Agency Priority Goal Action Plan

Reducing Opioid Morbidity and Mortality

Goal Leaders:

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Performance.gov

Fiscal Year 2020, Quarter 3

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	Complete	CMS	Awards Issued
Publish Report to Congress entitled: Report on Evidence-Based Opioid Analgesic Prescribing Guidelines	Q1, FY 2020	Complete	FDA	Report to Congress published on 6/11/20
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	Published 12/19/19. NASEM Link: opioid prescribing guidelines for acute pain
Start enrolling opioid treatment programs in Medicare	Q3, FY 2020	Complete	CMS	
Publish Action Plan to prevent opioid abuse and misuse and enhance access to Medication-Assisted Treatment	Q3, FY 2020	In Progress	CMS	Report has been drafted and is in clearance.
Hold interagency meeting to discuss systems modeling and potential applications	Q3, 2020	Postponed	FDA, NIH, CDC	Postponed to October 2020 due to COVID-19.

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	Complete	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, NIDA, FDA are planning a meeting in late 2020.
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 Q3

- AHRQ produced five statistical briefs analyzing the geography, costs, comorbidities, and social determinants of health for opioid related healthcare; completed three systematic reviews on management of chronic pain to support the CDC guidelines and one review on interventions for substance abuse treatment in adolescents; and supported the development of USPSTF recommendation statements on prevention of illicit drug use in children and adolescents and screening for illicit drug use in primary care.
- 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 an 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, was cancelled and rescheduled for July 22, 2020. CDC provided an update to the BSC/NCIPC on the formation of the Opioid Workgroup on July 22, 2020. The Opioid Workgroup roster and meeting presentations are available on the BSC/NCIPC website. Additional meeting topics included an update on the CDC Opioid Prescribing Estimates Project and on Management of Acute and Chronic Pain: Opportunities for Stakeholder Engagement and Public Comment. From July 22 to August 21, 2020, CDC is soliciting input from several stakeholder groups through individual conversations via a notice in the Federal Register.
  - 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 Q3

- Starting January 1, 2020, CMS began reimbursing providers for 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. As of June 23, 2020 CMS had enrolled 755 OTPs.
- On June 11, 2020, FDA published the "Report on Evidence-Based Opioid Analgesic Prescribing Guidelines " (Report to Congress).
- HRSA awarded more than $20 million under the Addiction Medicine Fellowship (AMF) Program, which will expand 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 substance use disorder prevention and treatment services. HRSA awarded over $8 million under the Nurse Education, Practice, Quality, and Retention/ Interprofessional Collaborative Practice: Behavioral Health Integration Program. The program aims to increase access to, and quality of, behavioral health services through team-based care models in interprofessional, nurse-led primary care teams in rural or underserved areas. HRSA-funded poison control centers managed 12,991 opioid substances exposure cases, fewer than the previous quarter's reported cases of 14,306. The data serve as a marker for patterns of opioid use/misuse as well as patterns of adverse medical outcomes associated with their use.

Overview Summary of Progress – FY 2020 Q3

- 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 pain and OUD treatment models. Despite the pandemic:
  - The Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome (ACT-NOW) program moved forward with selection of over 26 sites in 20 states, site certifications, and the finalization of the protocols.
  - The NIH HEAL funded Justice Community Opioid Initiative Network (JCOIN) developed and disseminated a list of more than 120 COVID-19 resources, guidelines, and emerging consensus statements for justice agencies and treatment programs.
- As of July 23, 2020, SAMHSA's Comprehensive Addiction Recovery Act grants successfully distributed 287,842 opioid overdose reversal kits, held 61,297 administration events, and contributed to the successful reversal of 31,687 opioid overdoses.
- HEALing Communities Study (NIH, SAMHSA) launched communication campaigns to combat stigma associated with medications for the treatment of opioid use disorder and completed the initial versions of community data dashboards.

Challenges to achievement of the APG posed by COVID-19

Challenges to Reducing Opioid Morbidity and Mortality

- Social isolation, financial burdens, and other consequences of COVID-19 may contribute to increases in substance use; opioid-related lung impairment may increase risk for serious effects from COVID-19
- Data reported by Millennium Health show increases in positive urine drug tests for non-prescribed fentanyl (31.96%) and heroin (12.53%) since the declaration of COVID-19 as a national emergency. Overdose submissions reported to ODMAP show similar increases.
- Increased prevalence of OD from fentanyl, which are harder to reverse
- Increased mortality from stimulants with and without combinations with opioids

Challenges to Increased Prescribing of Medications

- Anecdotal reports of longer wait times and treatment facility closures
- Burden of COVID-19 on healthcare systems may be a barrier to treatment for SUD
- Patients may not seek care in order to avoid exposure to COVID-19
- Fewer overdose patients being treated in ED and reduced referral to treatment

Policy Changes During Pandemic that Ameliorate Challenges

- In March 2020, SAMHSA issued guidance to facilitate SUD treatment during the pandemic including the use of telemedicine and telephone
- On March 16, 2020, SAMHSA issued guidance allowing 28 days of take-home doses of methadone for stable patients, and 14 days of take-home doses for less stable patients deemed able to handle 14 days of take-home doses.
- On March 17, 2020, Medicare and Medicaid expanded telemedicine reimbursement rules to allow providers to:
  - Conduct telehealth with patients located in their homes and outside of designated rural areas
  - Practice remote care, even across state lines, through telehealth
  - Deliver care to both established and new patients through telehealth
  - Bill for telehealth services (both video and audio-only) as if they were provided in person
- On March 20, 2020, SAMHSA and DEA released guidance for e-prescribing and initiation of MOUD
  - Allows prescribing of buprenorphine without an in-person medical evaluation
  - Treating new patients with methadone requires an in-person evaluation
- Effective March 23, 2020, the DEA issued an Exception to Separate Registration Requirements Across State Lines
  - Allows providers to provide SUD treatment across state lines
  - Applies to the prescription of MOUD via telemedicine

Key Indicators : FY 2020 Q3

Indicator	Target Value Q3 FY 2020	Target Percent Increase	Actual Value Q3 FY 2020	Actual Percent Increase	Final Target Value* Q4 FY 2021	Final Target Percent Increase
DATA waivered providers	88,061	21.375%	86,870	19.73%	113,908	57%
Naloxone prescriptions	283,348	18.75%	249,017	4.36%	357,914	50%
Unique buprenorphine patients	764,797	5.625%	791,496	9.31%	832,679	15%
Long-acting injectable or implantable buprenorphine prescriptions	9,970	37.50%	10,423	43.75%	14,502	100%
Extended release naltrexone prescriptions	87,438	9.375%	70,350	-12.00%	99,929	25%

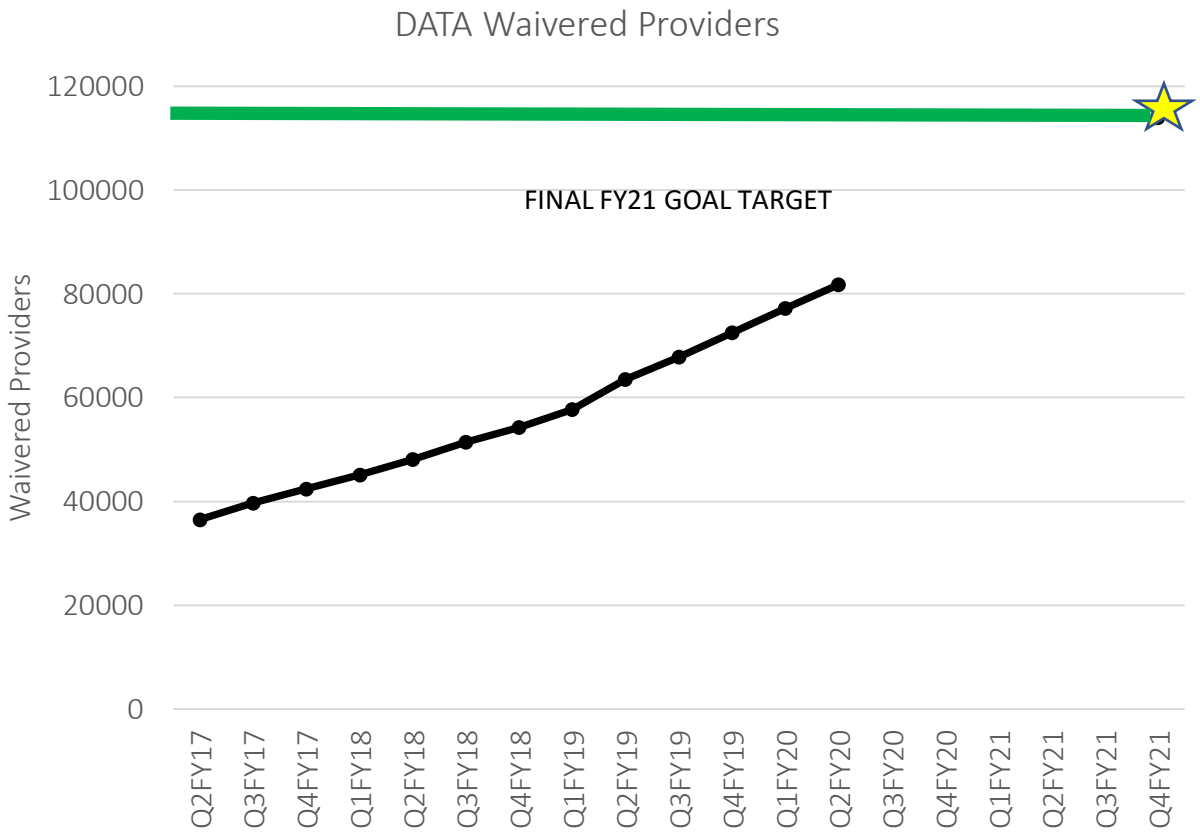
Met or exceeded goal; moving toward goal, did not meet; moving in the wrong direction

Colors reflect the current quarter

• Key Indicators

Total DATA waivered providers

Q2FY17	36,454
Q3FY17	39,715
Q4FY17	42,370
Q1FY18	45,175
Q2FY18	48,121
Q3FY18	51,415
Q4FY18	54,217
Q1FY19	57,724
Q2FY19	63,543
Q3FY19	67,789
Q4FY19	72,553
Q1FY20	77,142
Q2FY20	81,700
Q3FY20	86,870



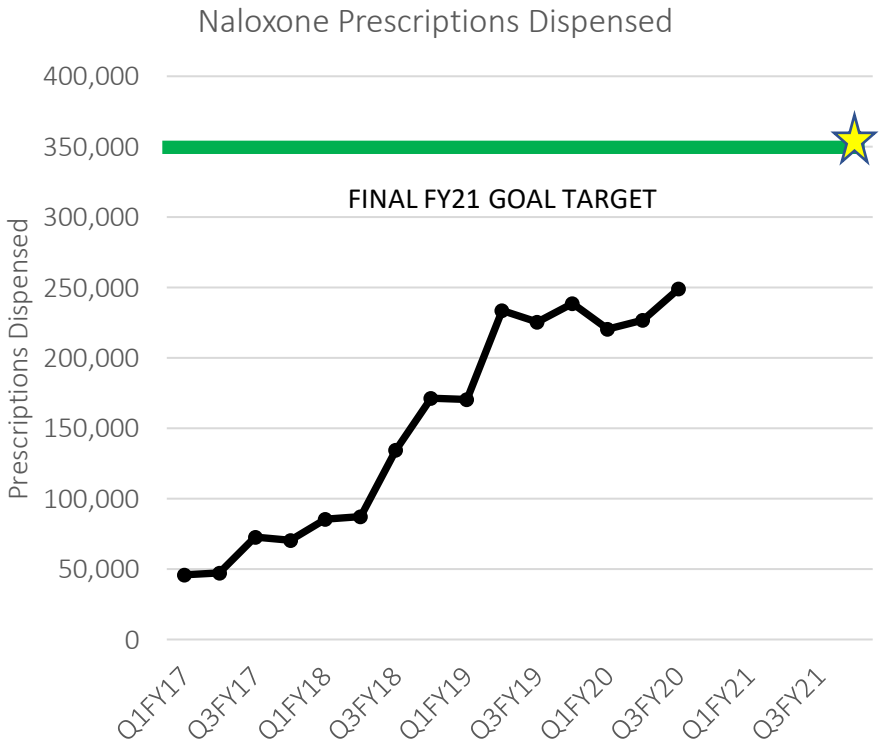
Source: SAMHSA

The number of DATA waivered providers has been increasing 6-10% per quarter. Note: this does not necessarily reflect the number of patients treated or retained in treatment.

• 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
Q3FY20	249,017



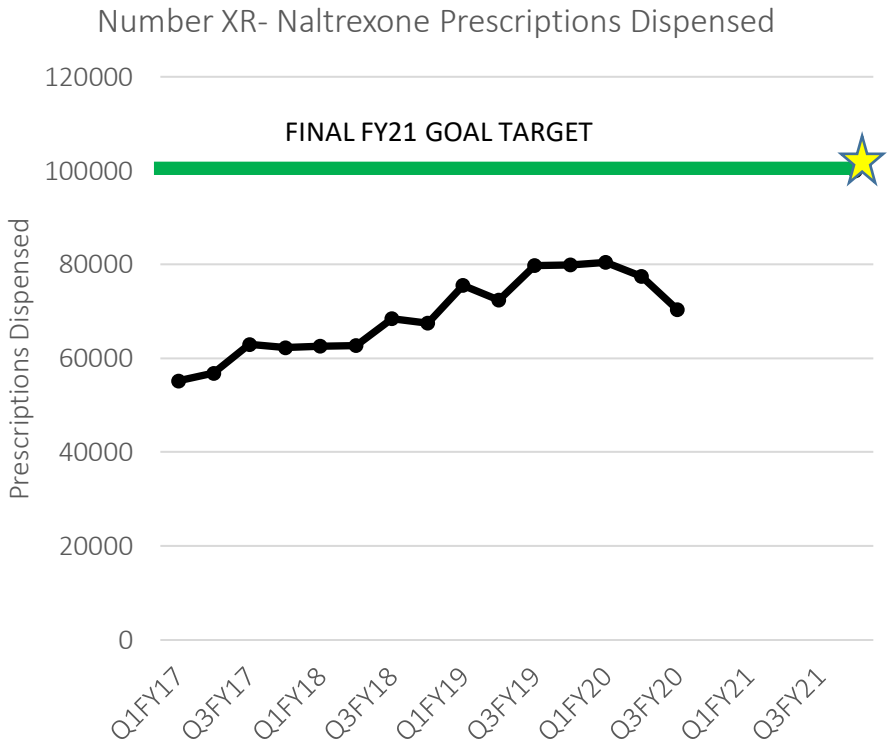
The rate of increase in naloxone prescriptions has declined since mid 2019, though in recent quarters the trajectory has been going up. This leveling off may reflect naloxone sources outside of prescriptions (such as community distribution).

Source: IQVIA National Prescription Audit. Retrieved July 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
Q3FY20	70,350



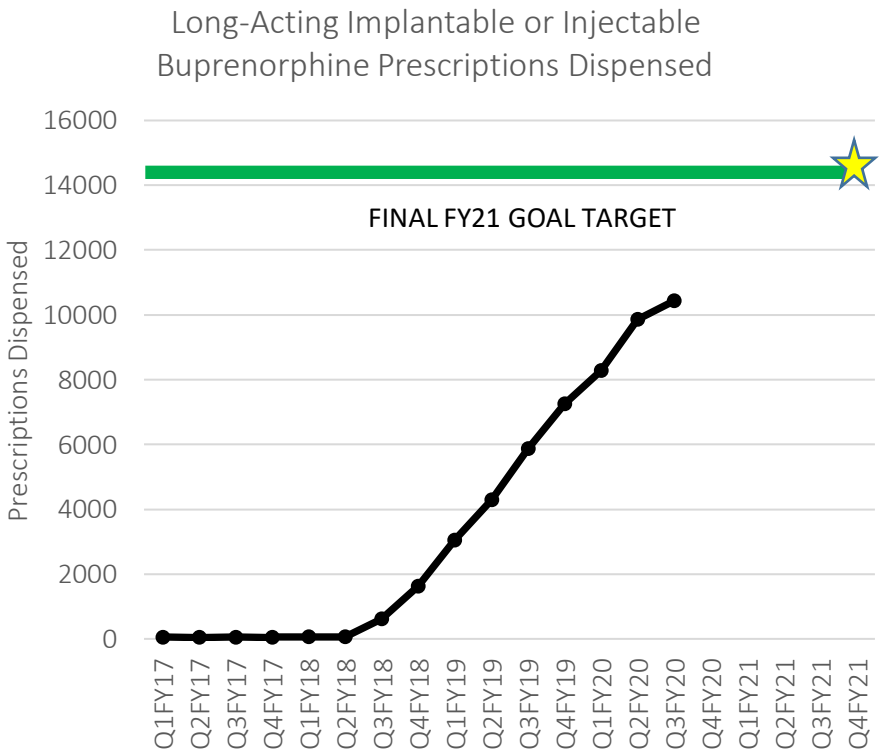
The number of naltrexone prescriptions dispensed was level before declining in Q3; reasons for Q3 decline uncertain, could reflect impact of COVID-19 pandemic.

Source: IQVIA National Prescription Audit. Retrieved July 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
Q3FY20	10,423

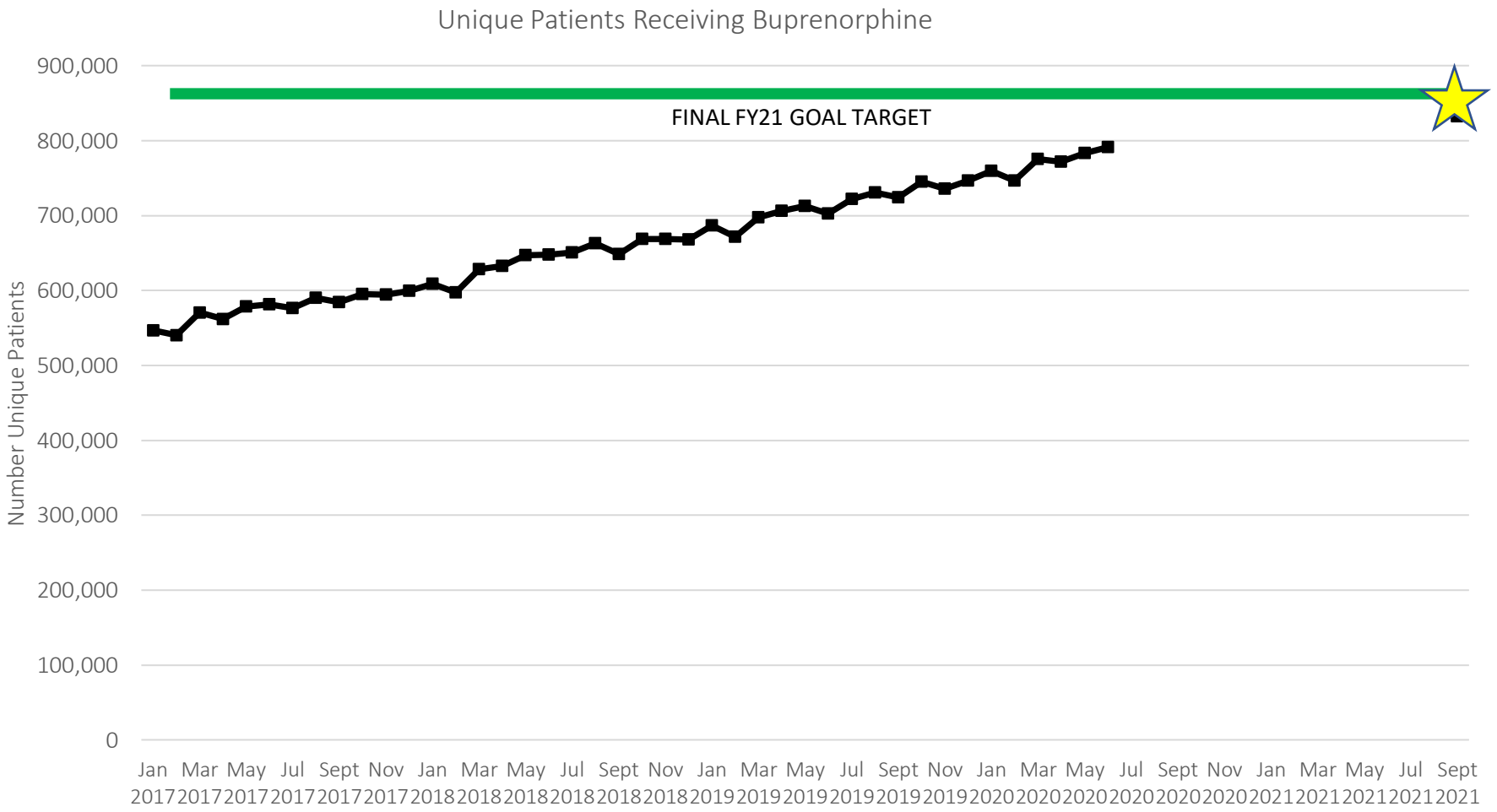


The number of long-acting buprenorphine prescriptions increased 162 fold following the entrance of an injectable form to the market.

Source: IQVIA National Prescription Audit. Retrieved July 2020.

• Key Indicators

Number of unique patients receiving buprenorphine



The number of buprenorphine patients tends to increase between 1-3% monthly, with occasional intermittent decreases.

Source: IQVIA Total Patient Tracker. Retrieved July 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
Apr 2020	771,733
May 2020	783,334
Jun 2020	791,496

Source: IQVIA Total Patient Tracker. Retrieved July 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).