



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL



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November 27, 2019

Report Number: A-04-19-00125

Ms. Stephanie McGee Azar
Commissioner
Alabama Medicaid Agency
501 Dexter Avenue
Montgomery, AL 36104

Dear Ms. Azar:

Enclosed are two U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), products entitled *Factsheet: Alabama's Oversight of Opioid Prescribing and Monitoring of Opioid Use* and *Summary of Alabama's Approach to Addressing the Opioid Crisis*. We will forward copies of these documents to the HHS action official noted on the following page. Thank you for responding to our questionnaire covering five categories related to opioids and for taking the time to meet with our staff to discuss the information.

Section 8M of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG website. Accordingly, these documents will be posted at <https://oig.hhs.gov/>.

If you have any questions or comments about these products, please direct them to the HHS action official. Please refer to report number A-04-19-00125 in all correspondence.

Sincerely,

Lori S. Pilcher
Regional Inspector General
for Audit Services

Enclosure

HHS Action Official:

Ms. Jackie Glaze
Acting Director, Regional Operations Group
Consortium for Medicaid and Children's Health Operations
Centers for Medicare & Medicaid Services
233 North Michigan Avenue, Suite 600
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FACTSHEET: Alabama's Oversight of Opioid Prescribing and Monitoring of Opioid Use

POLICIES AND PROCEDURES

State laws, regulations, guidance, and policies related to oversight of opioid prescribing and monitoring of opioid use (e.g., policies for prescribing opioids).

State-wide Laws, Regulations, and Guidance Related to Opioids

- On July 13, 2016, the Governor of Alabama and 45 other Governors (including those of Guam, American Samoa, and Puerto Rico) signed the “Compact to Fight Opioid Addiction,” which is a commitment to build on State efforts to fight opioid addiction by:
 - taking steps to reduce inappropriate opioid prescribing;
 - leading efforts to change the Nation’s understanding of opioids and addiction; and
 - taking actions to ensure a pathway to recovery for individuals with addiction.
- On December 15, 2016, the Governor signed Executive Order No. 27, which established the Alabama Council on Opioid Misuse and Addiction, to gather and review data outlining the problem facing Alabama.
- On August 8, 2017, the Governor signed Executive Order No. 708 (superseding Executive Order No. 27) establishing the Alabama Opioid Overdose and Addiction Council (the Council).
 - The Council’s purpose included developing a comprehensive strategic plan to combat the opioid crisis in Alabama.
 - The Council is co-chaired by the State Health Officer, the Commissioner of the Alabama Department of Mental Health (ADMH), and the State Attorney General.
- On March 28, 2018, Alabama enacted Senate Bill 39 establishing trafficking fentanyl and fentanyl analogues (controlled substances from a material, mixture, or preparation that contains any chemical structure like that of the chemical structure of any other controlled substance) as crimes.

This factsheet shows Alabama's responses to our questionnaire covering five categories related to opioids:

- Policies and Procedures
- Data Analytics
- Outreach
- Programs
- Other

This information is current as of October 2019. See page 11 for a list of State entities involved with oversight of opioid prescribing and monitoring of opioid use. See page 12 for a glossary of terms used in this factsheet.



FACTSHEET: Alabama's Oversight of Opioid Prescribing and Monitoring of Opioid Use

Medicaid Policies Related to Opioids

- The Alabama Medicaid Agency (AMA) requires prior authorization for beneficiaries with chronic pain (with some exceptions) to receive sustained release oral opioids. The beneficiary must meet the following requirements for prior authorization:
 - Alternative pain management therapies must have been unsuccessful.
 - If the beneficiary has a history of substance abuse or addiction, a treatment plan must be included.
- For beneficiaries diagnosed with opioid use disorder (OUD), AMA requires that:
 - beneficiaries obtain prior authorization for opioid dependence medication (including buprenorphine and naloxone);
 - prescribing physicians attest to reviewing the beneficiary's Prescription Drug Monitoring Program (PDMP) record prior to prescribing opioid dependence medication; and
 - beneficiaries sign an opioid dependence consent form informing them of State and Federal regulations concerning the prescribing of controlled substances, the effects of opioids, and the requirement for drug screenings.
- On November 1, 2018, AMA implemented a policy to limit short-acting prescription opioids for beneficiaries with no opioid claims history in the past 180 days. The policy includes the following limits on opioid prescriptions (excluding hospice, long-term care, and cancer patients):
 - a maximum supply of 7 days for adults,
 - a maximum supply of 5 days for children aged 18 and younger, and
 - a maximum of 50 morphine milligram equivalent (MME) per day on a claim.
- On August 1, 2019, AMA implemented a policy to deny opioid claims that exceed a cumulative 250 MME per day. AMA implemented a phase-in period to deny opioid claims that exceed a cumulative 200 MME daily limit but are less than 250 MME per day for claims without prior authorization. AMA will gradually decrease the daily cumulative MME limit every 4 months by 50 MME until it reaches the Centers for Disease Control and Prevention recommendation of 90 MME per day.
- In addition to the above policies, AMA implemented:
 - a therapeutic duplication policy so that multiple drugs within the same therapeutic class will not be dispensed to the beneficiary;
 - the preferred drug list (PDL), which requires prior authorization for certain antidepressants, anxiolytics, sedatives, hypnotics, and narcotic analgesics covered by AMA;
 - an accumulation policy that prevents beneficiaries from having more than a 14-day supply of opioids on hand;



FACTSHEET: Alabama's Oversight of Opioid Prescribing and Monitoring of Opioid Use

- a policy requiring beneficiaries to use 85 percent of their original opioid prescription before they can receive a refill; and
- monthly maximum units on controlled substances that require an override prior to dispensing more units than the Food and Drug Administration's approved indication.

Laws, Regulations, and Guidance on Prescription Drug Monitoring Program Data

- Effective August 1, 2004, the Alabama Legislature established the PDMP. The PDMP is a program developed to promote the public health and welfare by detecting diversion, abuse, and misuse of prescription medications classified as controlled substances under the Alabama Uniform Controlled Substances Act.
- The Alabama State Board of Medical Examiners (ABME) and Alabama State Board of Pharmacy implemented policies (Alabama Administrative Code 540-X-4-.09) regarding opioid dosages to prevent controlled substance diversion, abuse, misuse, addiction, and doctor-shopping. When using the PDMP, physicians should:
 - use the PDMP in a manner consistent with good clinical practice for controlled substance prescriptions totaling 30 MME or less per day;
 - review patient prescribing history through the PDMP at least two times per year when prescribing controlled substances of more than 30 MME per day;
 - document the use of risk and abuse mitigation strategies in the patient's medical record; and
 - query the PDMP to review patient prescribing history every time a prescription for more than 90 MME per day is written.

Laws, Regulations, and Guidance Related to Treatment

- ABME's *Policy on DATA 2000: Guidelines for the Treatment of Opioid Addiction in the Medical Office* (Alabama Administrative Code 540-X-21) identifies guidelines for the treatment of OUD in office-based settings.
 - Physicians who wish to prescribe or dispense buprenorphine for the treatment of OUD must:
 - be licensed in Alabama;
 - have a valid Drug Enforcement Agency (DEA) controlled substances registration and identification number;
 - comply with Federal and State regulations applicable to controlled substances; and
 - hold a current waiver with the Substance Abuse and Mental Health Services Administration (SAMHSA).
 - Physicians who treat OUD must offer (or refer patients for) appropriate counseling and other services.



FACTSHEET: Alabama's Oversight of Opioid Prescribing and Monitoring of Opioid Use

- Physicians cannot delegate the prescribing of buprenorphine to non-physicians, but non-physician professionals can evaluate and monitor patients, or provide other elements of care.
- Patient assessments are used to determine a patient's eligibility for treatment, provide the basis for a treatment plan, and establish a baseline measure to evaluate a patient's response to treatment.

Laws, Regulations, and Guidance on Naloxone

- On June 4, 2015, the Governor signed Alabama House Bill 208 into law:
 - permitting the prescribing and dispensing of opioid antagonists (including naloxone) to anyone at risk of experiencing an opioid overdose, as well as to family members, friends, or others in a position to assist a person at risk of experiencing an opioid overdose and
 - providing immunity from civil or criminal liability to:
 - physicians and dentists who prescribe opioid antagonists;
 - pharmacists who dispense opioid antagonists; and
 - individuals who administer opioid antagonists.
- On May 3, 2016, the Governor signed Alabama House Bill 379 into law:
 - authorizing Alabama's State Health Officer or a county health officer to publish a standing order for dispensing opioid antagonists;
 - authorizing registered nurses employed by the State Health Department or a county health department to dispense opioid antagonists; and
 - providing these individuals immunity from civil and criminal liability.
- On March 8, 2018, the Alabama State Health Officer signed a standing order for the distribution of naloxone that can be used in place of a prescription from a regular healthcare provider.

DATA ANALYTICS

Data analysis that the State performs related to opioid prescribing and monitoring of opioid use (e.g., analyzing data to determine the number of opioid prescriptions written by providers to detect high-prescribing providers).

- AMA routinely performs data analytics on opioid prescribing and pharmacy trends. It has a robust in-house analytical unit which performs routine analyses and other analyses as necessary. Information from analytical reviews is used for policy development. Examples of analyses performed to track opioid prescribing and use are:
 - opioid prescribing trends by age, provider specialty, and location;



FACTSHEET: Alabama's Oversight of Opioid Prescribing and Monitoring of Opioid Use

- opioid drug spending trends; and
- neonatal abstinence syndrome trends.
- AMA uses a contractor for drug utilization review (DUR).
 - The objective of DUR is to improve the quality of pharmaceutical care by ensuring that prescriptions are appropriate, medically necessary, and unlikely to result in adverse medical outcomes.
 - The DUR program includes reviewing, analyzing, and interpreting patterns of drug usage to reduce the frequency of fraud, abuse, gross overuse, and inappropriate or medically unnecessary care.

OUTREACH

Outreach that the State provides related to preventing potential opioid abuse and misuse (e.g., opioid-related training for providers).

Outreach to Providers

- AMA issues newsletters to providers and pharmacists via email, fax, mail, and the AMA website. The newsletters include notifications on policy changes and updates to the PDL.
- The AMA DUR Board and the Pharmacy and Therapeutics Committee delivered opioid presentations at public meetings, which are also available online. These presentations covered information such as opioid prescribing and cost trends, initiatives to reduce opioid prescribing, and upcoming policy changes.
- AMA uses a contractor to provide face-to-face training on AMA policy changes and to consult with prescribers and pharmacists. For example:
 - Prior to decreasing the allowable opioid cumulative MME in November 2018, AMA queried the top 50 prescribers and pharmacists of recent opioid claims and the contractor trained them on the upcoming policy change.
 - During 2013 and 2015, AMA used the contractor to consult with high prescribers of opioids to show them how they compared with similar prescribers. As a result, opioid prescriptions decreased among top prescribers.
- ADMH provides reimbursement for medication-assisted treatment (MAT) through a contracting process with certified providers. The Alabama School of Alcohol and Other Drug Studies, in partnership with ADMH and Alabama Department of Public Health (ADPH), provides training for physicians and other medical providers on MAT and how to incorporate MAT into a practice. In addition to MAT training, qualified individuals participate in buprenorphine waiver training.



FACTSHEET: Alabama's Oversight of Opioid Prescribing and Monitoring of Opioid Use

- ADMH started an initiative to educate pharmacy students across Alabama about the existence of the State Health Officer's naloxone standing orders for Alabama pharmacies. ADMH's goal is to solve the problem of a lack of public awareness that naloxone can be purchased directly from pharmacies under these standing orders.
- Every physician licensed to practice in Alabama who distributes, prescribes, or dispenses any controlled substance must obtain an Alabama Controlled Substances Certificate (ACSC) annually.
 - Each holder of the ACSC is required to obtain continuing medical education in controlled substance prescribing every 2 years.
 - Controlled substance prescribing education includes instruction on controlled substance prescribing practices, recognizing signs of abuse or misuse of controlled substances, or controlled substance prescribing for chronic pain management.

Outreach to Patients

- ADMH provides vital resources on its website to help people suffering from addiction, their family members, providers, and professionals find needed information, such as:
 - the DEA tool for locating drug disposal locations;
 - the buprenorphine treatment practitioner locator;
 - helpline phone numbers; and
 - information on the Centers for Disease Control and Prevention guidelines for prescribing opioids for chronic pain.
- ADMH distributed naloxone nasal spray to law enforcement, fire departments, substance abuse treatment programs, and addiction recovery community groups.
- ADMH launched the media campaign, "My Smart Dose," to encourage proper prescription use among teenagers and college students.
 - The campaign partnered with businesses near college campuses and college sporting venues to use the "My Smart Dose" materials to reach students and family members.
 - The campaign includes information relating to prescription drug and opioid misuse. The website includes prevention and treatment resources, downloadable public service announcements, posters, digital and social media banners, a self-assessment, and a 24-hour helpline.



FACTSHEET: Alabama's Oversight of Opioid Prescribing and Monitoring of Opioid Use

- ADMH also launched the media campaign, “Courage for All,” which focuses on awareness and treatment of opioid addiction, including the courage to make a change and seek help.
 - The campaign partnered with businesses to use the “Courage for All” materials within their establishments.
 - The campaign includes a website with treatment resources, downloadable public service announcements, posters, digital and social media banners, a self-assessment, and a 24-hour helpline.
- ADMH also participates in the “National Recovery Month” initiative. Each September, tens of thousands of prevention, treatment, and recovery programs around the country participate in this initiative. ADMH participates to increase awareness and understanding of mental illness and substance use disorder (SUD) and promote the message that behavioral health is essential to health, prevention works, treatment is effective, and people do recover.

PROGRAMS

State programs related to opioids (e.g., opioid-use-disorder treatment programs).

Prevention Programs

- Alabama participates in “National Prescription Drug Take Back Day” in April and October of each year that allows beneficiaries, family members, friends, and community members to dispose of unused or unwanted medications. Alabama prevention providers also host their own similar initiatives in local communities in collaboration with law enforcement agencies.
- There are numerous permanent prescription drug drop boxes located throughout Alabama where beneficiaries, family members, friends, and community members can drop off prescription drug medications at any time. The prescription drug drop boxes are made available through collaborative efforts with Alabama prevention providers, coalitions, and law enforcement agencies.

Detection Programs

Prescription Drug Monitoring Program

- The Alabama PDMP is part of the ADPH Pharmacy Division. The goals of the program are:
 - to provide information for practitioners and pharmacists regarding a patient’s controlled substance use;



A-04-19-00125
November 2019

FACTSHEET: Alabama's Oversight of Opioid Prescribing and Monitoring of Opioid Use

- to reduce prescription drug abuse by providers and patients;
- to reduce time and effort to explore leads and assess the merits of possible drug diversion cases; and
- to educate physicians, pharmacists, policymakers, law enforcement, and the public regarding the diversion, abuse, and misuse of controlled substances.
- State-licensed controlled substance prescribers and pharmacists, authorized representatives from AMA, certifying boards, and physician delegates have access to the PDMP. Law enforcement can also gain access while working on active cases.
- The Alabama Legislature approved \$1.1 million in its 2019 budget to update the software for the PDMP, improve its effectiveness, and reduce unnecessary or duplicative prescriptions.

Lock-In Program

- The Lock-In Program is designed to help AMA prevent beneficiaries from abusing controlled substances, monitor care more closely, and facilitate appropriate prescribing habits.
- Medicaid and pharmacy data are used to calculate risk scores for beneficiaries based on the number of controlled substance prescriptions and the quantity of those prescriptions reimbursed by AMA. Each month, 200 beneficiaries with the highest risk scores are identified for lock-in review by a clinical pharmacist.
 - Beneficiaries identified as using controlled substances without medical justification or clinical appropriateness are recommended for lock-in.
 - Beneficiaries that use multiple doctors and pharmacies are also recommended for lock-in.
- Beneficiaries that are placed in the Lock-In Program receive notification that they are being locked into one pharmacy and one physician. The beneficiary may then choose which pharmacy and physician they will use.
- Beneficiaries in the Lock-In Program are reviewed annually for continued inclusion in the program.

Opioid-Use-Disorder Treatment Programs

- There are 21 opioid treatment programs (OTPs) in Alabama certified by SAMHSA and ADMH.



A-04-19-00125
November 2019

FACTSHEET: Alabama's Oversight of Opioid Prescribing and Monitoring of Opioid Use

- OTPs must demonstrate the capacity to provide a basic regimen of treatment services appropriate to the client's developmental and cognitive levels and other assessed needs (Alabama Administrative Code 580-9-44). OTPs provide the following core services, including:
 - MAT with methadone, buprenorphine, or naltrexone;
 - drug and alcohol screening;
 - medically supervised withdrawal or detoxification;
 - case management, including advocacy and monitoring; and
 - treatment for co-occurring mental disorders (at some OTPs).
- OTPs complete a comprehensive medical examination of each client within 14 days of each admission that includes:
 - a complete medical history;
 - a tuberculosis skin test or chest x-ray (if the skin was ever previously positive);
 - screening tests for sexually transmitted diseases;
 - other laboratory tests as clinically indicated by the client's history and physical examination; and
 - a pregnancy test as appropriate prior to administration of any medications.
- Individuals must meet specific criteria for enrollment at an OTP. Adults must be diagnosed with an OUD and meet one of the following to enroll at an OTP:
 - are currently physiologically dependent upon an opioid and became physiologically dependent at least 1 year before seeking admission, or
 - have a history of opioid use and are susceptible to relapse to opioid addiction leading to high-risk behaviors with potentially life-threatening consequences, but do not have a 1-year history of addiction, including:
 - pregnant women;
 - individuals who have been released from incarceration within 6 months (if they were eligible for admission prior to incarceration);
 - individuals who have had opioid maintenance therapy of at least 6 months within the previous 2 years; and
 - individuals who are HIV positive.
- Individuals under age 18 must obtain written authorization from the State Opioid Treatment Authority to enroll at an OTP and have either:
 - two unsuccessful attempts at drug-free treatment within a year or
 - unsuccessful attempts at short-term detoxification.



FACTSHEET: Alabama's Oversight of Opioid Prescribing and Monitoring of Opioid Use

OTHER

Other State activities related to opioids that are not covered by the other categories in this factsheet.

- SAMHSA awarded ADMH grants to address Alabama's opioid crisis, for example:
 - The Opioid State Targeted Response grant and State Opioid Response grant are based on Alabama's opioid death rate and unmet need for OUD treatment.
 - The Medication Assisted Treatment-Prescription Drug and Opioid Addiction grant addresses a targeted capacity expansion. This grant targets citizens in Jefferson and Walker counties because they have a significantly higher opioid overdose and opioid overdose death rate per population.
 - These grants are dedicated to:
 - expanding and enhancing access to MAT for people with an OUD;
 - improving public awareness of Alabama's opioid crisis;
 - increasing available treatment options;
 - increasing the availability of naloxone in unserved areas of Alabama;
 - decreasing illicit opioid drug use; and
 - decreasing the use of prescription opioids in a non-prescribed manner.
- ADMH was awarded a grant from the Bureau of Justice Assistance to develop a centralized data repository allowing for rapid response to outbreaks of overdoses and other opioid-related events and providing a framework to measure the progress of initiatives addressing the crisis.
- CMS awarded AMA \$5 million for a planning grant that will increase the capacity of Medicaid providers to deliver SUD treatment or recovery services through an ongoing assessment of the SUD treatment needs of the State; recruitment, training, and technical assistance for Medicaid providers that offer SUD treatment or recovery services; and improved reimbursement for and expansion of the number or treatment capacity of Medicaid providers.
- The Alabama Department of Corrections and ADMH are creating a pilot program that will deliver MAT to opioid-addicted inmates, and eligible inmates that complete the program will continue community MAT to assist their recovery after release.
- ADMH trains individuals in long-term recovery (at least 2 years) to be Certified Recovery Support Specialists and to assist others in recovery.
- ADMH was awarded a "First Responder Expansion of Education and Distribution of Overdose Medication" grant from SAMHSA. The catchment area for the grant comprises 14 rural counties and 2 urban counties.



FACTSHEET: Alabama's Oversight of Opioid Prescribing and Monitoring of Opioid Use

ALABAMA ENTITIES

Alabama State Board of Medical Examiners: ABME is Alabama's administrative and regulatory agency charged with protecting the health and safety of the citizens of Alabama. Its duties include issuing Alabama Controlled Substances Certificates, annually renewing the certificates, and investigating and reviewing complaints against practitioners.

Alabama State Board of Pharmacy: The Alabama State Board of Pharmacy Board regulates the practice of pharmacy and the management and operation of pharmacies in Alabama.

Alabama Department of Mental Health: ADMH serves more than 200,000 Alabama citizens with mental illnesses, intellectual disabilities, and SUD. The department strives to serve, empower, and offer support to create awareness while promoting the health and well-being of Alabamians.

Alabama Department of Public Health: ADPH is the primary State health agency for Alabama. Its mission is to promote, protect, and improve Alabama's health.

Alabama Medicaid Agency: AMA is the State agency that administers Alabama's Medicaid program and provides a system of financing health care for eligible Alabamians in accordance with established statutes and Executive Orders.

Drug Utilization Review Board: AMA's DUR Board is a board composed of physicians and pharmacists that performs reviews designed to improve the quality of pharmaceutical care by ensuring that prescriptions are appropriate, medically necessary, and unlikely to result in adverse medical outcomes.

Pharmacy and Therapeutics Committee: AMA's Pharmacy and Therapeutics Committee was established by State law in 2003 to review and recommend to AMA classes of drugs to be included in the PDL. The committee develops its PDL recommendations by considering the clinical efficacy, safety, and cost effectiveness of a product.

State Opioid Treatment Authority: The ADMH Office of Pharmacy Services serves as the State Opioid Treatment Authority administrator in conjunction with the Office of Substance Abuse Treatment Services and the Office of Certification. This office also works directly with consumers, families, and consumer groups to resolve pharmacy related problems and medication accessibility issues.



FACTSHEET: Alabama's Oversight of Opioid Prescribing and Monitoring of Opioid Use

GLOSSARY OF TERMS

medication-assisted treatment: MAT is an OUD treatment combining the use of medications (methadone, buprenorphine, or naltrexone) with counseling and behavioral therapies.

morphine milligram equivalents: The amount of milligrams of morphine an opioid dose is equal to when prescribed.

naloxone: A prescription drug that can reverse the effects of an opioid overdose and can be life-saving if administered in time. The drug is sold under the brand names Narcan and Evzio.

neonatal abstinence syndrome: A withdrawal syndrome that can occur in newborns exposed to certain substances, including opioids, during pregnancy.

opioid antagonist: Opioid antagonist drugs such as naloxone are used in the treatment of opioid dependence and in the reversal of an opioid overdose.

opioids: Natural or synthetic chemicals that interact with opioid receptors on nerve cells in the body and 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, and morphine. Opioid pain medications are generally safe when taken for a short time and as prescribed by a doctor, but because they produce euphoria in addition to pain relief, they can be misused.

opioid use disorder: A problematic pattern of opioid use that causes significant impairment or distress. A diagnosis is based on specific criteria, such as unsuccessful efforts to cut down or control use, or use resulting in social problems and a failure to fulfill obligations at work, school, or home, among other criteria.

Prescription Drug Monitoring Database: A State-run electronic database that tracks controlled substance prescriptions. A PDMP helps providers identify patients at risk of opioid misuse, abuse, or overdose due to overlapping prescriptions, high dosages, or co-prescribing of opioids with benzodiazepines.



Summary of Alabama's Approach to Addressing the Opioid Crisis

POLICIES AND PROCEDURES

- In 2017, the Governor established the Alabama Opioid Overdose and Addiction Council to combat the opioid crisis.
- The Alabama Medicaid Agency (AMA) implemented multiple policies to limit prescription opioids including reducing allowable morphine milligram equivalent dosages, decreasing the maximum on-hand supply, and restricting timing of refills.
- Effective March 2018, the State Health Officer published a standing order for the distribution of naloxone that can be used in place of a prescription from a regular healthcare provider.

DATA ANALYTICS

- AMA performs analytics of its claims data to track opioid prescribing, including analyses of opioid prescribing trends by age, provider specialty, and location.
- AMA uses drug utilization review to improve the quality of pharmaceutical care by ensuring that prescriptions are appropriate, medically necessary, and unlikely to result in adverse medical outcomes.

OUTREACH

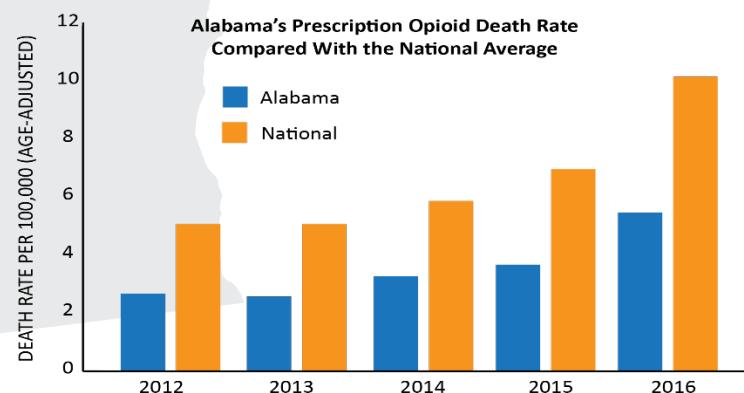
- AMA uses a contractor to train providers on policy changes and to consult with high prescribers of opioids.
- The Alabama Department of Mental Health (ADMH) opioid website provides resources to help individuals find drug disposal locations, treatment providers, and helpline phone numbers, as well as helping providers find information such as the Centers for Disease Control and Prevention (CDC) guidelines for prescribing opioids for chronic pain.

PROGRAMS

- AMA's Lock-In Program is designed to help prevent beneficiaries from abusing controlled substances, monitor their care more closely, and facilitate appropriate prescribing habits.
- Alabama has 21 opioid treatment programs certified by the Substance Abuse and Mental Health Services Administration and ADMH.

OTHER

- The Bureau of Justice Assistance awarded a grant to ADMH to develop a centralized data repository allowing for rapid response to outbreaks of overdoses and other opioid-related events, as well as providing a framework to measure the progress of initiatives addressing the crisis.
- ADMH trains individuals to become Certified Recovery Support Specialists and to assist others in recovery.



Source: CDC WONDER online database. Accessed at <https://wonder.cdc.gov/mcd-icd10.html> on December 22, 2017.

Note: Because deaths from illegally made fentanyl cannot be distinguished from deaths from pharmaceutical fentanyl in the data source, these data include both.

