

COMPREHENSIVE ADDICTION AND RECOVERY ACT OF 2016**PUBLIC LAW: 114 - 198**

Overview: On July 22, President Obama signed into law the Comprehensive Addiction and Recovery Act of 2016 (CARA). CARA creates a framework for opioid abuse prevention and treatment and authorizes \$181 million in new spending to address the opioid epidemic. Bipartisan support and overwhelming vote margins (407–5 in the House and 92–2 in the Senate) are evidence that this issue was an important one. CARA aims to strengthen prevention, treatment, and recovery efforts, largely by empowering medical professionals and law enforcement officials with funding and tools.

CARA includes several provisions that recognize that pharmacists have a role in combating the opioid epidemic:

- A pharmacist will be a member of the Task Force on Pain Management
- Grants will be available for states to implement strategies for pharmacists to dispense drugs or devices approved for emergency treatment of a suspected overdose
- Successful drug management programs, also called “lock-in” provisions, designed by health plan pharmacists for Medicaid programs and the commercial market may now be implemented for at-risk beneficiaries in the Medicare Part D program; however the regulatory process will define many of the features of that program
- Pharmacists will be included as one of the stakeholders in a group created by the Secretary of HHS to provide input on various aspects of several topics including the impact of drug management programs on patients and determination of clinical appropriateness to define “at-risk”

Other provisions allow for partial fills for Schedule II controlled substances in retail pharmacies and the creation of a federal pain management Task Force to identify inconsistencies between best practices for pain management and opioid prescribing guidelines. That Task Force will include a pharmacist. CARA also requires the FDA to work with an advisory committee before approving opioids that are not abuse-deterrent.

The law reauthorizes the National All Schedules Prescription Electronic Reporting Act (NASPER). NASPER provides grants to state prescription drug monitoring programs (PDMPs). The grants are to be utilized to encourage states to improve their PDMPs by increasing interoperability and the use of health information technology (HIT), e-health records, health information exchanges and e-prescribing. Those tools will ensure timely access to a patient’s prescription drug history and thus reduce “drug seekers” access to opioids.

CARA includes the following titles:

Title I: Prevention and Education

Title II: Law Enforcement and Treatment

Title III: Treatment and Recovery

Title IV: Addressing Collateral Consequences

Title V: Addiction and Treatment Services for Women, Families, and Veterans

Title VI: Incentivizing State Comprehensive Initiatives to Address Prescription Opioid Abuse

Title VII: Miscellaneous

Title VIII: Kingpin Designation Improvement

Title IX: Department of Veteran Affairs

PROVISIONS OF INTEREST TO AMCP MEMBERS

Sec. 101: Task Force on Pain Management

This section directs the Secretary of Health and Human Services (HHS), in cooperation with the Secretary of Veteran Affairs, and the Secretary of Defense, to convene a Pain Management Best Practices Inter-Agency Task Force. Members of the Task Force will include representatives from:

1. Department of Health and Human Services;
2. Department of Veteran Affairs;
3. Department of Defense;
4. Office of National Drug Control Policy;
5. Licensed and practicing physicians and pharmacists;
6. Experts in the field of pain research and addiction;
7. Representatives from several named organizations including hospitals and state medical boards; and
8. Experts in the health of members of the armed forces, veterans and minority groups.

The Task Force must also include individuals representing rural and underserved areas.

This Task Force is charged with identifying, reviewing, and, as appropriate, determining whether there are gaps in or inconsistencies between best practices for pain management. The Task Force shall take into consideration:

1. Existing pain management research;
2. Evidence based guidelines;
3. Efforts from States and medical professional organizations aimed at developing improved pain management strategies, including consideration of differences within and between classes of opioids and the availability of ADF opioids;
4. The management of high risk populations;
5. The CDC 2016 Guidelines for Prescribing Opioids for Chronic Pain; and
6. Private sector, state and local government efforts related to pain management and prescribing pain medication.

Within one year of convening, this Task Force will release its findings and recommendations to the relevant federal agencies and the public. The public will have at least 90 days to submit

comments on any proposed updates and recommendations. This Task Force will sunset in 3 years.

How AMCP can be Involved:

- **Submit a recommendation for a licensed and practicing pharmacist to be on the Task Force**
- **Provide information on differences within and between classes of opioids and availability of ADF opioids**
- **Provide information on managing high risk populations and prescribing best practices**
- **Respond during the public comment period**

Sec. 102: Awareness Campaigns

HHS will use existing programs and activities to advance the education and awareness of the public regarding the risk of abuse of prescription opioids if such drugs are not taken as prescribed. These awareness campaigns will address, among other things:

- (1) The dangers of opioid abuse;
- (2) The prevention of opioid abuse, including safe disposal of prescription medications and other safety precautions; and
- (3) Detection of early warning signs of addiction.

Education and awareness campaigns shall also consider any association between prescription opioid abuse and heroin use, as well as the similarities between heroin and opioids and the effects on the human body.

How AMCP can be Involved:

- **Provide information on safe disposal of medications and other safety precautions**

Sec. 103: Community-Based Coalition Enhancement Grants to Address Local Drug Crises

This section authorizes the Director of National Drug Control Policy, in coordination with the Administrator of the Substance Abuse and Mental Health Services Administration, to make grants to organizations that have documented, using local data, rates of opioid or methamphetamine use that are significantly higher than the national average. These organizations are directed to use these grants to implement comprehensive community wide strategies to address local drug crises, as well as emerging drug issues in the area served. To be eligible for a grant, an eligible organization must submit to the director a detailed, comprehensive, multi-sector plan for addressing the local drug issue.

Sec. 106: FDA Opioid Action Plan

This section requires FDA to refer all new drug applications for opioids to an FDA advisory committee. A new opioid would be exempted if the Secretary of HHS deems that such review is not in the interest of protecting and promoting public health or that such a review is unnecessary based on a review of the relevant scientific literature. Also the Secretary has to submit a notice

containing the rationale for such findings to the House Energy and Commerce Committee and the Senate Committee on Health, Education, Labor and Pensions.

Before approving any labeling or labeling change for opioids intended for use in a pediatric population, the Secretary of HHS must convene an FDA Pediatric Advisory Committee to seek recommendations for the inclusion of information on drug labels.

The Secretary of HHS, acting through the Commissioner of Food and Drugs, will evaluate Extended Release/Long Acting Opioids Risk Evaluation and Mitigation Strategy (REMS), and in consultation with relevant stakeholders, is required to develop recommendations regarding education programs for prescribers on opioids. Recommendations shall address which prescribers should participate in such a program and how often participation in such program is necessary.

This section also requires the FDA to release a final version of guidance no more than 18 months after the end of the period for public comment on the draft guidance titled *General Principles for Evaluating the Abuse Deterrence of Generic Solid Opioid Drug Products*.

How AMCP can be Involved:

- **Provide FDA with comments on the opioid review process and pediatric labeling**
- **Participate in development of stakeholder education and recommendations on the extended release/long acting opioid REMS program**

Sec. 107: Improving Access to Overdose Treatment

This section authorizes the Secretary of HHS to award grants, no more than \$200k, to federally qualified health centers (as defined in section 1861(aa)) of the Social Security Act) to expand access to drugs or devices approved for emergency treatment of opioid overdoses. This grant may be used to:

1. Establish a program for prescribing drugs and devices for emergency treatment of opioid overdose;
2. Train and provide resources to providers and pharmacists on the prescribing of drugs and devices used to treat opioid overdose;
3. Purchase drugs used to reverse opioid overdose; (No more than 20% of grant can be used for this);
4. Off-set co-payments and other cost sharing associated with such drugs and devices; (No more than 20% of grant can be used for this);
5. Connect patients who have experienced an opioid overdose with appropriate treatment, including medication-assisted treatment options, counseling, and behavioral therapy.

As a condition for receiving a grant, the state has to provide an evaluation of activities funded by the grant and any other information that the Secretary may reasonably require.

This section also permits the Secretary of HHS to provide to prescribers within federally qualified health centers, no more than 180 days after CARA's enactment, best practices for prescribing drugs and devices intended to treat opioid overdose.

How AMCP can be Involved:

- **Participate in the development of clinical guidelines**
- **Provide information on the ability of pharmacists to provide Medication – assisted treatment options and counseling.**

Sec. 108: NIH Opioid Research

This section authorizes NIH to intensify clinical research with respect to understanding pain, the discovery of and development of therapies for chronic pain, and the development of alternatives to opioids for effective pain treatment. This research shall consider recommendations made by the Interagency Pain Research Coordinating Committee in concert with this Pain Management Best Practices Inter-Agency Task Force, and in accordance with the National Pain Strategy, the Federal Pain Research Strategy, and the NIH-Wide Strategic Plan for FY 16 – 20.

How AMCP can be Involved:

- **Provide input and data on the research based on programs and services provided by managed care pharmacists and literature published in the *Journal of Managed Care and Specialty Pharmacy***

Sec. 109: National All Schedules Prescriptions Electronic Reporting Reauthorization

This section reauthorizes and amends NASPER, which provides grants to foster the establishment of State-administered controlled substance monitoring systems (PDMPs) and ensure that health care providers have access to the accurate, timely prescription history information that they may use as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions.

The Controlled Substance Monitoring Program is also amended to authorize the Secretary of HHS to mandate minimum requirements for criteria used by the states in their PDMPs. However, the Secretary must publish for public comment the minimum requirements for criteria for the states to apply for a grant. This program would require states requesting a grant to provide a plan to apply the latest advances in health IT, to the extent practicable, and to also incorporate the information from the PDMPs into the workflow of prescribers and dispensers.

If a state receives a grant, then it must facilitate prescriber and dispenser's use of the PDMP, and provide education on the benefits of using the program. Also the state would be required to submit data to the Secretary to facilitate the monitoring and evaluating the success of the state's program. This information will also be made available for research. This provision includes \$10 million dollars appropriated for each fiscal year between 2017 and 2021 was included.

How AMCP can be Involved:

- **AMCP will continue its efforts to encourage PDMPs to allow access to the data by health plans and pharmacy benefit managers**
- **AMCP will continue its efforts to encourage data sharing among PDMPs and across state lines**
- **AMCP will continue its efforts to encourage states to develop real time solutions for PDMP data sharing integrated into the workflow of pharmacies and prescribers**

Sec. 110: Opioid Reversal Medication Access and Education Grant Programs

This section allows states to receive grants to implement strategies for pharmacists to dispense an FDA approved or cleared drug or device for emergency treatment of known or suspected opioid overdose. This provision encourages pharmacies to dispense opioid overdose reversal medication pursuant to a standing order and to develop or provide training materials that persons authorized to prescribe or dispense for emergency treatment may use to educate the public.

Sec. 303: Medication-assisted Treatment for Recovery from Addiction

This section expands the number of practitioners capable of prescribing naloxone by permitting nurse practitioners and physician assistants who are licensed under State law to prescribe Schedules III -V medications for the treatment of pain. Before participating, they must have completed at least 24 hours of training on opioid maintenance, detoxification, and best practices.

This section also requires that those who prescribe medications to treat opioid use disorders have the capacity to provide directly, or by referral, appropriate counseling and other appropriate ancillary services. This section clarifies that the Administration may, by regulation, increase the maximum number of patients to which a single prescriber may provide medications for opioid use disorder. Currently, the maximum number of patients a practitioner can treat with naloxone at any given time is 30; however HHS is authorized to increase it to 100.

How AMCP can be Involved:

AMCP will continue to advocate through the regulatory process that in states where the pharmacist has authority to prescribe that they be included

Sec. 702: Partial Fills of Schedule II Controlled Substances

Amends the Controlled Substances Act to allow a prescription for a Schedule II to be partially filled if not prohibited by state law subject to the following requirements: the prescription is written and filled in accordance with this section and Drug Enforcement Administration regulations;; is requested by the patient or practitioner; and the total quantity dispensed does not exceed the total quantity prescribed. Any remaining portion of a partially filled prescription may be filled but must be filled not later than 30 days after the prescription was written. In an emergency situation, the remainder of the prescription may be filled not later than 72 hours after the prescription is issued.

Sec. 704: Programs to Prevent Prescription Drug Abuse under Medicare Part C and D

This section amends the Social Security Act by adding language that permits prescription drug plan PDP sponsors to establish drug management programs (DMPs), also known as lock-in provisions, for at-risk Medicare Part D beneficiaries. This Act shall apply to PDPs (and MA-PD plans) for plan years beginning on or after January 1, 2019. These programs are voluntary; the PDP and MA-PD plans are not required to implement one.

Under these programs, PDP sponsors may limit a beneficiary's access to coverage for frequently abused drugs – a controlled substance - as defined by the Secretary to one prescriber and pharmacy. In some cases, the member may be allowed to use more than one pharmacy or prescriber. Before including an at risk beneficiary in a DMP, the PDP must provide the beneficiary with two notices, verify with the beneficiaries' provider that the beneficiary qualifies as being at risk and allow the beneficiary to appeal after each notice. The second notice shall be provided no less than 30 days after the first, and will inform the beneficiary that his or her provider designated them as being at risk. Patients in hospice or who live in a long term care facility that contracts with a single pharmacy are exempted from this section.

The classification of at risk beneficiary means the individual is identified through the use of clinical guidelines that indicate misuse or abuse of prescription drugs that are developed by the Secretary of HHS in consultation with PDP sponsors and other stakeholders, including pharmacists. This section also instructs the Secretary to establish rules and procedures that require PDP sponsors operating a DMP for at-risk beneficiaries to provide the Secretary data pertaining to patterns of prescription drug use outside normal patterns and that may indicate fraudulent, medically unnecessary, or unsafe use.

It was the sense of Congress that plans should consider using e-prescribing and other health information technology tools to support combating fraud. No later than 1 year after the CARA is enacted, the Secretary shall submit to the appropriate congressional committees a report on ways to improve upon the appeals process. This report shall include an analysis comparing the appeals processes under parts C and D. In developing this report the Secretary shall solicit feedback from stakeholders, such as beneficiaries, consumer advocates, plan sponsors, pharmacy benefit managers, pharmacists, providers, independent evaluators, and pharmaceutical manufacturers.

Further, before January 1, 2017, the Secretary shall convene stakeholders, including individuals entitled to benefits under part A or B, advocacy groups representing such individuals, physicians, pharmacists, and other clinicians, retail pharmacies, plan sponsors, entities delegated by plan sponsors, and biopharmaceutical manufacturers for input on:

1. The anticipated impact of DMPs for at-risk beneficiaries on cost-sharing and access to prescription drugs;
2. The use of an expedited appeals process;
3. The types of enrollees that should be treated as exempted individuals;
4. The manner in which terms and definitions should be applied, such as the use of clinical appropriateness in determining whether an enrollee is an at-risk beneficiary;
5. The information to be included in the notices;
6. Evidence-based prescribing guidelines for opiates; and
7. The sharing of claims data under parts A and B with PDP sponsors.

No later than one year after the date of the enactment of this Act, the Secretary shall promulgate regulations to carry out the provisions of, and amendments made by this section.

This section also expands the authority of the Medicare Drug integrity Contractors (MEDICs). PDP and MA-PD plans must submit to the Secretary of HHS and the MEDIC, a monthly report of any provider of services or supplies that may facilitate the abuse or diversion of frequently abused drugs by beneficiaries and the name and prescription records of individuals at-risk. Under any contract entered into under this section with the MEDIC, the Secretary of HHS may authorize those contractors to directly accept prescriptions and necessary medical records from entities such as pharmacies, PDP, MA-PD plans and physicians in order to provide information relevant to the determination of whether an individual is an at-risk beneficiary for prescription drug abuse. The PDP or MA-PD may also request a determination from the MEDIC as to whether a beneficiary is at risk.

How AMCP can be Involved:

- **AMCP will advocate during the regulatory process to maintain patient protections but to minimize the time frame between when a patient is identified as at-risk and when the PDP can actually enroll them in the program that will help them to manage their addiction**

Sec. 705: Excluding Abuse-Deterrent Formulations of Prescription Drugs from the Medicaid Additional Rebate Requirement for New Formulations of Prescription Drugs

This section excludes abuse-deterrent formulation of a drug (as determined by the Secretary), regardless of whether such abuse deterrent formulation is an extended release formulation from the Medicaid additional rebate requirement. This section applies to drugs that are paid for by a State in calendar quarters beginning on or after the enactment date of this Act.