



Agency Priority Goal Action Plan

Reducing Opioid Morbidity and Mortality

Goal Leaders:

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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, 2019, by September 30, 2021:
 - 1) Treatment—Increase uptake of medications for the treatment of opioid use disorder:
 - a) Increase by 15 percent 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 percent the number of prescriptions for long-acting injectable or implantable buprenorphine from retail, long-term care, and mail-order pharmacies in the U.S.
 - c) Increase by 25 percent the number of prescriptions for extended-released naltrexone from retail, long-term care, and mail-order pharmacies in the U.S.
 - d) Increase by 57 percent the number of providers with a DATA 2000 waiver authorizing buprenorphine prescribing for opioid use disorder treatment.
 - 2) Overdose intervention—Increase availability and access to overdose-reversing drugs:
 - a) Increase by 50 percent the number of prescriptions dispensed for naloxone in U.S. outpatient retail and mail-order pharmacies.

Overview

Challenge

- The crisis of opioid addiction and overdose in the United States continues to claim far too many lives, driven by highly potent illicit synthetic opioids in the drug supply. In 2018, 2 million people in the U.S. had an opioid use disorder, and 46,802 Americans died from a drug overdose 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. Strengthen public health data and reporting
 3. Advance the practice of pain management
 4. Target the availability and distribution of overdose-reversing drugs
 5. Support cutting-edge research

Leadership

Divisions Operating as Goal and Deputy Goal Leaders:

- Office of the Assistant Secretary for Health (OASH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- National Institutes of Health (NIH)
- Centers for Disease Control and Prevention (CDC)

Goal Team:

- Agency for Healthcare Research and Quality (AHRQ)
- Office of the Assistant Secretary for Planning and Evaluation (ASPE)
- Centers for Medicare and Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)

Goal Structure & Strategies

HHS's strategies are from the Department's [5-Point Plan](#):

- Improve access to prevention, treatment, and recovery support services to prevent the health, social, and economic consequences associated with opioid misuse and addiction, and to enable individuals to achieve long-term recovery.
- Strengthen public health data reporting and collection to improve the timeliness and specificity of data, and to inform a real-time public health response as the epidemic evolves.
- Advance the practice of pain management to enable access to high-quality, evidence-based pain care that reduces the burden of pain for individuals, families, and society while also reducing the inappropriate use of opioids and opioid-related harms.
- Target the availability and distribution of overdose-reversing medications to ensure the broad provision of these drugs to people likely to experience or respond to an overdose, with a particular focus on targeting high-risk populations.
- Support cutting-edge research that advances our understanding of pain, overdose and addiction, leads to the development of new treatments, and identifies effective public health interventions to reduce opioid-related health harms.

Key Milestones

More information on HHS’s strategies for Reducing Opioid Morbidity and Mortality can be found in HHS’s [5-Point Plan](#).

Milestone Summary				
Key Milestone	Milestone Due Date	Status	Owner	Comments
Award Medicaid funds to state Medicaid agencies implementing a model with care delivery partners in the community	Q1, FY 2020	Awards Issued	CMS	See details under “Overview Summary of Progress –FY 2020 Q1”
Publish Report to Congress entitled: Report on Evidence-Based Opioid Analgesic Prescribing Guidelines	Q1, FY 2020	Complete	FDA	
Publish National Academies of Science, Engineering, and Medicine consensus report on a framework to support the development of clinical practice guidelines or the evaluation of existing clinical practice guidelines for opioid analgesic prescribing	Q2, FY 2020	Complete	FDA	
Start enrolling opioid treatment programs in Medicare	Q3, FY 2020	Enrolled over 600 OTPs	CMS	See details under “Overview Summary of Progress –FY 2020 Q2”
Publish Action Plan to prevent opioid abuse and misuse and enhance access to Medication-Assisted Treatment	Q3, FY 2020	In Progress	CMS	
Hold interagency meeting to discuss systems modeling and potential applications	Q3, 2020	In Progress	FDA, NIH, CDC	

Key Milestones *(continued)*

More information on HHS's strategies for Reducing Opioid Morbidity and Mortality can be found in HHS's [5-Point Plan](#).

Milestone Summary				
Key Milestone	Milestone Due Date	Status	Owner	Comments
Award Overdose Data to Action Grants and Injury Control Research Grants	Q4, FY 2020, FY 2021	On track	CDC	Prior to the FY 2020-2021 reporting cycle, HHS successfully awarded Year 1 of Overdose Data to Action (OD2A) funds in September 2019. Preparing for Year 2 OD2A, which will begin Sept. 2020.
Engage stakeholders to support the development of evidence-based guidelines for the treatment of pain associated with specific diseases and surgical procedures	Q4, FY 2020	In Progress	FDA	
Validate modeling systems as a potential decision tool to inform and guide opioid policy interventions that impact public health	Q4, 2020	In Progress	FDA, NIH, CDC	This work is ongoing. CDC scheduled a second interagency meeting on 4/2/20 to discuss next steps, including data needs, data access and model structure.
Award the National Health Service Corps Continuation Award Enhancement for current NHSC clinicians with a 2000 Data Waiver	Q4, FY 2020	In Progress	HRSA	
Develop a model to estimate naloxone need associated with the dynamic prescription opioid, heroin, and synthetic opioid use trends in the US and potential future shifts in use among these opioids	Q4, FY 2020	In Progress	NIH	
Award funding to support innovative scientific solutions to the opioid crisis through the NIH Helping to End Addiction Long-term Initiative	Q4, FY 2020, FY 2021	In Progress	NIH	
Award Grants for First Responder Training for Opioid Overdose Reversal Drugs	Q4, FY 2020	In Progress	SAMHSA	
Award State Opioid Response Supplement Grants	Q4, FY 2020	In Progress	SAMHSA	
Fund Provider Clinical Support System-University	Q4, FY 2020	In Progress	SAMHSA	
Award Rural Communities Opioid Response Program Grants	Q4, FY 2021	In Progress	HRSA	

Overview Summary of Progress – FY 2020 Q1

- AHRQ awarded a three year contract “Identifying and Testing Strategies for Management of Opioid Use and Misuse In Older Adults in Primary Care Practices” to evaluate how to address rising morbidity and mortality among older adults due to opioid use; published a Technical Brief on treatment alternatives for acute pain; and added six new opioid related measures to the annual National Healthcare Quality and Disparities Report.
- On December 4, 2019, the Board of Scientific Counselors of the National Center for Injury Prevention and Control (BSC/NCIPC) established an Opioid Workgroup (OWG) at CDC’s request. The workgroup will report to the BSC/NCIPC, a federal advisory committee. The primary purpose of the OWG is to provide expert input and observations to the BSC/NCIPC on a possible update or expansion of the CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. Due to ongoing response activities associated with the COVID-19 pandemic, the meeting of the BSC/NCIPC scheduled for April 30, 2020, has been cancelled. Planning is underway to schedule a BSC/NCIPC meeting for July 2020. The July meeting will include discussion of the agenda items originally scheduled for the April meeting, including an update on the formation of the Opioid Workgroup. Once confirmed, the July meeting date will be posted on CDC’s BSC/NCIPC website. In addition, in the coming weeks, a Federal Register Notice will be published to provide meeting and registration details.
 - Non-fatal overdose data: 42 grantees are using syndromic surveillance data to report nonfatal overdoses to CDC in 2-4 weeks of an emergency department visit.
 - Fatal overdose data: 20 recipients successfully submitted fatal overdose surveillance data at the end of January; CDC is actively reviewing and analyzing the data.

Overview Summary of Progress – FY 2020 Q1

- On December 19, 2019, the National Academies of Sciences, Engineering, and Medicine released a consensus report, commissioned by the FDA, on framing [opioid prescribing guidelines for acute pain](#).
- HRSA published the Addiction Medicine Fellowship (AMF) Notice of Funding Opportunity, a \$26.7 million investment in expanding the number of fellows at accredited AMF and Addiction Psychiatry Fellowship programs trained as addiction medicine specialists who work in underserved, community-based settings that integrate primary care with mental health disorders and with substance use disorder prevention and treatment services. HRSA intends to make approximately 33 awards of up to \$800,000 each.
- NIH-funded research – including 375 research projects in 41 states under its HEAL (Helping to End Addiction Long-term) Initiative – continued progress in the areas of 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.
- SAMHSA's Comprehensive Addiction Recovery Act grants successfully distributed 211,874 opioid overdose reversal kits, held 42,663 administration events, and contributed to the successful reversal of 23,489 opioid overdoses (as of Q1 2020).
- HEALing Communities Study (NIH, SAMHSA) completed the collection of baseline data and the message testing for the communication campaign.

Overview Summary of Progress – FY 2020 Q2

- AHRQ published a funding announcement for management of opioids in older adults, posted the final reports for three systematic reviews to support CDC guideline development (Long-Term Opioid Treatment of Chronic Pain, Noninvasive Nonpharmacological Treatment for Chronic Pain, and Nonopioid Pharmacologic Treatment for Chronic Pain), and added additional state-level data through 2019 to the HCUP Fast Stats pathway for Opioid-Related Hospital Use.
- On December 4, 2019, the Board of Scientific Counselors of the National Center for Injury Prevention and Control (BSC/NCIPC) established an Opioid Workgroup (OWG) at CDC's request. The workgroup will report to the BSC/NCIPC, a federal advisory committee. The primary purpose of the OWG is to provide expert input and observations to the BSC/NCIPC on a possible update or expansion of the CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. Due to ongoing response activities associated with the COVID-19 pandemic, the meeting of the BSC/NCIPC scheduled for April 30, 2020, has been cancelled. Planning is underway to schedule a BSC/NCIPC meeting for July 2020. The July meeting will include discussion of the agenda items originally scheduled for the April meeting, including an update on the formation of the Opioid Workgroup. Once confirmed, the July meeting date will be posted on CDC's BSC/NCIPC website. In addition, in the coming weeks, a Federal Register Notice will be published to provide meeting and registration details.
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Overview Summary of Progress – FY 2020 Q2

- Starting January 1, 2020, CMS will cover certain services at Opioid Treatment Programs (OTPs) through bundled payments for Opioid Use Disorder (OUD) treatment services. Under the new benefit, Medicare covers: agonist and antagonist medications; counseling; individual and group therapy; and toxicology testing. CMS also finalized a bundled payment for episodes OUD treatment furnished by physicians and other practitioners in the office setting.
- On April 2, 2020, FDA announced the funding opportunity, “Cooperative Agreement to Support an Evidence-based Clinical Practice Guideline for the Treatment of Acute Dental Pain” ([RFA-FD-20-029](#)).
- HRSA issued the National Health Service Corps (NHSC) Substance Use Disorder (SUD) Workforce Loan Repayment Program (LRP) Application and Program Guidance (APG), National Health Service Corps Rural Community LRP APG, and the National Health Service Corps LRP APG on February 20, 2020, which will recruit and retain medical, nursing, and behavioral/mental health clinicians with specific training and credentials to provide evidence-based SUD treatment and counseling in eligible communities. Currently, over a third of the traditional NHSC program participants are behavioral health providers. Additionally, HRSA issued the Opioid Impacted Family Support Program (OIFSP) Notice of Funding Opportunity (NOFO) on January 21, 2020. OIFSP will support training programs that expand the number of peer support specialists and other behavioral health-related paraprofessionals who are trained to work in integrated, interprofessional teams that provide services to children whose parents are impacted by opioid use disorder (OUD) and other SUDs, and their family members who are in guardianship roles.

Overview Summary of Progress – FY 2020 Q2

- More than 350 researchers were convened for the NIH HEAL (Helping to End Addiction Long-term) Initiative PI meeting, to establish an investigator network across the broad scope of HEAL research; HEAL invests in research to enhance pain management and improve prevention and treatment of opioid use, opioid use disorder, and overdose. Research advances under the NIH HEAL Initiative include:
 - The HEALthy Brain and Child Development (HBCD) grantees were provided support to investigate the consequences to infants of opioid exposures during pregnancy.
 - The NIH HEAL funded Justice Community Opioid Initiative Network (JCOIN) completed surveys of drug courts, prisons and veterans programs to inform development of systems improvement programs for justice involved populations through bi-directional research/practice collaboration.
- As of May 15, 2020, SAMHSA's Comprehensive Addiction Recovery Act grants successfully distributed 273,471 opioid overdose reversal kits, held 60,133 administration events, and contributed to the successful reversal of 31,078 opioid overdoses (as of Q2 2020).
- HEALing Communities Study (NIH, SAMHSA) completed the initial presentations of evidence based practices to the communities, and developed plans to continue coalition and research activities despite travel and meeting restrictions.

Key Indicators : FY 2020 Q1

Indicator	Target Value Q1 FY 2020	Target Percent Increase	Actual Value Q1 FY 2020	Actual Percent Increase	Final Target Value* Q4 FY 2021	Final Target Percent Increase
DATA waived providers	77,719	7.12%	77,142	6.33%	113,908	57%
Naloxone prescriptions	253,522	6.25%	220,407	-7.63%	357,914	50%
Unique buprenorphine patients	737,680	1.88%	746,866	3.15%	832,679	15%
Long-acting injectable or implantable buprenorphine prescriptions	8,157	12.5%	8,269	14.0%	14,502	100%
Extended release naltrexone prescriptions	82,441	3.13%	80,367	0.4%	99,929	25%

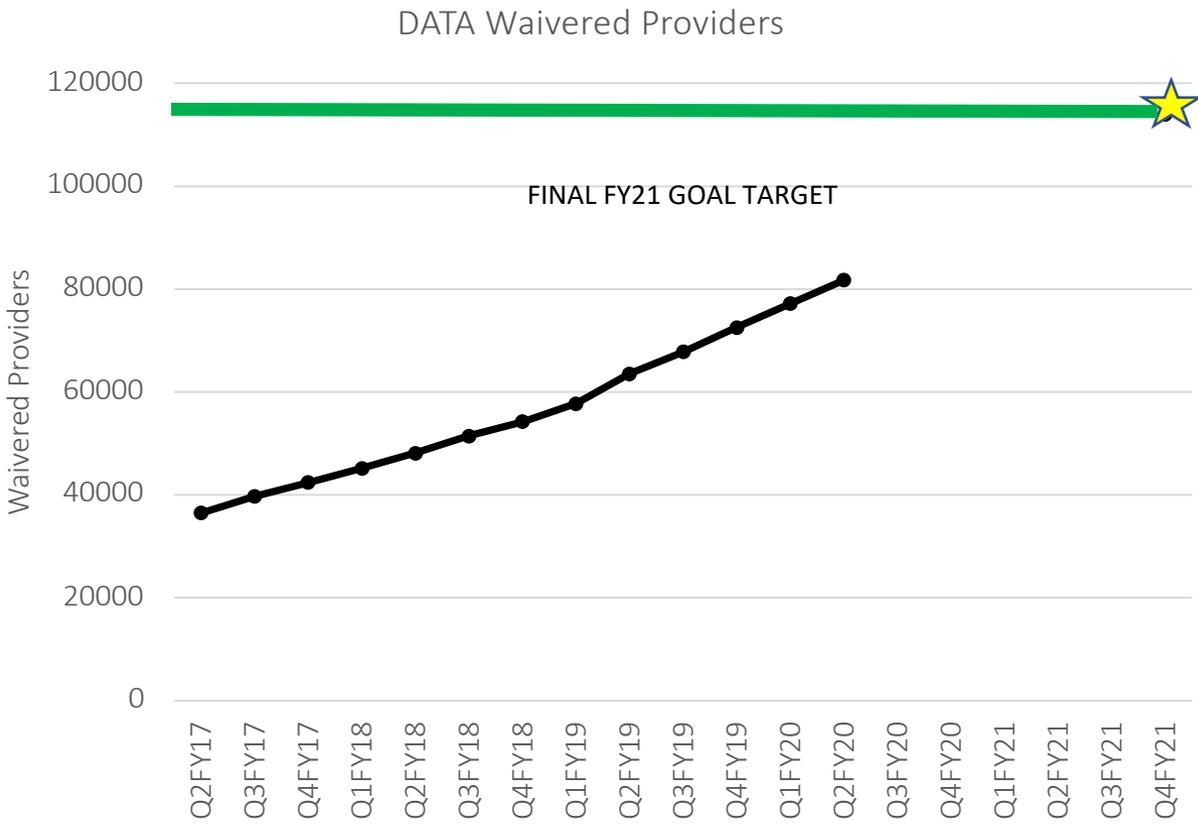
Key Indicators : FY 2020 Q2

Indicator	Target Value Q2 FY 2020	Target Percent Increase	Actual Value Q2 FY 2020	Actual Percent Increase	Final Target Value* Q4 FY 2021	Final Target Percent Increase
DATA waived providers	82,892	14.25%	81,700	12.61%	113,908	57%
Naloxone prescriptions	268,435	12.5%	226,723	-4.98%	357,914	50%
Unique buprenorphine patients	751,221	3.75%	775,137	7.05%	832,679	15%
Long-acting injectable or implantable buprenorphine prescriptions	9,064	25%	9,851	36%	14,502	100%
Extended release naltrexone prescriptions	84,939	6.25%	77,485	-3.07%	99,929	25%

• Key Indicators

Total DATA waived providers

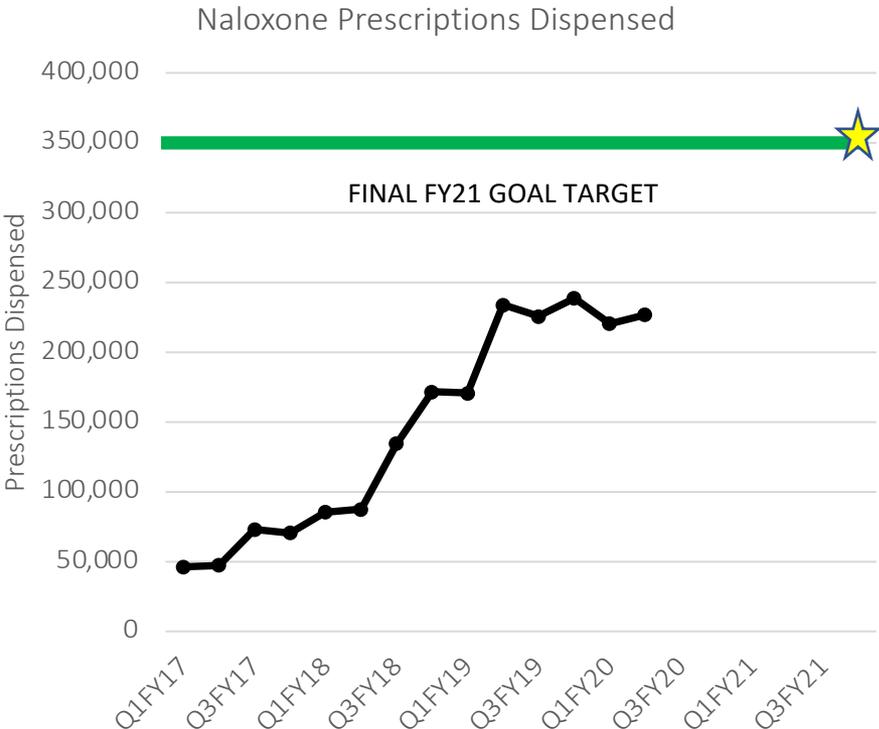
Q2FY17	36454
Q3FY17	39715
Q4FY17	42370
Q1FY18	45175
Q2FY18	48121
Q3FY18	51415
Q4FY18	54217
Q1FY19	57724
Q2FY19	63543
Q3FY19	67789
Q4FY19	72553
Q1FY20	77142
Q2FY20	81700



• Key Indicators

Number of naloxone prescriptions dispensed

Q1FY17	46,218
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
Q1FY20	220,407
Q2FY20	226,723

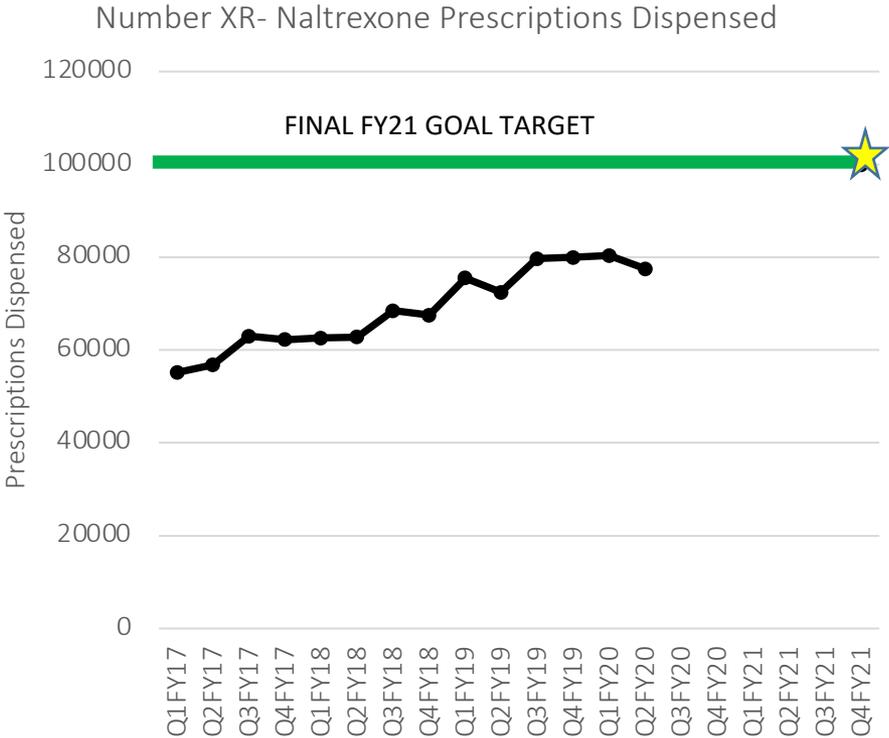


Source: IQVIA National Prescription Audit. Retrieved May 2020. Note: These data are for the retail and mail service channels only and do not include the long-term care channel.

• Key Indicators

Number of extended-release naltrexone prescriptions dispensed

Q1FY17	55,155
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	79,943
Q1FY20	80,367
Q2FY20	77,485

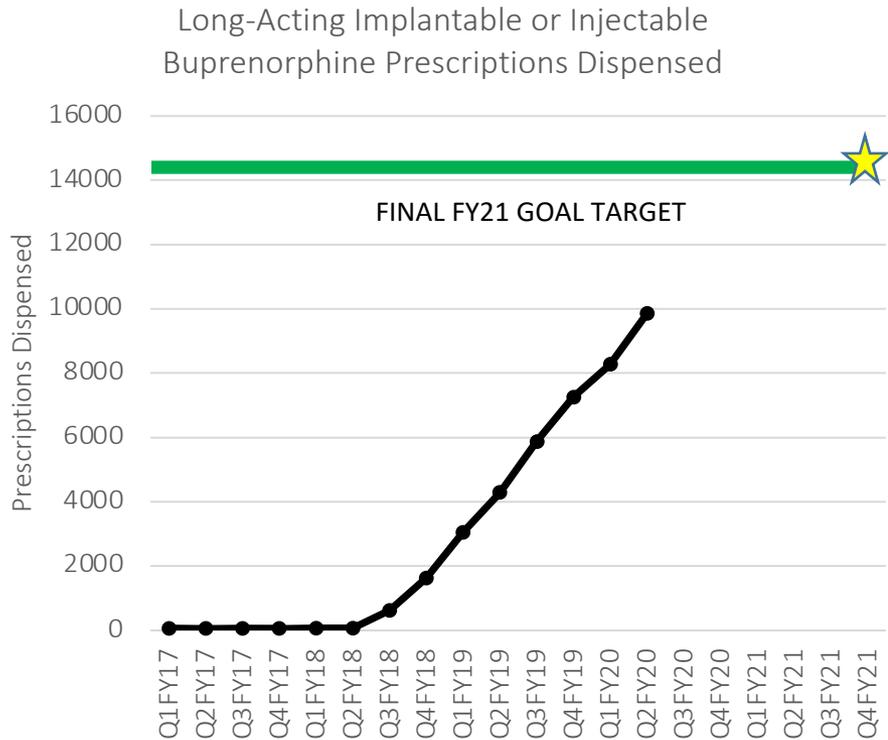


Source: IQVIA National Prescription Audit. Retrieved May 2020.

• Key Indicators

Number of long-acting implantable or injectable buprenorphine prescriptions dispensed

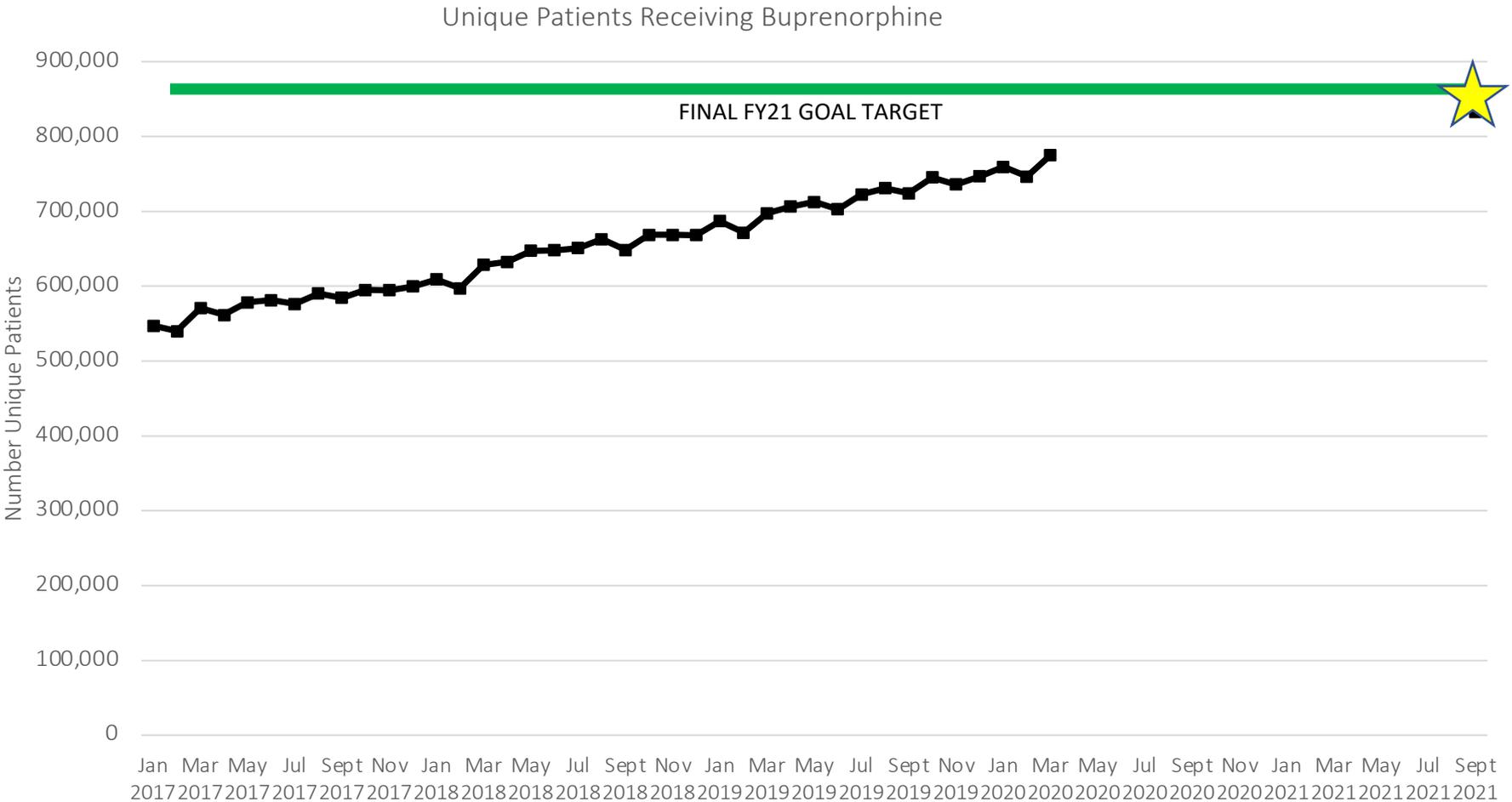
Q1FY17	69
Q2FY17	54
Q3FY17	66
Q4FY17	63
Q1FY18	68
Q2FY18	64
Q3FY18	625
Q4FY18	1,626
Q1FY19	3,046
Q2FY19	4,283
Q3FY19	5,873
Q4FY19	7,251
Q1FY20	8,269
Q2FY20	9,851



Source: IQVIA National Prescription Audit. Retrieved May 2020.

• Key Indicators

Number of unique patients receiving buprenorphine



Source: IQVIA Total Patient Tracker. Retrieved May 2020.

• Key Indicators

Number of unique patients receiving buprenorphine

Jan 2017	547,208
Feb 2017	540,054
Mar 2017	570,746
Apr 2017	561,787
May 2017	578,301
Jun 2017	581,298
Jul 2017	576,197
Aug 2017	590,176
Sept 2017	584,623
Oct 2017	595,075
Nov 2017	594,649
Dec 2017	599,551
Jan 2018	608,893

Feb 2018	597,274
Mar 2018	628,345
Apr 2018	632,609
May 2018	647,355
Jun 2018	647,963
Jul 2018	650,959
Aug 2018	662,683
Sept 2018	648,262
Oct 2018	668,488
Nov 2018	668,454
Dec 2018	668,029
Jan 2019	686,929
Feb 2019	671,305

Mar 2019	697,439
Apr 2019	706,496
May 2019	712,535
Jun 2019	702,755
Jul 2019	722,453
Aug 2019	730,776
Sept 2019	724,068
Oct 2019	745,402
Nov 2019	735,841
Dec 2019	746,866
Jan 2020	759,323
Feb 2020	746,273
Mar 2020	775,137

Source: IQVIA Total Patient Tracker. Retrieved May 2020.

Data Accuracy and Reliability

Data are 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. IQVIA has adjusted their data reporting to remove prescriptions that are voided or reversed. This caused a break in the trend line between FY 2018 and FY 2019.

One limitation of the data is that it is not possible to distinguish between when the medications are used to treat opioid use disorder and when they are used to treat other conditions. 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.

While IQVIA data allow for tracking of naloxone dispensed by pharmacies, these numbers do not capture naloxone distribution through other avenues, such as overdose education and naloxone distribution programs administered by states, cities, and community organizations.

The number of providers with a DATA 2000 waiver is provided by SAMHSA; it should be noted that this reflects all clinicians who have received a waiver and does not indicate Drug Enforcement Administration registration status or current prescribing.

Additional Information

Stakeholder / Congressional Consultations

HHS's activities for this APG are part of the Department's approach for implementing The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act).