹⁰² for buprenorphine products that emphasized the importance of preventing barriers to obtaining medications for OUD. These policy changes have been

associated with a steep decline between 2018 and 2019 in the proportion of Part D plans requiring prior authorization for buprenorphine products.¹⁰³

CMS, along with the Office of the National Coordinator for Health Information Technology (ONC), has taken steps to evaluate and address other process and clinical workflow factors contributing to barriers associated with prior authorization.¹⁰⁴

4.2.3.1.4 *Cost Sharing*

High cost sharing can create burdens for individuals in accessing MAT, which has led some advocates to suggest MAT drugs be maintained on the lowest cost-sharing tiers.¹⁰⁵ In the regulations implementing the new benefit for OUD treatment services furnished by OTPs, CMS adopted a copayment amount of zero for OUD treatment services, including any MAT drugs furnished by an OTP as part of an episode of care.¹⁰⁶

4.2.3.2 **Screening and Other Therapies that Treat and Minimize Risk of Opioid Misuse and Abuse**

4.2.3.2.1 *Identifying Patients*

Screening for risk of SUD/OUD could include taking a medical history, review of medical records, querying prescription drug monitoring programs (PDMPs), and urine toxicology screenings, when clinically indicated. The PMTF reports that a lack of sufficient compensation for time and payment for the time-consuming but vital evaluation and re-evaluation of chronic pain conditions may have contributed to barriers in providers engaging in the treatment of chronic pain.

A growing body of research is now taking the spotlight of the opioid crisis off prescription opioid medication and attributing most overdoses to the misuse of heroin and illicitly made fentanyl. In 2019, approximately 73% of opioid overdose deaths involved synthetic opioids other than methadone.¹⁰⁷ A Massachusetts study of opioid-related deaths revealed that only 1.3 percent of individuals had an active opioid prescription; instead, most had used heroin or fentanyl, while nearly a quarter died from a mix of illegal and prescription drugs.¹⁰⁸ Another study that examined emergency department (ED) use of prescription opioids used to treat pain found that six months after an ED visit, only 1 percent of patients were still using opioid medications.¹⁰⁹ The environment for patients with pain to receive care, especially from primary care clinicians, has become increasingly difficult; some reports have indicated only one in five clinicians will accept new patients with chronic pain disorders or those using opioids.¹¹⁰

Medicare SBIRT services are offered in physicians' offices and outpatient hospitals under the PFS and the OPPS, respectively. At present, time-based Healthcare Common Procedure Coding System codes allow providers to bill for periods of 5–14 minutes, 15–30 minutes, and greater than 30 minutes.

4.2.3.2.2 *Naloxone*

CMS promotes improved access to naloxone by requiring that the antidote appear on all Medicare Part D formularies, and by encouraging sponsors to include at least one naloxone product on a generic or Select Care Tier. Select Care Tiers provide for \$0 or low cost-sharing for those plans that utilize such a tier model. CMS encourages Part D plan sponsors to ensure coverage for beneficiaries at risk, and recommends targeted education of prescribers and enrollees on co-prescribing of naloxone to prevent accidental overdoses and to sensitively address the needs of beneficiaries with OUD.

The CDC reports that primary care providers only prescribed about two naloxone prescriptions for every 100 high-dose opioid prescriptions.¹¹¹ CMS recognizes that some beneficiaries may need naloxone to address the use of illegal opioids and recommends that prescription of opioids should not be the only factor plans consider when determining the clinical appropriateness of prescribing naloxone.¹¹² CMS also encourages Part D sponsors to consider more innovative approaches, such as patient-specific pharmacy messaging to alert pharmacists to provide naloxone to at-risk beneficiaries taking opioids in states that allow for standing naloxone orders. CMS also recommends targeted education of prescribers and enrollees on co-prescribing naloxone.¹¹³

4.2.3.3 **Highlights: Medicare Payment and Coverage Policies Related to OUD Treatment**

- Lack of coverage for FDA-approved methadone for MAT under Medicare may create a disincentive to referrals for effective OUD treatment. CMS's inclusion of OTPs as entities that can bill to Medicare under the 2020 PFS, as mandated by the SUPPORT for Patients and Communities Act, is likely to increase access to methadone for MAT. For CY 2020, CMS provided that there will be no beneficiary co-payment for OUD services furnished by OTP facilities covered under Medicare Part B.
- Percentage-based add-on payments may create an incentive for providers to use more expensive drugs because the percentage-based add-on has the unintended consequence of generating increased revenue for more expensive drugs.¹¹⁴
- Utilization management controls such as prior authorization are needed to make treatments available and affordable, however, it may sometimes present delays and barriers to beneficiary access to MAT for OUD.
- Placing MAT drugs on higher cost-sharing tiers may result in disincentives and barriers for beneficiaries to receive MAT. Placing MAT drugs on lower cost-sharing tiers helps to promote affordability and availability of MAT drugs. Allowing Part D sponsors to perform mid-year formulary changes when a generic equivalent of a prescription drug becomes available may help to increase the availability and use of lower cost prescription drugs.

4.3 Medicaid Payment and Coverage Policies

In response to Section 6032(b)(1) of the SUPPORT for Patients and Communities Act, this section provides a review of Medicaid payment and coverage policies encompassing two general areas: (1) therapies that manage chronic and acute pain; and (2) MAT and other therapies that treat and minimize risk of opioid misuse and abuse.

4.3.1 Therapies that Manage Chronic and Acute Pain

This section outlines federal Medicaid payment and coverage policies and evaluates incentives or disincentives related to pain management approaches.

4.3.1.1 Policies Related to Opioids

Federal and state governments have worked to improve appropriate opioid prescribing and management in the Medicaid program. The most prevalent areas of focus for states in this regard include adoption of policies related to pharmacy benefit strategies, DUR programs, prescribing guidelines, PDMP requirements, and quality measures. However, variability exists across the states.

4.3.1.1.1 Pharmacy Benefit Strategies

CMS has provided education about the appropriate management of opioids and effective pharmacy benefit strategies and has taken a series of actions to help Medicaid program administrators and providers stay abreast of the most recent information and emerging strategies related to the use of prescription opioids. Table 2 presents examples of communications.

Table 2. CMS Communications about Opioid Prescribing and Pharmacy Benefit Management Strategies

Communication	Title	Audience	Key Content
Center for Medicaid and Children's Health Insurance Program (CHIP) Services (CMCS) Informational Bulletin, August 5, 2019	<i>State Guidance for Implementation of Medicaid Drug Utilization Review (DUR) provisions included in Section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act</i>	State Medicaid Program Leaders	Provides information on new DUR provisions in Section 1004 and the requirements regarding opioid prescription claim review limitations, the monitoring of antipsychotic medication in children, processes to detect fraud and abuse, and managed care programs. ¹¹⁵

Communication	Title	Audience	Key Content
Center for Medicaid and CHIP Services (CMCS) Informational Bulletin, February 22, 2019	<i>Medicaid Strategies to Facilitate for Non-Opioid Pharmacologic and Non-Pharmacologic Chronic Pain Management</i>	State Medicaid Program Leaders, Prescribers	Expands on prior guidance and provides information on state promotion on non-opioid options for chronic pain management; details the CDC guidelines and non-pharmacologic and non-opioid pharmacologic therapy coverage options. ¹¹⁶
Center for Medicaid and CHIP Services (CMCS) Informational Bulletin, January 17, 2017	<i>State Flexibility to Facilitate Timely Access to Drug Therapy by Expanding the Scope of Pharmacy Practice using Collaborative Practice Agreements, Standing Orders or Other Predetermined Protocols</i>	State Medicaid Program Leaders, Prescribers, Pharmacists	Explains the flexibilities available to expand scope of practice and services of pharmacists to increase timely access to drug therapy, such as collaborative practice agreements and “standing orders.” ¹¹⁷
Center for Medicaid and CHIP Services (CMCS) Informational Bulletin, January 28, 2016	<i>Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction</i>	State Medicaid Program Leaders	Emphasizes the importance of provider and pharmacist training, dissemination of opioid prescribing guidelines, sufficient methadone policies (e.g., removing it from the preferred drug list); pharmacy benefit practices (e.g., prior authorization and quantity limits); and use of PDMPs. ¹¹⁸
Drug Diversion Toolkit, February 2016	<i>Prescription Opioids: An Overview for Prescribers and Pharmacists</i>	Prescribers, Pharmacists	Discusses prescription opioid diversion; mechanisms, reasons for, and signs and symptoms of, abuse; opioid-related regulations; PDMPs; risk management; and how to decrease the likelihood of diversion. ¹¹⁹

Under Section 1927(d) of the Social Security Act, states may implement utilization management techniques.¹²⁰ Even for preferred medications, states may choose to implement prior authorization to improve quality and manage drug classes that have been identified as requiring additional monitoring. This helps ensure that drugs are being prescribed for the right patients and for the appropriate reasons, while still monitoring drug expenditures. Pharmacy benefit management strategies for opioids that states have reported they instituted or plan to institute in their FFS programs include:

- Quantity limits
- Clinical criteria claim system edits
- Step therapy prior authorization criteria
- Other prior authorization

- Use of preferred drug lists
- Required use of PDMPs¹²¹

Some states have also worked to align their Medicaid MCO pharmacy benefit management policies with their FFS requirements.¹²²

4.3.1.1.2 *Drug Utilization Review Policies and Programs*

CMS and Congress have leveraged state Medicaid DUR programs to increase information collection and transparency. States must operate DUR management programs to ensure prescriptions are: (1) appropriate; (2) medically necessary; and (3) not likely to result in adverse medical results. Section 1927(g) of the Social Security Act requires states to implement DUR programs that include both prospective and retrospective reviews of prescription drug claims in order to recognize issues related to drug allergies, therapeutic duplications, contraindications, incorrect dosage or duration, clinical misuse, fraud, abuse, and medically unnecessary care.¹²³ States are also required to complete annual surveys designed by CMS describing overall prescribing practices, and their DUR programs' operations and impacts. In recent years, CMS has included key questions in the survey about strategies to ensure appropriate opioid utilization.

Additionally, in accordance with Section 1004 of the SUPPORT for Patients and Communities Act, states must implement management strategies for opioids that include:

- **Claim review limitations:**
 - Prospective safety edits on subsequent fills for opioid prescriptions
 - Prospective safety edits on maximum daily morphine milligram equivalents (MMEs) on opioid prescriptions to limit the daily morphine milligram equivalent (as recommended by clinical guidelines) reviews on opioid prescriptions exceeding these above limitations on an ongoing basis
 - Reviews on concurrent utilization of opioids and benzodiazepines as well as opioids and antipsychotics on an ongoing periodic basis.
- **Fraud and abuse identification:** The DUR program has established a process that identifies potential fraud or abuse of controlled substances by enrolled individuals, healthcare providers, and pharmacies (as designed and implemented by the state).

In issuing guidance related to Section 1004, CMS noted:

“Although the text of the provisions added by the SUPPORT for Patients and Communities Act (and therefore, this guidance) addresses only MCOs in the managed care context, CMS encourages states to act consistently in imposing the new requirements on all managed care plans with regards to the new responsibilities added by the SUPPORT for Patients and Communities Act. States may include Prepaid Ambulatory Health Plans (PAHP) and Prepaid Inpatient Health Plans (PIHP) when implementing SUPPORT for Patients and Communities Act updates. CMS intends to consider future rulemaking to implement the requirements of the SUPPORT for Patients

and Communities Act discussed in this Bulletin uniformly for all Medicaid managed care plans.”¹²⁴

CMS posts annual surveys, as well as summary reports of state-level data, on the Medicaid.gov website. For federal fiscal year (FFY) 2017, the majority of states had edits in place to limit the quantity of short- and long-acting opioids.¹²⁵ In addition, 24 states had established recommended MME Daily Dose edits, and 44 states had limits on daily milligrams of buprenorphine prescribed.¹²⁶ CMS has also posted mapping tools on the CMS website that demonstrate geographically the number and percentage of opioid prescriptions in both the Medicaid and Medicare programs.¹²⁷

4.3.1.1.3 *Prescribing Guidelines*

CMS has promoted the use of evidence-based opioid prescribing guidelines and best practices for chronic pain among providers in various tools and initiatives such as informational bulletins, and the Quality Improvement Organization program.^{128, 129} The Agency has required adoption of opioid prescribing guidelines as a condition of some Section 1115 demonstration waiver approvals focused on improving access to SUD treatment.¹³⁰ In October 2019, as noted in Section 2.1, HHS issued guidance on best practices with respect to appropriate dosage reduction or discontinuation of long-term opioid analgesics and screening and risk identification for supportive therapies and/or continuation of opioids as needed.

4.3.1.1.4 *PDMP Requirements*

PDMPs exist in almost every state, plus the District of Columbia, Guam, and Puerto Rico.¹³¹ Specific requirements related to PDMPs, such as the types of controlled substances that must be reported and the entities that must submit data, vary by state law. Section 5042 of the SUPPORT for Patients and Communities Act requires that by October 2021, states must mandate that covered providers consult a qualified PDMP for a patient’s drug history before they prescribe controlled substances, unless providers document why they are unable to conduct such a check despite a good-faith effort. States will determine the form, manner, and timing of these mandated PDMP consultations. Additionally, by 2023, states must report to HHS regarding annual data about use of PDMPs by covered providers before prescribing controlled substances, and aggregated trend data regarding quantities of certain opioids prescribed and for what durations, by specified populations.¹³² These statutory requirements enhance CMS efforts to encourage states to adopt policies that require providers to check PDMPs before prescribing controlled substances.¹³³ Beginning in 2017, CMS also began to require some states to implement strategies to increase the use and functionality of PDMPs as a condition of Section 1115 demonstration approvals.¹³⁴

CMS provided guidance to states on PDMP standards in a June 11, 2018 letter (SMD Letter #18-006) and in the Interoperability Standards Advisory published by the ONC entitled “Prescriber’s Ability to Obtain a Patient’s Medication History from a Prescription Drug Monitoring Program.” In this guidance, CMS encouraged states to take a standards-based approach to the electronic prescribing of controlled substances, interstate data sharing of PDMP data, electronic case reporting, and electronic health records (EHRs) integration.¹³⁵

4.3.1.1.5 Quality Measures

Provisions in Section 1139A of the Social Security Act, as amended by Section 401(a) of the Children’s Health Insurance Program Reauthorization Act (CHIPRA) of 2009 and Section 1139B of the Social Security Act, as amended by Section 2701 of the Affordable Care Act^{136, 137} required HHS to develop core quality measure sets for children and adults in Medicaid and CHIP. Most states collect and report at least some data on the Child and Adult Core Sets, which include measures related to primary care, maternal health, chronic conditions, behavioral health, experience of care, and dental health. The Adult Core Set includes several measures related to opioid prescribing and SUD treatment:¹³⁸

- Use of Opioids at High Dosages in Persons Without Cancer (26 states reported in FFY 2019)¹³⁹
- Initiation and Engagement of Alcohol and Other Drug Abuse or Dependence Treatment (38 states reported in FFY 2019)¹⁴⁰
- Follow-up After Emergency Department Visit for Alcohol and Other Drug Abuse or Dependence (36 states reported in FFY 2019)¹⁴¹
- Concurrent Use of Opioids and Benzodiazepines (22 states reported in FFY 2019)¹⁴²
- Use of Pharmacotherapy for Opioid Use Disorder (added to the Health Home Core Set and the 2020 Medicaid Adult Core Set)¹⁴³

The SUPPORT for Patients and Communities Act will require states to report behavioral health measures, which include the SUD-related measures listed earlier, from the Adult Core Set beginning in the 2024 reporting year.¹⁴⁴

CMS launched the Medicaid and CHIP Scorecard initiative in June 2018 to promote greater transparency and accountability for the program’s administration and outcomes. The Scorecard, which was updated in November 2019, comprises a range of data and quality measures across three pillars: state health system performance, and the state and federal administrative accountability pillars. The Scorecard includes two relevant measures: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment, and Use of Opioids at High Dosages in Persons Without Cancer.¹⁴⁵ CMS envisions that the Scorecard will be strengthened by the availability of more timely, accurate, and complete data collected through the Transformed Medicaid Statistical Information System, as state reporting continues to improve.¹⁴⁶ As the Scorecard evolves, CMS may consider additional measures related to substance use. CMS also requires states to report additional measures as part of a Medicaid waiver or demonstration program.

4.3.1.2 Non-Opioid Pain Management Therapies

In the Medicaid program, CMS has provided guidance about opportunities to incorporate non-opioid pain management therapies into state benefit and demonstration programs. With the exception of Section 1004 of the SUPPORT for Patients and Communities Act and other specific DUR related provisions, CMS may generally only recommend and provide guidance to states about non-opioid pain management therapies, but not impose additional requirements.

4.3.1.2.1 Non-Opioid Medications

In guidance issued in early 2019, CMS suggested that states consider adopting pharmacy benefit strategies that prioritize non-opioid analgesics for non-cancer-related chronic pain when clinically appropriate.¹⁴⁷ For brief background, states opting to provide Medicaid coverage of prescription drugs must do so consistent with sections 1902(a)(54) and 1927 of the Social Security Act, which establish certain requirements for states and manufacturers related to prescription drugs that satisfy the definition of a covered outpatient drug at section 1927(k) of the Social Security Act. Medicaid programs generally manage their usage of drugs covered under their state plan through coverage criteria typically developed through a state's Pharmacy and Therapeutics committee and/or DUR board. Pursuant to Section 1927(d) of the Social Security Act, States may use utilization management controls, such as prior authorization or formularies, to promote efficient delivery of care and to control costs. Even for preferred medications, states may choose to implement prior authorization to improve quality and manage drug classes that have been identified as requiring additional monitoring intended as a means of ensuring that drugs are being prescribed for the right patients and for the appropriate reasons, while still monitoring drug expenditures. Drugs may be subject to prior authorization, preferred drug lists, and limits on quantities that can be dispensed.¹⁴⁸ Medicaid programs are also allowed to cover over-the-counter medications (based on state policy) if a patient has a prescription from an authorized prescriber.¹⁴⁹

4.3.1.2.2 Non-Pharmacologic Services

States have a variety of authorities under the Medicaid program for covering non-opioid pain management services. Although federal Medicaid law requires coverage of inpatient hospital, outpatient hospital, physician, and certified pediatric and family nurse practitioner (NP) services for categorically needy populations, it generally does not mandate coverage of any specific type or category of non-opioid management of acute or chronic pain. Those decisions are generally left to states, with some exceptions, such as through the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit, under which states must provide all children under age 21 who are eligible for this benefit with medically necessary Medicaid services even if those services are not included in the state plan. A variety of statutory and regulatory authorities allow state Medicaid programs to cover non-pharmacological pain management therapies and supportive services. CMS illustrated key strategies for covering non-opioid pain therapies in its February 22, 2019, Informational Bulletin, *Medicaid Strategies for Non-Opioid Pharmacologic and Non-Pharmacologic Chronic Pain Management*.¹⁵⁰ Table 3 provides a summary.

Table 3. Examples of Medicaid Authorities Allowing Coverage of Non-Pharmacologic Pain Management Services¹⁵¹

Authority	Services that May be Covered
Rehabilitative Services	States may cover biofeedback, cognitive behavioral therapy, occupational therapy, and physical therapy under the optional rehabilitative services state plan benefit.

Authority	Services that May be Covered
Physical Therapy and Related Services	States may cover physical or occupational therapy as optional state plan benefits.
Other Licensed Practitioner Services	Depending on state law, Medicaid programs may be able to cover acupuncture or chiropractic care as an “other licensed practitioner” service.
Preventive Services	Physical activity counseling could be covered as a preventive service.
Health Homes	States may use the Section 1945 Health Homes optional benefit to enhance non-pharmacologic management of chronic pain (by covering care coordination and related services that might help patients to better understand their conditions and support them in making needed lifestyle changes).
Innovative state plan amendment options, 1115 demonstrations, managed care, and other payment strategies (e.g., bundled payment)	Each of these authorities may provide additional options for addressing chronic pain. For example, a state could apply for an 1115 demonstration to enable certain additional services, such as acupuncture, to be offered in limited geographic regions. In a risk-based managed care arrangement, a managed care plan may voluntarily agree to cover additional benefits that are not covered under the state Medicaid plan as long as their costs are not incorporated into the capitation rates. In addition, for state Medicaid plan services, a state may use different payment strategies, such as a bundled rate for pain management that could include a range of services for a given condition.

A 2018 review of 15 Medicaid managed care plans found that for beneficiaries with low back pain, most plans covered limited physical and occupational therapy (14 plans); chiropractic care (12 plans), transcutaneous electrical nerve stimulation (TENS) (10 plans), and steroid injections (nine plans).¹⁵² Other therapies (e.g., acupuncture, therapeutic massage, psychological interventions, and facet injections) and surgeries such as laminectomy and discectomy were covered less often, which may present a barrier to effective pain management for some beneficiaries.¹⁵³

4.3.1.3 Highlights: Medicaid Payment and Coverage Policies Related to Pain Management

- A variety of statutory and regulatory authorities allow state Medicaid programs to cover a wide array of non-pharmacological pain management therapies and supportive services. However, states generally do not cover every non-opioid pain management therapy, and some may be subject to utilization management controls such as prior authorization or step therapy. Current state Medicaid policies related to non-opioid pain management may impede providers’ ability to offer a full range of services.
- Emphasis on pharmacy benefit management (PBM) strategies and DUR should continue to play a valuable role in addressing risks related to prescribing opioids. Although current PBM and DUR policies vary across states, all states have some requirements in place. Further, new SUPPORT for Patients and Communities Act provisions requiring safety edits for opioids should bring additional uniformity across programs.

- A new federal policy requiring Medicaid providers to check PDMPs should incentivize more providers to check, and more states to improve the functionality of, their respective PDMPs.
- Some, but not all, states have adopted opioid prescribing guidelines for chronic pain across Medicaid FFS and managed care programs. The SUD Section 1115 demonstrations include an expectation that states implement opioid prescribing guidelines.

4.3.2 Therapies that Treat and Minimize Risk of Opioid Misuse and Abuse

Historically, all state Medicaid programs have covered some types of medications for MAT, and most states cover a variety of behavioral health counseling services. Despite significant gains in the number of Medicaid beneficiaries receiving MAT between 2013 and 2017, a large gap in treatment existed before October 1, 2020, when a new coverage mandate for MAT to treat OUD took effect through September 30, 2025. In 2017, fewer than half of Medicaid beneficiaries with OUD received treatment.¹⁵⁴

States have used different Medicaid authorities to cover OUD treatment over time. As noted in an October 2019 Medicaid and CHIP Payment and Access Commission (MACPAC) report to Congress on utilization management of MAT in Medicaid, MAT medications were historically typically covered through the optional Medicaid prescription drug benefit under Section 1905(a)(12) of the Social Security Act, while counseling related to MAT historically generally fell under the optional Medicaid rehabilitative services benefit under Section 1905(a)(13).¹⁵⁵ In its June 2018 Report to Congress, MACPAC emphasized that the SUD treatment continuum of care should encompass outpatient services (including at primary care and other non-specialty sites), intensive outpatient services, partial hospitalization, residential treatment, and MAT.¹⁵⁶ However, its analysis of publicly available state Medicaid documents, such as state plan and Section 1115 demonstration information, found that only 12 states reimbursed along that full continuum of care at that time.¹⁵⁷

On average, MACPAC's review showed that in 2018 states covered only six of the nine levels of care established by the American Society for Addiction Medicine for adults ages 21–64. These levels of care are early intervention, outpatient services, intensive outpatient services, partial hospitalization, clinically managed low-intensity residential services, clinically managed population-specific high-intensity residential services, clinically managed high-intensity residential services, medically monitored intensive inpatient services, and medically managed intensive inpatient services.¹⁵⁸ Residential treatment and partial hospitalization represented the largest, but not the only, coverage gaps, though all states cover some level of outpatient services.¹⁵⁹ Recent efforts by CMS and Congress to address the Institutions for Mental Diseases (IMDs) exclusion may help address residential care gaps (described in section 4.3.2.3.1).

MACPAC also cited information from SAMHSA indicating that only 62 percent of specialty facilities offering SUD treatment accepted Medicaid for at least some services in 2016, compared to a private insurance participation rate of 68 percent. However, the rate of specialty facility Medicaid acceptance varies by state. MACPAC suggested that low payment rates in some states and for some services, among other barriers, may contribute to decreased Medicaid provider

participation.¹⁶⁰ An April 2019 report commissioned by MACPAC and released in November 2019 examined prescribing patterns for buprenorphine among NPs and Physician Assistants (PAs) and Physicians to treat OUD in the Medicaid population. The report observed a 12 percent increase in buprenorphine prescriptions among Medicaid beneficiaries (twice the increase in buprenorphine prescriptions for all patients) from July 2017 to June 2018, noting that out of all patients with buprenorphine prescriptions, approximately 40 percent had at least one prescription paid for by Medicaid. Further, it found that “Medicaid beneficiaries were more likely to receive buprenorphine prescriptions from advanced practitioners than patients covered by Medicare or commercial insurance, and those who paid in cash.”¹⁶¹ Further discussion of access issues related to buprenorphine waivers can be found in Section 4.4.

From October 1, 2020 through September 30, 2025, sections 1902(a)(10)(A) and 1905(a)(29) of the Social Security Act (as amended and added by section 1006(b) of the SUPPORT for Patients and Communities Act), require Medicaid state plans to cover all drugs approved under section 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), including methadone, and all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) to treat opioid use disorders, as well as related counseling services and behavioral therapy, for categorically needy populations, unless the state obtains an exception for a MAT provider shortage or for state legislative delay from CMS.

4.3.2.1 Medications for MAT

Historically, although every state Medicaid program covered some form of medication for MAT, states’ coverage policies and their Medicaid benefit designs often differed. However, as noted above, for a five year period beginning October 1, 2020, all states must cover all drugs and biologicals that are approved or licensed by the FDA for MAT to treat opioid use disorders and related counseling services and behavioral therapies. To the extent such MAT drugs and biologicals meet the definition of a covered outpatient drug, the utilization management tools set forth at section 1927(d) of the Social Security Act can apply. Consistent with section 1927(d) of the Social Security Act, states may subject any covered outpatient drug to prior authorization and certain other utilization management techniques. A state plan may require, as a condition of coverage or payment for a covered outpatient drug, the approval of the drug before its dispensing for any medically accepted indication only if the system providing for such approval: (1) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and (2) with the exception of a few drugs excluded from this provision, is able to dispense at least a 72-hour supply of a covered outpatient prescription drug in an emergency situation as defined by the HHS Secretary.¹⁶² A state may also impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under the Social Security Act.¹⁶³

In its October 2019 report, MACPAC examined national trends as well as approaches taken by eight states under both FFS and managed care. MACPAC observed a wide variation in

utilization management policies among states but found it difficult to determine the extent to which these policies posed barriers to MAT access in the time frame studied. Overall, fewer states assigned preferred status to MAT drugs in 2018 as compared to 2011–2013, which may have had a negative impact on beneficiaries’ access to these medications. However, over the same period there was also a reduction in the number of states requiring prior authorization, lifetime limits, and counseling.¹⁶⁴

4.3.2.2 Other Therapies that Treat and Minimize Risk of Opioid Misuse and Abuse

4.3.2.2.1 Screening for Risk

Most, but not all, state Medicaid programs cover screening services. Under Medicaid, states may provide SBIRT services in several ways: as physician services, services of other licensed practitioners, preventive services, and rehabilitative services.¹⁶⁵ MACPAC noted that in 2012, 34 states and the District of Columbia included some type of screening, intervention, and referral under Medicaid.¹⁶⁶

4.3.2.2.2 Outpatient Counseling and Rehabilitation Services

States appear to provide coverage for outpatient counseling and rehabilitation services, including the types of counseling and behavioral therapies likely envisioned as part of MAT. One survey of state Medicaid programs inquired about benefits specific to behavioral health services for categorically eligible adults age 21 and older in FFS programs as of July 1, 2018. The number of states reporting certain types of coverage for behavioral health services is summarized in Appendix D, Table 12. Many of the services provided have limitations, such as prior authorization requirements, or restrictions related to the amount, duration, or sites of services.¹⁶⁷

4.3.2.2.3 Recovery Support Services and Case Management

States use various Medicaid authorities to provide recovery support services, including the state plan rehabilitative services option, Section 1115 demonstrations, the optional health homes benefit, and certified community health clinics.¹⁶⁸ There is no consistent definition of recovery support services in the Medicaid program, though many states cover the various types of services described in Appendix D, Table 13. Section 1008 of the SUPPORT for Patients and Communities Act requires the Comptroller General of the United States to submit a report to Congress about the provision of peer support services under the Medicaid program, including recommendations for improving access to peer support services, by October 24, 2020.

Case management is an optional Medicaid benefit that states can cover through the state plan under section 1905(a)(19) of the Social Security Act and 42 C.F.R. 440.169 and 441.18. States can also opt to cover case management under other benefits and authorities, such as through Section 1115 demonstrations, or the optional rehabilitative services or health home benefits. See Appendix D, Table 14. MACPAC has highlighted the importance of case management in

ensuring that patients have an uninterrupted continuum of care. Case management activities may include working with patients in recovery to assess whether they need additional services, assisting patients as they transition out of facility-based care, and helping them access different types of services.

4.3.2.3 Key Policies Addressing Medicaid Payment and Coverage of SUD Services

Both federal and state governments have worked diligently to expand access to MAT and SUD treatment by harnessing a variety of statutory and regulatory levers to improve SUD payment and coverage.

4.3.2.3.1 Services Provided in Institutions for Mental Diseases

One commonly cited barrier to SUD treatment is the statutory “IMD exclusion” described in section 1905(a)(30)(B) of the Social Security Act, which generally prohibits Medicaid payment for care or services provided to individuals who have not attained 65 years of age and who are a patient in an institution for mental diseases (IMD). An IMD is defined in section 1905(i) of the Social Security Act as “a hospital, nursing facility, or other institution of more than 16 beds, that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care, and related services”). One strategy CMS has employed to address the opioid epidemic has been to facilitate federal matching funds for care provided to beneficiaries who are short-term residents in IMDs primarily to receive treatment for an opioid use disorder, through section 1115 demonstrations. In 2016, CMS amended Medicaid managed care rules to allow states to receive Federal Financial Participation (FFP) for capitation payments made to MCOs and PIHPs for enrollees ages 21–64 receiving inpatient treatment in an IMD, so long as the facility is a hospital providing psychiatric or substance use disorder inpatient care or a sub-acute facility providing psychiatric or substance use disorder crisis residential services, for stays of no more than 15 days in the period covered by a capitation payment. This is addressed in regulation at 42 C.F.R. 438.3(e), which describes the use of “in lieu of” services, and 438.6(e), which describes the permissibility of FFP for capitation payments when an IMD is utilized.

The SUPPORT for Patients and Communities Act made several changes related to the IMD exclusion. Section 5052 of the SUPPORT for Patients and Communities Act allows states to receive, as a state plan amendment option, federal financial participation for services provided to Medicaid beneficiaries ages 21–64 with at least one SUD that are receiving SUD treatment in an eligible IMD during FYs 2019–2023. Federal financial participation is available for a maximum of 30 days per 12 month period. Section 1013 of the SUPPORT for Patients and Communities Act codifies the current managed care provisions allowing IMD coverage as an “in lieu of” service at section 1903(m)(7) of the Social Security Act. Section 1007 of the SUPPORT for Patients and Communities Act clarifies the ability of states to cover services for infants with neonatal abstinence syndrome (NAS) on an inpatient or outpatient basis at residential pediatric recovery centers. Section 1012 of the SUPPORT for Patients and Communities Act is exception to the IMD exclusion for pregnant and postpartum women with SUD for services provided outside of the IMD. Prior to section 1012 of the SUPPORT for Patients and Communities Act,

Medicaid would not pay for services that pregnant and postpartum women received outside of the IMD.

A recent MACPAC report to Congress, mandated by the SUPPORT for Patients and Communities Act and published December 30, 2019, further details: types of services provided by IMDs; Medicaid funding authorities and coverage limitations placed on IMD services; state requirements and standards for IMDs and how states determine those requirements and standards are met; and protections for patients in behavioral health facilities. The report notes that federal oversight and guidance related to IMD facilities varies by different facility characteristics, and state oversight of IMDs is fragmented.¹⁶⁹

4.3.2.3.2 *Section 1115 Demonstration Projects*¹⁷⁰

Section 1115 demonstrations have been a significant part of CMS's strategy to combat the opioid epidemic. These projects are typically five-year, budget-neutral demonstrations that allow states to modify their programs and test new practices to improve health outcomes for Medicaid beneficiaries. CMS has actively encouraged states to begin using Section 1115 demonstrations to pursue system transformation with regard to SUD coverage and care delivery.¹⁷¹ In July 2015, CMS announced an opportunity for states to request flexibility to offer services to certain individuals (including non-elderly adults) who are short-term residents in IMDs under a demonstration.¹⁷²

In November 2017, CMS announced a streamlined Medicaid Section 1115 demonstration opportunity, announcing the ability of states to receive federal matching funds to expand and facilitate a continuum of care for beneficiaries with SUD subject to CMS approval. The announcement reiterated the potential inclusion of services for enrollees who are short-term residents in IMDs, such as residential treatment facilities.¹⁷³ These demonstrations also include expectations that participating states take action to improve the quality of care in residential treatment settings and increase care coordination. As of November 2019, CMS has approved 27 state Section 1115 demonstrations to increase access to inpatient treatment and residential treatment of SUD and OUD.¹⁷⁴ In these demonstrations, states are expected to develop implementation plans describing how they will meet specific goals and milestones, as described in CMS's November 2017 announcement.

Goals

- Increased rates of identification, initiation, and engagement in treatment
- Increased adherence to and retention in treatment
- Reductions in overdose deaths, particularly those due to opioids
- Reduced utilization of emergency departments and inpatient hospital settings for treatment where the utilization is preventable or medically inappropriate through improved access to other continuum of care services
- Fewer readmissions to the same or higher level of care where the readmission is preventable or medically inappropriate
- Improved access to care for physical health conditions among beneficiaries

Milestones

- Access to critical levels of care for OUD and other SUDs
- Widespread use of evidence-based, SUD-specific patient placement criteria
- Use of nationally recognized, evidence-based SUD program standards to set residential treatment provider qualifications
- Sufficient provider capacity at each level of care
- Implementation of comprehensive treatment and prevention strategies to address opioid abuse and OUD
- Improved care coordination and transitions between levels of care

As specified under the terms of each demonstration, states must also report on certain performance and quality measures for these demonstrations, including a measure set agreed upon by CMS and each state. The measures are intended to gauge progress on required milestones. Throughout these demonstrations, states will detail their progress towards meeting the milestones and measure objectives through regular quarterly and annual monitoring reports, periodic calls with CMS, and evaluations.^{175,176} CMS is also undertaking an internal cross-state analysis to review trends across states over time, as well as a robust meta-evaluation to identify drivers of changes in outcomes.

4.3.2.3.3 State Plan Authorities

Numerous Medicaid state plan option authorities give states flexibility to pursue payment and coverage design changes that will enable them to better address the opioid epidemic. MACPAC identified three different authorities that have been used to modify benefit and delivery systems.¹⁷⁷

- **Health Homes Option:** The health home optional state plan benefit under section 1945 of the Social Security Act enables states to create health homes to coordinate care for beneficiaries with chronic conditions, including SUD. This option provides for higher federal match for state expenditures on health home services (90 percent) for the first eight fiscal year quarters that a state's health home state plan amendment is in effect. Section 1006(a) of the SUPPORT for Patients and Communities Act provides two additional quarters of enhanced match for certain SUD-focused health home state plan amendments (bringing the total to 10 quarters). CMS has created guidance for states about the extended enhanced federal medical assistance percentage (FMAP) period¹⁷⁸ and established an online Health Home Information Resource Center.¹⁷⁹
- **State Plan Rehabilitative Services Option:** As discussed earlier, states have the option to cover rehabilitative services as part of their state plans. Rehabilitative services are broadly defined under federal Medicaid law and could include many different types of medical or remedial services recommended by a physician or other licensed practitioner to reduce physical or mental disability and improve function. Many states have used this option to cover SUD treatment for enrollees.
- **State Plan Rehabilitation Bundled Payment Option:**

Section 223 of the Protecting Access to Medicare Act of 2014 (Public Law 113-93) authorized certified community behavioral health clinics (CCBHCs) demonstration programs in states to improve the availability and quality of community mental health services. The eight states selected to participate in the demonstration are paid a prospective payment system (PPS) rate and offer evidence-based practices, such as MAT to treat OUD, as well as whole-person care under nine broad statutory categories of services: (1) patient-centered treatment planning, (2) crisis mental health services, (3) screening, assessment, and diagnosis (including risk assessment), (4) outpatient mental health and substance use services, (5) outpatient clinic primary care screening and monitoring for key health indicators and health risk, (6) psychiatric rehabilitation services, (7) peer support and counselor services and family supports, (8) targeted case management, and (9) intensive, community-based mental health services for members of the armed forces and veterans). Certain CCBHC demonstration states have elected to expand or otherwise continue their programs under FFS or managed care Medicaid authority to reimburse providers a bundled payment rate (similar to a PPS rate) in an outpatient provider setting. While participation in the CCBHC demonstration authorized under section 223 of the Protecting Access to Medicare Act is limited, more generally this bundled payment is an option available to all interested states for providing SUD as well as behavioral health services to Medicaid enrolled beneficiaries.

- **Section 1915(i) State Plan Option for Home- and Community-Based Services (HCBS) and Section 1915(c) HCBS Waivers:** These options enable states to provide opportunities for certain Medicaid beneficiaries to receive services in their own home or community rather than institutions or other isolated settings under the state plan or through waivers. States may focus on populations with specific needs, including people with SUD, and may offer services such as case management, partial hospitalization, psychosocial rehabilitation, counseling, personal care, and more.¹⁸⁰

4.3.2.3.4 Medicaid Expansion

Many states have enhanced access to SUD treatment coverage by expanding Medicaid under the ACA. The ACA authorized states to receive enhanced federal funds in exchange for covering adults aged 19 through 64 with incomes up to 133 percent of the federal poverty level in their Medicaid programs. For this expansion group, health plans must offer services to treat SUD. A review by the Kaiser Family Foundation found that in 2017, a disproportionate share of non-elderly adults with OUD were covered by Medicaid, and that Medicaid enrollees were much more likely to receive treatment compared to those with private insurance (44 percent vs. 24 percent).¹⁸¹ A recent study supported by the National Institutes of Health (NIH) suggests that Medicaid expansion improves access to SUD treatment.¹⁸²

4.3.2.4 Justice-Involved Individuals

In April 2016, CMS provided guidance encouraging states to facilitate access to Medicaid coverage for justice-involved individuals. Inmates at correctional institutions are generally excluded from receiving Medicaid services while incarcerated because FFP is prohibited in most instances. However, inmates may still be enrolled in Medicaid (with suspended benefits) and

eligible to receive services upon release. Given the prevalence of SUD among justice-involved individuals,¹⁸³ ensuring access to treatment services can support successful transitions back into the community. Guidance in 2016 provided clarity on eligibility standards for justice-involved individuals and encouraged Medicaid programs to work with state and local correctional facilities to coordinate enrollment, re-enrollment, and/or initiation of services for eligible individuals at re-entry. The majority of states have strategies in place to coordinate Medicaid coverage for individuals leaving jails or prisons.¹⁸⁴ Pursuant to Section 5032 of the SUPPORT for Patients and Communities Act, HHS will develop best practices, as well as information on utilizing 1115 demonstrations, to assist justice-involved individuals in transitioning back to the community.

4.3.2.5 Highlights: Medicaid Payment and Coverage Policies Related to OUD Treatment

- Utilization control policies for rehabilitation, including MAT, may hinder access to care. Utilization policies that could potentially create incentives or disincentives contributing to the opioid epidemic include copayments, prior authorization, preferred drug lists, limits on counseling services, or duration of inpatient services.
- States do not always provide coverage for a full continuum of OUD treatment services – for example, many states do not cover services related to peer support and case management. With the Section 1115 demonstrations focused on SUD and OUD, CMS is providing state Medicaid programs with options for improving the continuum of care available to Medicaid beneficiaries in their states and improving access to treatment, including MAT.
- Medicaid Section 1115 demonstration projects have been a key tool in CMS’s strategy to combat the opioid epidemic, allowing CMS not to apply certain statutory limitations that otherwise could act as barriers to states facilitating a full continuum of care for beneficiaries with SUD. In particular, CMS has approved several demonstration projects that include expenditure authority to which the statutory “IMD payment exclusion” does not apply, under certain circumstances. The SUPPORT for Patients and Communities Act made several additional changes related to the IMD payment exclusion to further enable states to cover a broad range of SUD treatment services.

4.4 Medicare and Medicaid Beneficiary Access to Care

In response to Section 6032(b)(4) of the SUPPORT for Patients and Communities Act, this section provides a review of Medicare and Medicaid beneficiaries' access to FDA-approved medication-assisted treatment and other therapies that manage chronic and acute pain and treat and minimize risk of opioid misuse and abuse, including barriers to access for beneficiaries residing in rural or medically underserved communities which for the purposes of this review are communities where beneficiaries face unique challenges in accessing a full continuum of OUD treatment and/or pain care. In addition to regulatory, geographic, health workforce, and other barriers that may disproportionately affect rural areas, certain populations such as pregnant women, individuals with SCD, racial and ethnic minorities, and justice-involved individuals encounter other obstacles to accessing the care they need. Sections 4.4.1 and 4.4.2 delineate critical barriers to care, key considerations for special populations, and examples of promising efforts to date for pain management and OUD treatment, respectively. Barriers to care related to Medicare and Medicaid coverage and payment policies are discussed in Sections 4.2 and 4.3. CMS's planned actions to improve Medicare and Medicaid beneficiaries' access to care are listed in Section 3.

4.4.1 Access to Therapies that Manage Chronic and Acute Pain

As discussed in Section 2.1, 19.6 million adults in the United States report high-impact pain that interferes with their daily life. Successful pain care necessitates patient-centered, multimodal, and multidisciplinary approaches to treatment, which establish a therapeutic alliance and take into account an individual's risk factors and obstacles to successful outcomes.¹⁸⁵ The following is a review of barriers to care, key considerations, and promising interventions to improve access to patient-centered care for the management of chronic and acute pain for Medicare and Medicaid beneficiaries.

4.4.1.1 Barriers to Access

The PMTF identified the following populations facing unique challenges associated with acute and chronic pain and access to pain care: children, older adults, women, pregnant women, individuals with SCD and other chronic relapsing pain conditions, individuals with cancer and in palliative care, racial and ethnic minority populations, active duty service members, and Veterans.¹⁸⁶

Beneficiaries with chronic and acute pain pertaining to these special populations and/or residing in rural communities may face a variety of barriers that impede access to adequate pain management, including the following obstacles identified by the PMTF; although not all of these barriers fall under the authority of CMS, they are included in the review based on their impact on Medicare and Medicaid beneficiaries' access to therapies that manage chronic and acute pain:

- Inadequate insurance coverage for pain management services, including in Medicare and Medicaid
- Shortages of medical and behavioral pain management specialists
- Provider underestimation of patient's reporting of pain

- Drug supply shortages
- Need for ongoing and innovative research on new pain management approaches
- Providers' fear of regulatory scrutiny (state, federal).¹⁸⁷

Barriers related to Medicare and Medicaid payment and coverage policies (such as the first bullet above) are discussed in Sections 4.2 and 4.3 of this report.

4.4.1.1.1 *Shortages of Medical and Behavioral Pain Management Specialists*

There is a shortage of clinicians specializing in pain compared to the number of people living with pain, especially in rural areas. These clinicians include pain physicians, psychiatrists, psychologists, pharmacists, nurses, NPs, PAs, physical therapists, social workers, and others who complete the multidisciplinary pain management team.¹⁸⁸ This shortage leaves primary care providers (PCPs) with a disproportionate burden, and often limited training and referral options, to support patients in managing their acute and chronic pain.¹⁸⁹ The problem is exacerbated by the insufficient coverage or reimbursement for the time needed to care for a patient with chronic pain, including increasing administrative burden at the state and federal levels. As noted in the PMTF report, providers lack incentives to train in pain management, and the vast majority of providers who are licensed to prescribe pain medication are not trained on safe and effective practices for opioid prescriptions. A more comprehensive pain care curriculum is needed at all levels of medical training (i.e., undergraduate and graduate).¹⁹⁰ Additionally, provider shortages are compounded for special populations such as children, since pain specialists are seldom trained in pediatric pain care. Lastly, providers who treat special populations, such as obstetrician-gynecologists or disease specialists, often lack linkages with pain specialists, creating additional hurdles for these populations to obtain the care they need.¹⁹¹

4.4.1.1.2 *Provider Underestimation of Patient's Reporting of Pain*

Providers rely on a patient's ability to report their feeling of pain, yet may tend to underestimate a patient's reporting of pain, which could lead to inadequate treatment.¹⁹² There is limited understanding of underlying pain mechanisms.¹⁹³ Physicians lack clinical best practice (CBP) guidelines to address specific causes of pain, patient comorbidities, psychosocial characteristics, certain demographics, and care delivery settings. Access to the most effective treatments will require adoption of CBPs in medical, dental, and clinical health systems. Further, CBPs for pain management need to be better incorporated into clinician training.¹⁹⁴ Clinicians, especially those in primary care settings, should feel empowered to help their patients manage their pain according to best practices.

Individuals with chronic pain taking opioid medications often feel shame and guilt from the messages they receive from family, friends, co-workers, and others. They may be rejected from practices or be unable to find primary or specialty care physicians to treat them. All of these experiences of stigma may lead to risk for behavioral health issues such as anxiety and depression.¹⁹⁵ For some individuals, inadequate or lack of access to pain care may also contribute to transitions to use of illicit drugs or even suicide. Strategies to reduce stigma and improve education on chronic pain are needed.¹⁹⁶ Providers who reject patients based on their

drug addiction, OUD, or participation in MAT may be violating Federal civil rights laws that prohibit discrimination on the basis of disability.

4.4.1.1.3 Need for Ongoing and Innovative Research on New Pain Management Approaches

Pain presents a tremendous public health challenge, which requires additional research and innovation to identify safer, more effective and affordable diagnostic and therapeutic options.¹⁹⁷ The 2019 PMTF Report identified gaps in research related to pain management for special populations, including chronic pain management in pregnancy and underlying factors related to differing pain sensitivity and/or responses to treatment in certain populations, including women and individuals with SCD. Additionally, the opioid crisis has highlighted a need for innovations in multimodal treatments for pain, as well as additional research to understand the mechanisms of pain,¹⁹⁸ and further evidence to inform treatment decisions in areas such as postoperative pain management using non-opioid analgesics alone or in combination with opioids as needed.¹⁹⁹

In an effort to incentivize research to improve approaches to pain management, the FDA launched an innovation challenge focusing on efforts to combat the opioid crisis through the development of innovative medical devices, some of which target therapies for pain.²⁰⁰ Over the last few years, the FDA has worked with drug makers to support the development of abuse-deterrent opioid drug formulations.²⁰¹ Furthermore, Section 6012 of the SUPPORT for Patients and Communities Act requires the Secretary of HHS to conduct a study and submit a report to Congress on access to abuse-deterrent opioid formulations for individuals with chronic pain enrolled in a prescription drug plan under Medicare, and the effectiveness of abuse-deterrent opioids on opioid abuse or misuse.²⁰²

Other research efforts such as NIH HEAL (Helping to End Addiction Long-term) Initiative are geared toward improving understanding of the transition from acute to chronic pain, accelerating the development of non-addictive pain medications, and exploring best practices for pain management, which might result in new clinical guidelines.²⁰³

4.4.1.2 Interventions to Improve Access

Various interventions have been designed to improve access to pain management. The following discussion highlights several examples, noting where each could be further refined.

4.4.1.2.1 Applying Clinical Best Practices in Pain Management

Providers are in a key position to balance the benefits of different pain medications against the risks of adverse clinical outcomes when they understand and apply best practices for assessment and treatment.^{204, 205} The 2019 PMTF Report stressed the need for providers to deliver an integrative pain treatment plan for individuals with chronic or acute pain, emphasizing that each plan should balance optimizing function, quality of life, and productivity while also minimizing the risk of OUD. The report highlighted existing gaps in clinical best practice guidelines for special populations including children, older adults, and individuals with SCD, as well as the importance of applying multimodal, multidisciplinary approaches and considering the psychological and social aspects of pain in addition to biological factors.²⁰⁶ The variety of complementary and integrative health approaches are often minimized in the management of

pain due to the lack of understanding of the effectiveness of these approaches, and lack of coverage.²⁰⁷ When considering pain management, adopting all these aspects of care into the assessment of a patient's condition and treatment plan creates a comprehensive, integrated, and more effective way to lead to improvements in the condition and quality of life.²⁰⁸

4.4.1.2.2 *Education*

Patient- and family-centered pain education is lacking, and greater awareness of pain syndromes is needed at a national level.²⁰⁹ Better education to understand pain management is needed at all levels of pain healthcare, especially for PCPs and case managers. The SUPPORT for Patients and Communities Act, for example, requires that the annual *Medicare & You* handbook for Medicare beneficiaries include references to educational resources on opioid use and pain management, a description of categories of non-opioid pain management treatments covered by Medicare, and a suggestion that beneficiaries talk to their physicians about opioid use and pain management.²¹⁰ Additionally, the CDC has created specific resources to support primary care providers with tools and resources to help patients manage pain effectively and safely, including a 2019 commentary to raise awareness about issues related to misapplication of the CDC's Guideline for Prescribing Opioids for Chronic Pain.²¹¹ CMS hosts multiple collaborative learning platforms to facilitate information sharing and practice reform among key stakeholder groups, and can offer a forum for the dissemination of best practices related to pain management. For example, please see section 4.2.2.4 for a discussion of CMS Quality Incentive Programs, such as the QIO Program. Given numerous education, training, and awareness-raising initiatives across federal agencies, additional collaboration to share information and resources across agencies and make these readily accessible to providers will also be highly beneficial.

Telehealth platforms (discussed in Section 4.4.2.2.1 below) can help address the limited availability of trained providers offering pain management by facilitating access to training and mentorship for professionals in rural areas. For example, Project ECHO uses multi-point videoconferencing to provide training and mentoring to community providers through virtual clinics.²¹² Likewise, increased education around clinical best practices for the treatment of acute and chronic pain may better equip providers to adequately manage both pain and clinical risk.

4.4.1.2.3 *Improving Drug Supply Systems*

Recommended solutions to address drug shortages disseminated by the Drug Shortages Task Force include:

- “Creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;
- Developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and
- Promoting sustainable private sector contracts (e.g., with payers, purchasers, and group purchasing organizations) to make sure there is a reliable supply of medically important drugs.”²¹³

4.4.1.3 Highlights: Medicare and Medicaid Beneficiary Access to Pain Management Care

- Several populations face unique challenges associated with acute and chronic pain and access to pain care, including people in rural communities, children, older adults, women, pregnant women, individuals with SCD and other chronic relapsing pain conditions, individuals with cancer and in palliative care, racial and ethnic minority populations, active duty service members, and Veterans.
- Factors such as stigma and provider underestimation of patient’s reporting of pain contribute to suboptimal pain management and may lead to unintended consequences such as patient abandonment, anxiety and depression, transition to illicit drug use, and even suicide.
- In order to meet the needs of the many people living with acute and chronic pain in the United States, more clinicians specializing in pain are required, as well as more comprehensive pain education at all levels of medical training.
- Ongoing, innovative research is needed to inform clinical best practices for the management of acute and chronic pain, especially for special populations. Further, providers should be supported to effectively interpret and apply available guidelines and best practices for pain management.
- Ongoing FDA-led efforts to address drug shortages are also critical for ensuring availability of timely and quality pain management therapies.

4.4.2 Access to Medication-Assisted Treatment and Other Therapies that Treat and Minimize Risk of Opioid Misuse and Abuse

As noted in Section 2.2, MAT has been proven effective in treating OUD, yet according to 2017 estimates, only 34 percent of adults between the ages of 18 to 64 with OUD received any treatment.²¹⁴ Further, the average delay between onset of OUD and initiation of treatment has been estimated to be four to seven years.²¹⁵ The following review provides a brief overview of barriers to care, key considerations, and promising interventions to improve access to effective and timely OUD treatment for Medicare and Medicaid beneficiaries.

4.4.2.1 Barriers to Access

A 2019 Consensus Study Report on medications for OUD from the National Academies of Sciences, Engineering and Medicine (hereinafter referred to as “NASEM Consensus Study Report”) found that certain populations face unique challenges and inequitable access to OUD treatment, including adolescents, older persons, pregnant women, sexual minorities, individuals with co-occurring disorders (e.g., psychiatric disorders, other SUDs, chronic pain, infectious diseases), racial and ethnic minorities, people of low socioeconomic status, including homeless populations, and those living in rural areas.²¹⁶ The NASEM Consensus Study Report also identified gaps or missed opportunities to provide OUD treatment across a broader range of care settings (e.g., office-based care settings, acute care, and criminal justice settings).²¹⁷ Further, Medicaid beneficiaries may experience more difficulty finding a practice that will take them as a

new patient or that can provide rapid access to treatment than patients with private insurance or willing to pay out of pocket.²¹⁸

Common barriers to OUD treatment for Medicare and Medicaid beneficiaries include:

- Health workforce restrictions/limitations (including provider shortages, inadequate professional education and training, state scope of practice regulations, and fragmented care delivery systems)
- Distance to/availability of facilities offering OUD treatment
- Stigma and discrimination
- Lack of coverage for the full continuum of OUD treatment
- Utilization management policies

Although these barriers are broadly relevant to Medicare and Medicaid beneficiaries, each subsection points to particular obstacles that may impede care for the special populations listed above. For the last two items related to coverage and utilization management policies, refer to Sections 4.2 and 4.3, where key issues related to coverage of MAT and other behavioral health services, drug utilization management policies such as prior authorization, and copayment are discussed.

4.4.2.1.1 *Health Workforce Barriers*

The health workforce faces numerous obstacles that limit its ability to provide timely, effective OUD treatment, including provider shortages, inadequate professional education and training, legal and regulatory barriers, and fragmented care delivery systems.

A variety of health professionals may offer treatment or services for individuals with OUD, including physicians, PAs, nurses, NPs, psychologists, social workers, and pharmacists, yet education about OUD and other SUDs is often neither mandatory nor standardized in many healthcare curricula in the United States. This leads to inconsistent treatment approaches and lack of awareness of best practices, such as the use of MAT.²¹⁹ While behavioral health interventions may enhance outcomes for individuals in SUD treatment, there is inadequate evidence to indicate which of these should be provided in combination with MAT. The NASEM Consensus Study Report concluded that a lack of availability of behavioral health services should not discourage providers from offering MAT.²²⁰ Some providers, however, are hesitant to offer MAT due a lack of awareness and negative perceptions of the use of MAT stemming from abstinence-based programs.²²¹

State and federal laws highly regulate the prescribing and dispensing of MAT. As noted in Section 2.2, access to methadone is limited to SAMHSA certified OTPs,²²² while buprenorphine can either be administered in an OTP or prescribed by a qualified practitioner in an office-based opioid treatment (OBOT) under the Drug Addiction Treatment Act of 2000 (DATA) waiver program.²²³ The Department of Health and Human Services issued a guideline in April 2021 to expand access to buprenorphine, in an effort to get evidence based treatment to more Americans with opioid use disorder..²²⁴

In the past, only physicians could receive the necessary waiver to prescribe buprenorphine. The SUPPORT for Patients and Communities Act sought to address the shortage of providers for SUD treatment by enabling other types of practitioner, such as NPs, PAs, and physicians who have graduated in good standing from an accredited U.S. school of allopathic or osteopathic medicine, to obtain DATA waivers and training to prescribe buprenorphine.²²⁵ However, many of these practitioner remain limited in their authority to offer prescriptions; for example, at least 28 states restrict NPs from prescribing if they are not collaborating with a physician in their practice.²²⁶ These restrictions further constrain access to MAT in rural areas already facing severe health workforce shortages.²²⁷ Availability of OTPs and DATA-waived practitioner in rural communities is discussed further in Section 4.4.2.1.2.

Many DATA-waived practitioner either are not actively prescribing, are prescribing well below their allowed capacity, or are not accepting new patients for treatment. A 2016 survey of DATA-waived rural physicians indicated that not all practitioner were actively prescribing buprenorphine, and only 56.2 percent were accepting new patients for treatment. Although 74.3 percent and 72.5 percent of all respondents accepted Medicaid and Medicare, respectively, significantly fewer physicians accepted Medicaid and Medicare in the East South Central and West South Central regions. Physicians with a 30-patient waiver were treating 8.8 patients on average, while physicians with a 100-patient waiver were treating an average of 56.9 patients.²²⁸ According to another study, DATA-waived practitioner cited barriers such as lack of patient demand, time constraints, reimbursement, prior authorization, and other insurance-related issues among the reasons for prescribing buprenorphine well below their patient limit, or not at all.²²⁹ Providers are often not reimbursed for their time along the full continuum of SUD treatment, including screening and care coordination.²³⁰

Equipping first responders to administer naloxone poses a critical opportunity to reduce fatal opioid overdoses, particularly in rural areas where trained personnel volume may be limited, and the distance they need to travel during a response is significant.²³¹

The NASEM Consensus Study Report noted that fragmented systems of care delivery and financing for OUD also pose barriers to care. Siloed treatment systems and lack of integration with primary care and other healthcare settings may be particularly detrimental to recovery for special populations such as individuals with OUD and co-occurring disorders. Additional research is needed on patient preferences and best practices to inform integrated delivery system approaches, such as provider co-location.²³²

Lastly, behavioral health services can be less effective if the provider lacks culturally specific knowledge relevant to the patients being treated, creating an additional barrier for some underserved populations.²³³ Linguistic barriers in care settings where interpretation is not provided as required or where reliance on family members or acquaintances impedes meaningful access for individuals with limited English proficiency (LEP).²³⁴ Recipients of Federal financial assistance, including Medicaid and Medicare Parts A, C and D, are required to comply with Title VI of the Civil Rights Act of 1964 (42 U.S.C. §§ 2000d et seq. and implementing regulation at 45 C.F.R. part 80) (Title VI) and Section 1557 of the Patient Protection and Affordable Care Act (42 U.S.C. § 18116 and implementing regulation at 45 C.F.R. part 92) (Section 1557). These laws require recipients to take reasonable steps to ensure meaningful access to their programs

and activities by individuals with LEP, which often includes providing language assistance services through a qualified interpreter, free of charge and in a timely manner.²³⁵ Both authorities generally discourage the use of a family member or acquaintance who is not qualified to interpret except under emergency circumstances where there is no qualified interpreter immediately available.²³⁶ Section 1557 specifically prohibits covered entities from requiring an individual with LEP to provide his or her own interpreter and from relying on an adult or child accompanying an individual except under emergency circumstances or when: 1) the individual with LEP specifically requests that an accompanying adult interpret or facilitate communication, 2) the accompanying adult is willing to do so, and 3) reliance on the accompanying adult is appropriate under the circumstances.²³⁷ Communication barriers and physical inaccessibility can also cause ineffective health care treatment.²³⁸

4.4.2.1.2 *Distance to/Availability of Facilities Offering OUD Treatment*

Another critical barrier to OUD treatment is the limited number and location of facilities and providers offering MAT and other therapies that treat OUD. The distance rural patients need to travel often deters them from completing treatment.²³⁹ OTPs are often not conveniently located²⁴⁰ and DATA-waived practitioner working in office-based settings may not be situated in areas of highest need.²⁴¹ Even where facilities with DATA-waived practitioner are available, they may be limited in their ability to offer access to complementary services such as case management.²⁴² Further, many behavioral approaches require multiple office visits to provide patients the necessary continuity of treatment to achieve positive results, thus compounding the challenge of distance to treatment.²⁴³

A 2019 Congressional Research Service report published the locations of certified OTPs and DATA-waived practitioner able to prescribe buprenorphine.²⁴⁴ Figure 4 shows the location of certified OTPs and the number of DATA-waived practitioner offering OBOT in each U.S. county.²⁴⁵ The results indicated the following:

- 39 percent of counties (5.5 percent of the population) had no DATA-waived practitioner.
- 80 percent of counties (24 percent of the population) had no OTPs.
- 38 percent of counties (5.2 percent of the population) had neither an OTP nor a DATA-waived practitioner.

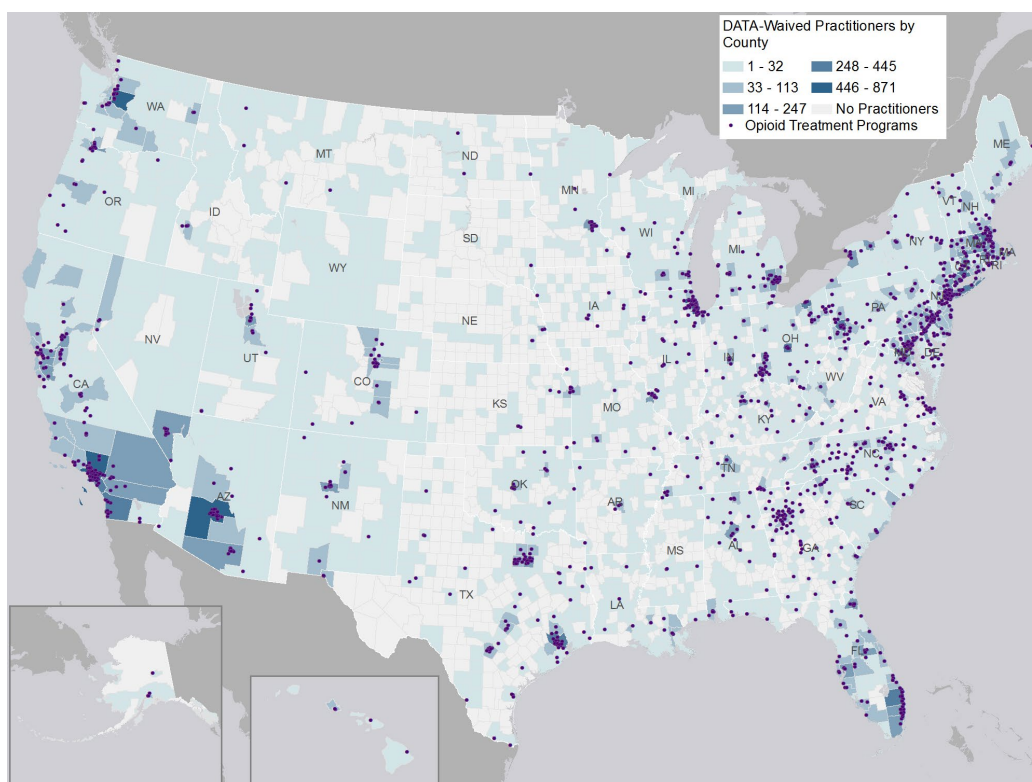


Figure 4. Location of OTPs and DATA-Waived Providers by County²⁴⁶

Nearly half (45 percent) of those counties with no OTP or DATA-waived practitioner are classified as rural according to the U.S. Census.²⁴⁷

Geographic barriers can be exacerbated by payment and coverage issues, for even if facilities offering MAT and other OUD services are available, many do not accept Medicaid. A 2018 article based on data from SAMHSA reported that, for 2016, out of 12,039 responding U.S. facilities only 319 of facilities offered all three forms of MAT, and only 234 of those accepted Medicaid. Eight states did not have a facility offering all three forms of MAT, and 14 states did not have a facility offering all forms of MAT that accepted Medicaid.²⁴⁸

In addition to OTPs and OBOTs, other care settings, such as acute care, criminal justice settings, and residential facilities (see discussion of IMD exclusion in Section 4.3.2.3.1) offer important underutilized opportunities to engage more individuals with OUD in treatment. Non-waivered providers in emergency rooms or other hospital settings are permitted to offer immediate MAT to patients under their care.²⁴⁹ Patients who initiate buprenorphine-based MAT in emergency departments, accompanied by a referral to OUD treatment, achieve better outcomes than patients referred for treatment without an initial dose or short-term prescription.²⁵⁰ However, many emergency departments and other potential entry points for individuals with OUD simply provide a referral to an OTP or OBOT without a “bridging” dose of MAT medication, or are not successful in making a linkage to post-discharge treatment.^{251, 252}

Criminal justice settings represent another critical gap in availability of treatment. Justice-involved individuals experience a significantly elevated risk of negative outcomes associated with OUD. Seventy-five percent of formerly incarcerated individuals with OUD were reported to relapse within the first three months of release from custody, and were 10 to 40 times more likely to die of an opioid overdose than the general population.²⁵³ Furthermore, numerous studies have found that offering MAT in correctional systems is associated with reductions in fatal overdoses²⁵⁴ and heroin use, as well as a significantly increased likelihood of engaging in treatment post-release, among other positive outcomes.²⁵⁵ However, states face policy and financial challenges to ensuring access to treatment in jails and prisons and facilitating post-release transitions to care, including a lack of qualified providers or registration as an OTP, restrictions related to controlled substances within jails and prisons, and termination of Medicaid coverage during incarceration.²⁵⁶

4.4.2.1.3 *Stigma and Discrimination*

Stigma also impacts the ability of people with OUD to access treatment. Numerous surveys have indicated negative attitudes toward individuals with OUD, even endorsing discriminatory and punitive measures over public health interventions and policies. This is further compounded for individuals with OUD in populations that experience marginalization, for example on the basis of race, ethnicity, or socioeconomic status.²⁵⁷ Stigma may also have a disproportionate impact in rural areas, where communities are small and anonymity is harder to maintain. Negative public perception surrounding SUD also impacts treatment uptake, deterring individuals from seeking services or even increasing the risk of relapse.²⁵⁸

Stigma also impacts providers' treatment decisions. A survey of all rural, DATA-waived physicians found that "attraction of drug users to their practice" was among the barriers cited by non-prescribers.²⁵⁹ Furthermore, providers may be opposed to prescribing MAT for OUD due to lack of understanding of the effectiveness of MAT, as well as concerns about diversion of OUD treatment, despite evidence to the contrary.²⁶⁰

Individuals with a drug addiction, including those on MAT, may be protected from discrimination under Federal civil rights laws that prohibit discrimination on the basis of disability, including Section 1557, Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. § 794, and implementing regulation at 45 C.F.R. part 84) (Section 504), and the Americans with Disabilities Act (42 U.S.C. §§ 12101 *et seq.*) (ADA). Drug addiction, including OUD, is a disability under these laws when the drug addiction substantially limits a major life activity. Under these authorities, qualified individuals with a disability may not be excluded from participation in programs and services, be denied the benefits of, or otherwise be subjected to discrimination based on the disability. Federal disability rights laws also protect individuals if they (1) have successfully completed a supervised drug rehabilitation program and are no longer engaging in the illegal use of drugs or have otherwise been rehabilitated successfully and are no longer engaging in the illegal use of drugs; (2) are participating in a supervised rehabilitation program and are no longer engaging in the illegal use of drugs; or (3) are erroneously regarded as engaging in such use, but are not engaging in such use.²⁶¹ For more information, please see HHS Office for Civil Rights' public information campaign on civil rights protections in response to

the national opioid crisis at <https://www.hhs.gov/civil-rights/for-individuals/special-topics/opioids/index.html>.

4.4.2.2 Interventions to Improve Access

Federal, state, and local governments and institutions have established various interventions to address these barriers that could be more widely implemented. This section discusses these interventions and where each could be further enhanced for the benefit of rural and medically underserved communities.

4.4.2.2.1 *Technological*

For some individuals seeking OUD treatment, technological interventions may provide viable alternatives for the delivery of MAT and other therapies that treat OUD. Various studies have demonstrated the effectiveness of providing behavioral health therapies via telehealth, including contingency management, motivational enhancement therapy, and recovery support services.^{262, 263} Additionally, studies have shown that MAT with buprenorphine can be followed with remote telehealth behavioral support, thus reducing geographical barriers to treatment and enabling access to a broader array of providers.^{264, 265} Section 3232 of SUPPORT for Patients and Communities Act directed the Attorney General, with the Secretary of HHS, to issue final regulations for a special registration for qualified healthcare providers to prescribe controlled substances via telemedicine under limited circumstances.²⁶⁶ This will open up new avenues to offer MAT to individuals with OUD who might otherwise have difficulty accessing treatment.

However, hurdles to widespread application of telehealth solutions remain—and telehealth cannot solve all geographic barriers.^{267, 268} The Federal Communications Commission is working toward closing this gap by providing \$112.2 million in funding to deploy broadband services to rural areas in California, Illinois, Indiana, Ohio, Iowa, Minnesota, and Wisconsin.²⁶⁹

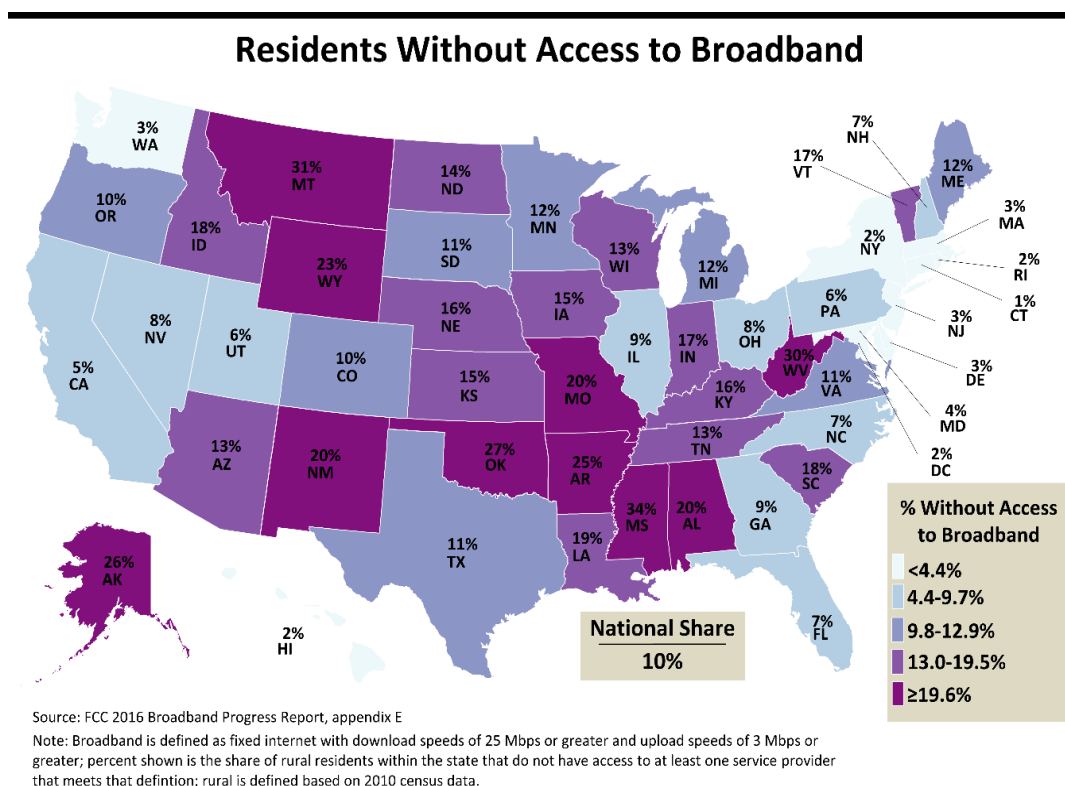


Figure 5. Residents Without Access to Broadband²⁷⁰

Furthermore, Medicaid telehealth coverage policies vary from state to state.²⁷¹ Medicaid guidelines require all providers to practice within the scope of their State Practice Act. Some states have enacted legislation that requires providers using telemedicine technology across state lines to have a valid state license in the state where the patient is located.²⁷²

As discussed in Section 4.4.1.2.2, efforts such as Project ECHO and the University of Washington TelePain model of videoconferencing could be viable methods of improving the training of professionals, particularly in rural areas.²⁷³ Other technologies also provide improvements to delivering MAT and other treatments for OUD. For example, some patients with limited transportation might benefit from use of treatment approaches that do not involve continuous medication or can be implanted and thus reduce the frequency of office visits. For example, the NeuroStim System-2 Bridge device, recently approved by the FDA, delivers electrical pulses from behind the patient's ear, which may provide relief from opioid withdrawal symptoms.²⁷⁴ The FDA also approved an implant for the delivery of a constant low dose of buprenorphine for maintenance treatment of opioid dependency,²⁷⁵ and a mobile app to provide cognitive behavioral therapy as part of outpatient OUD treatment using buprenorphine and contingency management.²⁷⁶ New treatments will continue to emerge and will add to the number of options available to providers to tailor OUD treatment to an individual's circumstances.

4.4.2.2.2 *Statutory and Regulatory*

Many state, federal, and local agencies have endeavored to mitigate access barriers through changes to statutes and regulations. One of the key mechanisms employed by CMS has involved promoting opportunities to leverage Section 1115 demonstrations to improve Medicaid beneficiaries' access to MAT, as described in Section 4.3.2.3.2.²⁷⁷

As noted in Section 4.3.2.3.1, Section 5052 of the SUPPORT for Patients and Communities Act established a limited exception to the IMD exclusion that allows states to receive limited federal funds for items and services provided to Medicaid beneficiaries age 21-64 with at least one SUD and are patients in an eligible IMD,²⁷⁸ and section 1006(b) establishes a requirement that state Medicaid programs cover all FDA-approved drugs, including methadone, and all FDA-licensed biological products to treat OUD, and counseling services and behavioral therapy with respect to the provision of such drugs and biological products from October 1, 2020 through September 30, 2025.²⁷⁹ The SUPPORT for Patients and Communities Act also designated, at Section 2001, the home as an option for telehealth services under Medicare, thus reducing the need for some beneficiaries to travel long distances.²⁸⁰ Additionally, Section 5032 of the SUPPORT for Patients and Communities Act introduces measures to promote state innovations to improve healthcare transitions for individuals being released from a correctional facility including through the use of Section 1115 demonstrations.²⁸¹

Other changes have been made to improve access to providers offering MAT. Section 3201 of the SUPPORT for Families and Communities Act expanded the patient limit for providers prescribing buprenorphine for MAT pursuant to the DATA 2000 waiver program. Those with a 30-patient limit can apply to increase it to 100, and those with a 100-patient limit can apply to increase it to 275.²⁸² However, as noted in Section 4.4.2.1.1, a majority of these providers are still not treating to capacity, and many do not accept Medicaid. Additional factors, including patient demand, insurance coverage, provider stigma, and scope of practice and other regulatory constraints, must be further explored to optimize the impact of DATA-waived providers.

Changes are also being introduced at state levels to overcome obstacles to offering MAT in correctional settings. Some states, such as Rhode Island, have mandated provision of MAT in correctional facilities through executive orders, while others, such as Maryland, have passed legislation mandating MAT in correctional facilities as well as post-release follow-up treatment and coordination.²⁸³ While Medicaid does not cover healthcare services during incarceration, some states have opted to suspend—rather than terminate—coverage to facilitate access to healthcare coverage upon re-entry.²⁸⁴

Efforts to improve initiation of MAT in acute settings are highlighted in Section 4.4.2.2.3 below. Other examples of innovations to expand treatment settings highlighted in the NASEM Consensus Study Report include community-based mobile medication units, group-based treatment for homeless individuals, treatment within syringe services programs, physician-pharmacist collaboration models, and methadone linkage programs to support transitions for individuals recently released from jail or prison. Additional research is needed to establish best practices and explore additional applications of these approaches.²⁸⁵

Several steps have been taken to reduce access barriers for the overdose reversal drug naloxone. In 2018, HHS released guidance for healthcare providers to prescribe or co-prescribe naloxone for individuals at risk for opioid overdose.²⁸⁶ The FDA has expressed support for efforts to make naloxone more accessible by through development of an over-the-counter version of the product.²⁸⁷ In the interim, many states have passed laws allowing the use of standing orders that permit pharmacies to dispense naloxone to a person at risk of an opioid overdose or to a bystander in a position to assist in treating an opioid overdose, without a prescription.²⁸⁸

4.4.2.2.3 *Financial*

Federal, state, and local governments are providing grant funding to help address barriers to SUD treatment. For example, SAMHSA provides grant funding to states and territories under the State Opioid Response (SOR) to allow states to focus on areas of greatest need, including access to treatment. In June 2018, SAMHSA announced SOR grants to expand and enhance prevention, treatment, and recovery in states hardest hit by the opioid epidemic. In addition, SAMHSA's Medication Assisted Treatment for Prescription Drug and Opioid Addiction program provides grants to expand access to MAT in states with the highest rates of opioid addiction treatment admissions²⁸⁹.

The Agency for Healthcare Research and Quality (AHRQ) is investing in a series of grants to discover the best support options for primary care practices in rural communities in delivering MAT. The practices involved in the initiative will provide access to MAT for more than 20,000 individuals with OUD by using innovative technology, including patient-controlled smartphone apps, and remote training and expert consultation using Project ECHO.²⁹⁰

Evidence-based strategies have emerged from federal, state, and institutional innovations to strengthen linkages or “bridges” to OUD treatment by offering rapid access MAT at the initial point of care, whether in an emergency department or community-based setting.²⁹¹ Federal grants are supporting implementation and replication of promising practices to increase the initiation of MAT during emergency room visits. For example, a SAMHSA Opioid STR grant supported a mobile recovery outreach team program for post-overdose outreach to patients in the emergency room to provide assessment, recovery support, coaching, and an easier path to MAT access.²⁹² These grants not only help find new approaches to connect patients with OUD to medication treatment, but also may improve access to behavioral approaches needed to support patient retention in treatment and recovery programs, such as motivational enhancement therapy and recovery support services.

Another intervention to address geographic access barriers involves the Rural Transportation Voucher programs funded by the Federal Transit Administration. These grants may help address transportation issues; however, sustaining continuous long-distance travel to complete MAT-related treatment might be too burdensome for many people.²⁹³

The SUPPORT for Patients and Communities Act includes multiple provisions to help cover the cost of training providers to offer SUD treatment, including authorization of \$48.5 million in planning grant awards to 15 state Medicaid agencies to increase the treatment capacity of providers to furnish services to address SUD including OUD,²⁹⁴ expansion of a grant program to offer training to first responders on safety around opioids,²⁹⁵ and a grant program to help

federally qualified health centers and rural health clinics offset the cost of training providers to dispense medications for treatment of OUD.²⁹⁶

4.4.2.3 Highlights: Medicare and Medicaid Beneficiaries' Access to OUD Treatment

- Several populations face unique challenges and inequitable access to OUD treatment, including: adolescents; older persons; pregnant women; sexual minorities; individuals with co-occurring disorders (e.g., mental disorders, other SUDs, chronic pain, infectious diseases); racial and ethnic minorities; people of low socioeconomic status, including homeless populations; and those living in rural areas.
- Stigma and discrimination impacts the ability of people with OUD to access treatment, influencing both individuals with OUD and providers.
- Health workforce barriers such as provider shortages, lack of training, and restrictions on prescribing MAT can impede beneficiaries' access to a full continuum of OUD treatment. Ongoing innovations should be pursued to support an array of multidisciplinary providers to attain the training and certification they need, ensure that providers are adequately reimbursed for time spent with OUD patients, and integrate OUD treatment into broader systems of care delivery.
- Distance to OUD treatment facilities and providers poses a significant barrier to care, particularly for individuals residing in rural communities. There are also gaps in access OUD treatment in care settings such as acute care (including emergency departments) and criminal justice settings. Continued pursuit of technological, financial and statutory solutions to improve the availability of OUD treatment at point of care, in criminal justice settings, and in rural areas are key to curbing the opioid crisis.

4.5 Payment and Coverage Policies for FDA-Approved Medical Devices

As required by Section 6032(b)(5) of the SUPPORT for Patients and Communities Act, this section provides a review of payment and coverage policies under Medicare and Medicaid related to medical devices that are non-opioid based treatments approved by the FDA for the management of acute pain and chronic pain, for monitoring substance use withdrawal and preventing overdoses of controlled substances, and for treating SUD, including barriers to patient access.

The FDA is responsible for regulating all medical products, including medical devices. For companies to obtain FDA approval to market a device in the United States, they are required to provide evidence that the device is safe to use and its effectiveness for a specific intended use.²⁹⁷

The FDA defines a medical device as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is:

- “recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.”²⁹⁸

Based on a review of the FDA Product Classification Database²⁹⁹ and the 510(k) Premarket Notification database of devices used for the management of acute pain and chronic pain, for monitoring substance use withdrawal and preventing overdoses of controlled substances, and for treating substance use disorder, the FDA has approved approximately 1,600 medical devices for pain relief and ~190 for SUD and OUD. For each type of medical device, there is anywhere from one device—for instance, in the case of “Computerized Behavioral Therapy Device for Psychiatric Disorders,” there is one device that has been approved (reSET-O™)—to hundreds of devices for some categories, such as in the case of “Inferential Current Therapy.”

4.5.1 Medicare Program Payment and Coverage Policies

Generally, medical devices are covered under Medicare if they fall within a Medicare benefit category, are not statutorily excluded, and are reasonable and necessary. Coverage under Medicare may be made on a claim-by-claim basis, or through local or national coverage determinations. Medical devices that may be covered under Medicare include:³⁰⁰

- Devices approved by the FDA through the Pre-Market Approval (PMA) process (Class III)
- Devices cleared by the FDA through the 510(k) process (Class II)

- FDA-approved Investigational Device Exemption (IDE) Category B Devices; and
- Hospital IRB-approved non-significant risk devices.

4.5.1.1 National Coverage Determinations and Local Coverage Determinations

Medicare National Coverage Determinations (NCDs) are determinations by the Secretary about whether or not a particular item or service is covered nationally under Medicare.³⁰¹ NCDs are only one mechanism to achieve Medicare coverage, and they represent only a small portion of the program's policies because devices can be covered through claim-by-claim adjudication or through local coverage determinations. Current NCDs that provide coverage of FDA-approved medical devices for the management of acute pain and chronic pain include coverage for electrical nerve stimulation devices, home oxygen devices, hospital beds, external pumps, and implanted pumps for the delivery of opioids. There are no NCDs specific to medical devices for the monitoring of substance use withdrawal, overdose prevention of controlled substances, or the treatment of SUDs. The following lists provide an overview of NCDs that pertain to services for the management of acute pain and chronic pain.³⁰²

- 10.2 – Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain
- 150.13 – Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis
- 160.7 – Electrical Nerve Stimulators
- 160.7.1 – Assessing Patients Suitability for Electrical Nerve Stimulation Therapy, Percutaneous Electrical Nerve Stimulation (PENS)
- 160.12 – Neuromuscular Electrical Stimulator (NMES)
- 160.13 – Supplies Used in the Delivery of TENS and NMES
- 160.27 – TENS for Chronic Low Back Pain
- 240.2.2 – Home Oxygen Use to Treat Cluster Headache
- 280.7 – Hospital Beds
- 280.14 – Infusion Pump, External Infusion Pumps, Morphine for Intractable Cancer Pain
- 280.14 – Infusion Pump, Implantable Infusion Pumps, Opioid Drugs for Treatment of Chronic Intractable Pain

There are medical devices used in the treatment of pain that are nationally not covered. For example, some NCDs have been issued to not cover or otherwise narrow use of these devices in the Medicare population, often due to a lack of evidence regarding patient health outcomes for the treatment. In other cases, such as the implantation of a specific type of artificial disk, the treatment is recognized as a procedure to reduce pain,³⁰³ but based on an analysis of the available evidence, CMS concluded the procedure is not considered reasonable or necessary for the Medicare population over 60 years of age³⁰⁴. The following is a list of NCDs for services that may include medical devices or items identified as not covered or not covered for a specific group of the population for pain management:

- 30.1 – Biofeedback Therapy
- 30.3 – Acupuncture
- 30.3.1 – Acupuncture for Fibromyalgia
- 30.3.2 – Acupuncture for Osteoarthritis
- 150.10 – Lumbar Artificial Disk Replacement: implantation of an artificial disk
- 150.11 – Thermal Intradiscal Procedures catheters/probes
- 160.2 – Treatment of Motor Function Disorders with Electric Nerve Stimulation
- 160.16 – Vertebral Axial Decompression
- 160.23 – Sensory Nerve Conduction Threshold Test

In January 2020, CMS issued a national coverage decision for Acupuncture for Chronic Low Back Pain covering up to 12 acupuncture visits performed by certain specified Medicare practitioners for Medicare patients with chronic low back pain, and an additional eight sessions for those who demonstrate improvement.³⁰⁵

Local coverage determinations (LCDs) are developed by Medicare Administrative Contractors with respect to whether or not a particular item or service is covered under Part A or Part B in particular geographic regions.³⁰⁶ In light of the issues associated with using opioids for acute and chronic pain, CMS issued guidance in 2019 summarizing some existing Medicare local coverage policies and non-pharmacologic treatment options for Medicare patients with chronic pain, including the following examples of LCDs that involve the coverage of devices used to treat chronic pain:

- Nerve Blockage for Chronic Pain and Neuropathy
- Spinal Cord Stimulators
- Peripheral Nerve Stimulation³⁰⁷

4.5.1.2 Medicare Payment Policies for Medical Devices

Medicare payment for medical devices depends on the benefit category in which the device falls. For example, medical devices may be paid for directly under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) benefit categories (if they meet the definition of DME, prosthetics, or orthotics, etc.), or indirectly as part of other services covered under Part A and B,³⁰⁸ including the OPSS and IPPS.

Section 1861(n) of the Social Security Act defines DME to include certain devices used at home, such as wheelchairs and hospital beds, but does not include all items and services that may be used in a home setting. Devices used at home that are covered under the DME, prosthetics, or orthotics benefit categories under Part B are generally paid based on the DMEPOS fee schedule or based on competitive rates established under the competitive bidding program (CBP). Class III devices are prohibited from being included in the CBP.^{309, 310} The next round of CBP contracts are expected to become effective in 2021. Under the ASC and OPSS payment systems,

payment for devices used as non-opioid alternatives for pain management is packaged with payment for the primary service, unless the device has transitional device pass-through payment status (described in more detail below), in which case separate payment is made. Stakeholders, including drug and device manufacturers, recently have requested separate payments for non-opioid pain management treatments (e.g., continuous nerve blocks, cooled thermal radio frequency ablation, and local anesthetics).³¹¹ Industry stakeholders have suggested various payment changes to CMS, including separate payment or assigning the primary service to a higher paying APC. Based on a review of data from stakeholders and Medicare claims data analysis, CMS did not find compelling evidence to suggest that revisions to its OPPS payment policies for non-opioid pain management alternatives were necessary for CY 2020. However, CMS has invited public comments that provide evidence to support revisions to its payment policies to provide separate payment help determine if current packaged payments are a barrier to care.

There are also special payment policies that can apply to medical devices. Under the OPPS, hospitals may receive separate transitional device pass-through payments for qualifying devices for at least two years and no more than three years. Devices qualify for pass-through payments through evidence of substantial clinical improvement and costs that exceed certain thresholds based on the APC to which they would be assigned.³¹² Beginning in CY 2020, devices may also qualify for device pass-through status if they receive FDA marketing authorization and are approved under the Breakthrough Devices Program established by the FDA under the authorization of the 21st Century Cures Act. Such devices do not need to demonstrate substantial clinical improvement to qualify for device pass-through status, provided they meet the other criteria (84 FR 61296).

Under the IPPS, devices are generally paid for as part of the bundled payment based on the MS-DRG. Hospitals can also receive a new technology add-on payment for new technologies meeting certain criteria that is in addition to the payment based on the MS-DRG.³¹³ Two modifications to the new technology add-on payment policy that impact new devices started on October 1, 2019. First, similar to the policy described above regarding OPPS, a device that is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation does not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. The second modification relates to the calculation of the maximum add-on payment amount, which increased from 50 percent to 65 percent.³¹⁴ The modification to the requirements for payment and increase in add-on payment amount might impact some of the devices that were selected through the *FDA Innovation Challenge: Devices to Prevent and Treat Opioid Use Disorder*, which were granted a Breakthrough Device designation.³¹⁵

4.5.2 Medicaid Program Payment and Coverage Policies

In Medicaid, certain medical supplies, equipment, and appliances are covered under the mandatory home health benefit.³¹⁶ When provided under this benefit, medical equipment and appliances are described as “items that are primarily and customarily used to serve a medical

purpose, generally not useful to an individual in the absence of a disability, illness or injury, can withstand repeated use, and can be reusable or removable.”³¹⁷ Under the home health services benefit, states are permitted to have lists of pre-approved medical equipment supplies and appliances for administrative ease, but states are prohibited from having absolute exclusions of coverage on medical equipment, supplies, and equipment, and must have a process for individuals to request items not on the list.³¹⁸ Medicaid coverage and payment is also authorized (but not required) for certain supplies and equipment used during physical, occupational, and speech/language therapy as part of the optional physical therapy and related services benefit.³¹⁹ Medical supplies, equipment and appliances covered under the Medicaid home health benefit could include equipment for the treatment and management of chronic pain, such as transcutaneous electrical nerve stimulators; however, specifications for coverage may differ by state, as in the cases of New York, Ohio, and North Dakota.^{320,321,322} CMS recently published a CMCS Informational Bulletin outlining in detail several approaches for states to provide coverage for non-opioid pain management alternatives, some of which could impact future coverage and payment of medical devices under Medicaid.³²³

State Medicaid FFS programs generally pay the lesser of the charges or the maximum price allowed for DME, as indicated on a fee schedule.³²⁴ States use a variety of methods to develop their maximum allowable price for covered equipment and supplies, often using one or a combination of the methods (e.g., Medicare rates or percentages of Medicare rates; percentage of retail prices; costs or charges; competitive bidding). Limits on federal matching, however, have been imposed recently for certain types of medical equipment. Specifically, the federal Medicaid reimbursement to states for certain DME paid under Medicaid FFS (in the aggregate) is limited to the Medicare payment amounts (in the aggregate) for such DME items and services.³²⁵

States are free to establish higher rates for certain items of DME if they determine that higher rates are needed under the Medicaid state plan, and this aggregate limitation does not expressly compel states to reduce the payment rates for certain DME.³²⁶ But since the statute limits FFP if the aggregate expenditures would exceed the Medicare rates in the aggregate, a reduction could be a consequence. Since states retain the flexibility to make payments at rates that best serve the needs of their Medicaid beneficiaries, this should be a consideration for DME used for pain management in light of the opioid crisis.

4.5.3 Barriers to Patient Access

Access to medical devices can be impacted by the time lapse between FDA’s approval of medical devices and CMS’s coverage decisions.³²⁷ To address this barrier, CMS is taking multiple steps, including a joint effort between FDA and CMS—the Parallel Review Program. This program aims to decrease the time between FDA approval and Medicare national coverage determinations by engaging manufacturers early in the process to ensure they are meeting CMS requirements and have CMS and FDA review the clinical trial proposal for the new device concurrently.³²⁸ The number of devices going through the program is small, as only five candidates are admitted per year.³²⁹

The DMEPOS CBP program is another area in which CMS and others have evaluated potential barriers to access. An Office of Inspector General assessment on the impact of the CBP program

on beneficiaries' access to devices concluded that this program did not appear to have disrupted access. Additional monitoring and assessment of the program's impact on beneficiary access to devices related to pain management could be performed for items such as TENS or braces.³³⁰ There is also a possibility of cost increases to beneficiaries living in non-competitive bidding areas (CBAs). According to the MEDPAC, beneficiaries living in non-CBAs might experience a potential cost barrier to access as "DMEPOS suppliers do not have to accept Medicare's fee schedule rate as payment in full and may bill beneficiaries for the difference between the fee schedule rate and what the supplier decides to charge for a given product," and "there is no cap on this billing practice."³³¹ This could create an access disparity for TENS devices, back braces, and knee braces.

The complexity of coverage policies potentially can result in knowledge gaps, additional healthcare costs to beneficiaries, and time-consuming tasks related to paperwork or coverage disputes, creating a barrier to the correct type of treatment and/or device.^{332,333} Lack of coverage for specific devices can also become an access barrier to non-opioid alternatives. For instance, the BRIDGE (a noninvasive percutaneous electrical nerve stimulator) has proven to be associated with a decrease in opioid withdrawal scores.³³⁴ The FDA has approved this device to be used as an aid to reduce symptoms related to opioid withdrawal. PENS may be covered by Medicare Administrative Contractors in some states; however, the determinations might be disease-specific and not necessarily indicate coverage for pain related to opioid withdrawal.³³⁵

Patients might also experience an access barrier to the correct treatment as a result of potential conflict of interest if treated by medical providers who have a financial interest such as royalties, licenses, or patents in medical devices for the treatment of pain and/or OUD. To respond to this potential conflict of interest, CMS implemented the Open Payments National Transparency Program.³³⁶ Through this program, manufacturers, including manufactures of medical devices, are required to report medical providers who have received any payments, which are captured in the Open Payments Database. Studies on patterns related to the prescription of opioid products have found that at least one in every 12 physicians has received a payment from an opioid manufacturer, and have also found an association with higher prescriptions of opioid products from physicians who have received payments from an opioid product manufacturer.^{337, 338} This behavior pattern could pose a potential concern for patients who are prescribed high-risk treatments that involve medical devices, especially class III devices in the future.

4.5.4 Highlights: FDA-Approved Medical Devices

- Medical devices are an important option for the treatment and management of pain, and prevention and treatment of OUD. With a shift in the way pain is treated, there is a greater need for ensuring appropriate coverage and payment policies for medical devices to mitigate possible access issues.
- Potential use of the Parallel Review Program, inclusion of medical devices as part of the Open Payments National Transparency Program, and the continuous assessment and updates of NCDs and LCDs are important steps to ensuring access to important medical devices in light of the opioid crisis.

4.6 Public Stakeholder Inputs to Action Plan Development

4.6.1 Consultation with the PMTF

The PMTF was overseen by HHS, and included representatives from relevant HHS agencies, the VA, the DoD, and the Office of National Drug Control Policy; nonfederal representatives included individuals and clinicians with expertise in pain management, pain advocacy, addiction, recovery, SUDs, mental health, and minority health, as well as patients and representatives from Veteran service organizations, the addiction treatment community, and groups with expertise in overdose reversal, such as first responders and hospitals. The PMTF's charter sunset on July 22, 2019, during the Action Plan development period.

The convening of the PMTF reflected the renewed attention to exploring alternative therapies for managing chronic and acute pain, and for examining payment and coverage policies that may inadvertently incentivize the use of opioids or disincentivize the use of alternative therapies. CMS met with the PMTF in a Public Meeting held on June 26, 2019, to seek the PMTF's recommendations and other questions regarding Section 6032.³³⁹ In this discussion, the PMTF directed CMS to the specific recommendations in its final report that are most relevant to the Action Plan; these recommendations are detailed in Appendix A and briefly summarized below.

The PMTF's final report, released on May 30, 2019, made a series of recommendations, including the following:

- Opioid therapy should be initiated only when the benefits outweigh the risks; the patient is experiencing significant acute or chronic pain that interferes with function and quality of life; and the patient is willing to continue to engage with the team on a comprehensive multidisciplinary treatment plan.
- Non-opioids should be used as first-line therapy whenever clinically appropriate in the inpatient and outpatient settings.
- Clinicians should use multidisciplinary and multimodal approaches, particularly for perioperative pain control in selected patients at higher risk for opioid use disorder.
- When opioids are clinically indicated, providers should consider the use of screening and prevention measures such as history taking, review of medical records, Prescription Drug Monitoring Program query, and urine toxicology screenings, as appropriate.
- When high-risk patients are identified, providers should consider referral to pain, mental health, and other specialists, including addiction medicine-trained physicians.
- Payment and coverage policies should support clinicians in executing these best practices.³⁴⁰

While the 2019 PMTF Report emphasizes the need to reduce unnecessary opioid exposure, it also recognizes that guidelines and policies intended to mitigate the adverse outcomes associated with opioids have in some cases resulted in unintended consequences, notably, the discontinuation or tapering of opioid therapy for certain patients with chronic pain who were successfully treated with opioids, leaving those patients with undertreated pain.³⁴¹ The PMTF

recommends that payment and coverage policies consider both the desire to reduce unnecessary opioid exposure and the need for leveraging opioids as part of a treatment plan when clinically indicated.

4.6.2 CMS Public Meeting, September 20, 2019

CMS hosted an interactive Public Meeting: Action Plan to Prevent and Manage Opioid Use Disorders and Substance Use Disorders, and Address Pain Management, on Friday, September 20, 2019, in Baltimore, MD, at the CMS Auditorium. The meeting was simultaneously broadcast online via YouTube. Per Section 6032, this public stakeholder meeting included representatives from the FDA, NIH, medical researchers, healthcare providers, the medical device industry, CMS, patients, and patient advocates. Additional speakers included representatives from the CDC and public health leaders. Session participants ranged from expert panels to the public to industry stakeholders.

Major takeaways, observations regarding recent CMS activity, and recurring themes that emerged throughout the meeting included:

- Pain management should be individualized, multimodal, and multidisciplinary.
- Care for OUD and pain management, particularly with transitional and chronic care services, should be better coordinated and integrated.
- Physicians should be better compensated for coordinating complex care.
- Technology should be better integrated into our healthcare system. It has the potential to improve many aspects, including access to services, provider support and training, coordination of care, and safer treatment modes.
- The CDC Guideline for Prescribing Opioids for Chronic Pain should not lead to forced tapering of opioid pain medication or to providers avoiding patients with pain management needs. It is non-regulatory and intended to inform clinicians' communication with patients.
- Medicare Part D opioid-related policies, including safety edits at point of sale and drug management programs are intended to achieve a more tailored approach that strikes a better balance between access to opioids and patient safety. There are exclusions, and patients and/or prescribers can request an exception at any time.
- Prison, rural, and aging populations have been greatly affected by this crisis and face unique challenges that make them particularly vulnerable.
- The addiction and pain management workforce should be increased and strengthened.
- MAT should be made widely accessible, emergency departments and community based providers should be equipped and trained to initiate MAT, and treatment should begin before withdrawal symptoms occur.
- Barriers should be removed from alternative modes of pain management, including non-opioid medication, medical devices, and restorative therapies. Patients and providers should be educated about the range of options, and insurers should expand coverage.

- SUD and chronic pain should be destigmatized in the healthcare system.

4.6.3 Request for Information

CMS posted a 17-question RFI on its website from September 11, 2019, through October 11, 2019. There were 378 submissions, of which 358 were unique submissions (non-duplicative and within scope).

Submitted comments included, but were not limited to, suggestions that CMS consider the following actions to address the opioid crisis:

Coverage and Payment

- Expand eligible providers who can provide pain treatment, SUD/ODU treatment, and MAT.
- Expand coverage to include non-opioid alternatives for pain management that are currently not covered.
- Expand coverage settings for SUD/ODU treatment and OTPs.
- Expand coverage of methadone and buprenorphine and remove the requirement for DATA waivers or allow non-DATA waived clinicians to administer these medications.
- Examine the evidence base for innovative pain management treatments.
- Create a payment bundle and/or a value-based payment model inclusive of specific patient types (e.g., expectant mothers and mothers in postpartum care).

Access

- Expand coverage of wrap-around and community support services for individuals with OUD.
- Examine whether reimbursement for time and/or therapeutics is a barrier for providers to deliver pain management services or SUD/ODU treatment.
- Expand access to opioid medication for patients with pain, who are inappropriately impacted by application of tapering guidelines.
- Improve access to pain management, including to opioids, for high-risk and underserved populations (e.g., racial, ethnic and sexual minorities; tribal groups; and individuals without access to transportation).
- List non-opioid analgesics as preferred drugs on formularies.
- Reduce the use of opioids before, during, and after surgery.
- Reduce out-of-pocket-costs for non-opioid therapies, MAT, and naloxone.
- Reduce prior authorization requirements for non-opioid pain management treatments.
- Remove prior authorization requirements and expand coverage for all FDA-approved medications for SUD/ODU.

Data

- Implement national standardization of PDMPs across states, in addition to ensuring interstate interoperability and cross-state access to PDMP data.
- Standardize the capture of information on opioid use, OUD treatment, and non-opioid treatment alternatives through EHRs.

Appendix A. Pain Management Best Practices Inter-Agency Task Force Recommendations Pertaining to the CMS Action Plan

On June 26, 2019, CMS convened virtually with the PMTF to discuss its recommendations with specific relevance to CMS payment and coverage policies for chronic and acute pain, service delivery models, access to therapies and medical devices, and other issues outlined in Section 6032 of the SUPPORT for Patients and Communities Act.³⁴² CMS directed a series of questions to the PMTF, and the PMTF shared recommendations for addressing identified gaps, inconsistencies, and updates in the management of acute and chronic pain in light of the ongoing opioid crisis. Tables in this appendix depict the final report recommendations that the PMTF identified during the virtual meeting when responding to six questions posed by CMS. Many of the PMTF's recommendations address more than one of the questions CMS asked the PMTF. In developing the Action Plan, CMS has taken these inputs into consideration.

CMS Question 1: Please identify any Medicare payment and coverage policies related to therapies that manage acute and chronic pain and minimize risk of opioid misuse and abuse. Have these payment and coverage policies resulted in incentives or disincentives that have contributed to the nation's opioid crisis? If so, how?

Table 4. CMS Question 1 and PMTF Responses

Section	Gap	Recommendation
2.2 Medication	GAP 2: Opioids are often used early in pain treatment. There has been minimal pain education in medical school and residency programs, and little guidance for PCPs on appropriate pain treatment approaches (see Section 3.3.3: Provider Education; see Section 3.4: Access to Pain Care).	RECOMMENDATION 2E: CMS and private payers should provide reimbursement that aligns with the medication guidelines the Task Force has described. Private payers and CMS should provide more flexibility in designing reimbursement models. RECOMMENDATION 2F: PBMs and payers should be more transparent about non-opioid pharmacologic options in their formulary, and the Task Force encourages state and federal regulators to review payer and PBM formularies to ensure that non-opioid options are on low-cost tiers.

2.2 Medication	GAP 4: Barriers include lack of coverage and reimbursement for buprenorphine as well as the lack of education and training on the proper usage of buprenorphine. There has been a lack of access to buprenorphine treatment for chronic pain.	RECOMMENDATION 4B: Encourage CMS and private payers to provide coverage and reimbursement for buprenorphine treatment, both for OUD and for chronic pain. Encourage primary use of buprenorphine rather than use only after failure of standard mu agonist opioids such as hydrocodone or fentanyl, if clinically indicated.
2.4 Interventional Procedures	GAP 2: Inconsistencies and frequent delays exist in insurance coverage for interventional pain techniques that are clinically appropriate for a particular condition and context.	RECOMMENDATION 2A: Encourage CMS and private payers to provide consistent and timely insurance coverage for evidence-informed interventional procedures early in the course of treatment when clinically appropriate. These procedures can be paired with medication and other therapies to improve function and quality of life (QOL). RECOMMENDATION 2B: CMS and other payers must restore reimbursement to nonhospital sites of service to improve access and lower the cost of interventional procedures.
3.1.2 Screening and Monitoring	GAP 1: Comprehensive screening and risk assessment of patients are time-consuming but vital for	RECOMMENDATION 1A: Encourage CMS and private payers to provide sufficient compensation for time and payment for services to implement the various screening measures (e.g., extensive history taking,

	proper evaluation of their chronic pain conditions. Lack of sufficient compensation for time and payment for services have contributed to barriers in best practices for opioid therapy.	review of medical records, PDMP query, urine toxicology screenings, when clinically indicated). These are vital aspects of risk assessment and stratification for patients on opioids and other medications. RECOMMENDATION 1B: Consider referral to pain, mental health, and other specialists, including addiction medicine-trained physicians when high-risk patients are identified.
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Question 2: Please identify any payment and service delivery models, including value-based models that may encourage the use of therapies that manage acute and chronic pain and treat and minimize the risk of opioid misuse and abuse that could be tested by CMS and Medicare/Medicaid and/or CHIP through CMS’s Innovation Center or by other federal agencies.

Table 5. CMS Question 2 and PMTF Responses

Section	Gap	Recommendation
2.1.1 Acute and Chronic Pain	GAP 1: Multimodal, non-opioid therapies are underutilized in the perioperative, inflammatory, musculoskeletal, and neuropathic injury settings.	<p>RECOMMENDATION 1A: Use procedure-specific, multimodal regimens and therapies when indicated in the perioperative period, including various non-opioid medications, ultrasound-guided nerve blocks, analgesia techniques (e.g., lidocaine, ketamine infusions), and psychological and integrative therapies to mitigate opioid exposure.</p> <p>RECOMMENDATION 1B: Use multidisciplinary and multimodal approaches for perioperative pain control in selected patients at higher risk for opioid use disorder (e.g., joint camps, Enhanced Recovery After Surgery [ERAS], Perioperative Surgical Home [PSH]).^{69,70} Key components for optimal pre-habilitation may include preoperative physical therapy (PT), nutrition, and psychology screening and monitoring; preoperative and postoperative consultation and planning for managing pain of moderate to severe complexity; preventive analgesia with preemptive analgesic non-opioid medications; and regional anesthesia techniques, such as continuous catheter-based local anesthetic infusion.</p> <p>RECOMMENDATION 1C: Encourage CMS and private payers to develop appropriate reimbursement policies to allow for a multimodal approach to acute pain in the perioperative setting and the peri-injury setting, including preoperative consultation to determine a multimodal plan for the perioperative setting.</p>

Section	Gap	Recommendation
3.1.2 Screening and Monitoring	GAP 1: Comprehensive screening and risk assessment of patients are time-consuming but vital for proper evaluation of their chronic pain conditions. Lack of sufficient compensation for time and payment for services have contributed to barriers in best practices for opioid therapy.	RECOMMENDATION 1A: Encourage CMS and private payers to provide sufficient compensation for time and payment for services to implement the various screening measures (e.g., extensive history taking, review of medical records, PDMP query, urine toxicology screenings, when clinically indicated). These are vital aspects of risk assessment and stratification for patients on opioids and other medications.
3.3.2 Patient Education	GAP 2: Patient expectations for pain management in the perioperative arena are frequently not aligned with current surgical practices or procedures that require pain management.	RECOMMENDATION 2C: CMS and private payers should recognize that the time spent educating and managing patients' expectations is cost-effective and provides a significant value that reduces the length of hospital stays and improves patients' postoperative pain management, allowing for faster recovery through earlier PT and mobility that decreases the risk for postoperative complications (e.g., blood clots). CMS and other payers should compensate according to physician-patient time spent.
3.4.2 Insurance Coverage for Complex Management Situations	GAP 1: Time and resources are insufficient for complex and safe opioid management.	RECOMMENDATION 1B: CMS and private payers should investigate and implement innovative payment models that recognize and reimburse holistic, integrated, multimodal pain management, including behavioral health.

Question 3: How can CMS improve access to therapies in Medicare and Medicaid that manage acute and chronic pain and minimize the risk of opioid misuse and abuse, including in rural or medically underserved communities? What key special populations should CMS target for improved access?

Table 6. CMS Question 3 and PMTF Responses

Section	Gap	Recommendation
3.4.2 Insurance Coverage for Complex Management Situations	GAP 1: Time and resources are insufficient for complex and safe opioid management.	RECOMMENDATION 1A: Reimburse complex opioid and non-opioid management consistent with the time and resources required for patient education; safe evaluation; risk assessment; reevaluation; and integration of alternative, non-opioid modalities. RECOMMENDATION 1B: CMS and private payers should investigate and implement innovative payment models that recognize and reimburse holistic,

Section	Gap	Recommendation
		integrated, multimodal pain management, including behavioral health.
3.4.2 Insurance Coverage for Complex Management Situations	GAP 3: Payers often do not reimburse for non-opioid pharmacologic therapies that are more expensive than opioids, such as long-acting local anesthetic injection/infusion and intravenous acetaminophen analgesia.	RECOMMENDATION 3A: CMS and other payers should align their reimbursement guidelines for non-opioid pharmacologic therapies with current clinical practice guidelines (CPGs).
3.4.2 Insurance Coverage for Complex Management Situations	GAP 4: Coordinated, individualized, multidisciplinary care for chronic pain management is a best practice, yet this model of care is difficult to achieve with current payment models.	RECOMMENDATION 4B: Payers should reimburse for pain management in a manner that facilitates access in underserved locations through telehealth or other technology-assisted delivery methods.

Question 4: How can CMS improve access to therapies, identify problematic payment and coverage policies, identify payment and service delivery models and increase access to medical devices, mobile apps, telementoring and telemedicine in Medicare and Medicaid that treats beneficiaries with both opioid use disorder and acute or chronic pain?

Table 7. CMS Question 4 and PMTF Responses

Section	Gap	Recommendation
2.4 Interventional Procedures	GAP 2: Inconsistencies and frequent delays exist in insurance coverage for interventional pain techniques that are clinically appropriate for a particular condition and context.	RECOMMENDATION 2A: Encourage CMS and private payers to provide consistent and timely insurance coverage for evidence-informed interventional procedures early in the course of treatment when clinically appropriate. These procedures can be paired with medication and other therapies to improve function and QOL [quality of life].

Section	Gap	Recommendation
2.5.1 Access to Psychological Interventions	GAP 1: Access to evidence-based psychological and behavioral health approaches for treating chronic pain and mental health comorbidities (e.g., post-traumatic stress disorder, depression, anxiety, mood disorders, SUD) is limited by geography, reimbursement, and education in primary care and specialty care settings.	RECOMMENDATION 1A: Increase access to evidence-based psychological interventions, including the full range of treatment deliveries (e.g., in-person, telehealth, internet self-management, mobile applications, group sessions, telephone counseling) and hub-and-spoke models. RECOMMENDATION 1C: Improve reimbursement policies for integrated, multidisciplinary, multimodal treatment approaches that include psychological and behavioral health interventions through traditional and nontraditional delivery methods (e.g., in-person, telehealth, internet self-management, mobile applications, group sessions, telephone counseling).
3.3.2 Patient Education	GAP 1: Current patient education is lacking for both acute and chronic pain.	RECOMMENDATION 1B: Explore and test innovative methods of delivering patient education and support for patients with acute or chronic pain using technology, particularly in rural areas that have limited access to multimodal treatment. Examples of means to provide patient access in such situations include telemedicine online support groups, networks of in-person support groups with training and guidance from leaders, and applications easily accessible on mobile devices.
3.3.3 Provider Education	GAP 1: Gaps exist in pain management understanding and education throughout the healthcare provider community. There is a need for further education regarding acute and chronic pain for all healthcare providers in professional school curricula, postgraduate education, and further clinical specialty training.	RECOMMENDATION 1C: Explore intensive continuing pain education for PCPs, including telehealth, tele-mentoring, and the Project ECHO model, as a means of providing pain education for PCPs by pain specialists. Consider the State Targeted Response Technical Assistance Consortium model for pain training as it currently exists for addiction training.
3.4.2 Insurance Coverage for Complex Management Situations	GAP 3: Payers often do not reimburse for non-opioid pharmacologic therapies that are more expensive than opioids, such as long-acting local anesthetic injection/infusion and intravenous acetaminophen analgesia.	RECOMMENDATION 3A: CMS and other payers should align their reimbursement guidelines for non-opioid pharmacologic therapies with current CPGs.

Question 5: How can CMS improve Medicare and Medicaid beneficiaries' access to medical devices that are non-opioid-based treatments for pain approved by the FDA for the management of acute and chronic pain and for preventing overdoses of controlled substances such as prescription opioids? What specific barriers exist in Medicare and Medicaid payment and coverage policies for/to beneficiaries to access such devices?

Table 8. CMS Question 5 and PMTF Responses

Section	Gap	Recommendation
2.4 Interventional Procedures	GAP 2: Inconsistencies and frequent delays exist in insurance coverage for interventional pain techniques that are clinically appropriate for a particular condition and context.	RECOMMENDATION 2A: Encourage CMS and private payers to provide consistent and timely insurance coverage for evidence-informed interventional procedures early in the course of treatment when clinically appropriate. These procedures can be paired with medication and other therapies to improve function and QOL. RECOMMENDATION 2B: CMS and other payers must restore reimbursement to nonhospital sites of service to improve access and lower the cost of interventional procedures.

Question 6: What are the recommendations of highest impact from the final task force report that can improve health outcomes for individuals with acute and/or chronic pain or individuals with chronic pain and OUD?

Table 9. CMS Question 6 and PMTF Responses

Section	Gap	Recommendation
2.1.1 Acute and Chronic Pain	GAP 1: Multimodal, non-opioid therapies are underutilized in the perioperative, inflammatory, musculoskeletal, and neuropathic injury settings.	RECOMMENDATION 1A: Use procedure-specific, multimodal regimens and therapies when indicated in the perioperative period, including various non-opioid medications, ultrasound-guided nerve blocks, analgesia techniques (e.g., lidocaine, ketamine infusions), and psychological and integrative therapies to mitigate opioid exposure. RECOMMENDATION 1C: Encourage CMS and private payers to develop appropriate reimbursement policies to allow for a multimodal approach to acute pain in the perioperative setting and the peri-injury setting, including preoperative consultation to determine a multimodal plan for the perioperative setting.

Section	Gap	Recommendation
2.4 Interventional Procedures	GAP 2: Inconsistencies and frequent delays exist in insurance coverage for interventional pain techniques that are clinically appropriate for a particular condition and context.	RECOMMENDATION 2B: CMS and other payers must restore reimbursement to nonhospital sites of service to improve access and lower the cost of interventional procedures.
3.1.2 Screening and Monitoring	GAP 1: Comprehensive screening and risk assessment of patients are time-consuming but vital for proper evaluation of their chronic pain conditions. Lack of sufficient compensation for time and payment for services have contributed to barriers in best practices for opioid therapy.	RECOMMENDATION 1A: Encourage CMS and private payers to provide sufficient compensation for time and payment for services to implement the various screening measures (e.g., extensive history taking, review of medical records, PDMP query, urine toxicology screenings, when clinically indicated). These are vital aspects of risk assessment and stratification for patients on opioids and other medications.
3.3.3 Provider Education	GAP 1: Gaps exist in pain management understanding and education throughout the healthcare provider community. There is a need for further education regarding acute and chronic pain for all healthcare providers in professional school curricula, postgraduate education, and further clinical specialty training.	RECOMMENDATION 1C: Explore intensive continuing pain education for PCPs, including telehealth, tele-mentoring, and the Project ECHO model, as a means of providing pain education for PCPs by pain specialists. Consider the State Targeted Response Technical Assistance Consortium model for pain training as it currently exists for addiction training.
3.4.2 Insurance Coverage for Complex Management Situations	GAP 1: Time and resources are insufficient for complex and safe opioid management.	RECOMMENDATION 1A: Reimburse complex opioid and non-opioid management consistent with the time and resources required for patient education; safe evaluation; risk assessment; reevaluation; and integration of alternative, non-opioid modalities.
3.4.2 Insurance Coverage for Complex Management Situations	GAP 3: Payers often do not reimburse for non-opioid pharmacologic therapies that are more expensive than opioids, such as long-acting local anesthetic injection/infusion and intravenous acetaminophen analgesia.	RECOMMENDATION 3A: CMS and other payers should align their reimbursement guidelines for non-opioid pharmacologic therapies with current CPGs.

Section	Gap	Recommendation
<p>3.4.2 Insurance Coverage for Complex Management Situations</p>	<p>GAP 4: Coordinated, individualized, multidisciplinary care for chronic pain management is a best practice, yet this model of care is difficult to achieve with current payment models.</p>	<p>RECOMMENDATION 4A: Payers should reimburse pain management using a chronic disease management model. CMS and private payers should reimburse for integrative, multidisciplinary pain care by using a chronic disease management model similar to that currently used to reimburse for cardiac rehabilitation and diabetes chronic care management programs. In addition, reimburse care team leaders for time spent coordinating patient care. A Current Procedural Terminology code should be developed for pain care coordination as well as team and group conferences to enable multidisciplinary care.</p> <p>RECOMMENDATION 4B: Payers should reimburse for pain management in a manner that facilitates access in underserved locations through telehealth or other technology-assisted delivery methods.</p>

Appendix B. Various Therapies that Manage Chronic and Acute Pain

Table 10. Various Pain Management Approaches³⁴³

Type of Therapy	Approaches
Pharmaceutical Therapies	Acetaminophen Non-steroidal anti-inflammatory drugs (NSAID) Anticonvulsants Antidepressants Musculoskeletal agents Antianxiety medications Opioids
Restorative Therapies (includes physical therapy, occupational therapy, and other movement modalities)	Therapeutic exercise Transcutaneous electric nerve stimulation (TENS) Massage therapy Traction Cold and heat therapy Therapeutic ultrasound (TU) Bracing
Interventional Procedures	Epidural steroid injections (ESIs) Facet joint nerve block and denervation injection Cryoneuroablation Radiofrequency ablation Peripheral nerve injections Sympathetic nerve blocks Neuromodulation Intrathecal medication pumps Vertebral augmentation Trigger points Joint injections Interspinous process spacer devices Regenerative/adult autologous stem cell therapy
Behavioral Health Approaches	Behavioral therapy Cognitive behavioral therapy Acceptance and commitment therapy (ACT) Mindfulness-based stress reduction (MBSR) Emotional awareness and expression therapy (EAET) Self-regulatory or psychophysiological approaches Contingency Management

Type of Therapy	Approaches
Complementary and Integrative Health	Acupuncture Massage and manipulative therapies Yoga Tai chi Spirituality

Appendix C. Therapies that Treat Opioid Use Disorder

The following are FDA-approved products for MAT:³⁴⁴

Buprenorphine products:

- Buprenorphine sublingual tablet
- Buprenorphine implant for subdermal administration
- Buprenorphine extended-release injection for subcutaneous use
- Buprenorphine/naloxone sublingual tablet
- Buprenorphine/naloxone buccal film
- Buprenorphine/naloxone sublingual film
- Buprenorphine/naloxone sublingual film for sublingual or buccal use

Methadone products:

- Methadone hydrochloride tablet
- Methadone hydrochloride oral concentrate
- Methadone hydrochloride wafer

Naltrexone products:

- Naltrexone for extended-release injectable suspension intramuscular
- Naltrexone Oral

Table 11. Behavioral Therapies to Treat Opioid Use Disorder³⁴⁵

Therapy	Description
Cognitive-Behavioral Therapy (CBT)	CBT therapies help patients identify and modify maladaptive or dysfunctional thinking and behavior patterns. Typically conducted as individual sessions over the short term (12 – 24 weeks), CBT therapy often involves reviewing the outcomes of substance use, increasing a patient’s coping abilities, and teaching self-monitoring techniques.
Contingency Management	In contingency management, patients receive rewards for demonstrating desired behaviors. For example, patients could receive vouchers for goods or services when they take part in treatment or have negative drug-screening (urine) tests.

Therapy	Description
Community Reinforcement Approach (CRA) Plus Vouchers	CRA Plus Vouchers is an intensive outpatient treatment framework lasting 24 weeks in which patients are rewarded and reinforced for reducing substance use. Individuals participate in counseling sessions that help them enhance relationships, sobriety skills, and supportive networks, and they may earn vouchers for providing negative drug screening (urine) tests.
Motivational Enhancement Therapy (MET)	In MET, motivational interviewing is used to help patients adopt healthier behaviors. MET may focus on helping individuals understand how their behaviors impede the achievement of their goals, or it may concentrate on improving a patient's self-efficacy, for example.
The Matrix Model	The Matrix Model is a structured, 16-week multimodal approach that combines family, group, and individual therapy; education; social support; and drug screening. Key areas of focus include recovery skills, self-help, and relapse prevention.
Twelve-step Facilitation Therapy (TSF)	In TSF, patients participate in individual counseling sessions over 12 weeks to facilitate engagement in 12-step programs, such as Alcoholics Anonymous, Narcotics Anonymous, or other programs.
Family Behavioral Therapy (FBT)	The goal of FBT is to help patients manage family matters as well as SUD. FBT may address basic necessities, mental health issues, conflict, activities of daily living, and more.
Recovery Support Services (RSS)	RSS helps to engage individuals in and support them throughout treatment and recovery. RSS often involves case management staff, recovery coaches, and/or peers in recovery from SUD treatment programs or local mental health organizations who encourage and assist patients in entering treatment, navigating the continuum of care, and living substance-free in the community.

Appendix D. Additional Tables on MAT Access

Table 12. Select Behavioral Health Treatment Services Provided by State Medicaid Programs^{346,347}

Behavioral Health Treatment Service	States with Medicaid Coverage
Psychiatric Services – Testing	43
Psychiatric Services – Evaluation	46
Psychological Testing	46
Individual Therapy	45
Group Therapy	45
Family Therapy	46
Inpatient Detoxification	43
Residential Rehabilitation	33
Outpatient Detoxification	31
Intensive Outpatient SUD Treatment	38

Table 13. Recovery Support Services Provided by State Medicaid Programs³⁴⁸

Recovery Support Service	States with Medicaid Coverage for Individuals with SUD
Comprehensive Community Supports: Services that address barriers that impede the development of skills necessary for independent functioning in the community.	27
Peer Support Services: Supportive services delivered by a person in recovery from a SUD.	37
Skills Training and Development: Services that help a beneficiary with a SUD acquire new skills, ranging from life skills to employment readiness and restoration to the community.	11
Supported Employment: Helps individuals achieve employment in community settings.	11
Supportive Housing: Evidence-based intervention that combines housing assistance with wrap-around support services for people experiencing homelessness, as well as other people with disabilities.	4

Table 14. Case Management Services Provided by State Medicaid Programs³⁴⁹

Case Management Service	States with Medicaid Coverage for Individuals with SUD
Recovery Management: Includes case management or checkups to assess where an individual is in the recovery cycle and what additional recovery support services may be necessary.	10
Transitional Case Management: Care management services for a patient following a discharge from a hospital or facility-based care.	15
Targeted Case Management: Case management services that assist individuals in gaining access to needed medical, social, educational, and other services.	39

Acronyms

Acronym	Definition
ACA	Affordable Care Act
AHRQ	Agency for Healthcare Research and Quality
APC	Ambulatory Payment Classification
APM	Alternative Payment Model
ASC	Ambulatory Surgical Center
ASP	Average Sales Price
BCPI	Bundled Payments for Care Improvement
CBA	Competitive Bidding Area
CBP	Clinical Best Practice
CBP	Competitive Bidding Program
CBT	Cognitive-Behavioral Therapy
CCBHC	Certified Community Behavioral Health Clinic
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
CMCS	Center for Medicaid and CHIP Services
CMS	Centers for Medicare & Medicaid Services
CPG	Clinical Practice Guideline
CRA	Community Reinforcement Approach
CY	Calendar Year
DATA	Drug Addiction Treatment Act of 2000
DME	Durable Medical Equipment
DMEPOS	Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
DMP	Drug Management Program
DoD	Department of Defense
DRG	Diagnosis-Related Group
DUR	Drug Utilization Review
ECHO	Extension for Community Healthcare Outcomes
eCQM	Electronic Clinical Quality Measure

Acronym	Definition
ED	Emergency Department
EHR	Electronic Health Record
EMTALA	Emergency Medical Treatment and Labor Act
EPSDT	Early and Periodic Screening, Diagnostic and Treatment benefit
ER	Extended-Release
ERAS	Enhanced Recovery After Surgery
FBT	Family Behavioral Therapy
FDA	Food and Drug Administration
FFP	Federal Financial Participation
FFS	Fee-for-Service
FFY	Federal Fiscal Year
FMAP	Federal Medical Assistance Percentage
FY	Fiscal Year
GDP	Gross domestic product
HCBS	Home- and Community-Based Services
HEAL	Helping to End Addiction Long-term
HHS	U.S. Department of Health and Human Services
HOPD	Hospital Outpatient Department
HRSA	Health Resources and Services Administration
IMD	Institution for Mental Diseases
InCK	Integrated Care for Kids
IPPS	Inpatient Prospective Payment System
IQR	Inpatient Quality Reporting
LCD	Local Coverage Determination
MA	Medicare Advantage
MAPD	Medicare Advantage-Prescription Drug
MACPAC	Medicaid and CHIP Payment and Access Commission
MAT	Medication-Assisted Treatment
MCO	Managed Care Organization
MedPAC	Medicare Payment Advisory Commission

Acronym	Definition
MET	Motivational Enhancement Therapy
MIPS	Merit-based Incentive Payment System
MME	Morphine Milligram Equivalent
MOM	Maternal Opioid Misuse
MS-DRG	Medicare Severity Diagnosis Related Group
NAS	Neonatal Abstinence Syndrome
NASEM	National Academies of Sciences, Engineering and Medicine
NCD	National Coverage Determination
NIH	National Institutes of Health
NMES	Neuromuscular Electrical Stimulator
NP	Nurse Practitioner
NSAID	Nonsteroidal Anti-Inflammatory Drug
OBOT	Office-Based Opioid Treatment
OMS	Overutilization Monitoring System
ONC	Office of the National Coordinator for Health Information Technology
OPPS	Outpatient Prospective Payment System
OTP	Opioid Treatment Program
OTS	Off-the-Shelf
ODU	Opioid Use Disorder
PA	Physician Assistant
PAHP	Prepaid Ambulatory Health Plan
PBM	Pharmacy Benefit Management
PCP	Primary Care Provider
PENS	Percutaneous Electrical Nerve Stimulation
PFS	Physician Fee Schedule
PDMP	Prescription Drug Monitoring Program
PIHP	Prepaid Inpatient Health Plan
PMA	Pre-Market Approval process
PMTF	Pain Management Best Practices Inter-Agency Task Force
PPS	Prospective Payment System

Acronym	Definition
QIN	Quality Innovation Network
QIO	Quality Improvement Organization
QOL	Quality of life
RFI	Request for Information
RSS	Recovery Support Services
RVU	Relative Value Unit
SAMHSA	Substance Abuse and Mental Health Services Administration
SBIRT	Screening, Brief Intervention, and Referral to Treatment
SCD	Sickle Cell Disease
STR	State Targeted Response
SUD	Substance Use Disorder
SUPPORT for Patients and Communities Act	Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act
TENS	Transcutaneous Electric Nerve Stimulation
TSF	Twelve-step Facilitation therapy
VA	Department of Veterans Affairs

Glossary

Term	Definition
Acute Pain	Pain that occurs suddenly, generally in response to a known injury, surgery, or infection, and resolves over the short or medium term as the body heals. ³⁵⁰
Addiction	As defined in the 2019 PMTF Report addiction is “A primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one’s behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death.” ³⁵¹
Chronic Pain	As defined in the CDC Guideline for Prescribing Opioids for Chronic Pain, 2016, pain that typically lasts >3 months or past the time of normal tissue healing. Chronic pain can result from a medical condition, injury, disease, inflammation, medical treatment, or other causes. ³⁵²
Inpatient Prospective Payment System (IPPS)	“Section 1886(d) of the Social Security Act sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. This payment system is referred to as the inpatient prospective payment system (IPPS). Under the IPPS, each case is categorized into a diagnosis-related group (DRG). Each DRG has a payment weight assigned to it, based on the average resources used to treat Medicare patients in that DRG.” ³⁵³
Institution for Mental Diseases (IMD)	Defined by Section 1905(i) of the Social Security Act as a “hospital, nursing facility, or other institution of more than 16 beds, that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care, and related services.” ³⁵⁴
MACPAC	Established by the Children’s Health Insurance Program Reauthorization Act of 2009 (Public Law No. 111-3), the Medicaid and CHIP Payment and Access Commission (MACPAC) is a non-partisan legislative branch agency that advises Congress, the Secretary of the U.S. Department of

Term	Definition
	Health and Human Services, and states about a variety of issues involving Medicaid and the State Children’s Health Insurance Program (CHIP).
Medically Underserved Areas and Populations (MUA/Ps)	<p>Medically Underserved Areas (MUAs) and Medically Underserved Populations (MUPs) identify geographic areas and populations with a lack of access to primary care services. MUAs have a shortage of primary care health services for residents within a geographic area such as:</p> <ul style="list-style-type: none"> • A whole county • A group of neighboring counties • A group of urban census tracts • A group of county or civil divisions. <p>MUPs are specific sub-groups of people living in a defined geographic area with a shortage of primary care health services. These groups may face economic, cultural, or linguistic barriers to healthcare.³⁵⁵</p>
Medication-Assisted Treatment	As defined in Section 6032(f) of the SUPPORT for Patients and Communities Act, the term “medication-assisted treatment” includes opioid treatment programs, behavioral therapy, and medications to treat substance abuse disorder.
MedPAC	The Medicare Payment Advisory Commission. Established by the Balanced Budget Act of 1997 (Public Law 105-33) in 1997, MedPAC is an independent congressional agency that advises Congress about Medicare program issues, such as payment, access to care, quality, and more.
Neonatal Abstinence Syndrome	According to the National Institute on Drug Abuse, a state of withdrawal resulting from drugs that have passed into a fetus’s bloodstream from the mother while she is pregnant, resulting in a baby’s drug dependency at birth. ³⁵⁶
Nonmedical Use of Prescription Drugs	<i>See Opioid Misuse</i>
Non-opioid Therapy	As defined by the CDC, non-opioid therapy refers to “methods of managing pain that does not involve opioids. These methods can include, but are not limited to, acetaminophen (Tylenol®) or ibuprofen (Advil®), cognitive behavioral therapy, physical therapy, acupuncture, meditation, exercise, medications for depression or for seizures, or interventional therapies (injections). ³⁵⁷
Opioid	According to the CDC, opioids are “natural, synthetic, or semi-synthetic chemicals that interact with opioid receptors on nerve cells in the body and

Term	Definition
	brain, and reduce the intensity of pain signals and feelings of pain. This class of drugs includes the illegal drug heroin, synthetic opioids such as fentanyl, and pain medications available legally by prescription, such as oxycodone, hydrocodone, codeine, morphine, and many others. Prescription opioids are generally safe when taken for a short time and as directed by a doctor, but because they produce euphoria in addition to pain relief, they can be misused and have addiction potential.” ³⁵⁸
Opioid Abuse	See <i>Opioid Use Disorder</i>
Opioid Addiction	See <i>Opioid Use Disorder</i>
Opioid Dependence	See <i>Opioid Use Disorder; Physical Dependence</i>
Opioid Misuse	“Taking an opioid medication in a manner or dose other than prescribed; taking someone else’s prescription, even if for a medical complaint such as pain; or taking a medication to feel euphoria (i.e., to get high). The term ‘nonmedical use of prescription drugs’ also refers to these categories of misuse.” ³⁵⁹
Opioid Use Disorder (OUD)	“Defined in the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) as a problematic pattern of opioid use leading to clinically significant impairment or distress. OUD was previously classified as Opioid Abuse or Opioid Dependence in DSM-IV. OUD has also been referred to as ‘opioid addiction.’” ³⁶⁰
Outpatient Prospective Payment System (OPPS)	Authorized by Section 1833(t) of the Social Security Act, in 2000, OPSS is the way that Medicare pays for most outpatient services at hospitals or community mental health centers under Medicare Part B. ³⁶¹
Overdose	According to the National Institute on Drug Abuse, an overdose “occurs when a person uses enough of a drug to produce a life-threatening reaction or death.” ³⁶²
Overutilization Monitoring System (OMS)	The Overutilization Monitoring System (OMS) is a reporting tool that supports Medicare Part D drug management programs and retrospectively identifies those beneficiaries who are at potential risk for abuse or misuse use of frequently abused drugs by meeting clinical guidelines/OMS criteria (i.e., using high levels of opioids from multiple prescribers and pharmacies). Sponsors review these cases and perform case management with the beneficiaries’ prescribers, limit at-risk beneficiaries’ coverage for

Term	Definition
	frequently abused drugs to certain prescribers and pharmacies, and apply beneficiary-specific point-of-sale claim edits. ³⁶³
Pain Management Best Practices Inter-Agency Task Force (PMTF)	As described in the PMTF Report, the 29-member Pain Management Best Practices Inter-Agency Task Force (PMTF, or Task Force) “was convened by the U.S. Department of Health and Human Services in conjunction with the U.S. Department of Defense and the U.S. Department of Veterans Affairs with the Office of National Drug Control Policy to address acute and chronic pain in light of the ongoing opioid crisis. The PMTF mandate is to identify gaps, inconsistencies, and updates and to make recommendations for best practices for managing acute and chronic pain.” ³⁶⁴
Physical Dependence	“Occurs because of physiological adaptations to chronic exposure to a drug. Someone who is physically dependent on medication will experience withdrawal symptoms when the use of the medicine is suddenly reduced or stopped or when an antagonist to the drug is administered. These symptoms can be minor or severe and can usually be managed medically or avoided by using a slow drug taper. Physical dependence is not the same as addiction.” ³⁶⁵
Prescription Drug Monitoring Program (PDMP)	PDMPs are typically statewide electronic databases that track information on specified controlled substances dispensed to patients. Information is generally made available to clinicians who prescribe medications and, in some cases, law enforcement, licensing boards, or others.
Screening, Brief Intervention and Referral to Treatment (SBIRT)	“Screening, Brief Intervention and Referral to Treatment (SBIRT) is an evidence-based practice used to identify, reduce, and prevent problematic use, abuse and dependence on alcohol and illicit drugs. The SBIRT model was incited by an Institute of Medicine recommendation that called for community-based screening for health risk behaviors, including substance use.” ³⁶⁶
Substance Use Disorder	“A medical illness caused by disordered use of a substance or substances. According to the Fifth Edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5), SUDs are characterized by clinically significant impairments in health, social function, and impaired control over substance use and are diagnosed through assessing cognitive, behavioral, and psychological symptoms. A SUD can range from mild to severe.” ³⁶⁷

Endnotes

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³ The Council of Economic Advisors. The Underestimated Costs of the Opioid Crisis. November 2017. Available: <https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf> (accessed on December 19, 2019).

⁴ Section 6032 of the SUPPORT for Patients and Communities Act (Pub. L. 115-271, Title VI, §6032).

⁵ The PMTF was convened under Section 101(b) of the Comprehensive Addiction and Recovery Act of 2016 (Public Law 114–198).

⁶ CMS. CMS Roadmap to Address the Opioid Epidemic. March 2019. Available: <https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf> (accessed on December 16, 2019).

⁷ State Medicaid agencies will implement the model in collaboration with select care-delivery partners over the course of a five-year performance period including one year of pre-implementation, one year of transition and three years of full implementation.

⁸ CMS. Maternal Opioid Misuse (MOM) Model. Fact Sheet. Available: https://www.cms.gov/sites/default/files/2019-02/02-08-2018%20Fact%20Sheet%20--%20Maternal%20Opioid%20Misuse%20%28MOM%29%20Model_NOFO%20updates%20%28FINAL%29.pdf (accessed on September 27, 2019).

⁹ The InCK Model is designed to strengthen performance on priority child health indicators, reduce avoidable inpatient stays and out-of-home placements, and establish sustainable, state-designed alternative payment models. State Medicaid agencies will work with select local entities during two years of pre-implementation and five years of implementation to conduct early identification and treatment of children with multiple physical, behavioral, or other health-related needs and facilitate integration and coordination of healthcare and case management services.

¹⁰ CMS. CMS announces new model to address impact of the opioid crisis for children. Press Release. August 23, 2018. Available: <https://www.cms.gov/newsroom/press-releases/cms-announces-new-model-address-impact-opioid-crisis-children> (accessed on September 27, 2019).

¹¹ As required by Section 6042 of the SUPPORT for Patients and Communities Act (42 U.S.C. 1395cc-6), the Value in Opioid Use Disorder Treatment model will create two new payments for highly coordinated and integrated OUD treatment services furnished to applicable beneficiaries, including: a per applicable beneficiary per month OUD care management fee, which the participant may use to “deliver additional services to applicable beneficiaries, including services not otherwise eligible for payment under [Title XVIII]”; and a performance-based incentive payment, which may include consideration of evidence-based MAT, as well as patient engagement and retention in treatment. Value in Treatment is expected to result in improved outcomes and cost savings among beneficiaries who have health and social needs that go beyond the clinical services currently covered by Medicare.

¹² CDC. Opioid Basics – Understanding the Epidemic. Available: [Prescription Opioid Overdose Death Maps | Drug Overdose | CDC Injury Center](#) (accessed on June 01, 2021).¹³ 2019 National Survey on Drug Use and Health. Mortality in the United States, 2018). Available [Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health \(samhsa.gov\)](#)

¹⁴ The Council of Economic Advisors. The Underestimated Costs of the Opioid Crisis. November 2017. Available: <https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf> (accessed on December 19, 2019).

¹⁵ Section 6032 of the SUPPORT for Patients and Communities Act (Pub. L. 115-271, Title VI, §6032).

¹⁶ Section 101(b) of the Comprehensive Addiction and Recovery Act of 2016 (Public Law 114–198).

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- ²² The Henry J. Kaiser Family Foundation (KFF). The Opioid Epidemic and Medicaid's Role in Facilitating Access to Treatment. Issue Brief. May 24, 2019. Available: <https://www.kff.org/medicaid/issue-brief/the-opioid-epidemic-and-medicaid-s-role-in-facilitating-access-to-treatment/> (accessed on December 18, 2019).
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- ²⁴ Section 6032(e) of the SUPPORT for Patients and Communities Act (Pub. L. 115-271, Title VI, §6032).
- ²⁵ Section 6032(b) of the SUPPORT for Patients and Communities Act (Pub. L. 115-271, Title VI, §6032).
- ²⁶ Dahlhamer, J., Lucas, J., Zelaya, C., et al. Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults - United States, 2016. MMWR Morb Mortal Wkly Rep. 2018;67(36):1001-1006. Available: <https://www.cdc.gov/mmwr/volumes/67/wr/mm6736a2.htm> (accessed on December 18, 2019).
- ²⁷ U.S. Department of Health and Human Services (HHS). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. May 2019. Available: <https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf> (accessed on December 18, 2019).
- ²⁸ Restorative therapies include a variety of modalities often implemented by physical or occupational therapists.
- ²⁹ Interventional procedures involve the diagnosis and treatment of pain with minimally invasive interventions that can reduce pain as well as minimize the use of other medications in some individuals.
- ³⁰ Behavioral health approaches include therapies addressing the psychological, emotional, behavioral, and social aspects of pain, as well as the specific challenges faced by people with pain who have a mental disorder. The use of a biopsychosocial approach to pain management may include any or all of the following: behavioral therapy, cognitive behavioral therapy, mindfulness-based stress reduction, and self-regulatory or psychophysiological approaches.
- ³¹ Complementary and Integrative Health includes a variety of interventions, including mind-body behavioral therapies, acupuncture and massage, osteopathic and chiropractic manipulation, meditative movement therapies (e.g., yoga, tai chi), and natural products.
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⁵⁵ The InCK Model is designed to strengthen performance on priority child health indicators, reduce avoidable inpatient stays and out-of-home placements, and establish sustainable, state-designed APMs. State Medicaid agencies will work with select local entities during two years of pre-implementation and five years of implementation to conduct early identification and treatment of children with multiple physical, behavioral, or other health-related needs.

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⁵⁷ As required by Section 6042 of the SUPPORT for Patients and Communities Act (42 U.S.C. 1395cc-6), the Value in Opioid Use Disorder Treatment model will create two new payments for highly coordinated and integrated OUD treatment services furnished to applicable beneficiaries, including: a per applicable beneficiary per month OUD care management fee, which the participant may use to “deliver additional services to applicable beneficiaries, including services not otherwise eligible for payment under [Title XVIII]”; and a performance-based incentive payment, which may include consideration of evidence-based MAT, as well as patient engagement and retention in treatment. Value in Treatment is expected to result in improved outcomes and cost savings among beneficiaries who have health and social needs that go beyond the clinical services currently covered by Medicare.

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⁶³ Section 1833(t)(22) of the Social Security Act, as added by Section 6082(a) of the SUPPORT for Patients and Communities Act, directs the Secretary to focus on covered OPD services (or groups of services) assigned to C-APCs, APCs that primarily include surgical services, and other services determined by the Secretary which generally involve treatment for pain management, and where appropriate, begin to make revisions to payments (treated as adjustments and made in a budget neutral manner) for services furnished on or after January 1, 2020.

⁶⁴ CMS’s review included an evaluation of the non-opioid drug Exparel,® which functions as a surgical supply. While CMS found no clear evidence that its packaging payment policy discourages the use of Exparel® in the HOPD setting, it did find a decline in the utilization of Exparel® in the ASC setting; as a result, CMS is unpackaging and making separate payment for the drug in ASCs (at average sales price + 6 percent for CYs 2019 and 2020) to encourage use of this type of drug rather than prescription opioids. CMS-1717-FC. Medicare Program; Changes to Hospital Outpatient Perspective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. Final Rule with comment period. 84 Fed. Reg. 61142, 61174-61180 (Nov. 12, 2019). Available: <https://www.federalregister.gov/documents/2019/11/12/2019-24138/medicare-program-changes-to-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center> (accessed on December 18, 2019).

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