

# The Opioid Epidemic: The Evolving Role of Nursing

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## Overview

Opioid dependence and associated drug-related overdoses and deaths are serious public health problems in the United States.

Registered nurses are on the front lines of addressing the epidemic by educating patients to understand the risks and benefits of pain treatment options, to include opioids, and by recognizing those at risk for substance use disorder.

Changes to the Controlled Substances Act allows APRNs with appropriate training to prescribe buprenorphine which significantly increases access to medication-assisted treatment for patients who need it.

Drug overdose deaths have risen steadily over the past two decades, with drug poisonings propelling unintentional injuries to become the third leading cause of all deaths in the United States (CDC, 2017d). From 1999 to 2013, the rate for drug poisoning deaths involving opioid analgesics nearly quadrupled (CDC, 2015).

Prescription drugs, especially opioid analgesics, initially were implicated in drug overdose deaths over the last decade. However, over the past few years, the opioid death toll has been exacerbated by other synthetic opioids, most notably illicit fentanyl and heroin. Deaths related to heroin have quadrupled between 2010 and 2015, similar to the rate of opioid overdose deaths between 1999 and 2015 (CDC, 2017b).

Registered Nurses (RNs), who are often the best equipped to assess a patient's pain and need for pharmacologic pain relief, are on the front lines of the opioid epidemic. Advanced Practice Registered Nurses (APRNs), whose education (including advanced pharmacology) prepare them to assume responsibility and accountability for assessment, diagnosis, and management of patients' problems (including the use

and prescription of pharmacologic interventions), play a critical role. This Issue Brief provides an overview of the role of RNS and APRNs, summarizes ANA initiatives, and outlines the federal government's response related to the opioid epidemic.

## Recognition of a National Epidemic

On October 21, 2015, in West Virginia, President Obama announced federal, state, local, and private-sector efforts aimed at addressing the prescription drug abuse and heroin epidemic. ANA was invited to participate along with more than 40 provider groups—representing doctors, dentists, APRNs, physician assistants (PAs), physical therapists, and educators. As a result, over 540,000 health care providers committed to complete opioid prescriber training within two years.

President Obama issued a memorandum to federal departments and agencies directing two important steps to combat the prescription drug abuse and heroin epidemic:

- 1) *Prescriber training*: Federal departments and agencies were instructed to provide training related to appropriate prescribing of opioid medications to federal health care professionals who prescribe controlled substances.
- 2) *Improving access to treatment*: Federal departments and agencies that provide, contract, reimburse, or otherwise facilitate access to health benefits were instructed to identify barriers to Medication-Assisted Treatment (MAT) for opioid use disorders and develop action plans.

In conjunction with the work of the White House, the U.S. Department of Health and Human Services (HHS) prioritized activities to address the opioid abuse epidemic. In March 2015, HHS released an Issue Brief describing evidence-based priorities (HHS, 2015). The initiative focused on two broad goals: 1) reducing opioid overdoses and overdose-related mortality, and 2) decreasing the prevalence of opioid use disorders. The priorities were grounded in the best available research and clinical science from federal, state, and stakeholder organizations. HHS also highlighted the development of an evaluation to identify the most effective strategies for obtaining the greatest public health impact.

To attain these goals, ANA joined with a large and diverse group of stakeholders to address:

- Opioid prescribing practices, to reduce opioid use disorders and overdose;
- Increased use of MAT to reduce opioid use disorders and overdose; and
- Expanded use of naloxone, used to treat opioid overdoses.

The opioid public health epidemic continues into the Trump administration, resulting in the declaration of a public health emergency in October 2017. While additional finances were not allocated, federal agencies have assigned resources to mitigate the epidemic. In March 2018, Congress passed a federal spending bill that includes a \$3.3 billion increase in funding to support prevention, treatment, and law enforcement activities across entities that help state and local governments (Quinn, 2018).

## The Critical Contribution of Nursing

In part, the current epidemic has been fueled by well meaning, but generally ineffective efforts to manage chronic pain. In comments concerning the National Pain Strategy, (HHS, 2016) developed by a diverse team of experts, ANA noted that nurses often lead the way in an attitudinal transformation toward pain management. ANA lauded the vision outlined in the National Pain Strategy, specifically:

- Prevention, early recognition, and intervention of pain issues in primary care settings;
- A person-centered, interdisciplinary approach to pain management; and
- Support for pain self-management strategies.

Because RNs practice in a variety of direct-care, care-coordination, leadership, and executive roles, they are often in a key position to help patients and their families understand the risks and benefits of pain treatment options. As educators and patient advocates, nurses are in a unique position to help patients with non-opioid pain management including other medication modalities, regional anesthetic interventions, surgery, psychological therapies, rehabilitative/physical therapy, and complementary and alternative medicine (CAM).

# Barriers to Effective Pain Management

Removing barriers is key to helping patients manage pain effectively. Nurses can facilitate reducing barriers to effective pain management. According to the 2011 Institute of Medicine (IOM) report, *Relieving pain in America: A blueprint for transforming prevention, care, education, and research*, barriers occur at the system, clinician, patient, and insurance levels (IOM, 2011).

- **System:** At the system level, barriers arise because clinical services are often organized along disease-specific lines. Existing clinical silos prevent effective exchange of ideas and best practices and impede the interdisciplinary approach needed for effective pain care.
- **Clinician:** Because best practices in pain prevention and treatment, particularly chronic pain, are continually evolving, clinicians would benefit from continuing education related to evidence-based guidelines. Clinicians also require resources to provide care coordination including identifying mental health, behavioral health, or CAM services.
- **Patient:** Patient-level barriers include consciously or unconsciously applying societal stigma to people reporting pain, particularly if they do not respond readily to treatment. Religious or moral beliefs and popular culture may also present barriers to people seeking care.
- **Insurance:** Insurance and third-party payers frequently limit reimbursement for or do not cover psychosocial and rehabilitative care, essential components of comprehensive care. Rehabilitation services are also often subject to insurance limits, especially under Medicare. In addition, CAM therapies used in pain management frequently are not covered by health insurance.

Nurses can lead the cultural transformation in pain prevention, care, education, and research and facilitate development of “a comprehensive population health-level strategy” by recognizing all barriers to effective preventive and pain management strategies (IOM, 2011).

## Prescribers as Gate Keepers for Prescription Opioids

Although comprehensive actions to address prescription opioid abuse must include all caregivers, prescribers, and patients; prescribers are the gatekeepers for minimizing inappropriate access. Interventions to improve safe and appropriate prescribing must balance the legitimate need for these drugs, with the need to curb dangerous practices. The safe and appropriate prescribing priority includes three objectives:

- 1) Improve clinical education and decision making to reduce inappropriate prescribing;
- 2) Enhance prescription monitoring and health information technology (health IT) to support appropriate pain management; and
- 3) Support data and best practice sharing to facilitate appropriate prescribing.

## Prescription Drug Monitoring Programs

In 2015, HHS set a goal to double the number of health care providers registered with prescription drug monitoring programs (PDMPs) by 2017. PDMPs are state-run electronic databases that provide a prescriber or pharmacist information regarding a patient’s prescription history, allowing providers to identify patients who are potentially misusing medications.

As of August 2017, all 50 states, the District of Columbia and the territory of Guam have a PDMP program (PDMP TTAC, 2017). However, there is no standard related to drugs monitored, or data collected or shared. As a result, HHS has proposed a national interoperable PDMP network (Health IT Now, 2018). Provider use of the PDMPs varies according to state mandate and ease of system access. Emerging research on the efficacy of PDMPs has shown mixed results, in part due to the lack of standardization among programs. The use of PDMPs

has allowed providers to engage with patients and change their practice to conform with evidence based, non-opioid pain management strategies. Providers have highlighted reticence to prescribe opioids, which some fear could result in ineffective pain management and lead to patients seeking illicit forms of pain relief (Finley, Garcia, Rosen, McGeary, Pugh, & Potter, 2017).

## Naloxone for Prescription and Illicit Opioid Overdose

Naloxone is a life-saving medication that rapidly blocks the effects of opioids when signs and symptoms of a prescription or illicit opioid (including heroin and fentanyl) overdose first appear. Although ineffective with overdoses associated with benzodiazepines, barbiturates, or stimulants, naloxone is consistent with the FDA approved indications for opioid abuse including:

- Receiving high doses of opioids for long-term chronic pain or rotating opioid medication regimens,
- Having been discharged from emergency medical care following opioid poisoning or intoxication,
- Taking certain extended-release or long-acting opioid medication, or
- Completing mandatory opioid detoxification or abstinence programs.

In order to expand its use, naloxone was included in the overdose toolkit released by SAMHSA. (SAMHSA, 2016a) In addition, under the July 2016 Comprehensive Addiction and Recovery Act (CARA), HHS is authorized to make grants to states to implement strategies for pharmacists to dispense naloxone pursuant to a standing order and to develop naloxone training materials for the public (ASAM, n.d.).

Overdose kits are increasingly common among providers and patients on long-term opioid therapy and others at risk for overdose. At a minimum, all kits should include:

- Nitrile gloves
- Naloxone/Narcan Nasal Spray/Naloxone auto-injector
- Syringes
- Needles (SAMHSA, 2016a)
- Optional supplies: alcohol pads, rescue breathing masks, and educational inserts (HRC, n.d.).

In April 2018, the Surgeon General released an advisory about naloxone urging patients and the public to:

- Talk with a doctor or pharmacist about obtaining the medication,
- Learn the signs of opioid overdose,
- Complete training to administer naloxone, and
- Use SAMHSA services to seek treatment and recovery services (Adams, V.J., n.d.).

The advisory also asks prescribers, substance use disorder (SUD) treatment providers, and pharmacists to:

- Learn how to identify patients at high risk for overdose,
- Follow CDC guidelines for prescribing opioids for chronic pain,
- Use prescription drug monitoring programs,
- Understand whether pharmacists are permitted to prescribe naloxone under their own license or under a standing order or collaborative agreement, and
- Prescribe or dispense the medication to those at increased risk of opioid overdose and to their friends and family (Adams, V.J., n.d.).

## Medication-Assisted Treatment for Opioid Use Disorders

MAT includes the use of medication along with counseling and other support and is the most effective form of treatment for opioid use disorders. Combined with behavioral therapy, effective MAT programs for opioid addiction decrease overdose deaths, result in cost savings, reduce transmissions of HIV and hepatitis C related to IV drug use, and mitigate associated criminal activity (NIH, 2016). While the goal of MAT is for all patients to become drug-free, some people with severe addictions may need to continue MAT indefinitely.

### Expanding Access to MAT

The increase in persons with SUD has quickly outpaced the capacity of substance abuse treatment centers. The Drug Addiction Treatment Act of 2000 (DATA 2000) and subsequent FDA approvals allow qualified providers to apply for a waiver to prescribe Schedule III, IV, and V narcotic drugs and the combination of buprenorphine and naloxone (Suboxone) for maintenance or detoxification treatment in the private-office setting (SAMHSA, 2000). CARA expands prescribing privileges of Nurse Practitioners (NPs) and PAs to include office-based opioid addiction treatment with buprenorphine. Until October 1, 2021, NPs and PAs may obtain a DATA 2000 waiver for up to 30 patients in states where they are authorized to prescribe Schedule III, IV, or V medications for pain after completing 24 hours of required training (SAMHSA, n.d.b). Yet, significant barriers remain. As of April 2017, 28 states prohibit NPs from prescribing buprenorphine unless they are collaborating with a doctor who has a federal license to prescribe the medication. Additionally, three states (Oklahoma, Tennessee and Wyoming) explicitly prohibit NPs from prescribing buprenorphine either independently or under a collaborative agreement with a physician while one state (Kentucky) prohibits PAs from prescribing buprenorphine (Vestal, 2017).

Providers have been slow to apply for the waiver and can only accept a limited number of patients (30 in the first year, then up to 100 and 275 after prescribing to 100 patients for at least one year). Of the 52,840 providers granted the waiver as of August 2018, only 4,304 (8%) are authorized to accept up to 275 patients (SAMHSA, n.d.c). Reasons cited for not participating in MAT include: (1) inadequate insurance reimbursement, (2) the need for detailed training and treatment protocols and access to referral agencies, (3) service is beyond the scope of the providers practice, or (4) opioid-addicted patients are considered undesirable for their clinics (Hostetter, M. and Klein, S. 2017)

### Psychiatric Nurses Support the Expansion of APRN Prescriptive Authority

In July 2013, the American Psychiatric Nurses Association (APNA) released a statement that noted the alarming rise in the number of patients *addicted to opioids and the shortage of physicians* who can provide office-based treatment. APNA “fully supports the expansion of advanced practice registered nurses’ prescriptive authority to include the prescription of buprenorphine and Suboxone in the treatment of persons who are addicted to opiates” (APNA, 2013).

## Storage and Disposal

In order to prevent prescription opioids from reaching unintended individuals, storage and disposal techniques should be addressed at the time of prescribing, disbursement, and during follow-up care planning. Interdisciplinary groups, including government agencies, consumer advocates, health care providers, and law enforcement have been educating patients and their families about safe storage and proper disposal techniques. Education should be provided throughout the care of the patient and presented at an appropriate reading level with culturally appropriate content.

### Safe Storage of Prescription Opioids

The CDC encourages patients to store medications out of children’s reach and sight and lock the safety cap consistently after each use (CDC, 2016b). Family members and house guests should also store medicines in a locked cabinet or lockbox between doses to prevent unintended use. The Safe Homes Coalition (SHC) advises keeping medications in original containers and avoiding mixing medications into one bottle (SHC, 2017).

## Disposal of Unused Opioids

The FDA recommends consumers follow disposal instructions provided on a medication bottle. When disposal instructions are not available, the FDA endorses three options for discarding unused or expired medications: (1) medicine take-back, (2) disposal in the household trash, and (3) flushing certain potentially dangerous medicines in the toilet. All expired and unused medications should be removed from the home quickly to reduce the chance of misuse.

- (1) **Medication take-back programs:** Two types of medication take-back programs are available: permanent DEA-registered collection sites including select retail/hospital/clinic pharmacies and law enforcement facilities, and periodic events such as national prescription drug take-back events.
- (2) **Disposal in household trash:** To dispose medication in household trash, mix (do not crush tablets or capsules) with an unpalatable substance such as dirt, cat litter, or used coffee grounds. Seal the mixture in a plastic bag and throw in the trash. Delete personal information from the prescription label before disposing.
- (3) **Flushing certain medications:** A small number of prescription drug labels instruct patients to immediately flush unneeded medication down the toilet when take-back programs are not readily available. Due to the risk to humans, including death from accidental exposure, flushing the medication far outweighs any potential risk to humans or the environment in the absence of a take-back program. (FDA, 2018b)

## Special Populations: Preventing Stigma

Stigma associated with opioid use disorder and treatment affects a diverse group of patients, communities, and caregivers and can cause patients to forgo life-saving medical services or withdraw from treatment. Considerations to prevent stigma should be applied in a variety of circumstances, including but not limited to mothers and newborns and secondary exposure cases.

### Mothers and Newborns

The need to identify and treat patients in the outpatient setting extends to expectant mothers. Over the past decade, an increase in the rate of maternal opioid use in pregnancy and subsequent neonatal abstinence syndrome (NAS) has been documented (Patrick et al., 2012). In light of the increased rate of SUD, additional capacity to identify and treat patients in outpatient settings is needed. Interventions should include: community-based treatment modalities that include pregnant women and training for nurses and midwives providing prenatal care.

Methadone has been considered the gold standard for treatment of maternal opioid use for decades, and evidence suggests that maintaining pregnant women on methadone can reduce adverse pregnancy outcomes caused by frequent withdrawal and the multiple health risks that accompany illegal drug use (Jones et al., 2010). Recent studies indicate that buprenorphine is at least as effective as methadone in preventing NAS. As part of CARA, the Residential Treatment Program for Pregnant and Postpartum Women was reauthorized (CADCA, n.d.). Overseen by SAMHSA's Center for Substance Abuse Treatment (CSAT), the program expands the availability of comprehensive, residential substance abuse treatment, prevention, and recovery support services for pregnant and postpartum women and their minor children (SAMHSA, n.d.a). CARA also authorizes CSAT to develop grants to enhance state services for women who are pregnant and postpartum while suffering from a SUD (CADCA, n.d.).

## School Nurses and Adolescents

School nurses are in unique positions to play a role in prevention of illicit opioid use, store and dispense prescribed opioids, act as first responders in the case of an overdose on campus and serve as child advocates in the planning of pain management. As a first responder, the school nurse possesses the education and ability to identify an emergent situation, manage the emergency until other medical personnel arrive and communicate with other health care providers (NASN, 2015). Individual states and school districts have set guidelines and policies relevant to stocking and training requirements to administer naloxone on school property. However, the National Association of School Nurses advocates that school nurses along with other school leaders need to be included in the decision to stock naloxone in schools (NASN, 2016). If naloxone is stocked on school property, the school nurse would be trained to administer the medication and address treatment of the student and any post trauma concerns of witnesses.

## Secondary Exposure

The rise in opioid overdoses presents the potential for exposure among first responders and other health care providers. Caution should be taken at clinics, hospitals, and other health care settings treating opioid overdose patients, specifically with cases involving fentanyl and its analogues. The National Institute for Occupational Safety and Health (NIOSH) suggests that the greatest risk for exposure is inhalation, mucous membrane contact, ingestion, and needle stick (CDC, 2017a).

For patients to receive timely and quality care while protecting providers, health care professionals require specialized training dedicated to conducting on-scene risk assessment related to fentanyl and its analogues. NIOSH makes recommendations for the use of Personal Protective equipment (PPE) including powder-free nitrile gloves to prevent exposure. More extensive PPE, ranging from face and eye protection to a filtering facepiece respirator, may be necessary to protect responders when high levels of exposure are anticipated. Healthcare providers should also be aware of the symptoms of a secondary exposure including the rapid onset of life-threatening respiratory depression.

NIOSH suggests that if a person or healthcare professional encounters illicit opioids, they should instantly remove clothing and use soap and water to thoroughly wash the contaminated area. No alcohol or bleach-based solutions should be used to clean contaminated skin. All contaminated clothing should be separated from other laundry and cleaned at the healthcare facility when possible. (NIOSH, 2018a).

NIOSH continues to evaluate possible secondary exposure to opioids by first responders and healthcare personnel. Thus far, toxicology results, when provided, have failed to confirm opioid exposure, although in several cases, symptom description meets the NIOSH definition for possible work-related opioid toxicity, defined as health effects experienced by an individual in the execution of his/her duties where opioids were suspected or known to be present (NIOSH, n.d.). ANA strongly urges the development of evidence-based standards in consultation with leading toxicology and other stakeholders to promptly verify suspected secondary exposure. Routine verification would help minimize fear of exposure during the normal execution of duties as well as highlight changes in types of opioids or other substances currently in circulation.

## Federal Action

### Federal Legislation

The growing opioid addiction and overdose epidemic gripping the nation has spurred Congressional action. Over the past year, lawmakers have sought a comprehensive approach to address the epidemic by advancing bills that would expand access to naloxone, enhance prevention education, reduce the prevalence of unused pain pills, offer providers student loan forgiveness, and increase collaboration with law enforcement and local criminal justice systems. The House Energy and Commerce Committee held hearings and markups on more than 60 pieces of legislation in May 2018.

In June 2018, the U.S. House of Representatives passed the *SUPPORT for Patients and Communities Act* (H.R. 6). This legislation is a package of dozens of bills designed to fight the opioid epidemic. Section 3003 permanently authorizes NPs and PAs to prescribe MAT while limiting prescription authority to five years for the other three categories of APRN. A study to collect data on efficacy and diversion related to all prescribers of MAT is also included. ANA is lobbying the U.S. Senate to include section 3003 as is in any opioids legislation brought to a vote.

ANA advocates for all RNs and APRNs to practice to the full extent of their education and practice authority, allowing individualized treatment plans for all patients and increased access to health care services, including MAT. For information on the additional federal legislation, see Appendix A.

## Federal Agencies

While all government agencies have developed a response to the opioid epidemic, the responses vary in scope, funding, reach, and effectiveness. ANA supports efforts that strengthen patient care and encourage access to treatment, recovery, and behavioral health services. However, ANA remains concerned that some federal agency level activities are not in line with principles critical to person-centered care and may deter those facing opioid use disorders from seeking effective treatment and recovery programs. A coordinated, funded, long-term effort is needed to ensure that patients are encouraged to seek appropriate care, without fear of reprisal or disciplinary action.

Through notices in the federal register, ANA provides comments to federal agencies on pressing issues of the nursing community. Through comment opportunities, ANA has supported:

- Removing barriers to effective treatment, including CAM;
- Promoting proper storage and disposal techniques;
- Allowing those with prescribing authority to practice to the full extent of their education and practice authority; and
- Eliminating arbitrary threshold drug amounts for patients with chronic pain and caution practice only when appropriate.

For more information on agency activities, see Appendix B.

## Conclusion

ANA, the premier nursing organization representing the nation's 4 million RNs, remains committed to leading educational and advocacy efforts to address the opioid epidemic. ANA will continue working with government agencies, the White House, ANA's organizational affiliates, and other stakeholders to engage RNs and APRNs in initiatives to address opioid prevention, treatment, and recovery strategies.



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## Appendix A: Federal Legislation

### Addiction Treatment Access Improvement Act of 2018

The *Addiction Treatment Access Improvement Act* (S. 2317/H.R. 3692), would make MAT prescribing authority for NPs and PAs permanent and extend prescribing authority to certified registered nurse anesthetists (CRNAs), certified nurse midwives (CNMs), and clinical nurse specialists (CNSs).

An increase in providers will extend access to treatment to more patients, particularly in rural areas where physicians who attained the educational requirements for prescribing MAT (DATA 2000 waiver), may be unavailable or in shortage. According to the DEA, as of February 21, 2017, there were 33,663 DATA-waived physicians compared to 1,247,716 total physicians. Between February 2017 and May 5, 2018, 5,649 NPs have obtained a DATA 2000 waiver compared to 248,000 total NPs. In less than two years, NPs have received almost as many waivers as physicians received in 17 years (2.3 percent of NPs v. 2.7 percent of physicians).

Further, the DEA has recognized the effectiveness of MAT. In its January 2018 report, the DEA highlighted the results of a large-scale November 2011 NIH study related to the treatment of prescription opioid addiction (DEA, 2018). The results showed that approximately 49 percent of participants reduced prescription painkiller abuse after receiving MAT for more than 12 weeks. This success rate dropped to 8.6 percent once MAT was discontinued. Reductions in prescription painkiller abuse were seen regardless of whether the patient reported chronic pain. Participants who received intensive addiction counseling did not show better outcomes when compared to those who did not receive additional counseling. MAT is a lifelong process and those receiving care by an NP could lose access to treatment when the program expires in 2021.

This legislation does not expand APRN scope of practice. Providers who attain the DATA 2000 waiver are authorized to prescribe this schedule of drugs. It follows that since APRNs can already prescribe opioids for pain, with the proper training and education, they should be able to prescribe MAT to treat opioid use disorder patients.

The ability for NPs and PAs to attain or maintain a DATA 2000 waiver is set to expire in 2021 due to a budgeting tactic created by Congress to keep the official cost estimate of the legislation down. In their January 2018 economic impact report, the DEA recognized that the temporary nature of the provision and the mandatory 24-hour training requirement (physicians are required to attend only 8 hours of training), NPs and PAs may be less inclined to invest time and resources to obtain a waiver. The impact of this disincentive will increase as the 2021 expiration date approaches.

The Congressional Budget Office (CBO), responsible for providing the official cost analysis of legislation to Congress, estimated that this legislation would cost taxpayers money while the DEA's analysis rules allow consideration of perspective savings from effects such as increased labor productivity and tax revenue. The DEA estimates the total economic burden of the opioid epidemic is \$75.7 billion or \$41,000 per patient. The net economic benefit of authorizing NPs and PAs to provide MAT, primarily due to increased labor productivity and decreased healthcare and legal costs, will be \$808 million, with a total net benefit of \$640-729 million dollars over five years. Based on the DEA's estimate that 5,235 NPs and PAs would obtain the waiver, the average costs savings would be approximately \$122,254-139,255 for every NP or PA who obtains the waiver.

While concerns regarding an increase in prescribers leading to more drug diversion have been raised, the risk is low according to the DEA. The DEA suggests that even if the medications are diverted, they are commonly used for treatment. They believe that diversion is a result of lack of access to legitimate addiction treatment services, suggesting that increasing the number of MAT prescribers may be an effective response to diversion (DEA, 2018).

The *Addiction Treatment Access Improvement Act* (S. 1455/H.R. 3692) has been introduced in both chambers of Congress. The original cosponsors include Sens. Rand Paul (R-KY), Margaret Hassan (D-NH), Susan Collins (R-ME) and Reps. Paul Tonko (D-NY) and Ben Ray Lujan (D-NM). ANA believes the bill takes a vital step forward, one that will greatly increase the number of providers who can treat opioid-dependent patients with approved MATs.

## Appendix B: Federal Agency Action

As of June 2018, federal agencies have taken the following actions to address the opioid epidemic:

### **Centers for Disease Control and Prevention (CDC):**

The CDC has developed guidelines for opioid prescribing for chronic pain to improve clinical decision making and reduce inappropriate opioid prescribing (CDC, 2016a). Since the publication of the *Guidelines*, the CDC has developed web-based resources to facilitate communication between providers and patients about the risks and benefits of opioid therapy for chronic pain (CDC, n.d.). Moreover, CDC's Prescription Drug Overdose: Prevention for States program, assists States by providing health departments with resources and support to implement interventions to prevent prescription drug overdoses. As of October 2017, the program funds 29 states. Through 2019, CDC intends to grant states annual awards to support work in four areas:

- 1) Prescription Drug Monitoring Programs (PDMPs) expansion and interoperability,
- 2) Community or Insurer/Health Systems interventions,
- 3) Policy evaluations, and
- 4) Rapid Response projects (CDC, 2017c).

### **Center for Medicare and Medicaid Services (CMS):**

The Comprehensive Addiction and Recovery Act (CARA) of 2016 was the first major federal addiction legislation in 40 years and one of the most comprehensive efforts undertaken to address the opioid epidemic (CADCA, n.d). As required by CARA, CMS established a framework for Part D sponsors to implement drug management programs, where sponsors can limit at-risk beneficiaries access to coverage for suspected frequently misused drugs.

In the 2019 Final Call Letter to Medicare Advantage Organizations and Prescription Drug Plan Sponsors, CMS implemented a limit on initial opioid prescription fills for treatment of acute pain to no more than seven days (CMS, April 2018). CMS also has increased access to MAT services to reduce opioid disorders and overdose (Giroir, B.P. and Brandt, K., 2018).

### **Department of Justice (DOJ):**

The DOJ has focused most of its efforts on targeting: 1) providers who are overprescribing, 2) healthcare fraud, and 3) illegal internet sales of dangerous drugs both in the United States and internationally. In 2018, the DOJ issued guidance on the use of capital punishment in drug-related prosecutions (OAG, 2018). ANA opposes both capital punishment and nurse participation in capital punishment (ANA, 2016).

### **Drug Enforcement Administration (DEA):**

DEA's 360 Strategy responds to the heroin and prescription opioids epidemic through: 1) coordinated law enforcement operations targeting all levels of drug trafficking organizations supplying drugs to neighborhoods; 2) diversion control that engages drug manufacturers, wholesalers, providers, and pharmacists to increase awareness of the opioid epidemic and encourages responsible prescribing and use of opioids; and 3) community outreach and partnership with local organizations to equip communities to address the opioid epidemic (DEA, 2017).

**Food and Drug Administration (FDA):** FDA's response to the opioid epidemic includes:

- 1) Expanding the use of advisory committees;
- 2) Developing warnings and safety information to immediate-release (IR) opioid labeling;
- 3) Strengthening post-market requirements;
- 4) Updating Risk Evaluation and Mitigation Strategy (REMS) Program;
- 5) Expanding access to abuse-deterrent formulations (ADFs) to discourage abuse;
- 6) Supporting better treatment; and
- 7) Reassessing the risk-benefit approval framework for opioid use (FDA, 2018a).

**Department of Health and Human Services (HHS):**

In 2017, HHS continued to address the opioid epidemic by developing a five point strategy:

- 1) Better addiction prevention, treatment, and recovery services;
- 2) Better public health data on the epidemic;
- 3) Advancing evidence-based methods of pain management;
- 4) Better targeting of overdose-reversing drugs; and
- 5) Support for cutting edge research on pain and addiction (HHS, 2018).

**Department of Homeland Security:**

An October 2017 Trump Administration Executive Order directs U.S. Immigration and Customs Enforcement to increase the number of Border Enforcement Task Forces, prompting Homeland Security Investigations to establish a three-pronged approach to combating opioids: International Partnerships, Law enforcement collaboration, and Undercover online operations in order to disrupt supply chain networks of illicit drugs (DHS, 2018).

**Health Resources and Services Administration (HRSA):**

HRSA funds community and rural health centers to expand mental health, substance abuse, and opioid treatment and recovery services, including the Rural Health Opioid Program and the Substance Abuse treatment Telehealth Network Grant Program. Supplemental funds were awarded to 25 states for MAT training under the Primary Care training and Enhancement program to integrate MAT into educational programs and primary care.

**National Institutes of Health (NIH):**

Helping to End Addiction Long-term (HEAL) Initiative successes include the development of the nasal form of naloxone and buprenorphine to treat opioid use disorder, and evidence supporting nondrug and mind/body techniques for pain management (NIH, 2018).

**Substance Abuse and Mental Health Services Administration (SAMHSA):**

SAMHSA's Opioid Treatment Technical Assistance Program educates and prepares opioid treatment programs for certification and accreditation by SAMHSA-approved bodies. The Substance Abuse Prevention and Treatment Block Grant Program supports states and community-based group's efforts to improve and expand existing substance abuse treatment services (SAMHSA, 2016b).