Cancer and the Comprehensive Addiction and Recovery Act (CARA)

The Comprehensive Addiction and Recovery Act (CARA, P.L. 114-198[1]) was signed into law on July 22, 2016. CARA was the first major legislative effort focused on addressing the opioid epidemic in the U.S. It authorized over $181 million in new funding to create a coordinated response to the epidemic through prevention, treatment, recovery, law enforcement, criminal justice reform, and overdose reversal.

ACS CAN supported the passage of CARA[2] and supports other balanced public policies that address addiction while maintaining access to necessary relief for individuals fighting pain from cancer and other serious illness. ACS CAN is also devoted to making sure the patient voice is heard in the current public policy debate on the problem of opioid addiction and overdose. Many provisions of CARA are now being implemented by federal and state agencies, and Congress is discussing another package of legislative proposals – often called CARA 2.0. As these discussions occur, the following provides a summary of the original legislation, how it affects cancer patients and survivors, and updates on how the law is being implemented.

Summary of Provisions in CARA 1.0[3]

- Expands prevention and educational efforts—particularly aimed at teens, parents and other caretakers, and aging populations—to prevent the abuse of methamphetamines, opioids and heroin, and to promote treatment and recovery;
- Expands the availability of naloxone to law enforcement agencies and other first responders to help in the reversal of overdoses to save lives;
- Expands resources to identify and treat incarcerated individuals suffering from addiction disorders promptly by collaborating with criminal justice stakeholders and by providing evidence-based treatment;
- Expands disposal sites for unwanted prescription medications to keep them out of the hands of potential abusers;
- Launches an evidence-based opioid and heroin treatment and intervention program to expand best practices throughout the country;
- Launches a medication-assisted treatment and intervention demonstration program; and
- Strengthens prescription drug monitoring programs to help states monitor and track prescription drug diversion and to help at-risk individuals access services.

CARA 1.0 Provisions Affecting Cancer Patients & Survivors

Pharmacy and Prescriber Lock-In Programs: The law authorized amendments to Medicare to allow Medicare Advantage and prescription drug plans (Parts C and D) to implement pharmacy and prescriber lock-in programs that require a patient to only obtain opioids from one pharmacy or one doctor. The Centers for Medicare and Medicaid Services (CMS) finalized the rule implementing these provisions for the 2019 plan year in April 2018.[4] Lock-ins will only apply if a patient is taking a high dosage of opioids

[1] https://www.congress.gov/bill/114th-congress/senate-bill/524/text
[2] See ACS CAN Press Release. House Passes Bipartisan Opioid Legislation. July 8, 2016. Available at https://www.acscan.org/releases/house-passes-bipartisan-opioid-legislation
[3] Summary taken from Community Anti-Drug Coalitions of America Factsheet. The Comprehensive Addiction and Recovery Act (CARA). Available at https://www.cadca.org/comprehensive-addiction-and-recovery-act-cara
[4] Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 2, 2018. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf

and appears to be pharmacy or prescriber "shopping," and the programs exclude patients with a diagnosis of cancer. It is not clear how CMS or Medicare C and D plans are defining this cancer exemption, and ACS CAN asked for more clarification in comments on the proposal.[5]

NIH Opioid Research: The law directs the National Institutes of Health (NIH) to intensify research into what causes pain, as well as possible alternatives to opioids for effective pain management. On October 13, 2017, the NIH Office of Pain Policy released the Federal Pain Research Strategy.[6] The strategy identifies critical gaps in basic and clinical research on the symptoms and causes of pain and makes recommendations to ensure coordination of research activities among agencies. ACS CAN is supportive of this work as it will lead to better treatments for cancer patients and survivors in pain.

Prescription Drug Monitoring Programs: The law increases and improves state-level coordination and efficiency of Prescription Drug Monitoring Programs (PDMPs). State-based PDMPs are in place across the country to detect potential abuse and to protect legitimate patient access to opioids for patients who need access to pain medications. Under CARA, PDMPs were strengthened and expanded to allow for better communication and data to be shared across state lines. ACS CAN supports PDMPS that are interoperable across states and integrated into clinical workflows. These programs protect cancer patients and survivors by flagging potential problems in care coordination.

Pain Management Best Practices Interagency Task Force: This task force, created by CARA, is charged with reviewing, modifying, and updating best practices for how pain medication is prescribed to patients. Better informed guidelines and care standards for physicians will help them better understand and treat patients with pain, including cancer patients and survivors. The task force has an approved charter,[7] but task force members have not yet been named.

FDA Opioid Action Plan: The law required the Food and Drug Administration (FDA) to create an opioid action plan, which the agency released in 2017.[8] The plan includes developing warnings and safety information for immediate-release opioid labeling, strengthening post-market data requirements to learn about the effects of long-term use of opioids, updating the risk evaluation and mitigation strategy (REMS) requirements for opioids, and expanding access to abuse-deterrent formulations. ACS CAN encourages FDA to implement all of these actions carefully so as not to create barriers to access for cancer patients and survivors.

[5] ACS CAN. Comments on CMS-4182-P. January 16, 2018. https://www.acscan.org/sites/default/files/ACS%20CAN%20Comments%20on%20Part%20C%20and%20D%20Rule%20Final.pdf
[6] National Institutes of Health. Interagency Pain Research Coordinating Committee. Federal Pain Research Strategy. https://iprcc.nih.gov/sites/default/files/iprcc/FPRS_Research_Recommendations_Final_508C.pdf
[7] Pain Management Best Practices Inter-Agency Task Force. Charter. October 24, 2017. https://www.hhs.gov/ash/advisory-committees/pain/charter/index.html
[8] FDA. FDA Opioids Action Plan. July 11, 2017. https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm484714.htm