

Agency Priority Goal Action Plan

Reducing Opioid Morbidity and Mortality

Goal Leaders:

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Overview

Challenge

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.

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.

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

AGENCY	ACTIVITY
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).

Strategy: Improve access to prevention, treatment, and recovery support services (continued)	
AGENCY	ACTIVITY
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 sixmonth 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.

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

AGENCY	ACTIVITY
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

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

AGENCY	ACTIVITY
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

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

AGENCY	ACTIVITY
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

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

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.

nealth 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.

Strategy: Strengthen public health data and reporting (continued)	
AGENCY	ACTIVITY
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

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.

Strategy: Support cutting-edge research (continued)	
AGENCY	ACTIVITY
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.

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.

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 ondemand 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.

Overview Summary of Progress – FY 2019 Q4

- o **APG Close-Out Statement:** HHS will continue this goal area for the FY 2020-2021 APG cycle.
- o AHRQ released its Medication-Assisted Treatment for Opioid Use Disorder Playbook and accompanying Medication-Assisted Treatment Tools and Resources Collection as resources for the implementation of MAT in primary care and other ambulatory care settings.
- CDC announced the awards for Overdose Data to Action (OD2A) to 47 states, Washington D.C, two territories, and 16 counties and cities, totaling over \$900 million spread across 3 years.
 - o Funded programs will yield information crucial to a better understanding of why, and among whom, overdoses and deaths are taking place.
 - o CDC and HHS will rapidly use that information to enhance prevention and response efforts across the country.
- o CMS approved section 1115 demonstrations in Delaware and Ohio—the 25th and 26th states to receive approval for these demonstrations—to increase access to and quality treatment for Opioid Use Disorder (OUD) and other Substance Use Disorders (SUDs) and issued guidance to States regarding the extended availability of enhanced matching funds for certain Medicaid health homes for individuals with SUD.
- o FDA issued a statement on the agency's continued efforts to increase availability of all forms of naloxone to help reduce opioid overdose deaths, and announced the approval of new packaging for brand-name over-the-counter loperamide to help curb misuse.

Overview Summary of Progress – FY 2019 Q4

- O HRSA issued approximately 1,100 awards totaling \$85 million through the Substance Use Disorder (SUD) Workforce Loan Repayment Program, which will support the recruitment and retention of health professionals needed in underserved areas to expand access to SUD treatment and prevent overdose deaths.
- o IHS completed Tribal Consultation and Urban Confer on the Special Behavioral Health Pilot Program to combat the opioid epidemic by developing a grant program on culturally appropriate prevention, treatment, and aftercare services for mental health and substance use disorders
- O NIH awarded approximately \$945 million to 375 research projects in 41 states under its HEAL (Helping to End Addiction Long-term) Initiative in FY19, and the majority of these grants were awarded in Q4. heal.nih.gov was launched to serve as a comprehensive resource on the research supported by HEAL.
- o SAMHSA's Comprehensive Addiction Recovery Act grants successfully distributed 49,004 opioid overdose reversal kits, held 9,611 administration events, and contributed to the successful reversal of 5,607 opioid overdoses.
- o HEALing Communities Study (NIH, SAMHSA) completed the pilot phase and began collection of baseline data.

Key Indicators: FY 2019 Q4

Total morphine milligram equivalents (MMEs)

change starting from the baseline of the new dataset.

Indicator

dispensed

MMEs /prescription

Naloxone prescriptions	238,609	257,310**
Unique buprenorphine patients	723,132	728,890
Long-acting injectable or implantable buprenorphine prescriptions	7,249	5,086**
Extended release naltrexone prescriptions	80, 129	75,978
*IQVIA has adjusted their data reporting to remove prescriptions that are voided or reversed. This caused a break in the trendline between FY 2018 and FY 2019. Goals have been revised to reflect the FY 2019 portion of desired		

Actual Value

Q4 FY 2019

27.5 billion

718

Final Target Value* Q4 FY

2019

718

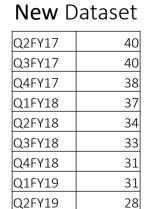
29 billion

^{**}HHS revised the naloxone goal to be more ambitious based on a linear projection of 2017-2018 data. The new goal is an 150 percent increase in prescriptions in FY 2019.

Total morphine milligram equivalents dispensed in BILLIONS

Original Dataset

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

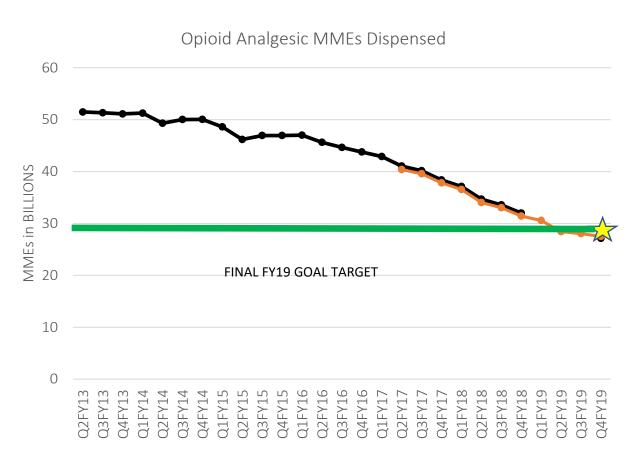


28

28

Q3FY19

Q4FY19

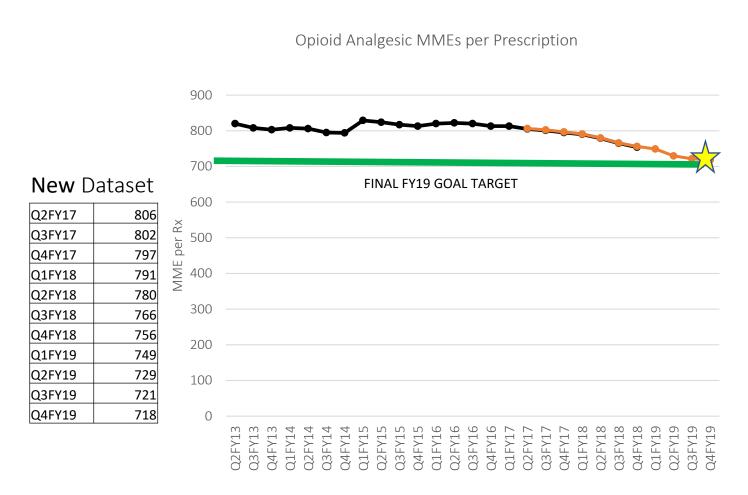


Source: IQVIA National Prescription Audit. Retrieved October 2018 and November 2019. Note: These data are for the retail and mail service channels only and do not include the long-term care channel.

Morphine milligram equivalents per prescription

Original Dataset

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



Source: IQVIA National Prescription Audit. Retrieved October 2018 and November 2019. Note: These data are for the retail and mail service channels only and do not include the long-term care channel.

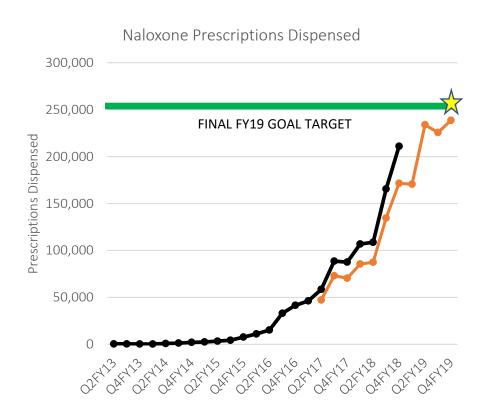
Number of naloxone prescriptions dispensed

Original Dataset

- 18111611	
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

New Dataset

Q2FY17	47,166
Q3FY17	73,014
Q4FY17	70,395
Q1FY18	85,497
Q2FY18	87,429
Q3FY18	134,539
Q4FY18	171,540
Q1FY19	170,575
Q2FY19	233,896
Q3FY19	225,618
Q4FY19	238,609



Source: IQVIA National Prescription Audit. Retrieved October, 2018 and November 2019. Note: These data are for the retail and mail service channels only and do not include the long-term care channel.

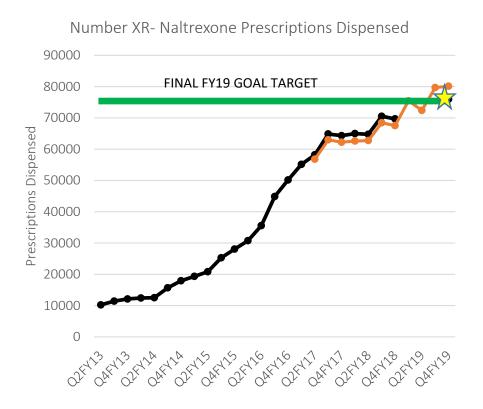
Number of extended-release naltrexone prescriptions dispensed

Original Dataset

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

New Dataset

Q2FY17	56,803
Q3FY17	62,994
Q4FY17	62,242
Q1FY18	62,602
Q2FY18	62,758
Q3FY18	68,457
Q4FY18	67,536
Q1FY19	75,480
Q2FY19	72,416
Q3FY19	79,709
Q4FY19	80,129



Source: IQVIA National Prescription Audit. Retrieved October 2018 and November 2019.

Number of long-acting implantable or injectable buprenorphine prescriptions dispensed

Original **Dataset**

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

New Dataset

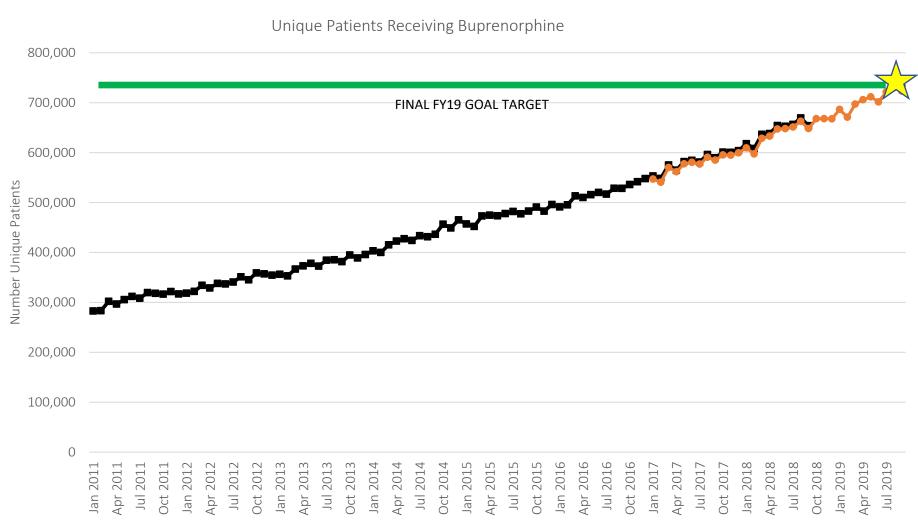
Q4FY18	1,626
Q1FY19	3,046
Q2FY19	4,283
Q3FY19	5,873
Q4FY19	7,249





Source: IQVIA National Prescription Audit. Retrieved October 2018 and November 2019.

Number of unique patients receiving buprenorphine



Source: IQVIA Total Patient Tracker. Retrieved October 2018 and November 2019.

Original Dataset

Original	
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

356,217
352,936
366,672
373,083
378,071
372,519
384,453
385,154
381,482
394,861
388,896
395,822
403,103
400,008
415,101
422,673
427,300
423,909
433,507
431,412
436,368
456,588
448,999
465,204

456,933
451,952
472,956
474,673
473,289
477,787
482,037
477,343
482,757
490,729
482,648
495,938
491,135
495,341
513,216
510,109
515,682
520,109
516,827
528,396
528,292
536,006
541,688
547,869

New Dataset

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

Oct 2018	667,972
Nov 2018	667,822
Dec 2018	667,642
Jan 2019	686,480
Feb 2019	670,931
Mar 2019	697,074
Apr 2019	705,856
May 2019	711,712
Jun 2019	701,607
July 2019	721,634
Aug 2019	729,979
Sept 2019	723,132

Source: IQVIA Total Patient Tracker. Retrieved October 2018 and November 2019.

APPENDIX

AHRQ

- o Completed a technical brief on treatment of acute pain and a systematic review on treatment for substance use disorders in adolescents. Four systematic reviews to support CDC guidelines on treatment of pain are scheduled for completion in 2020.
- o Awarded two contracts, a technical brief and a pilot project, to improve the understanding and management of opioid analgesics in older adults and to lay the groundwork for future research. Results will be available in 2020.
- o On October 1, 2019, AHRQ released its Medication-Assisted Treatment for Opioid Use Disorder (MAT for OUD) Playbook, which is a comprehensive guide for implementing MAT in primary care and other ambulatory care settings.
- o The MAT Tolls and Resources Collection was released with the playbook. It is a searchable resource organized by topic to address a broad spectrum of patient and community needs.

CDC

- O Developed the *Quality Improvement and Care Coordination: Implementing the CDC Guideline for Prescribing Opioids for Chronic Pain* (QI/CCP) that offers healthcare systems and practices a provider-focused resource to help move the content of the CDC Guideline into clinical practice to support providers as they provide the best possible healthcare to their patients with five health systems. Recently an extension for Cohort I was approved on 7/29/19, with the new period of performance for the combined projects ending on 9/22/20.
- o Added a third pilot site at Duke Health as part of ongoing collaboration with ONC on the integration of PDMPs and EHRs. The subcontract was signed 8/28/19 with Duke, and a Kick-off meeting is being coordinated.

CMS

- o Awarded nearly \$48.5 million to 15 states to help them plan demonstrations to increase the capacity of Medicaid providers to deliver SUD treatment and recovery services.
- o Announced two new innovative model programs to support advances in the coordination of clinical care: the Maternal Opioid Misuse (MOM) model for pregnant and postpartum women and infants, and the Integrated Care for Kids (InCK) model.
- o Issued guidance on "Help for Moms and Babies" to state Medicaid agencies that creates an exception to the Institutions for Mental Diseases (IMD) limitation for pregnant and postpartum women for treatment for a SUD. This provision implements sec. 1012 of the SUPPORT Act.

CMS

- o Issued a guidance to states about SUPPORT Act sec. 1007, entitled "Caring Recovery for Infants and Babies." Under this provision, Medicaid agencies can now cover a broad array of support services for babies who were exposed to opioids before birth, including, but not limited to, assessments, development of care plans, swaddling, feeding, and specialized care of the infants.
- o Announced two new innovative model programs to support advances in the coordination of clinical care: the Maternal Opioid Misuse model for pregnant and postpartum women and infants, and the Integrated Care for Kids model.
- o Released a Request for Information and held a public listening session to gather input from stakeholders to develop an Action Plan (SUPPORT Act Sec. 6032) that will guide agency actions to prevent opioid misuse and increase access to MAT.

FDA

- o Issued joint warning letters with DEA, warning website operators illegally selling opioids on Sept. 6
- o Held a Part 15 public hearing "Standards for Future Opioid Analgesic Approvals and Incentives for New Therapeutics to Treat Pain and Addiction," to receive stakeholder input on the approval process for new opioids and how FDA might best consider the existing armamentarium of therapies, among other factors, in reviewing applications for new opioids to treat pain on Sept. 17

HRSA

- Issued awards:
 - Nine awards totaling approximately \$3.5 million through the Primary Care Training and Enhancement: Integrating Behavioral Health and Primary Care Program, which will support innovative training programs that integrate behavioral health care into primary care, particularly in rural and underserved settings, with a special emphasis on the treatment of opioid use disorder.
 - One hundred awards totaling \$10 million through the National Health Service Corps Rural Community Loan Repayment Program to support providers working in rural communities who use evidence-based treatment models to treat SUD and OUD.
 - Forty-nine awards totaling approximately \$58 million for the Opioid Workforce Expansion
 Program Professionals program, which will train behavioral health professionals in the provision
 of OUD and other SUD prevention, treatment, and recovery services in high need and high
 demand areas. Additionally, the Opioid Workforce Expansion Program Paraprofessionals
 program made 16 awards totaling approximately \$12 million.
 - Nearly \$200 million (1,208 awards) to Health Center Program recipients through the FY 2019
 Integrated Behavioral Health Services Supplemental Funding, which will increase access to high
 quality integrated behavioral health services, including prevention or treatment of mental
 health conditions and/or SUD, including OUD.
 - Eighty awards totaling \$80 million through the Rural Communities Opioid Response Program -Implementation program, for which grantees will work to strengthen and expand OUD/SUD prevention, treatment, and recovery service delivery in high-risk rural communities.

HRSA

- Issued awards (continued):
 - Twelve awards totaling \$8.2 million through the RCORP-Medication Assisted Treatment (MAT) Expansion program, for which grantees will establish or expand existing MAT programs in eligible hospitals, health clinics, or tribal organizations in order to increase the number of access points where rural individuals with OUD can receive evidence-based treatment.
 - Three awards totaling \$20 million through the RCORP-Rural Centers of Excellence on Substance Use Disorders program, which will support the identification, translation, dissemination, and implementation of evidence-based programs and best practices related to the treatment and prevention of SUD within rural communities, with a focus on the current opioid crisis.
 - Two awards totaling approximately \$3.3 million through the Strengthening Systems of Care for People Living with HIV and Opioid Use Disorder program, which will strengthen system-level collaborations and networks of care in 15 states between the Ryan White HIV/AIDS Program and other federal, state, and local entities funded to respond to the opioid epidemic to ensure access to behavioral health care and treatment for people living with HIV who have OUD.
 - Poison Control Centers continued to fight on the front line of the opioid epidemic to save lives, managing over 53,000 opioid misuse and abuse cases as of August 2019.
 - Four Phase-2 winning teams for supporting tech innovations to improve access to care for pregnant women and new moms through the Addressing Opioid Use Disorder in Pregnant Women and New Moms Challenge. The four winners received a share of \$125,000 and have advanced to Phase 3 of the challenge.

IHS

- Developed and released two Clinical Reporting System measures to monitor implementation of the IHS American College of Obstetricians and Gynecologists recommendations and track screening and referral for treatment for substance use disorder in women of child-bearing age.
- Created curriculum and conducted a pilot training session for a community-worker naloxone train-the-trainer model to increase naloxone distribution via peer models
- Developed and released an <u>opioid stewardship workbook</u> that can be customized and adopted at local and regional levels to improve opioid prescribing safety.
- O Developed and released the "E-prescribing Controlled Substance Prescriptions" (EPCS) Resource and Patient Management System software platform to improve patient safety and reduce potential for diversion or misuse of controlled substances. EPCS ensures the integrity and authenticity of controlled substance prescription transmission both internally and externally.

NIH

- o HEAL-supported 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
- o <u>heal.nih.gov</u> was launched to serve as a comprehensive resource on the research supported by HEAL.

SAMHSA

- o SAMHSA provided 57 continuation grants for the State Opioid Response program in September 2019
- o SAMHSA awarded the Provider's Clinical Support System-University grant to 20 new grantees in September 2019
- o Waivered prescribers to prescribe buprenorphine for opioid addiction treatment (as of October 5, 2019) include:
 - o For physicians: 41,802 at the 30-patient limit; 10,351 at the 100-patient limit; and 5,158 at the 275-patient limit
 - o For nurse practitioners: 10,549 at the 30-patient limit; 2,462 at the 100-patient limit; and 204 at the 275-patient limit
 - o For physician assistants: 2,787 at the 30-patient limit; 620 at the 100-patient limit; and 71 at the 275-patient limit
 - o For certified nurse specialists: 1 at the 30-patient limit and 3 at the 100-patient limit
 - o For certified nurse midwives: 2 at the 30-patient limit
 - o For certified registered nurse anesthetists: 1 at the 30-patient limit

Collaborative Milestones

HEALing Communities Study (NIH/NIDA, SAMHSA)

- o 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 percent
- Create integrated set of evidence-based interventions tested across health care, behavioral health, justice, and other community-based settings
- o Target areas for intervention: 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
- o Create defined community prevention and treatment models to reduce addiction and overdose deaths in communities nationwide

Data Accuracy and Reliability

Data is from the IQVIA (formerly IMS Health and Quintiles) suite of data derived from pharmacy, wholesaler, distributor, and other drug distribution data streams. These data are projected to the national and state level based on a proprietary algorithm. IQVIA utilizes a robust QA/QC process before releasing data, and HHS, along with many private companies, have used these data to track healthcare trends. IQVIA-derived data are in the peer-reviewed literature and have served as data inputs for HHS regulatory decisions.

One limitation of the data is that it is not possible to distinguish between medications used to treat opioid use disorder from other indications. For instance, naltrexone may be used for alcohol use disorder as well as opioid use disorder, and buprenorphine may be used in the treatment of pain as well as for opioid use disorder. Local research and other sources will be sought to address this limitation but the proportion for these other uses is not expected to shift over time. Tracking the overall number of patients treated should provide stable estimates of changes in the number of patients treated for opioid use disorder.