



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

- 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

- 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.
- 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.

Overview Summary of Progress – FY 2019 Q3

- AHRQ 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.
- CDC received applications for [Overdose Data to Action Notice of Funding Opportunity](#) from 47 states + DC, 2 territories, and 17 localities.
 - Funding will support states, eligible territories, and select cities/counties in enhancing the quality and timeliness of data on opioid prescribing and morbidity and mortality.
 - These data will inform and target prevention and response initiatives at the state and local level.
- CMS approved section 1115 demonstrations in Minnesota and Nebraska—the 23rd and 24th 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.
- FDA announced a new requirement that opioid labeling be changed to guide prescribers on how to safely and gradually taper opioids when necessary and approved the first generic naloxone nasal spray in April.

Overview Summary of Progress – FY 2019 Q3

- HRSA made 120 awards for the FY 2019 Rural Communities Opioid Response Program – Planning, totaling \$24 million.
- IHS's Tribal Consultation and Urban Confer solicited guidance on the Special Behavioral Health Pilot Program for combatting the opioid epidemic.
- NIH issued 12 grants in July 2019 to form the Justice Community Opioid Innovation Network to support research on quality addiction treatment for OUD in criminal justice settings nationwide and issued grants in four states (Kentucky, Massachusetts, New York, and Ohio) in April 2019 to support the HEALing Communities Study.
- SAMHSA released Funding Opportunity Announcements for the Drug-Free Communities Support Program, the First Responders-Comprehensive Addiction and Recovery Act, the Rural Opioid Technical Assistance Grants, the Provider's Clinical Support System-Universities Grants, and the Tribal Opioid Response Grants.
- HEALing Communities Study (NIH, SAMHSA) issued research site grant awards were issued to University of Kentucky, Lexington; Boston Medical Center, Boston; Columbia University, New York City; and Ohio State University, Columbus in April 2019

Key Indicators : FY 2019 Q3

Indicator	Target Value Q3 FY 2019	Actual Value Q3 FY 2019	Final Target Value* Q4 FY 2019
Total morphine milligram equivalents (MMEs) dispensed	28 billion	28 billion	27 billion
MMEs /prescription	724	721	718
Naloxone prescriptions	245,603	225,618	257,310**
Unique buprenorphine patients	707,716	701,660	728,890
Long-acting injectable or implantable buprenorphine prescriptions	4,685	5,873	5,086**
Extended release naltrexone prescriptions	74,197	79,709	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 change starting from the baseline of the new dataset.

**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.

•Key Indicators

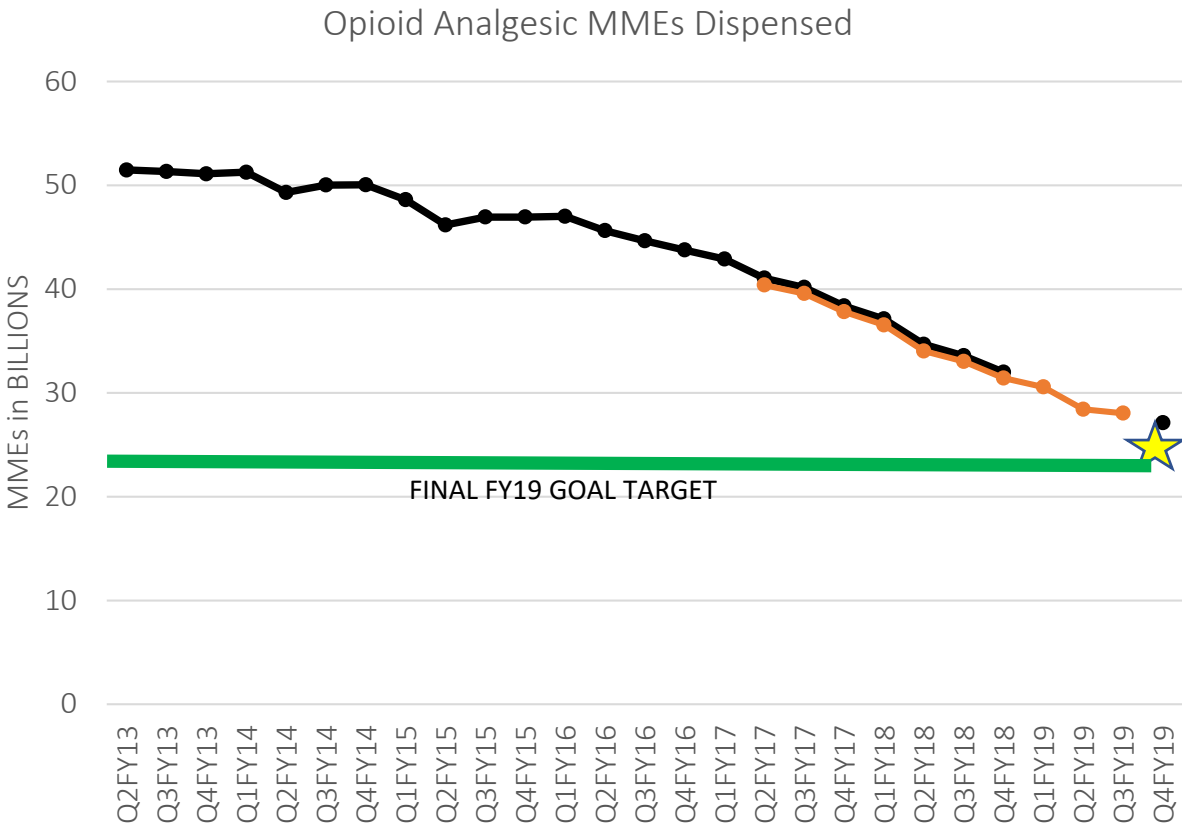
Total morphine milligram equivalents dispensed in BILLIONS

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

New Dataset

Q2FY17	40
Q3FY17	40
Q4FY17	38
Q1FY18	37
Q2FY18	34
Q3FY18	33
Q4FY18	31
Q1FY19	31
Q2FY19	28
Q3FY19	28



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

• Key Indicators

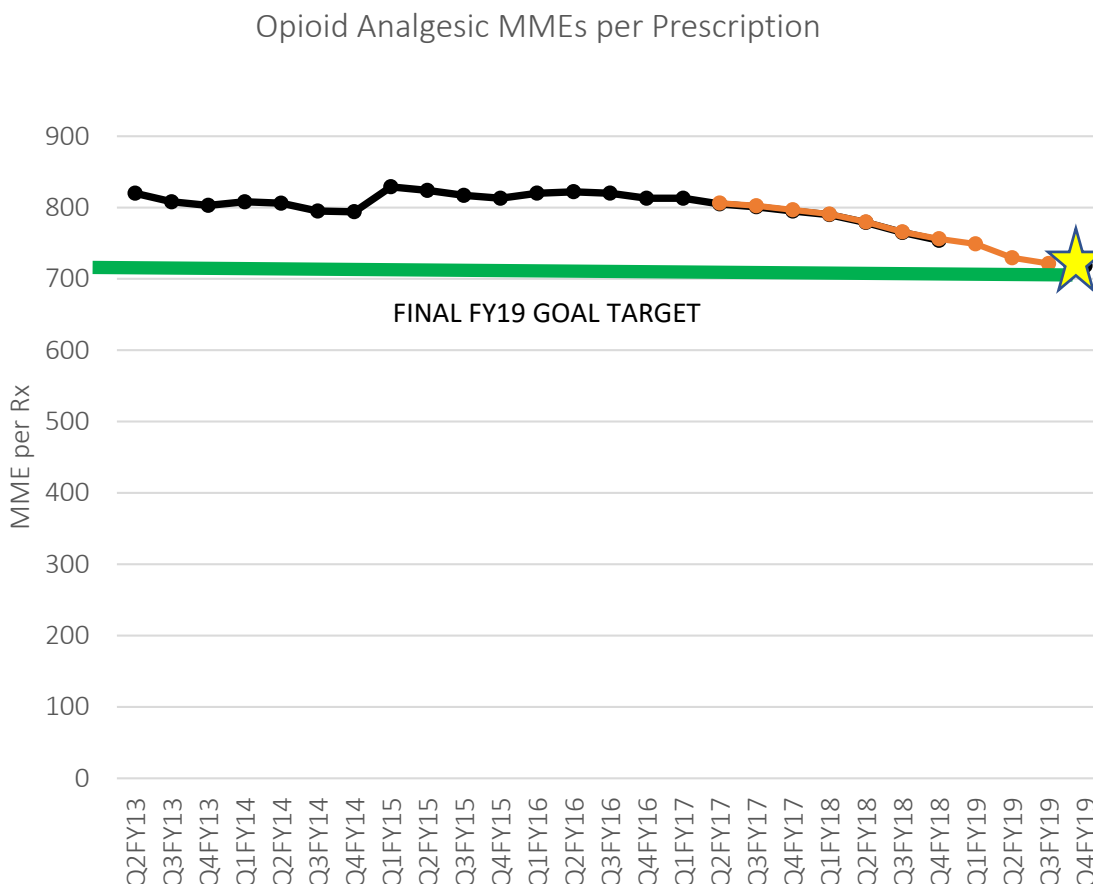
Morphine milligram equivalents per prescription

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

New Dataset

Q2FY17	806
Q3FY17	802
Q4FY17	797
Q1FY18	791
Q2FY18	780
Q3FY18	766
Q4FY18	756
Q1FY19	749
Q2FY19	729
Q3FY19	721



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

• Key Indicators

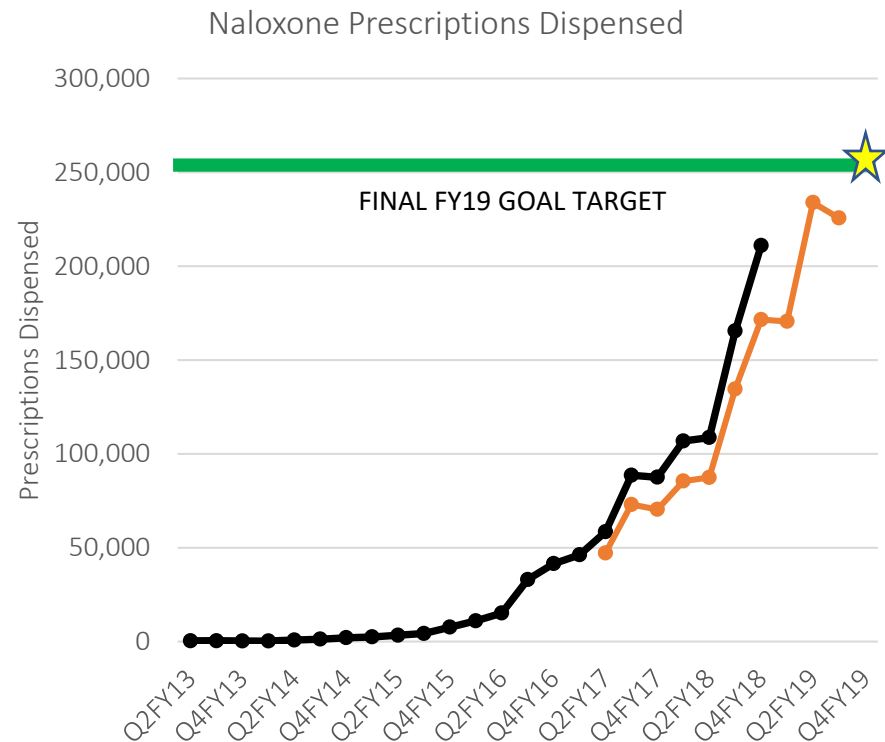
Number of naloxone prescriptions dispensed

Original Dataset

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



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

• Key Indicators

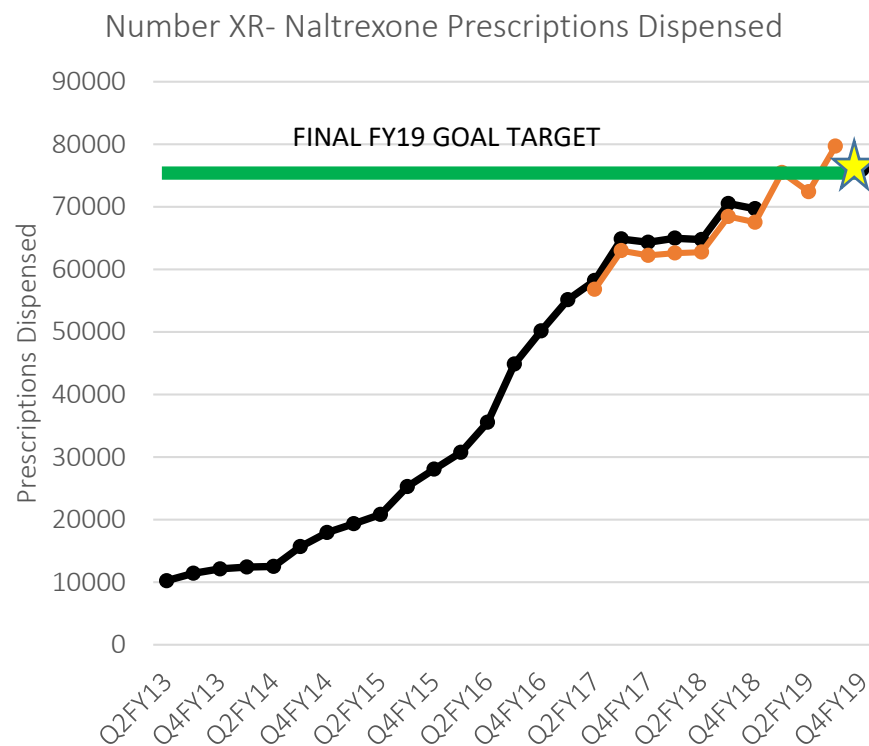
Number of extended-release naltrexone prescriptions dispensed

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



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

• Key Indicators

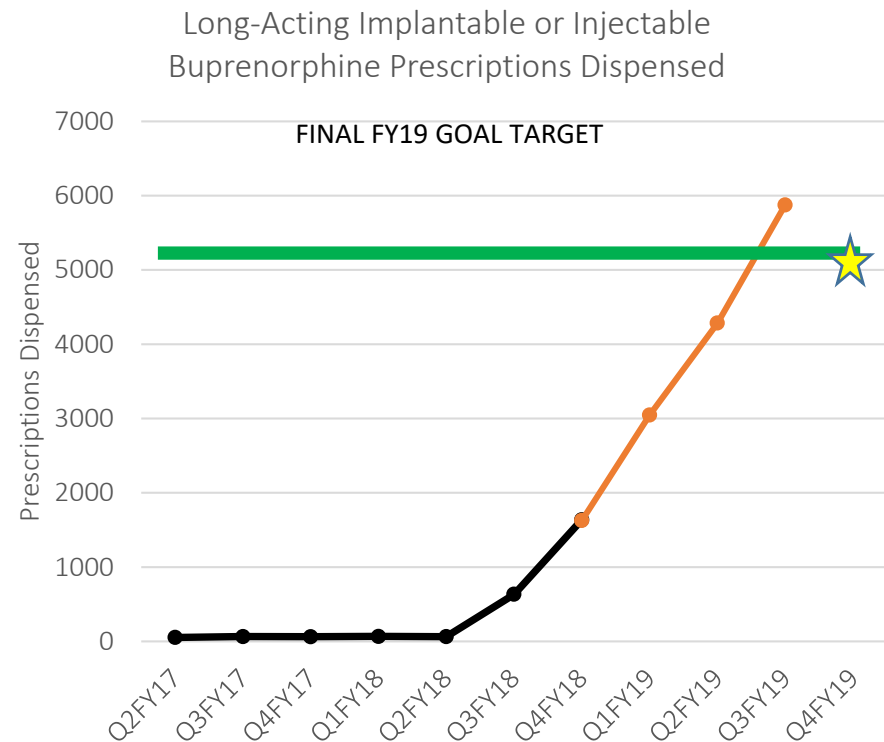
Number of long-acting implantable or injectable buprenorphine prescriptions dispensed

Original Dataset

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

New Dataset

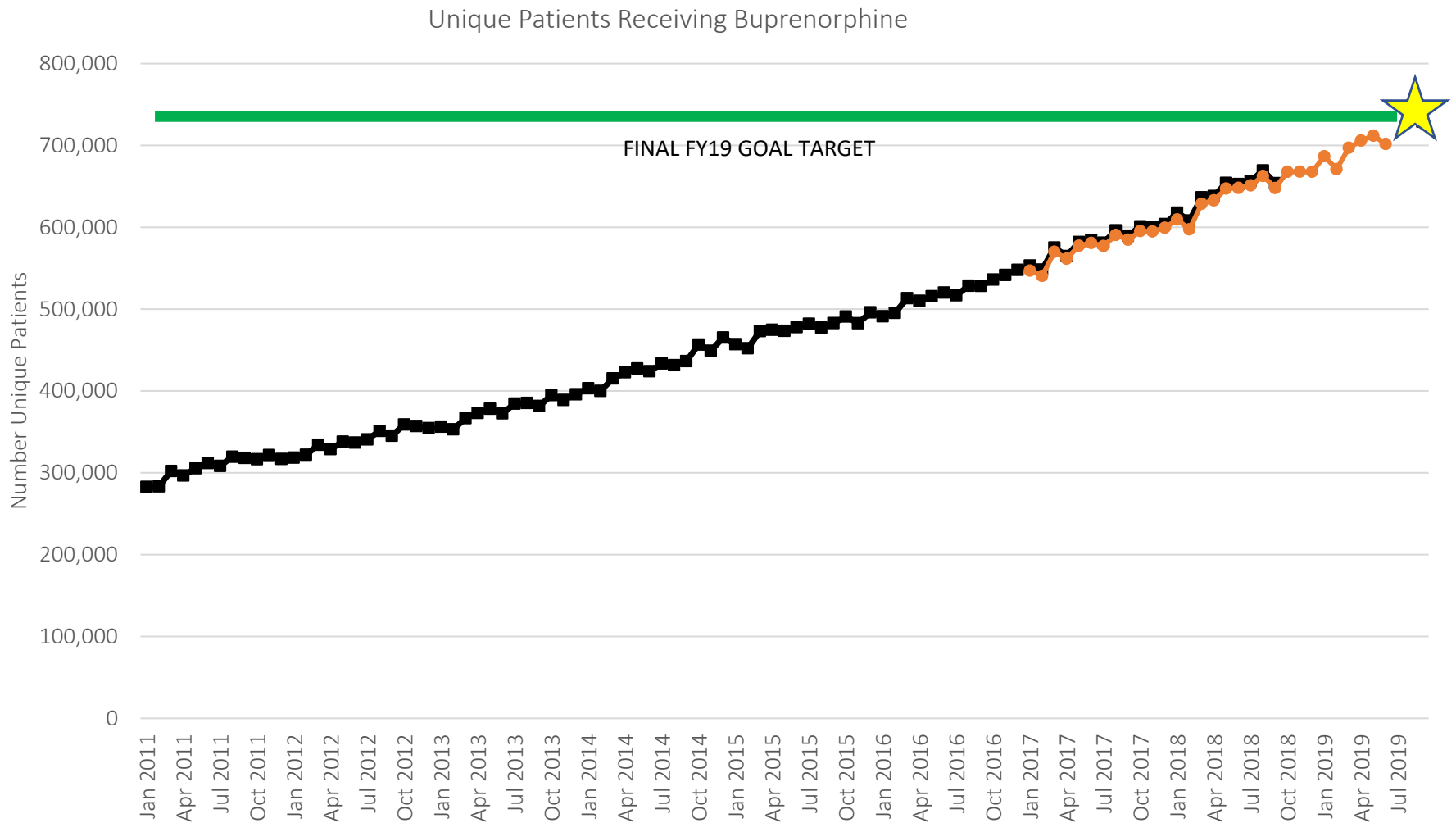
Q4FY18	1,626
Q1FY19	3,046
Q2FY19	4,283
Q3FY19	5,873



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

• Key Indicators

Number of unique patients receiving buprenorphine



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

• Key Indicators

Original Dataset

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

New Dataset

Jan 2017	546,833
Feb 2017	540,562
Mar 2017	569,983
Apr 2017	561,504
May 2017	577,403
Jun 2017	580,684
Jul 2017	577,083
Aug 2017	590,448
Sept 2017	584,734
Oct 2017	595,268
Nov 2017	594,838
Dec 2017	599,365
Jan 2018	609,468
Feb 2018	597,343
Mar 2018	628,659
Apr 2018	632,867
May 2018	647,153
Jun 2018	648,021
Jul 2018	651,033
Aug 2018	662,611
Sept 2018	647,902
Oct 2018	667,810
Nov 2018	670,017
Dec 2018	667,578
Jan 2019	686,430
Feb 2019	670,799
Mar 2019	697,220
Apr 2019	705,938
May 2019	711,835
Jun 2019	701,660

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

APPENDIX

Summary of Progress – FY 2019 Q3

AHRQ

- 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.
- 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.
- Presented to the Patient Safety Organization (PSO) Annual Meeting (April 30-May 2) recommendations on how PSOs can address the opioid crisis and the Patient Safety Network published a primer on opioid safety
- Published data on a number of opioid topics, including:
 - Rates of opioid use among adults with chronic pain
 - Relationships among race/ethnicity, social determinants, and prescription opioid utilization

Summary of Progress – FY 2019 Q3

CDC

- Received applications for [Overdose Data to Action Notice of Funding Opportunity](#) from 47 states + DC, 2 territories, and 17 localities
 - Funding will support states, eligible territories, and select cities/counties in enhancing the quality and timeliness of data on opioid prescribing and morbidity and mortality.
 - These data will inform and target prevention and response initiatives at the state and local level.

Morbidity Strategy	Number of States	Mortality Strategy	Number of States
Tier 1 (every 2 weeks)	31	Tier 1 (6-11 month time lag)	29
Tier 2 (monthly)	12	Tier 2 (8-13 month time lag)	14
Tier 3 (quarterly)	4	Tier 3 (planning year, then 8-13 month time time lag)	6
Tier 4 (planning year)	2		

- Released [commentary](#) in New England Journal of Medicine “No Shortcuts to Safer Opioid Prescribing” and the accompanying [Media Statement](#) “CDC Advises Against Misapplication of the Guideline for Prescribing Opioids for Chronic Pain”
- Released [study](#) in American Journal of Preventive Medicine finding more than half of people who misuse prescription opioids also binge drink

Summary of Progress – FY 2019 Q3

CMS

- Published a report comparing opioid utilization patterns among Medicare fee-for-service beneficiaries with sickle cell disease to other beneficiaries with complex pain syndromes as well as two data highlights detailing the first-ever national prevalence rate of sickle-cell disease among Medicare Fee-for-Service and Medicaid beneficiaries
- Published a Notice of Funding Availability that provides State Medicaid agencies with information to apply for planning grants that will aid in the treatment and recovery of SUDs, including OUD
- Published guidance to inform states about claiming 100 percent federal Medicaid matching funds for certain expenditures related to qualifying Prescription Drug Monitoring Programs (PDMPs)
- Approved section 1115 demonstrations in Minnesota and Nebraska—the 23rd and 24th states to receive approval for these demonstrations—to increase access to and quality treatment for OUD and other SUD
- Released a proposed rule implementing Section 6062 of the SUPPORT Act that would allow clinicians to choose to complete prior authorizations online, which reduces burden for providers through a more streamlined process for performing prior authorization for Part D prescriptions
- Issued guidance to States regarding the extended availability of enhanced matching funds for certain Medicaid health homes for individuals with SUD
 - Authority for the extension was recently enacted in section 1006(a) of the SUPPORT Act.

Summary of Progress – FY 2019 Q3

FDA

- Hosted its second Online Opioid Summit to combat illegal online opioid sales on April 2
- Announced a new requirement that opioid labelings be changed to guide prescribers on how to safely and gradually taper opioids when necessary.
- Approved first generic naloxone nasal spray on April 19
- Launched a public education campaign to encourage safe removal of unused opioid pain medicines from homes
- Hosted an HHS interagency meeting (with CDC and NIH) to discuss data needs in opioid systems modeling
- Opened a public docket to request information on requiring fixed-quantity blister packaging for certain opioid pain medicines to help decrease unnecessary exposure to opioids
- Held a public advisory committee meeting to discuss safety and utility of higher-dose opioid analgesics on June 11-12
- Issued draft guidance, “Opioid Analgesic Drugs: Considerations for Benefit-Risk Assessment Framework” on June 20

Summary of Progress – FY 2019 Q3

HRSA

- Began reviewing applications for three programs that will expand the substance use disorder and opioid workforce
- Began accepting applications for the new National Health Service Corps Rural Community Loan Repayment Program, which supports health care professionals working to combat the opioid epidemic in rural communities
- Made 120 awards for the FY 2019 Rural Communities Opioid Response Program – Planning, totaling \$24 million
- Began reviewing applications for four related RCORP programs, including RCORP—Medication Assisted Treatment Expansion
- Began reviewing applications for a program that will support entities that serve as System Coordination Providers to leverage resources at federal, state, and local levels to ensure people with HIV who have OUD have access to appropriate SUD care, treatment, and services

Summary of Progress – FY 2019 Q3

IHS

- Released the Special General Memorandum requiring Federal Indian Health Service Facilities to create an action plan identifying local medication assisted treatment (MAT) resources and coordinating patient access to those services when indicated
- Released recommendations developed in collaboration with the American College of Obstetricians and Gynecologists' Committee on American Indian and Alaska Native Women's Health, that will assist IHS Providers in improving maternal participation in early prenatal care, improving screening for substance use disorder, and increasing access to MAT for pregnant women and women of child-bearing age
- Expanded capacity to host IHS-based online DATA waiver training
- Tribal Consultation and Urban Confer solicited guidance on the Special Behavioral Health Pilot Program for combatting the opioid epidemic, which will:
 - Support the development, documentation, and sharing of locally designed and culturally appropriate prevention, treatment, and aftercare services for mental health and substance use disorders
 - Provide services and technical assistance to grantees to collect and evaluate performance of the program
- Released software to automate near real-time reporting of controlled substance dispensing to PDMPs

Summary of Progress – FY 2019 Q3

NIH

- Continued 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
- Expects to award \$945 million in support of HEAL Initiative research by the end of FY 2019
- 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
- Issued 12 grants in July 2019 to form the Justice Community Opioid Innovation Network to support research on quality addiction treatment for OUD in criminal justice settings nationwide
- Issued grants in four states (Kentucky, Massachusetts, New York, and Ohio) in April 2019 to support the HEALing Communities Study to test the impact of implementing an integrated set of evidence based practices to reduce opioid overdose fatalities by 40 percent (see Collaborative Milestones slide #21)

Summary of Progress – FY 2019 Q3

SAMHSA

- Determined that by April 2019 Prevent Prescription Drug and Opioid Overdose-Related Deaths and First Responders Comprehensive Addiction and Recovery Act grantees SAMHSA's 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
- Released Funding Opportunity Announcements for the Drug-Free Communities Support Program, the First Responders-Comprehensive Addiction and Recovery Act, the Rural Opioid Technical Assistance Grants, the Provider's Clinical Support System-Universities Grants, and the Tribal Opioid Response Grants
- Awarded the Provider's Clinical Support System-Medication Assisted Treatment Grant to the American Academy of Addiction Psychiatry
- Waivered prescribers to prescribe buprenorphine for opioid addiction treatment (as of May 31, 2019):
 - For physicians: 58,724 at the 30-patient limit; 5,375 at the 100-patient limit; and 5,102 at the 275-patient limit
 - For nurse practitioners: 11,367 at the 30-patient limit and 1,856 at the 100-patient limit
 - For physician assistants: 3,031 at the 30-patient limit and 517 at the 100-patient limit

Collaborative Milestones

HEALing Communities Study (NIH/NIDA, SAMHSA)

- 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
- 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
- Create defined community prevention and treatment models to reduce addiction and overdose deaths in communities nationwide
- Issued research site grant awards were issued to University of Kentucky, Lexington; Boston Medical Center, Boston; Columbia University, New York City; and Ohio State University, Columbus in April 2019
 - Coordinated by RTI International, based in North Carolina