Reducing Opioid Morbidity and Mortality

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Overview

Challenge

- o The crisis of opioid addiction and overdose in the United States continues to worsen, and the illicit drug supply increasingly contains more potent and dangerous opioids. In 2016, 2.1 million people in the U.S. had an opioid use disorder, and 116 people died each day from drug overdoses involving opioids, exacting an enormous societal toll.

Opportunity

- o The urgency of this crisis has unified HHS around the goals most likely to prevent opioid misuse, treat existing opioid addiction, and prevent opioid overdose, with the immediate aim of preventing further increases in these negative outcomes. Specifically, HHS will:
    1. Improve access to prevention, treatment and recovery support services
    2. Target the availability and distribution of overdose-reversing drugs
    3. Strengthen public health data and reporting
    4. Support cutting-edge research
    5. Advance the practice of pain management

Overview

Goal Statement
- o Reduce opioid-related morbidity and mortality through: 1) improving access to prevention, treatment and recovery support services; 2) targeting the availability and distribution of overdose-reversing drugs; 3) strengthening public health data and reporting; 4) supporting cutting-edge research; and 5) advancing the practice of pain management.
- o Starting from the baseline of September 30, 2017, by September 30, 2019:
  1. Reduce opioid prescribing as measured by morphine milligram equivalents (MME) :
     a. Decrease by 25% the MME of opioid analgesics dispensed in U.S. outpatient retail and mail service pharmacies
     b. Decrease by 10% the morphine milligram equivalents (MME) per prescription in opioid analgesic prescriptions dispensed in U.S. outpatient retail and mail service pharmacies.
  2. Increase naloxone access:
     a. Increase by 30% the number of prescriptions dispensed for naloxone in U.S. outpatient retail and mail service pharmacies.
  3. Increase uptake of medications for the treatment of opioid use disorder:
     a. Increase by 25% the number of unique patients receiving prescriptions for buprenorphine in U.S. outpatient retail pharmacies (excluding implantable or long-acting injection products).
     b. Increase by 100% the number of prescriptions for long-acting injectable or implantable buprenorphine from retail, long-term care, and mail service pharmacies in the U.S.
     c. Increase by 25% the number of prescriptions for extended-released naltrexone from retail, long-term care, and mail-order pharmacies in the U.S.

Goal Structure & Strategies

Strategy: Improve access to prevention, treatment, and recovery support services

Rationale: Access to prevention, treatment and recovery support services are crucial for reducing the public health burden of opioid use disorder (OUD). Medication-assisted treatment (MAT) is the standard of care for OUD, and has been shown to reduce drug use and associated risky behavior and negative health outcomes. Very few of those who need MAT receive it at all, and fewer still receive it for a therapeutic duration of time. The activities below support improved services access, and quantitative progress will be reflected in the indicator tracking increased uptake of medications for the treatment of OUD.

AGENCY	ACTIVITY
AHRQ	To advance the field of evidence-based clinical decision support, AHRQ will create clinical decision support artifacts for safe opioid prescribing and make them publicly available through their national CDS Connect Repository.
CDC	CDC's Opioid Prevention in States (OPIS) initiative will continue to equip states in supporting opioid overdose prevention efforts, including the enhancement of PDMPs within clinical and public health settings, insurer and community interventions, evaluation of state-level policies, and other innovative strategies that states can employ.
CDC	CDC will continue to support implementation of the RxAwareness campaign, which educates consumers on the risks of prescription opioids, and will evaluate the campaign launch.
CDC	As part its partnership with law enforcement and High Intensity Drug Trafficking Areas, CDC will support the piloting of 13 community-level projects through the Heroin Response Strategy which will help inform responses to opioid overdoses at the local level.

Goal Structure & Strategies

AGENCY	ACTIVITY
Strategy: Improve access to prevention, treatment, and recovery support services (continued)	
CDC	CDC will help communities prevent and combat infectious diseases stemming from the opioid crisis by tracking disease patterns, alerting states to risks of disease outbreaks, and supporting proven prevention strategies, including those for engaging people who inject drugs into treatment.
CDC	CDC will continue to provide guidance to emergency responders to prevent occupational exposure to fentanyl including through the Health Hazard Evaluations (HHE) Program.
CMS	CMS will continue to work with states to support and to improve opioid use prevention and treatment efforts, including medication-assisted treatment and alternative treatments (e.g. 1115 opioid/SUD demonstration waivers, including certain Institution for Mental Disease (IMD) facility exclusion waivers, quality metrics, technical assistance).
CMS	CMS will improve provider education and outreach efforts and introduce new tools and data sources that provide information to help reduce overprescribing and support efforts in response to the crisis (e.g. Opioid heat map, data based reports and Component-specific education efforts).

Goal Structure & Strategies

AGENCY	ACTIVITY
Strategy: Improve access to prevention, treatment, and recovery support services (continued)	
CMS	CMS will look to integrate responses to the opioid crisis into CMS regulations and sub-regulatory guidance (e.g., integrating the CDC guidelines into Medicare payment rules and conditions of participation).
HRSA	HRSA will provide additional funding and ongoing technical support to: ● Health centers to further increase capacity to provide substance abuse services, focusing on the treatment, prevention, and awareness of opioid misuse and their integration into primary care. ● Rural health organizations to improve the overall health and well-being of rural residents through the delivery of opioid related prevention (education and outreach), treatment, and recovery efforts.
HRSA	HRSA is supporting the National Governors Association's Preventing NAS Learning Lab, a six-month effort to improve states' capacity to prevent and reduce opioid-related NAS. This project will take place January - August 2018.
HRSA	HRSA-funded Rural Research Centers are expected to continue producing policy briefs and other publications addressing opioid use in rural areas in 2018.

Goal Structure & Strategies

AGENCY	ACTIVITY
**Strategy: Improve access to prevention, treatment, and recovery support services (continued)**	
IHS	IHS will increase access to MAT services via: ● Telemedicine models through adoption of an IHS Internet Eligible Controlled Substance Prescriber policy ● Tracking of IHS prescribers authorized to prescribe buprenorphine ● Development of mandatory training at all levels of IHS staff on the opioid epidemic
IHS	IHS will develop a comprehensive neonatal abstinence syndrome guideline to improve screening, detection, and referral to treatment for pregnant and parenting individuals.
NIH	NIH's NIDA supports a portfolio of implementation science research to improve the dissemination, use, and sustainability of evidence- based treatment of OUD.
NIH	NIH's NIDA supports a portfolio of clinical research for rigorous study of: ● Comparative effectiveness of treatments for OUD ● Clinical decision support for OUD management in general healthcare settings ● Emergency department linkage to care for OUD ● Infant outcomes to inform MAT choices for OUD during pregnancy

Goal Structure & Strategies

AGENCY	ACTIVITY
Strategy: Improve access to prevention, treatment, and recovery support services (continued)	
NIH	NIH's NIDA supports NIDAMED, a clinician education and outreach program that develops and disseminate science-based resources on opioids and substance use disorder (SUD) that educate health professionals and those in training about screening, addressing, and treating SUD; and enhancing awareness of addiction as a treatable brain disorder.
SAMHSA	Continue to provide national leadership and support to advance prevention efforts through the following programs: ● State Opioid Response, State Targeted Response, and Tribal Opioid Response grant funding and targeted technical assistance ● Substance Abuse Prevention and Treatment block grant prevention set aside ● Strategic Prevention Framework Partnership for Success (SPF-PFS) and Strategic Prevention Framework for Prescription Drugs (SPF-Rx) ● Drug Free Communities Support Program and the Community-based Coalition Enhancement Grants

Goal Structure & Strategies

AGENCY	ACTIVITY
Strategy: Improve access to prevention, treatment, and recovery support services (continued)	
SAMHSA	Continue to provide national leadership and support to expand access to treatment services through the following: ● State Opioid Response, State Targeted Response, and Tribal Opioid Response grant funding and targeted technical assistance ● Substance Abuse Prevention and Treatment block grant ● MAT for Prescription Drug and Opioid Addiction (MAT PDOA) grants ● Targeted funding such as the Pregnant and Postpartum Women treatment grants and Drug Court grants ● Oversight of Opioid Treatment Programs and the DATA waiver process ● Provision of education and training via PCSS-MAT ● Leveraging the Addiction Technology Transfer Centers (TTCs) and other TTCs and training and technical assistance programs ● Publication of TIP 63 "Medications for Opioid Use Disorder" and other evidence-based resources
SAMHSA	Continue to provide national leadership and support for the broader dissemination and implementation of recovery support services through the following: ● Building Communities of Recovery grants ● State Opioid Response, State Targeted Response, and Tribal Opioid Response grant funding and targeted technical assistance ● Dissemination of Best Practices from the SAMHSA Policy Lab ● Leveraging the Addiction Technology Transfer Centers (TTCs) and other TTCs and training and technical assistance programs

Goal Structure & Strategies

Strategy: Target the availability and distribution of overdose-reversing drugs

Rationale: Opioid overdose can be reversed by the opioid antagonist naloxone. Naloxone is a vital tool in the fight against opioid overdose, though issues of access and increasing potency of illicit opioids pose practical challenges. The activities below support improved access to overdose reversal medication, and quantitative progress will be reflected in the indicator tracking increased naloxone access.

AGENCY	ACTIVITY
AHRQ	AHRQ will continue to disseminate the findings of their recently completed systematic evidence review on the Management of Suspected Opioid Overdose with Naloxone by Emergency Medical Services Personnel which was released in late November.
FDA	Model Drug Facts Label Comprehension Study for OTC naloxone to be completed by FDA in Spring 2019
IHS	IHS is developing an Indian Health Manual policy to issue naloxone to law enforcement agencies and other first responders and is expanding the number of pharmacist collaborative practice agreements to prescribe naloxone.
NIH	NIH's NIDA supports research to: ● Evaluate naloxone distribution programs ● Develop novel overdose reversal medications
SAMHSA	Continue to provide national leadership and support for naloxone and overdose prevention through the following: ● CARA First Responders grant funding ● State Opioid Response, STR, TOR, and targeted technical assistance ● Preventing Prescription Drug/Opioid Overdose Related Deaths grant funding ● Substance Abuse Prevention and Treatment block grant

Goal Structure & Strategies

Strategy: Strengthen public health data and reporting	
Rationale: In order to most effectively address resources and tailor strategy to the areas and populations most affected by the opioid crisis, it is crucial to have accurate and timely data reporting. The activities below address improved public health data concerning opioid addiction and overdose.	

AGENCY	ACTIVITY
AHRQ	AHRQ will update their HCUP Fast Stats public web-portal to include state and national level trends in opioid related hospital and emergency department use with 2017 data allowing local and regional decision makers to understand trends in their communities as they develop local responses to the crisis.
CDC	CDC's Enhanced State Opioid Overdose Surveillance (ESOOS) program will improve the timeliness of reporting of nonfatal and fatal opioid overdoses and associated risk factors in 33 funded states, using innovative strategies such as syndromic surveillance and improved reporting of toxicology and death scene investigations.
CDC	Through the OPIS initiative, CDC will support using prescribing data to inform community responses, such as implementing academic detailing for providers in high prescribing communities. CDC will also continue to leverage data from QuintilesIMS, which helped inform county-level prescribing maps, for broad data dissemination and evaluation activities in 2018.
HRSA	HRSA will collect quarterly progress report data from HRSA grantees to measure program outcomes and track progress related to opioid related activities, including: ● 1,178 health centers grantees who received $200 million from HRSA in September 2017 to increase access to substance abuse and mental health services. ● 13 rural health organizations who received nearly $3.1 million in HRSA funding in September 2017 under the Rural Health Opioid Program and the Substance Abuse Treatment Telehealth Network Grant Program.

Goal Structure & Strategies

AGENCY	ACTIVITY
Strategy: Strengthen public health data and reporting (continued)	
IHS	IHS tracks key metrics to follow opioid prescribing trends, naloxone distribution patterns, buprenorphine prescribing, and diagnosis of opioid use disorders across IHS facilities.
NIH	NIH's NIDA supports the National Drug Early Warning System, which is a nationwide public health surveillance system to monitor emerging drug use trends to enable quick response to potential outbreaks of illicit drugs such as heroin and to identify increased use of designer synthetic compounds.
NIH	NIH's NIDA supports the Monitoring the Future Study, which measures drug use and related attitudes among a national sample of 8th, 10th, and 12th graders.
SAMHSA	Continue to provide critical surveillance data on the opioid crisis through the following: ● National Survey on Drug Use and Health ● Treatment Episode Data Set ● Implementation of the new Drug Abuse Warning Network ● National Survey of Substance Abuse Treatment Services

Goal Structure & Strategies

Strategy: Support cutting-edge research	
Rationale: Cutting-edge research is underway to improve existing treatments for pain, addiction, and overdose and to develop entirely new ways of understanding and addressing these serious public health issues define the current opioid crisis. The activities below support expansion of such research.	
AGENCY	**ACTIVITY**
AHRQ	AHRQ will continue their initiative exploring how to reduce barriers and support rural primary care practices providing MAT. AHRQ is also disseminating important research findings through their Academy for Integrating Behavioral Health and Primary Care, a web portal targeting primary care practices.
CDC	CDC will continue to fund innovative research to prevent opioid misuse and overdose through the Injury Control Research Centers, to conduct a longitudinal study assessing the real-world client outcomes of three types of MAT and counseling without medication for individuals with opioid use disorder, and to study adverse outcomes associated with NAS.
FDA	Fostering the Development of Novel Pain Treatment Therapies ● Support development of innovative ADFs, data to inform benefit-risk assessment ● Ensure ADF label nomenclature enables providers to adequately distinguish between the risk of abuse and the risk of addiction
NIH	To provide scientific solutions to help end the opioid crisis, NIH's NIDA, NINDS and other Institutes are supporting a wide range of research on pain and addiction, from basic science of the complex neurological pathways involved in pain and addiction, to services and implementation science to develop and test treatment models, to integrating behavioral interventions with medication-assisted therapy, to forging strategic partnerships to advance safer, non-addictive treatments for pain.

Goal Structure & Strategies

AGENCY	ACTIVITY
Strategy: Support cutting-edge research (continued)	
NIH	The NIH has launched the HEAL (Helping End Addiction Long-term) Initiative to accelerate scientific solutions to address the opioid crisis, including the development of better treatments for pain, opioid use disorder, and opioid overdose.
SAMHSA	SAMHSA is building on existing partnerships with the NIH to improve the research to practice pipeline and is committed to promoting evidence-based practices and service delivery models. The newly formed National Mental Health and Substance Use Policy Laboratory and the Office of the Chief Medical Officer is leading research efforts for SAMHSA. Additionally, the National Mental Health and Substance Use Policy Laboratory is working to address the opioid crisis through its evaluation of models that would benefit from further development and through expanding, replicating, or scaling evidence-based practices across wider areas as we seek to increase access to and delivery of the best treatment services for opioid use disorders across America.

Goal Structure & Strategies

Strategy: Advance the practice of pain management	
Rationale: Over-prescribing of opioid medications was one factor that led to the precipitous increase in opioid addiction and overdose now faced by the U.S. Improved pain management will reduce overall opioid exposure and opioid supply. The activities below support advancement in the practice of pain management, and quantitative progress will be reflected in the indicator tracking a reduction in morphine milligram equivalents.	

AGENCY	ACTIVITY
CDC	CDC will continue to support the implementation of the Guideline for Prescribing Opioids for Chronic Pain through the release of supportive materials and resources, including a series of interactive training modules addressing topics such as dosing and titration and assessing and addressing opioid use disorder. CDC is evaluating the impact of the Guideline by evaluating prescribing rates before and after the release of the Guideline.
CDC	CDC is piloting the implementation of quality improvement (QI) measures informed by the 12 recommendation statements contained in the Guideline in 6 large health care systems. These measures are intended for health systems and clinics to use as a way to track prescribing rates and provide feedback to clinicians.
CDC/AHRQ	CDC is collaborating with the Agency for Healthcare Research and Quality to assess the evidence on nonpharmacological treatments for chronic pain; the report will be finalized in 2018.
CDC/IHS	CDC is working with the National Indian Health Board (NIHB) on a 9-month project to reduce opioid overdose in tribal communities; this will include a toolkit for Tribal Health Centers and Indian Health Service facilities.

Goal Structure & Strategies

Strategy: Advance the practice of pain management (continued)	

AGENCY	ACTIVITY
IHS	In February 2018, the IHS released a revision to the Indian Health Manual Chapter 30 "Chronic Non-Cancer Pain Management." The policy revisions promote appropriate pain management, emphasize use of non-opioid/non-pharmacological treatments for pain, emphasize patient reassessment and engagement in the treatment plan. The IHS revised the "IHS Essential Training on Pain and Addiction" prescriber course to align with the revised policy and developed on-demand content with continuing medical education credits. The IHS also released an abbreviated course to serve as refresher training in January 2018.
NIH	The NIH Pain Consortium is involved with implementation of the National Pain Strategy and has published three educational modules from the Centers of Excellence in Pain Education on better pain treatment, with and without opioids.
NIH	NIH supports a broad portfolio of basic and clinical research on mechanisms of pain, novel targets for pain medications, and nonpharmacological treatments for pain. Developing improved treatments for pain is also a key focus of the NIH HEAL initiative.
SAMHSA	SAMHSA's National Mental Health and Substance Use Policy Laboratory and the Office of the Chief Medical Officer is engaging in efforts related to pain care and the appropriate use of opioid analgesics, in collaboration with HHS partners and external stakeholders. In addition, SAMHSA's PCSS MAT will include training for providers on appropriate opioid prescribing.

Summary of Progress – FY18 Q4

AHRQ

- AHRQ will continue their initiative exploring how to reduce barriers and support rural primary care practices providing medication-assisted treatment (MAT), and in August 2018 issued a special emphasis notice soliciting cutting-edge health delivery system research to address the opioid crisis. AHRQ is also disseminating important research findings through their Academy for Integrating Behavioral Health and Primary Care, a web portal targeting primary care practices.

- Release of Special Emphasis Notice: AHRQ Announces Interest in Health Services Research to Address the Opioids Crisis The purpose of this notice is to inform the research community that AHRQ is interested in receiving health services research grant applications to advance our Nation's understanding of the opioids crisis and provide solutions for addressing it.

- Release of New Web Based Toolkit: Six Building Blocks: A Team-Based Approach to Improving Opioid Management in Primary Care

Summary of Progress – FY18 Q4

CDC

o Overdose Prevention in States (OPIS) Surge Support: CDC provided funding awards to all 50 states and newly provided assistance to 4 territories with an additional $155 million under the Public Health Crisis Response mechanism Opioid Prevention in States (OPIS–S2) to scale up prevention and response activities.

o Tribal Grants: CDC is also allotting supplemental funds to 11 Tribal Epidemiology Center recipients as well as 15 tribal entities. American Indians/Alaska Natives (AI/AN) are experiencing increased mortality from opioid overdoses.

o Prescribing Estimates Project: CDC has convened two meetings of the federal advisory workgroup that is under NCIPC's Board of Scientific Counselors. The Opioid Prescribing Estimates Workgroup is providing expert input on CDC's plan for developing best practice opioid prescribing estimates for certain acute and chronic pain conditions.

CDC (cont)

o Quality Improvement and Care Coordination: CDC developed the Quality Improvement and Care Coordination: Implementing the CDC Guideline for Prescribing Opioids for Chronic Pain resource, which is intended to help healthcare systems integrate the Guideline and associated quality improvement measures into their clinical practice. This resource offers primary care providers, practices, and healthcare systems a framework for managing patients who are on long-term opioid therapy.

Summary of Progress – FY18 Q4

CMS

o Issued a series of policies in Medicare rulemaking to advance several key opioid objectives, including: 1) requested comment on a physician bundled payment for substance use disorder (SUD) treatment; 2) finalized a proposal to pay separately at average sales price plus 6 percent for non-opioid pain medications used for post-surgical pain management in ambulatory surgery centers (ASCs); 3) updated quality measures related to leveraging prescription drug monitoring programs (PDMPs), encouraging opioid use disorder (OUD) treatment plans, and removing pain-related questions that could incentivize opioid prescribing.

o Announced Integrated Care for Kids (INCK), a new model through the Center for Medicare and Medicaid Innovation (CMMI) focused on child-centered local service delivery and state payment model aimed at reducing expenditures and improving the quality of care for children covered by Medicaid and the Children's Health Insurance Program (CHIP), including for children with OUD.

o Approved two additional states' 1115 Medicaid demonstrations (Washington, New Hampshire) to increase access to OUD treatment and medication-assisted treatment, bringing the total up to 15 states with such demonstrations (11 within the past year).

Summary of Progress – FY18 Q4

FDA

o FDA is conducting an iterative, multi-modal social science research project aimed at obtaining a clearer understanding of current knowledge, attitudes, behaviors, and perceptions about opioid use, misuse, and addiction among health care providers, patients, and the lay public. Survey data collection has been completed for this project, and FDA is currently analyzing the data.

o In conjunction with the non-profit Partnership for Drug-Free Kids, FDA developed and promoted a nationwide prescriber education campaign called "Search and Rescue" that gives healthcare providers the resources they need to prescribe opioids responsibly and prevent the misuse of medicine in their practices.

o On Aug. 22, FDA awarded a contract to the National Academies of Sciences, Engineering, and Medicine (NASEM) to help advance the development of evidence-based guidelines for appropriate opioid analgesic prescribing for acute pain resulting from specific conditions or procedures.

Summary of Progress – FY18 Q4

FDA (cont)

o On Sept. 18, FDA approved the final Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS). This expanded REMS now applies to all opioid analgesics intended for outpatient use, and it includes several measures to help better communicate the serious risks regarding the use of opioid pain medications to patients and health care professionals.

o On Sept, 28, FDA awarded a social science research project exploring healthcare provider's understanding of abuse-deterrent formulation (ADF) opioids.

o In 2018 to date, FDA has conducted 12 public meetings (including seminars, workshops, advisory committees, and patient focused drug development meetings), and 6 additional public meetings are planned for the rest of 2018, including an advisory committee meeting to discuss naloxone co-prescribing.

Summary of Progress – FY18 Q4

HRSA

o In September, HRSA awarded over $396 million to combat the opioid crisis. The investments will enable HRSA-funded community health centers, academic institutions, and rural organizations to expand access to integrated substance use disorder and mental health services. This includes:

- o $352 million awarded to 1,232 community health centers across the nation to increase access to substance use disorder and mental health services through the Expanding Access to Quality Substance Use Disorder and Mental Health Services

- o $25.5 million to over 120 rural organizations to increase access to substance use prevention and treatment services serving rural populations across the country, including $19 million awarded to 95 organizations under the Federal Office of Rural Health Policy's Rural Communities Opioid Response Program-Planning, and nearly $6.5 million to 26 rural organizations to expand the reach of the Rural Health Opioid Program.

- o $18.5 million awarded to support Behavioral Health Workforce Education and Training and Enhancing Behavioral Health Workforce for Health Centers.

Summary of Progress – FY18 Q4

HRSA (cont)

o HRSA also launched the Addressing Opioid Use Disorder in Pregnant Women & New Moms Challenge, which will award prizes to support tech innovations to improve access to SUD treatment, recovery, and support services for pregnant women with opioid use disorder, their infants, and families, especially in rural and geographically isolated areas.

Summary of Progress – FY18 Q4

IHS

o IHS developed and implemented comprehensive multi-level training to address the opioid epidemic including:

  o A program to educate non-prescribing clinicians on the fundamentals of pain management and safe opioid prescribing.

  o A community-level opioid tutorial for non-healthcare providers including health system support staff, community members, school staff, and first responders.

o IHS launched a new website located at www.ihs.gov/opioids that includes information surrounding effective pain management and the opioid epidemic for AI/AN populations.

o IHS developed a comprehensive and culturally adapted neonatal abstinence syndrome guideline to improve screening, detection, and referral to treatment for pregnant and parenting individuals.

Summary of Progress – FY18 Q4

NIH

o HEAL Initiative: NIH is continuing to support cutting-edge research through the HEAL (Helping to End Addiction Long-term) Initiative, an aggressive effort to speed scientific solutions to stem the national opioid public health crisis. Research priorities include the development of new non-addictive pain medications, more flexible medication options and behavioral interventions for treating OUD, the comparison of different treatments for neonatal abstinence syndrome, and implementation science to develop and test OUD treatment models. In Q4FY18 alone, HEAL has:

   o Announced the innovative Acute to Chronic Pain Signatures Program to understand the origins of chronic pain.

   o Awarded new research grants and contracts to :

      o Develop new models for the development of pain medications.

      o Study the impact of behavioral interventions for the prevention of OUD, or as a complement to MAT for OUD. These grants coordinate with SAMHSA State Targeted Response (STR) grants.

      o Fund development of novel treatments for OUD and overdose, including medication, immunotherapies, and devices.

NIH (cont)

- o Issued new funding notices and opportunities calling for research to:
  - o Identify and validate new targets for the treatment of pain, using innovative modeling and imaging technologies.
  - o Identify biomarkers for pain diagnosis and treatment response.
  - o Develop a new network to evaluate pain medications in early-phase clinical trials.
  - o Launch the HEALing Communities Study, in collaboration with SAMHSA, to test the effect of integrating evidence-based interventions for OUD, such as MAT, in an array of community-based settings within a small number of communities hardest hit by the opioid crisis (SEE COLLABORATIVE MILESTONES).

Summary of Progress – FY18 Q4

OASH

- o Pain Management Best Practices Inter-Agency Task Force (Task Force): The Comprehensive Addiction and Recovery Act of 2016 (CARA) directs the Secretary of Health and Human Services, in cooperation with the Secretary of Veterans Affairs and Secretary of Defense, to convene the Task Force. The Task Force was established to propose updates and recommendations on clinical best practices for managing chronic and acute pain. The second public meeting of the Task Force was convened on September 25-26, 2018. The Task Force discussed draft recommendations.

- o National Pain Strategy: OASH and NIH are leading the implementation of the Strategy. It is the first coordinated plan to reduce the burden of chronic pain in the U.S.; and to achieve a system of care in which all people receive high quality, evidence-based pain care. HHS staff divisions and operating divisions, including OASH, NIH, SAMHSA, CDC, FDA, HRSA, CDC, CMS, AHRQ and IHS are identifying deliverables for 2018. For example, the Professional Education and Training Subcommittee recently met to identify an actionable mechanism to work with accreditation organizations to for educating health care professionals in ways that help reduce opioid misuse.

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Summary of Progress – FY18 Q4

SAMHSA

SAMHSA continues to focus on advancing prevention, treatment, and recovery support services, and overdose prevention through: 1) funding to build state and local capacity; 2) education, training and technical assistance; and 3) data collection, analysis and evaluation to track emerging trends, identify what works, and support the integration of evidence into practice.

o SAMHSA awarded 57 State Opioid Response (SOR) grants for a total of $930,000,000. The grants address the opioid crisis by increasing access to MAT using the three Food and Drug Administration (FDA) approved medications for the treatment of OUD, reducing unmet treatment need, and reducing opioid overdose related deaths through the provision of prevention, treatment, and recovery activities for OUD. States received funding based on a formula, with a 15 percent set-aside for the ten states with the highest drug overdose mortality rate.

o SAMHSA awarded 134 Tribal Opioid Response (TOR) grants for a total of $50 million. The grants address the opioid crisis in tribal communities by increasing access to culturally appropriate and evidence-based treatment, including MAT.

SAMHSA (cont)

o SAMHSA awarded the Rural Opioids Technical Assistance Grants (ROTA) of about $8.3 million to 13 grantees. This program is a collaborative effort with USDA in which SAMHSA awarded supplements to existing Cooperative Extension grants to develop and disseminate training and technical assistance for rural communities on addressing opioid issues.

o In September 2018, SAMHSA awarded the Prevention Technology Transfer Centers Cooperative Agreements (PTTC) of about $7 million to 12 grantees. These grants comprise a regional network of training and technical assistance focused on substance misuse prevention, including opioids. These grants will work with the Addiction Technology Transfer Centers (ATTCs) which will provide training on the treatment of substance use disorders, including opioid use disorders.

o In support of training and education, SAMHSA announced the availability of funding for the three-year Provider's Clinical Support System – Universities grant program. In September 2018, SAMHSA awarded 28 three-year grants for a total of about $4 million. These programs will expand/enhance access to MAT services for persons with an OUD seeking or receiving MAT through ensuring the education and training of students in the medical, physician assistant and nurse practitioner fields.

SAMHSA (cont)

o SAMHSA awarded the Center of Excellence for Protected Health Information Related to Mental and Substance Use Disorders (CoE-PHI) of $1 million to 1 grantee. The purpose of this program is to establish one National Center of Excellence to develop and disseminate training, technical assistance, and educational resources for healthcare practitioners, families, individuals, states, and communities on privacy laws and regulations related to mental and substance use disorders.

o In September 2018, SAMHSA awarded 128 Targeted Capacity Expansion: Medication Assisted Treatment – Prescription Drug and Opioid Addiction (MAT-PDOA) grants to public and private non-profit organizations and tribes and tribal organizations. These organizations are located in states with the highest rates of primary treatment admissions for heroin and opioids per capita and include those with the most dramatic increases for heroin and opioids, as identified by SAMHSA's 2015 Treatment Episode Data Set.

Summary of Progress – FY18 Q4

SAMHSA (cont)

o   SAMHSA's Grants to Prevent Prescription Drug and Opioid Overdose-Related Deaths (PDO), first funded in FY2016, and First Responders Comprehensive Addiction and Recovery Act (FR-CARA) grantees, first funded in FY2017, address prescription drug/opioid overdose-related deaths by providing prevention training to first responders and other key community sectors and improving access to naloxone/other FDA approved opioid-overdose reversal kits. To date, PDO and FR-CARA grantees led over 6,200 training events and successfully distributed over 67,000 opioid overdose reversal kits. They reported 6,411 administration events and the successful reversal of 6,000 opioid overdoses.

o   As required by law, SAMHSA is currently engaged in the National Academy of Sciences' review of the Comprehensive Addiction and Recovery Act (CARA) programs. CARA programs to be reviewed are the Pregnant and Partum Women (PPW) Pilot, Building Communities of Recovery (BCOR); First Responder; and Improving Access to Overdose Treatment (OD Treatment Access). This review will be shared as interim and final reports to Congress, in 2021 and 2023 respectively.

SAMHSA (cont)

o SAMHSA developed and released the following publications: Implementing Tobacco Cessation Programs in Substance Use Disorder Treatment Settings (June 2018); Updated: Opioid Overdose Prevention Toolkit (September 2018); and the Healthy Pregnancy Healthy Baby Fact Sheets (September 2018).

Collaborative Milestones

Special Populations

- On July 24, 2018, CDC, CMS, IHS, NIH, SAMHSA and Office of Minority Health (OMH) held the first Partnerships to Advance Tribal Health (PATH) National Town Hall event on Combatting Opioids and other Substance Abuse in Tribal Communities and a Joint Tribal Advisory Committee meeting comprising tribal leaders from the tribal advisory committees of SAMHSA, CDC, CMS, IHS, NIH, and OASH. The purpose was to create a forum for sharing information on the Department of Health and Human Services (HHS's) 5-Point Strategy to Combat the Opioids Crisis that supports tribal communities; tribal prevention, treatment, and recovery models that are making a difference in reducing opioid and other substance abuse; and opportunities for maximizing existing resources in the future. Over 120 people participated in person and over 8,500 engaged online through livestream and social media.

- SAMHSA continues to engage with the Department of Agriculture (USDA) and the Department of Justice (DOJ) to advance efforts related to rural opioid use disorder prevention and treatment.

Collaborative Milestones

HEALing Communities

- NIH/NIDA, in collaboration with SAMHSA, will support the HEALing Communities Study to test the immediate impact of implementing an integrated set of evidence based practices for prevention and treatment of OUD in select communities with high rates of opioid overdose mortality, with a focus on significantly reducing opioid overdose fatalities by 40%.

- An integrated set of evidence-based interventions will be tested across healthcare, behavioral health, justice, and other community-based settings.

- Targeted areas for intervention include decreasing the incidence of opioid use disorder, increasing the number of individuals receiving medications for opioid use disorder treatment, increasing treatment retention beyond 6 months, receiving recovery support services, and expanding the distribution of naloxone.

- This research will help define community prevention and treatment models that are most likely to reduce addiction and overdose deaths in communities nationwide.

Collaborative Milestones

o The HHS Behavioral Health Coordinating Council (BHCC) Activities: The BHCC is co-chaired by the Assistant Secretary for Health and the Assistant Secretary for Mental Health and Substance Use. It is a coordinating body consisting of HHS Operating Divisions and Staff Divisions that provides guidance and recommendations on HHS behavioral health issues, including those relevant to opioid use.

   o The Integrated Behavioral Health and Primary Care Subcommittee is focused on advancing telemedicine and Medication-Assisted Treatment and is developing additional guidance for providers and grantees.

   o Protecting Our Infants Act Strategy : The Opioids and Controlled Substances Subcommittee is implementing a work plan for the Protecting Our Infants Act Strategy and drafting a report to Congress under the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 to address the balance between patient access to controlled substances and measures to prevent diversion and misuse.

Key Indicators : Fiscal Year 2018 Fourth Quarter (Through September 2018)

Indicator	Target Value Q4FY18	Actual Value Q4FY18	Final Target Value FY19
Total morphine milligram equivalents dispensed	33 billion	32 billion	29 billion
Morphine milligram equivalents /prescription	755	754	713
Naloxone prescriptions	100,656	211,014	113,785*
Unique buprenorphine patients	663,233	653,737	736,925
Long-acting injectable or implantable buprenorphine prescriptions	95	1,635	126*
Extended release naltrexone prescriptions	72,378	69,697	80,420

*Target revision pending

o   Total morphine milligram equivalents dispensed in BILLIONS

Q2FY13	51
Q3FY13	51
Q4FY13	51
Q1FY14	51
Q2FY14	49
Q3FY14	50
Q4FY14	50
Q1FY15	49
Q2FY15	46
Q3FY15	47
Q4FY15	47
Q1FY16	47
Q2FY16	46
Q3FY16	45
Q4FY16	44
Q1FY17	43
Q2FY17	41
Q3FY17	40
Q4FY17	38
Q1FY18	37
Q2FY18	35
Q3FY18	34
Q4 FY18	32
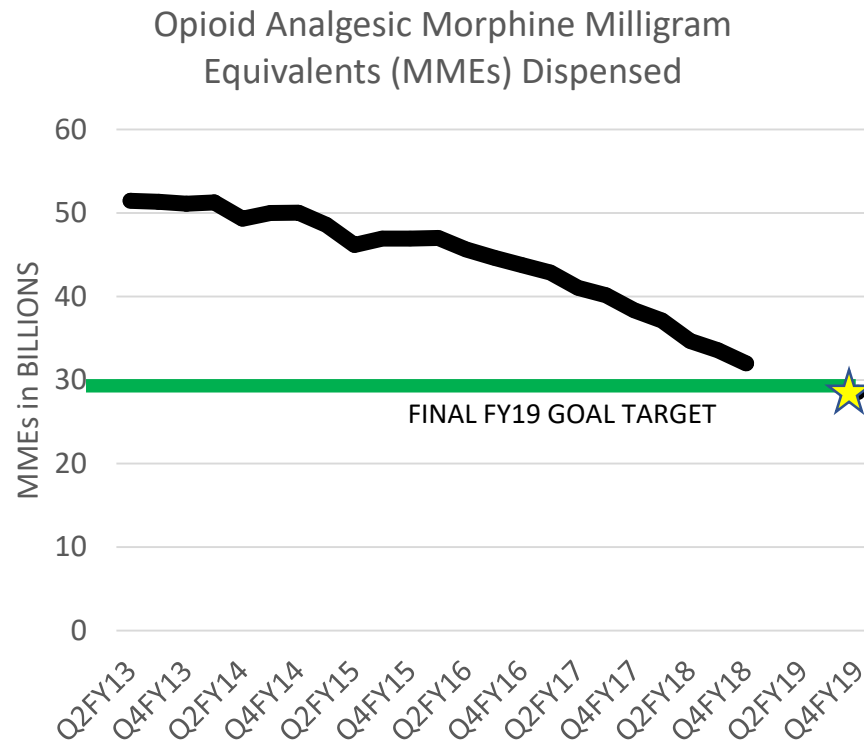
Opioid Analgesic Morphine Milligram Equivalents (MMEs) Dispensed

FINAL FY19 GOAL TARGET

Source: IQVIA National Prescription Audit (NPA). Retrieved October 29, 2018. Note: These data are for the retail and mail service channels only and do not include the long-term care channel in NPA.

• Key Indicators

o Morphine milligram equivalents per prescription

Q2FY13	820
Q3FY13	808
Q4FY13	803
Q1FY14	808
Q2FY14	806
Q3FY14	795
Q4FY14	794
Q1FY15	829
Q2FY15	824
Q3FY15	817
Q4FY15	813
Q1FY16	820
Q2FY16	822
Q3FY16	820
Q4FY16	813
Q1FY17	813
Q2FY17	805
Q3FY17	801
Q4FY17	795
Q1FY18	790
Q2FY18	779
Q3FY18	765
Q4 FY18	754

Opioid Analgesic Morphine Milligram Equivalents (MMEs) per Prescription
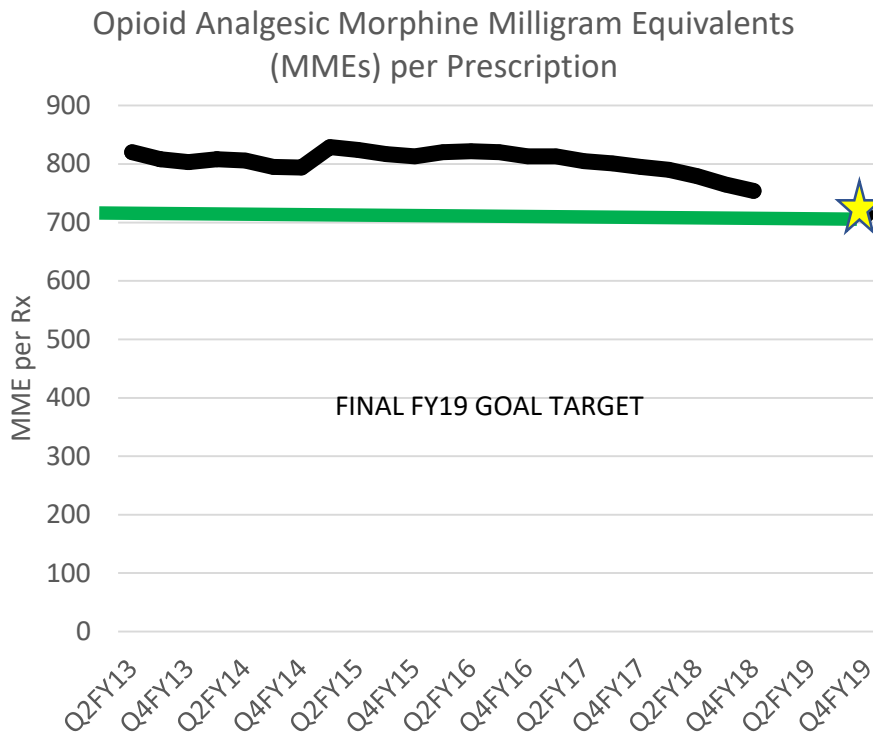
FINAL FY19 GOAL TARGET

Source: IQVIA National Prescription Audit (NPA). Retrieved October 29, 2018. Note: These data are for the retail and mail service channels only and do not include the long-term care channel in NPA.

• Key Indicators

o Number of naloxone prescriptions dispensed

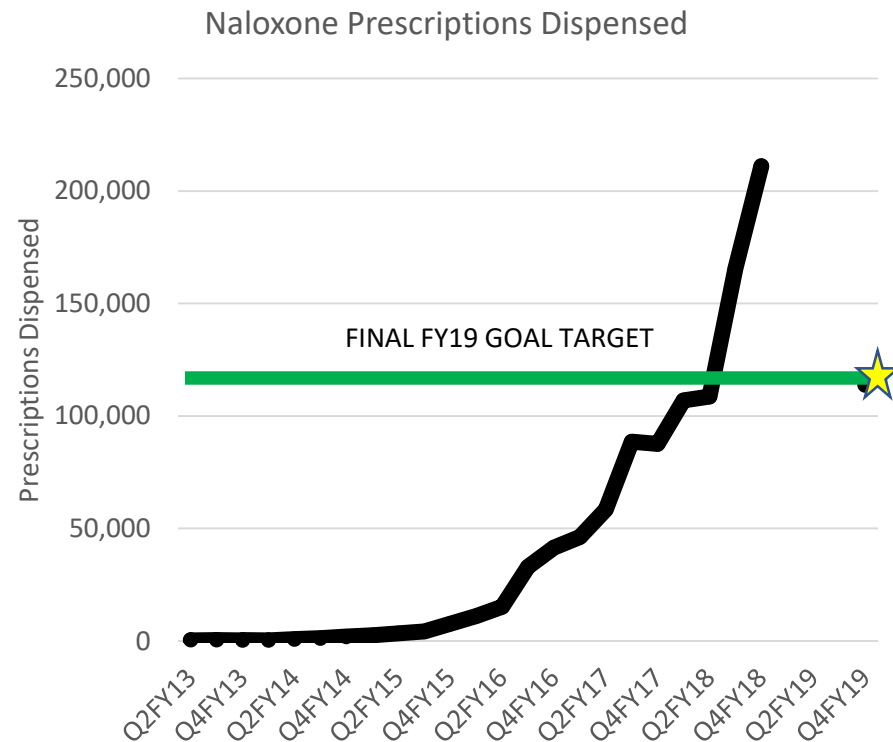|	
Q2FY13	436
Q3FY13	464
Q4FY13	352
Q1FY14	340
Q2FY14	798
Q3FY14	1,269
Q4FY14	2,048
Q1FY15	2,490
Q2FY15	3,343
Q3FY15	4,295
Q4FY15	7,687
Q1FY16	11,056
Q2FY16	15,170
Q3FY16	33,050
Q4FY16	41,493
Q1FY17	46,218
Q2FY17	58,473
Q3FY17	88,607
Q4FY17	87,527
Q1FY18	106,864
Q2FY18	108,702
Q3FY18	165,446
Q4 FY18	211,014

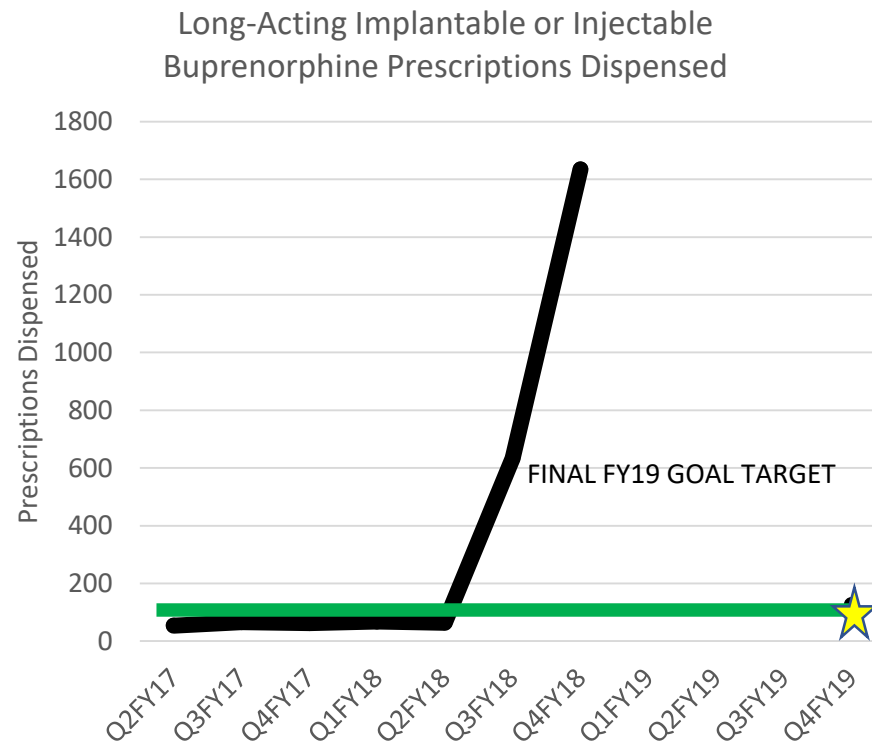Naloxone Prescriptions Dispensed

FINAL FY19 GOAL TARGET

Source: IQVIA National Prescription Audit (NPA). Retrieved October, 2018. Note: These data are for the retail and mail service channels only and do not include the long-term care channel in NPA.

• Key Indicators

o Number of long-acting implantable or injectable buprenorphine prescriptions dispensed

Q2FY17	54
Q3FY17	66
Q4FY17	63
Q1FY18	68
Q2FY18	64
Q3FY18	633
Q4 FY18	1,635

Long-Acting Implantable or Injectable Buprenorphine Prescriptions Dispensed

FINAL FY19 GOAL TARGET

Source: IQVIA National Prescription Audit (NPA). Retrieved October 29, 2018.

Key Indicators

o   Number of extended-release naltrexone prescriptions dispensed

Q2FY13	10,251
Q3FY13	11,442
Q4FY13	12,143
Q1FY14	12,438
Q2FY14	12,525
Q3FY14	15,687
Q4FY14	17,950
Q1FY15	19,350
Q2FY15	20,830
Q3FY15	25,286
Q4FY15	28,058
Q1FY16	30,758
Q2FY16	35,566
Q3FY16	44,877
Q4FY16	50,167
Q1FY17	55,155
Q2FY17	58,205
Q3FY17	64,864
Q4FY17	64,336
Q1FY18	64,982
Q2FY18	64,775
Q3FY18	70,523
Q4 FY18	69,697
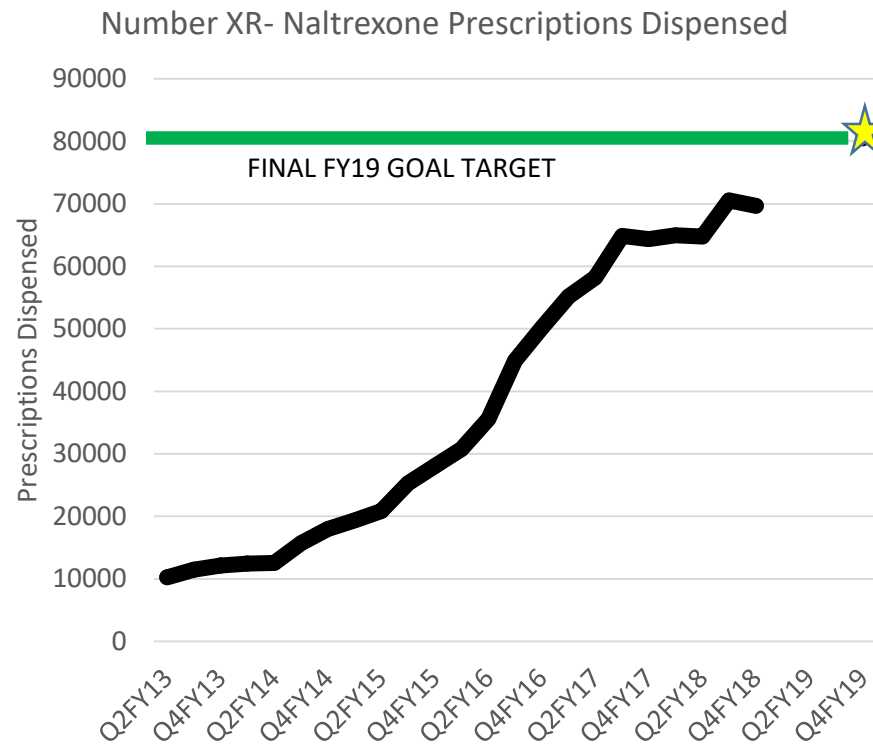
Number XR- Naltrexone Prescriptions Dispensed

FINAL FY19 GOAL TARGET

Source: IQVIA National Prescription Audit (NPA). Retrieved October 29, 2018.

• Key Indicators

o Number of unique patients receiving buprenorphine

Unique Patients Receiving Buprenorphine

FINAL FY19 GOAL TARGET
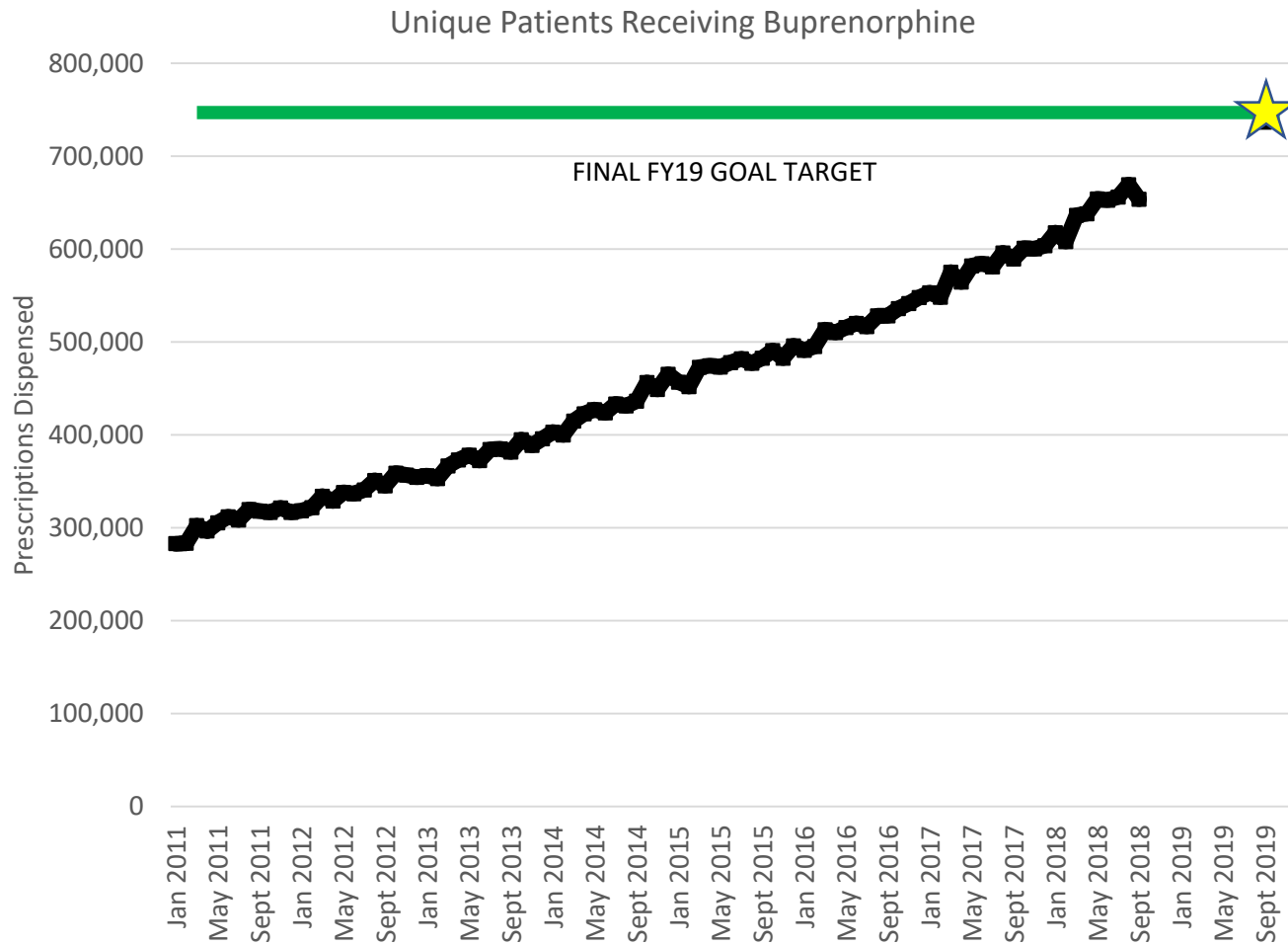
Source: IQVIA Total Patient Tracker. Retrieved October 29, 2018.

Key Indicators

o Number of unique patients receiving buprenorphine (data corresponds to previous graph)

Jan 2011	282,680
Feb 2011	283,299
Mar 2011	302,038
Apr 2011	296,560
May 2011	305,414
Jun 2011	311,828
Jul 2011	308,331
Aug 2011	319,571
Sept 2011	318,069
Oct 2011	316,515
Nov 2011	321,562
Dec 2011	316,717
Jan 2012	318,347
Feb 2012	321,877
Mar 2012	334,108
Apr 2012	328,860
May 2012	337,959
Jun 2012	336,796
Jul 2012	340,684
Aug 2012	351,043
Sept 2012	345,195
Oct 2012	358,867
Nov 2012	356,973
Dec 2012	354,349

Jan 2013	356,217
Feb 2013	352,936
Mar 2013	366,672
Apr 2013	373,083
May 2013	378,071
Jun 2013	372,519
Jul 2013	384,453
Aug 2013	385,154
Sept 2013	381,482
Oct 2013	394,861
Nov 2013	388,896
Dec 2013	395,822
Jan 2014	403,103
Feb 2014	400,008
Mar 2014	415,101
Apr 2014	422,673
May 2014	427,300
Jun 2014	423,909
Jul 2014	433,507
Aug 2014	431,412
Sept 2014	436,368
Oct 2014	456,588
Nov 2014	448,999
Dec 2014	465,204

Jan 2015	456,933
Feb 2015	451,952
Mar 2015	472,956
Apr 2015	474,673
May 2015	473,289
Jun 2015	477,787
Jul 2015	482,037
Aug 2015	477,343
Sept 2015	482,757
Oct 2015	490,729
Nov 2015	482,648
Dec 2015	495,938
Jan 2016	491,135
Feb 2016	495,341
Mar 2016	513,216
Apr 2016	510,109
May 2016	515,682
Jun 2016	520,109
Jul 2016	516,827
Aug 2016	528,396
Sept 2016	528,292
Oct 2016	536,006
Nov 2016	541,688
Dec 2016	547,869

Jan 2017	553,127
Feb 2017	548,236
Mar 2017	575,146
Apr 2017	564,749
May 2017	581,884
Jun 2017	584,361
Jul 2017	581,081
Aug 2017	596,044
Sept 2017	589,540
Oct 2017	600,979
Nov 2017	600,495
Dec 2017	603,720
Jan 2018	617,767
Feb 2018	608,144
Mar 2018	636,506
Apr 2018	638,066
May 2018	654,147
Jun 2018	652,682
July 2018	656,350
Aug 2018	669,400
Sept 2018	653,737

Source: IQVIA Total Patient Tracker. Retrieved October, 29 2018.