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U.S. Department of Health & Human Services Report to Congress

Summary of Review and Recommendations for the Medicare and Medicaid Programs to Prevent Opioid Addictions and Enhance Access to Medication-Assisted Treatment

A Report Required by the SUPPORT for Patients and Communities Act

Prepared by the Centers for Medicare & Medicaid Services

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1. Introduction

The opioid crisis in the United States is a serious public health issue affecting many individuals, including those 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 requires 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 to enhance access to medication-assisted treatment”⁴ in collaboration with the Pain Management Best Practices Inter-Agency Task Force (PMTF).⁵

Section 6032(e) of the SUPPORT for Patients and Communities Act requires that the Secretary of HHS submit, and make public, a report to Congress that includes:⁶

- (1) A summary of the results of the Secretary’s review and any recommendations under the action plan;⁷
- (2) The Secretary’s planned next steps with respect to the action plan; and
- (3) An evaluation of price trends for drugs used to reverse opioid overdoses (such as naloxone), including recommendations on ways to lower such prices for consumers.

1.1 Background

As the largest healthcare payer in the United States, the Centers for Medicare & Medicaid Services (CMS) is actively addressing the opioid epidemic. CMS developed an agency-wide *CMS Roadmap: Fighting the Opioid Crisis*, including a framework that articulates three key focus areas: prevention, treatment, and data.⁸



Figure 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(b) of the SUPPORT for Patients and Communities Act⁹ (CMS Action Plan).¹⁰ These inputs include:

- An analysis of Medicare and Medicaid payment and coverage policies with potential relevance to the opioid crisis.
- An 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.

Based on these inputs, the CMS Action Plan sets forth: foundational concepts and key themes related to the opioid crisis; agency actions as part of its strategic initiative to address the opioid crisis; an analysis of key Medicare and Medicaid coverage and payment policies related to pain management and treatment of opioid use disorder, including medication-assisted treatment (MAT);¹¹ a review of beneficiaries' access to care; and a review of payment and coverage policies for medical devices approved by the Food and Drug Administration (FDA).

As required by Section 6032(e) of the SUPPORT for Patients and Communities Act, this report provides a brief synopsis of the CMS Action Plan, highlighting recommendations with regard to CMS actions to address the opioid crisis, key findings from the analysis of coverage and payment policies and review of beneficiaries' access to care, and next steps with respect to the CMS Action Plan. Additionally, this report includes an evaluation of price trends for drugs used to reverse opioid overdoses, and outlines recommendations to lower the prices of such drugs for consumers.

2. Summary of Results: Review and Recommendations Under the Action Plan

This section summarizes recommendations and key themes from the CMS Action Plan, and is organized according to the three pillars of Prevention, Treatment, and Data to align with the framework in the agency-wide *CMS Roadmap: Fighting the Opioid Crisis*¹² (see Figure 1).

2.1 Recommendations

In developing the CMS Action Plan, CMS adopted numerous recommendations in consideration of current policies and public stakeholder input, and identified actions to pursue as part of its strategic initiative to fight the opioid crisis. These recommendations are detailed below.

2.1.1 Prevention

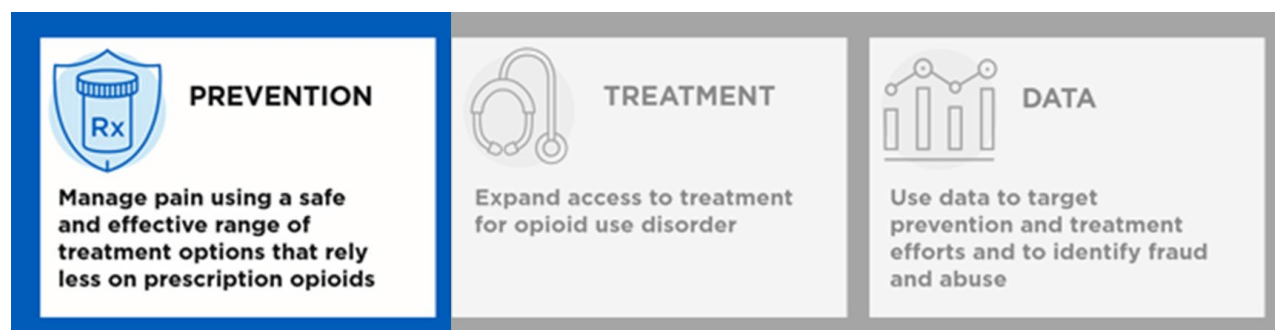


Figure 2. CMS Roadmap: Key Areas of Focus (Prevention)

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 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.

2.1.2 Treatment



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

Medicare

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

- Broaden the 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, MAT, 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)¹³ Model: seeks to improve coordination and integration of care for pregnant and postpartum Medicaid beneficiaries with OUD.¹⁴
- Integrated Care for Kids (InCK)¹⁵ 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.¹⁶
- OUD Treatment Demonstration (Value in Opioid Use Disorder Treatment):¹⁷ creates two new payments for OUD treatment services furnished to applicable Medicare beneficiaries participating in the demonstration program.

2.1.3 Data



Figure 4. 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.

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

This section provides a brief synopsis of themes that emerged from the analysis of stakeholder inputs to the CMS Action Plan, described above, as well as key findings from a review of:

1. Medicare and Medicaid payment and coverage policies relevant to the opioid crisis.
2. Medicare and Medicaid beneficiaries' access to the full range of treatment options for OUD and pain management.
3. FDA-approved medical devices.

Themes and key findings are organized according to the CMS Roadmap pillars of Prevention, Treatment, and Data.

2.2.1 Prevention

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**. Stakeholder inputs emphasized the following:

- Pain management is optimal when 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 (for example, 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.

CMS has taken this feedback under consideration and, where feasible, has undertaken initiatives to address these issues and enhance Medicare and Medicaid beneficiaries' access to a full continuum of pain care. The key findings below, further detailed in the CMS Action Plan, reflect incentives or disincentives to safe and effective pain management as well as barriers and promising interventions that were identified in the review.

Medicare Payment and Coverage Policies¹⁸

- The Medicare hospital Inpatient Prospective Payment and Outpatient Prospective Payment Systems are not designed to incentivize particular treatments, for example promoting the use of opioid analgesics over non-opioid analgesics/Continued assessment and evaluation of additional data and evidence are warranted to determine if changes are appropriate.
- 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 Medicare Part C. CMS has offered new flexibilities under the Medicare Advantage program by allowing plans to offer targeted benefits and cost-sharing reductions for enrollees with chronic pain or with SUD.
- CMS has worked 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 limitations in place 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.

Medicaid Payment and Coverage Policies¹⁹

- A variety of statutory and regulatory authorities²⁰ 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. Prior authorization helps make treatments available and affordable. 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 and reviews for opioids should bring additional uniformity across programs.
- A new federal policy requiring Medicaid providers to check prescription drug monitoring programs (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.

Medicare and Medicaid Beneficiary Access to Care²¹

- 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 Sickle Cell Disease 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, discrimination, and provider underestimation of patients' reporting of pain contribute to suboptimal pain management and may lead to unintended consequences such as inadequate or lack of access to care, patient abandonment, anxiety and depression, transition to illicit drug use, and even suicide.
- 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.

Payment and Coverage Policies for FDA-Approved Medical Devices²²

- 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 the inclusion of medical devices as part of the Open Payments National Transparency Program, and the continuous assessment and updates of National Coverage Determinations and Local Coverage Determinations are important steps to ensuring access to important medical devices in light of the opioid crisis.

2.2.2 Treatment

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**. Stakeholder input emphasized the following:

- 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.
- MAT would be more widely accessible if offered in a variety of settings, including emergency departments and community settings.

- Barriers to prescribing OUD treatment 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.

CMS has taken this feedback under consideration and, where feasible, has undertaken initiatives to address these issues and to improve access to a full range of OUD treatment options for Medicare and Medicaid beneficiaries. The key findings below, further detailed in the CMS Action Plan, reflect incentives or disincentives to timely and effective OUD treatment as well as barriers and promising interventions that were identified in the review.

Medicare Payment and Coverage Policies²³

- Prior to 2020, lack of coverage for FDA-approved methadone for MAT under Medicare may have created a financial disincentive to referrals for effective OUD treatment. CMS's inclusion of opioid treatment programs (OTPs) as entities that can bill to Medicare under the 2020 Medicare 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 for Part B drugs administered in the outpatient/office setting may create a financial incentive for providers to use more expensive drugs because the percentage-based add-on may generate increased revenue for more expensive drugs.
- Utilization management controls such as prior authorization that can be used by Part D plans to make medications more accessible and affordable, 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. CMS allows Part D sponsors to perform mid-year formulary changes when a generic equivalent of a prescription drug becomes available to help increase the availability and use of lower cost prescription drugs.

Medicaid Payment and Coverage Policies²⁴

- 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 evidence-based treatment, including MAT.

- Medicaid Section 1115 demonstration projects have been a key tool in CMS’s strategy to combat the opioid epidemic, allowing CMS to not 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 not subject to the statutory “Institutions for Mental Disease (IMD) payment exclusion,” which is one commonly cited barrier to SUD treatment. 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.

Medicare and Medicaid Beneficiary Access to Care²⁵

- 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., 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.
- Stigma and discrimination impact 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 to 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 the point of care, in criminal justice settings, and in rural areas is key to curbing the opioid crisis.

Payment and Coverage Policies for FDA-Approved Medical Devices²⁶

- 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.

2.2.3 Data

Data can be leveraged to help aid providers and payers in ensuring appropriate treatment for pain management and OUD. Stakeholder input noted the following:

- 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.

Existing efforts underway at CMS to harness key data and analytic tools to understand and address the opioid crisis include:

- **The Part D Prescriber Public Use File**, 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**, 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 to better identify gaps in measurement and quality improvement efforts with respect to combating the opioid crisis.²⁷ Programs with measures to address the opioid epidemic include the Quality Payment Program, Hospital Payment Programs, and the Medicaid Adult Core Set.

3. Planned Next Steps with Respect to the Action Plan

CMS continues to advance strategic efforts outlined in the CMS Action Plan (see Section 2.1 above) to prevent OUD, enhance access to evidence-based treatment for OUD, and leverage data to target prevention and treatment efforts and support fraud, waste, and abuse detection. The CMS Action Plan aligns with the *CMS Roadmap: Fighting the Opioid Crisis*.²⁸ The Roadmap will continue to be updated with activities and successes as the agency's plans progress.

CMS is implementing several changes to payment and coverage policies required under the SUPPORT for Patients and Communities Act that align with the CMS Action Plan recommendations summarized in Section 2.1 above. The agency continues to monitor and respond to this changing crisis, in collaboration with relevant federal and state entities and public stakeholder groups.

On March 13, 2020, national state of emergency concerning the novel coronavirus disease (COVID-19) outbreak was declared in the United States.²⁹ While CMS continues to prioritize the opioid epidemic, the agency is also actively responding to the COVID-19 pandemic, implementing rapid policy changes and waiver approvals in support of rapid state and federal responses. The quick execution of these policy changes to address the COVID-19 emergency is likely to impact CMS's approach and timeline to implement the recommendations outlined earlier in this report.

The COVID-19 pandemic presents unique challenges for individuals requiring pain care and/or OUD treatment. Preliminary evidence suggests that individuals with OUD may be at elevated risk for severe illness due to COVID-19, given the adverse impact of OUD on the respiratory system.³⁰ Individuals with OUD are also more likely to experience homelessness or incarceration, which are associated with increased risk for transmission of COVID-19.³¹ Furthermore, the need for social distancing during the COVID-19 pandemic may exacerbate existing barriers to treatment and reduce access to existing support services and networks.

CMS has taken several steps to address the immediate needs of Medicare and Medicaid beneficiaries during the pandemic and will continue to assess further actions that may be required.³² For example, "eligible originating site" requirements have been temporarily waived under the Medicare program to allow telehealth services to be provided outside of rural areas and/or in a beneficiary's home.³³ Additionally, CMS temporarily lifted provider licensing restrictions that prevented a provider in one state from offering telehealth services to a patient in a different state, provided this change is consistent with state law.^{34,35}

Similarly, Medicaid has leveraged numerous statutory mechanisms to allow states greater flexibility under the state of emergency, such as Section 1135 waivers, Section 1115 waivers, Section 1915(c) Appendix K, and State Plan Amendments. Numerous states have amended Medicaid policies to enhance access to and coverage of telehealth services.^{36,37}

To ensure an effective ongoing response to the opioid crisis, CMS will consider key data and metrics that can be leveraged to monitor the impact of COVID-19 on the incidence of OUD among Medicare and Medicaid beneficiaries, as well as access to OUD treatment and pain care.

Finally, CMS will develop a strategy to carefully assess the impact of the evolving policy changes, both temporary and permanent, implemented under the state of emergency. While these

policy changes have been made in response to a crisis, they may offer an opportunity to test the effectiveness of these policies in improving access to care and health outcomes for individuals who are at risk of OUD.

4. Price Trends for Drugs Used to Reverse Opioid Overdoses

The life-saving overdose reversal drug naloxone is a core component of the efforts to combat the opioid crisis. Naloxone is a competitive opioid antagonist that displaces opioids from receptors in the brain, and can effectively reverse respiratory depression and reduce the likelihood of fatality, injury, and organ damage.³⁸ Expanding access to naloxone is a key evidence-based strategy to reduce opioid injury and death recommended by leading health agencies and organizations, including CMS,³⁹ the Centers for Disease Control and Prevention (CDC), Substance Abuse and Mental Health Services Administration, World Health Organization, American Public Health Association, American Medical Association, and the American Pharmacists Association.⁴⁰

The FDA approved three forms of naloxone, including injectable formulations (injectable naloxone), auto-injectors (Evzio), and nasal sprays (Narcan).⁴¹ Evzio has been discontinued by the manufacturer. Additionally, numerous community distribution programs and harm reduction programs offer intranasal naloxone rescue kits; however, current data on prices and utilization of these kits is limited.⁴² A 2014 survey of community-based programs found that over 150,000 naloxone kits had been provided between 1996 and June 2014.⁴³ While all forms of naloxone require a prescription, most states and the District of Columbia have taken steps to ease access to naloxone in response to the opioid crisis. As of December 2018, 47 states and the District of Columbia had enacted standing orders that allow pharmacists to either dispense or directly prescribe naloxone to patients; however, many pharmacists may be unaware of the broader authority in their state to provide naloxone.⁴⁴

Clinical practice guidelines recommend that providers co-prescribe naloxone to patients at high risk of opioid overdose;⁴⁵ however, although the number of naloxone prescriptions dispensed doubled between 2017 and 2018, only one prescription was dispensed for every 69 high-dose opioid prescriptions in 2018.⁴⁶

Access to naloxone may be influenced by a number of factors, such as state and federal laws regulating prescribing, stigma, health disparities, the price of naloxone products, and patient cost-sharing. Per the legislative requirement in section 6032(e)(3) of the SUPPORT for Patients and Communities Act, this section will provide: “an evaluation of price trends for drugs used to reverse opioid overdoses (such as naloxone), including recommendations on ways to lower such prices for consumers.”

4.1 Evaluation of Price Trends for Drugs Used to Reverse Opioid Overdoses

4.1.1 Naloxone Pricing and Cost-Related Trends

There are currently two formulations of naloxone: an injectable form (syringe or vial), a nasal spray. There was also an auto-injector form that was recently discontinued. The FDA first approved naloxone in 1971 as an injection for reversing opioid overdose, and generic versions became available in 1985.⁴⁷ In 2015, the FDA fast-tracked the approval the first nasal spray formulation (Narcan).⁴⁸

Generic formulations of injectable naloxone are now produced by several manufacturers. The nasal spray formulation (Narcan) remains available only as a brand-name drug. Despite the more recent availability of new dosage forms that may be easier to administer, between 2009 and 2015 the annual number of naloxone prescriptions increased only from 2.8M to 3.2M.⁴⁹ Moreover, a CDC report noted that from 2012 to 2018, naloxone dispensing from retail pharmacies increased from 1,282 prescriptions (0.4 per 100,000) in 2012 to 556,847 (170.2) in 2018.⁵⁰ In addition, the market for naloxone remains small, about \$290M in annual sales, according to one estimate.⁵¹

To examine the pricing trends in the various available forms of naloxone on the market, we looked at the price changes for the available dosage forms and strengths over the last five years. This analysis does not account for products that are available for free. We focused on National Average Drug Acquisition Cost (NADAC) data; when those data were unavailable, we used wholesale acquisition cost (WAC) data. CMS produces the NADAC, a monthly drug pricing file that represents the average price retail community pharmacies paid for prescription drugs based on the invoice prices they submit to the NADAC file outside contractor. The WAC amounts are published prices for drugs sold to wholesalers that manufacturers report to database companies. The WAC does not include the charges wholesalers add to sell the drug products to retail community pharmacies. The WAC price is used in the analysis below when a NADAC is not available.

- **Injectable Forms:** Naloxone is available in several injectable forms, which include a prefilled syringe, a vial from which the product can be drawn into a syringe, and a carpject, which is a form of injector.
 - The NADAC price of the prefilled syringe form of the drug has been stable at about \$16.50 over the last five years.
 - The vial form of the drug currently ranges in WAC price from \$6 to \$16, depending on the labeler. The prices have remained relatively stable over the last five years.
 - The WAC price of the carpject has remained relatively stable at \$15.44 since 2015.
- **Nasal Spray:** The NADAC price for Narcan, the nasal spray form of naloxone, has remained relatively stable at \$62.50 since 2015. There are no generics available on the market at this time.
- **Auto-injector:** The auto-injector form of the drug has been made by only one manufacturer, Kaleo, with the brand name Evzio. This drug has been discontinued by the manufacturer. There were two strengths of this product, 0.4 mg/ml and 2 mg/ml. This product had the most dramatic price increase of all available naloxone products, with the NADAC price of the drug increasing from \$933 in the fourth quarter of 2015 to \$4,666 in the first quarter of 2016, an increase of about 400 percent. The drug's manufacturer terminated participation in the Medicaid drug rebate program (MDRP) in 2017, which means this drug is not eligible for federal financial participation in Medicaid, nor does the manufacturer pay Section 1927 rebates to states. Because the manufacturer did not participate in the MDRP, most states were not likely to cover the drug since federal funds were not available. The most recent WAC price of the drug ranges from \$4,688 to \$5,125. An authorized generic version of the drug was also discontinued by IJ Therapeutics, which is a subsidiary of Kaleo. The most recent WAC price for their product was \$225.

In 2018, more than half of all naloxone prescriptions dispensed to individuals with commercial insurance, Medicare, Medicaid, and self-pay required an out-of-pocket (OOP) payment.⁵² Specifically, 24.5% of prescriptions required an OOP of less than \$10; 21.9% required between \$10 and \$50; and 5.8% required greater than \$50 in OOP payments.⁵³

4.1.2 Naloxone Utilization and Spending-Related Trends

The majority of naloxone sales are injectable formulations, which are mostly sold in clinical and non-retail settings such as hospitals, clinics, health departments, and institutions that supply first responders.⁵⁴ However, the number of prescriptions filled in retail settings accounted for a growing proportion of total naloxone dispensing between 2013 and 2017.⁵⁵ In the retail setting, most of the naloxone prescriptions filled (over 70%) were for the nasal spray Narcan, followed by the auto-injector Evzio (20%), which reflects the significant price differential between the two products.⁵⁶ The list price per two units of Narcan is about \$150, compared to over \$4,000 per two units of Evzio.⁵⁷

In 2018, roughly half (51.1%) of naloxone prescriptions were dispensed to commercially insured patients, followed by Medicare (35.9%), Medicaid (10.7%), and self-pay patients (2.4%).⁵⁸ Medicare patients in particular may be more likely to face financial burden from out-of-pocket costs; most naloxone prescriptions paid by Medicare (71.1%) required OOP cost sharing versus less than 50% of prescriptions covered by Medicaid or commercial payers.⁵⁹ In April 2019, CMS, as part its Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Policies and 2020 Draft Call Letter, encouraged Medicare Part D plans to lower patients' cost-sharing for naloxone.⁶⁰

Medicare

Naloxone is covered under Medicare Part D and Medicare Advantage Prescription Drug (MA-PD) plans, though formulary inclusion of specific products and copay costs vary significantly by plan. Table 1 below summarizes the averages and ranges of 2019 Medicare beneficiary out-of-pocket costs per naloxone fill by product type.

Table 1. 2019 Medicare Average and Range of Beneficiary Out-of-Pocket Naloxone Costs

Product Name*	Average	Minimum	Maximum
Evzio**	\$25.23	\$0.00	\$2,888.03
Naloxone HCl	\$5.09	\$0.00	\$268.96
Narcan	\$15.79	\$0.00	\$433.23
All Combined	\$15.28	\$0.00	\$2,888.03

*Out-of-pocket costs are the amount the beneficiary paid per fill at the pharmacy counter, from all benefit phases, copays, and coinsurance, excluding contributions from others, regardless of dosage units. Note that many beneficiaries who utilize these drugs are often eligible for the Part D low-income subsidy program that may reduce the out-of-pocket cost to \$0.

**Evzio was discontinued by the manufacturer in October 2020.

Tables 2–4 below summarize average spending for naloxone from Medicare Parts D and B and Medicaid Programs from 2015 to 2019, drawn from the CMS Drug Spending Dashboards.⁶¹

According to the CMS Drug Spending Dashboards (see Tables 2 and 3), the annual growth in average spending per dosage unit of naloxone in Medicare Part D increased across all forms of

naloxone between 2015 and 2019. The highest rate of increase (63.1%) was observed for Evzio, which also had the highest per unit cost and fewest beneficiaries. In comparison, the annual growth rate for naloxone HCl was 1.47%, and for Narcan was 0.89%. Medicare Part B program data was only available for naloxone HCl, which had an 11.95% decrease in annual growth rate in average spending per dosage unit over the same period.

Table 2. Medicare Part D Naloxone Spending⁶²

Description*	Evzio**	Naloxone HCl	Narcan
Total Spending (2019)	\$9.9 M	\$ 692,184.11	\$51.2 M
Total Dosage Units (2019)	1,896	46,547	789,481
Total Beneficiaries (2019)	1,896	19,584	358,536
Average Spending per Dosage Unit (2019)	\$ 5,224.35	\$ 14.88	\$ 64.97
Change in Average Spending per Dosage Unit (2018 – 2019)	-0.23%	-1.86%	0.94%
Annual Growth Rate in Average Spending per Dosage Unit (2015 – 2019)	63.1%	1.47%	0.89%

*The Part D Drug Spending Dashboard focuses on average spending per dosage unit and change in average spending per dosage unit over time. Dosage units refer to the drug products in the form in which they are marketed for use. Multiple dosage units and strengths may exist for a particular drug.

**Evzio was discontinued by the manufacturer in October 2020.

Table 3. Medicare Part B Naloxone Spending⁶³

Description*	Naloxone HCl
Total Spending (2019)	\$ 9,965
Total Beneficiaries (2019)	353
Average Spending per Dosage Unit (2019)	\$ 15.43
Change in Average Spending per Dosage Unit (2018 – 2019)	-34.06%
Annual Growth Rate in Average Spending per Dosage Unit (2015 – 2019)	-11.95%
Average Sales Price in 2019	\$16.27

*The Part B Drug Spending Dashboard focuses on average spending per dosage unit and change in average spending per dosage unit over time. For Part B, the quantity of a drug in a dosage unit is the same as the quantity of the drug in one Healthcare Common Procedure Coding System (HCPCS) billing unit, that is, the amount of drug in the HCPCS code descriptor. The Part B Drug Spending Dashboard also includes information on the payment amounts for many HCPCS codes that are paid under Part B.

Medicaid

According to the Federal Fiscal Year 2018 Drug Utilization Review Survey⁶⁴, all states provided Medicaid coverage for at least one formulation of naloxone without prior authorization.

According to a recent analysis for 2018, 23 states required a copayment, which ranged from \$0.50 to \$4.00 for individual prescriptions, and one state had tiered pricing based on the cost of the drug.⁶⁵

According to the CMS Drug Spending Dashboards (see Table 4), the annual growth in average spending per dosage unit of naloxone in Medicaid programs decrease by 1.22% for naloxone HCl between 2015 and 2019, and decreased by 1.76% for Narcan over the same period.

Table 4. Medicaid Naloxone Spending⁶⁶

Description*	Naloxone HCl	Narcan
Total Spending 2019	\$2.1M	\$45.5M
Avg Spending per Dosage Unit 2019	\$32.46	\$58.79
Change in Avg Spending per Dosage Unit (2018-2019)	3.54%	3.08%
Annual Growth Rate in Avg Spending per Dosage Unit (2015-2019)	-1.22%	-1.76%

*The Dashboard focuses on average spending per dosage unit and change in average spending per dosage unit over time. Units refer to the drug unit in the lowest dispensable amount. Multiple dosage units may exist for a particular drug.

4.2 Recommendations to Lower Prices for Consumers

As required by Section 6032(e)(3) of the SUPPORT for Patients and Communities Act, this section presents CMS’s recommendations to lower the prices of opioid overdose reversal drugs, as part of the agency’s strategic initiative to combat the opioid crisis.

CMS will continue to explore strategies for lowering drug prices. Specifically, the agency will review recommendations to reduce the prices of opioid overdose reversal drugs from the upcoming President’s Budget for HHS.

Acronyms

Acronym	Definition
BCPI	Bundled Payments for Care Improvement
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
DUR	Drug Utilization Review
ERAS	Enhanced Recovery After Surgery
FDA	Food and Drug Administration
FFS	Fee-for-Service
HCPCS	Healthcare Common Procedure Coding System
HHS	Department of Health and Human Services
IMD	Institutions for Mental Disease
InCK	Integrated Care for Kids
MAT	Medication-Assisted Treatment
MCO	Managed Care Organization
MDRP	Medicaid Drug Rebate Program
MOM	Maternal Opioid Misuse
NADAC	National Average Drug Acquisition Cost
OOP	Out-of-Pocket
OTP	Opioid Treatment Program
ODD	Opioid Use Disorder
PBM	Pharmacy Benefit Management/Manager
PDMP	Prescription Drug Monitoring Program
PFS	Physician Fee Schedule
PMTF	Pain Management Best Practices Inter-Agency Task Force
SUD	Substance Use Disorder
SUPPORT	Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment
WAC	Wholesale Acquisition Cost

Endnotes

¹ CDC. Opioid Basics – Understanding the Epidemic (Atlanta, GA: CDC, National Center for Health Statistics; 2017. Available: <https://www.cdc.gov/drugoverdose/data/prescribing/overdose-death-maps.html> (accessed on June 01, 2021).² 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 \(samhsa.gov\)](#).

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 Pain Management Best Practices Inter-Agency Task Force was convened under Section 101(b) of the Comprehensive Addiction and Recovery Act of 2016 (Public Law 114–198).

⁶ Section 6032 of the SUPPORT for Patients and Communities Act (Pub. L. 115-271, Title VI, §6032).

⁷ Developed in response to Section 6032(b) of the SUPPORT for Patients and Communities Act.

⁸ 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).

⁹ Section 6032(b) of the SUPPORT for Patients and Communities Act requires a review, under the Medicare and Medicaid programs, of: payment and coverage policies related to the treatment of OUD, including medication-assisted treatment, and the management of chronic and acute pain; beneficiaries’ access to the full range of treatment options for OUD and pain management; and payment and coverage policies related to FDA-approved medical devices 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. Further, it requires recommendations on ways to address the opioid crisis through payment and service delivery models to be tested by the Center for Medicare and Medicaid Innovation and through data collection efforts that could facilitate research and policy-making.

¹⁰ CMS. CMS Action Plan to Prevent and Enhance Treatment for OUD.

¹¹ 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.

¹² 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 September 27, 2019).

¹³ 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.

¹⁴ 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).

¹⁵ 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.

¹⁶ 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).

¹⁷ 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.

¹⁸ Details of the review of Medicare payment and coverage policies can be found in Section 4.2 of the CMS Action Plan to Prevent and Enhance Treatment for OUD.

¹⁹ Details of the review of Medicaid payment and coverage policies can be found in Section 4.3 of the CMS Action Plan to Prevent and Enhance Treatment for OUD.

²⁰ For example, Medicaid Section 1115 waivers; Section 1905(a) of the Social Security Act; 42 CFR Part 440, Subpart A. See also: CMCS Informational Bulletin: Medicaid Strategies for Non-Opioid Pharmacologic and Non-Pharmacologic Chronic Pain Management. February 22 2019. Available: <https://www.medicare.gov/sites/default/files/federal-policy-guidance/downloads/cib022219.pdf> (accessed on March 16, 2020).

²¹ Details of the review of Medicare and Medicaid beneficiary access to care can be found in Section 4.4 of the CMS Action Plan to Prevent and Enhance Treatment for OUD.

²² Details of the review of payment and coverage policies for FDA-approved medical devices can be found in Section 4.5 of the CMS Action Plan to Prevent and Enhance Treatment for OUD.

²³ Details of the review of Medicare payment and coverage policies can be found in Section 4.2 of the CMS Action Plan to Prevent and Enhance Treatment for OUD.

²⁴ Details of the review of Medicaid payment and coverage policies can be found in Section 4.3 of the CMS Action Plan to Prevent and Enhance Treatment for OUD.

²⁵ Details of the review of Medicare and Medicaid beneficiary access to care can be found in Section 4.4 of the CMS Action Plan to Prevent and Enhance Treatment for OUD.

²⁶ Details of the review of payment and coverage policies for FDA-approved medical devices can be found in Section 4.5 of the CMS Action Plan to Prevent and Enhance Treatment for OUD.

²⁷ CMS. Meaningful Measures Hub. July 2019. Available: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html> (accessed on September 27, 2019).

²⁸ 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 March 13, 2020).

²⁹ On January 31, 2020, the Secretary of HHS declared a public health emergency for the entire United States (retroactive to January 27, 2020), under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19. See: <https://www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html>.

On March 13, 2020, the President of the United States issued a Proclamation declaring a national emergency concerning the novel coronavirus disease (COVID-19) outbreak, beginning March 1, 2020. See: <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/> (and also made a National Emergency Determination under the Stafford Act on March 13, 2020. See: <https://www.whitehouse.gov/briefings-statements/letter-president-donald-j-trump-emergency-determination-stafford-act/>). On March 18, the President also invoked the emergency powers through and Executive Order under the Defense Production Act of 1950. See: <https://www.whitehouse.gov/presidential-actions/executive-order-prioritizing-allocating-health-medical-resources-respond-spread-covid-19/>.

³⁰ National Institute on Drug Abuse. COVID-19: Potential Implications for Individuals with Substance Use Disorders. April 6, 2020. Available: <https://www.drugabuse.gov/about-nida/noras-blog/2020/04/covid-19-potential-implications-individuals-substance-use-disorders>

³¹ Ibid.

³² CMS. Coronavirus Waivers and Flexibilities. Available: <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>

³³ CMS. Medicare Telehealth Frequently Asked Questions (FAQs). March 17, 2020. Available: <https://www.cms.gov/files/document/medicare-telehealth-frequently-asked-questions-faqs-31720.pdf>

³⁴ While many states have also modified licensing requirements during the public health emergency, Medicare and Medicaid providers are still subject to state restrictions. Federation of State Medical Boards. (2020). U.S. States and Territories Modifying Requirements for Telehealth in Response to COVID-19. Retrieved: <https://telehealth.hhs.gov/providers/policy-changes-during-the-covid-19-public-health-emergency/>

³⁵ Assistant Secretary for Preparedness and Response. Waiver or Modification of Requirements under Section 1135 of the Social Security Act. March 13, 2020. Available: <https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx>

³⁶ CMS. COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers. June 12, 2020. Available: <https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf>

³⁷ CMS. Coronavirus Waivers and Flexibilities. Available: <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>

³⁸ Corso, C., Townly, C. Intervention, Treatment and Prevention Strategies to Address Opioid Use Disorders in Rural Areas: A Primer On Opportunities for Medicaid Safety Net Collaboration. National Academy for State Health Policy. September 2016. Available: <https://nashp.org/wp-content/uploads/2016/09/Rural-Opioid-Primer.pdf>

³⁹ 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>

⁴⁰ Corso, C., Townly, C. Intervention, Treatment and Prevention Strategies to Address Opioid Use Disorders in Rural Areas: A Primer On Opportunities for Medicaid Safety Net Collaboration. National Academy for State Health Policy. September 2016. Available: <https://nashp.org/wp-content/uploads/2016/09/Rural-Opioid-Primer.pdf>

⁴¹ HHS. U.S. Surgeon General's Advisory on Naloxone and Opioid Overdose. Office of the Surgeon General. April 5, 2018. Available: <https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html>

⁴² Medicaid Evidence-Based Decisions Project. Best Practices in Naloxone Treatment Programs for Opioid Overdose. Policy Report: Center for Evidence-Based Policy, Oregon Health & Science University. July 2015. Available: http://centerforevidencebasedpolicy.org/wp-content/uploads/2016/11/MED_best_practices_naloxone_report_final_2015.pdf

- ⁴³ Wheeler, E., Jones, S., et al. Opioid Overdose Prevention Programs Providing Naloxone to Laypersons – United States, 2014. Morbidity and Mortality Weekly Report. June 19, 2015. Available: <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6423a2.htm>
- ⁴⁴ Network of Public Health Law. Legal interventions to reduce overdose mortality: naloxone access and overdose Good Samaritan Laws. December 2018. Available: <https://www.networkforphl.org/wp-content/uploads/2020/01/legal-interventions-to-reduce-overdose.pdf>
- ⁴⁵ HHS. HHS recommends prescribing or co-prescribing naloxone to patients at high risk for an opioid overdose. Assistant Secretary of Health Press Office. December 19, 2018. Available: <https://www.hhs.gov/about/news/2018/12/19/hhs-recommends-prescribing-or-co-prescribing-naloxone-to-patients-at-high-risk-for-an-opioid-overdose.html>
- ⁴⁶ CDC. Still Not Enough Naloxone Where It’s Most Needed. Press Release. August 6, 2019. Available: <https://www.cdc.gov/media/releases/2019/p0806-naloxone.html>
- ⁴⁷ Gupta, R. Shah, N., Ross, J. The Rising Price of Naloxone—Risks to Efforts to Stem Overdose Deaths. New England Journal of Medicine. December 8, 2016. Available: <https://www.nejm.org/doi/full/10.1056/NEJMp1609578>
- ⁴⁸ Ibid.
- ⁴⁹ Ibid.
- ⁵⁰ Guy, G., Haegerich, T., Evans, M. et al. Vital Signs: Pharmacy-Based Naloxone Dispensing—United States, 2012-2018. Morbidity and Mortality Weekly Report. August 9, 2019. Available: <https://www.cdc.gov/mmwr/volumes/68/wr/mm6831e1.htm>
- ⁵¹ Weiner, J., Murphy, S., Behrends, C. Expanding Access to Naloxone: A Review of Distribution Strategies. Issue Brief: University of Pennsylvania, Leonard Davis Institute of Health Economics and Center for Health Economics of Treatment Interventions for Substance Use Disorder, HCV, and HIV. May 29, 2019. Available: <https://ldi.upenn.edu/brief/expanding-access-naloxone-review-distribution-strategies>
- ⁵² Guy, G., Haegerich, T., Evans, M. et al. Vital Signs: Pharmacy-Based Naloxone Dispensing—United States, 2012-2018. Morbidity and Mortality Weekly Report. August 9, 2019. Available: <https://www.cdc.gov/mmwr/volumes/68/wr/mm6831e1.htm>
- ⁵³ Ibid.
- ⁵⁴ Weiner, J., Murphy, S., Behrends, C. Expanding Access to Naloxone: A Review of Distribution Strategies. Issue Brief: University of Pennsylvania, Leonard Davis Institute of Health Economics and Center for Health Economics of Treatment Interventions for Substance Use Disorder, HCV, and HIV. May 29, 2019. Available: <https://ldi.upenn.edu/brief/expanding-access-naloxone-review-distribution-strategies>
- ⁵⁵ Ibid.
- ⁵⁶ Ibid.
- ⁵⁷ Ibid.
- ⁵⁸ Guy, G., Haegerich, T., Evans, M. et al. Vital Signs: Pharmacy-Based Naloxone Dispensing—United States, 2012-2018. Morbidity and Mortality Weekly Report. August 9, 2019. Available: <https://www.cdc.gov/mmwr/volumes/68/wr/mm6831e1.htm>
- ⁵⁹ Ibid.
- ⁶⁰ CMS. 2020 Medicare Advantage and Part D Rate Announcement and Final Call Letter Fact Sheet. April 1, 2019. Available: <https://www.cms.gov/newsroom/fact-sheets/2020-medicare-advantage-and-part-d-rate-announcement-and-final-call-letter-fact-sheet>
-

⁶¹ CMS. CMS Drug Spending Dashboards. December 19, 2019. Available: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs>

⁶² CMS. Medicare Part D Drugs. CMS Drug Spending Dashboard. CMS Office of Enterprise Data and Analytics. November 2018. Available: https://portal.cms.gov/wps/portal/unauthportal/unauthmicrostrategyreportslink?evt=2048001&src=mstrWeb.2048001&documentID=203D830811E7EBD80000080EF356F31&visMode=0¤tViewMedia=1&Server=E48V126P&Project=OIPDA-BI_Prod&Port=0&connmode=8&ru=1&share=1&hiddensections=header,path,dockTop,dockLeft,footer

⁶³ CMS. Medicare Part B Drugs. CMS Drug Spending Dashboard. CMS Office of Enterprise Data and Analytics. October 2018. Available: https://portal.cms.gov/wps/portal/unauthportal/unauthmicrostrategyreportslink?evt=2048001&src=mstrWeb.2048001&documentID=AEC7511A11E817EF2FBA0080EFC5E3D8&visMode=0¤tViewMedia=1&Server=E48V126P&Project=OIPDA-BI_Prod&Port=0&connmode=8&ru=1&share=1&hiddensections=header,path,dockTop,dockLeft,footer

⁶⁴ National Medicaid Drug Utilization Review (DUR) Federal Fiscal Year (FFY) 2019 Fee-For-Service (FFS) Annual Report 2019. <https://www.medicaid.gov/medicaid/prescription-drugs/downloads/drug-utilization-review/2018-dur-ffs-summary-report.pdf>

⁶⁵ Kaiser Family Foundation. Medicaid Behavioral Health Services: Naloxone Available in at Least One Formulation Without Prior Authorization. 2018. Available: <https://www.kff.org/other/state-indicator/medicaid-behavioral-health-services-naloxone-available-in-at-least-one-formulation-without-prior-authorization/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>

⁶⁶ CMS. Medicaid Drugs. CMS Drug Spending Dashboard. CMS Office of Enterprise Data and Analytics. November 2018. Available: https://portal.cms.gov/wps/portal/unauthportal/unauthmicrostrategyreportslink?evt=2048001&src=mstrWeb.2048001&documentID=5F64C954492FB32858CD51B154EB2308&visMode=0¤tViewMedia=1&Server=E48V126P&Project=OIPDA-BI_Prod&Port=0&connmode=8&ru=1&share=1&hiddensections=header,path,dockTop,dockLeft,footer