Reducing Opioid Morbidity and Mortality

Goal Leaders:

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Overview

Challenge

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

Opportunity

o   The urgency of this crisis has unified HHS around the goals most likely to prevent opioid misuse, treat existing opioid addiction, and prevent opioid overdose, with the immediate aim of preventing further increases in these negative outcomes. Specifically, HHS will:

1.   Improve access to prevention, treatment and recovery support services

2.   Target the availability and distribution of overdose-reversing drugs

3.   Strengthen public health data and reporting

4.   Support cutting-edge research

5.   Advance the practice of pain management

Overview

Goal Statement

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

Overview: Summary of Progress – FY19 Q2

o AHRQ has released Multiple new tools and resources, e.g.: the Academy for Integrating Behavioral Health and Primary Care has expanded the medication-assisted treatment (MAT) for Opioid Use Disorder (OUD) Environmental Scan to more than 400 tools and resources to help providers, patients, and communities implement MAT in rural primary care settings; the Patient-Centered Clinical Decision Support Learning Network has released its *Stakeholder-driven Action Plan for Improving Pain Management, Opioid Use, and Opioid Use Disorder Treatment Through Patient-Centered Clinical Decision Support;* the Evidence Based Practice Centers posted *Treatment for Acute Pain: An Evidence Map.*

o CDC has released the latest overdose death statistics: [Drug and Opioid-Involved Overdose Deaths—United States, 2013-2017](#) highlighting expanding geographic reach and impact of synthetic opioids.

o CDC contributed to NASEM Workshop on Applying Clinical Practice Guidelines for Prescribing Opioids for Acute Pain, and provided new opioid trainings for providers: 1. *Determining Whether to Initiate Opioids for Chronic Pain ;* and 2. *Implementing CDC's Opioid Prescribing Guideline into Clinical Practice.*

o CMS and NIH are collaborating to ensure that research efforts are effectively targeted to inform coverage for pain treatments without addiction liability, and CMS issued a Bulletin provided information to states looking for ways to promote non-opioid options for chronic pain management in their Medicaid programs.

o CMS released Notice of Funding Opportunity announcements for two models: the Maternal Opioid Misuse (MOM) model to improve the quality of care and reduce costs for pregnant and postpartum Medicaid beneficiaries with OUD and their infants through state-driven care transformation. The Integrated Care for Kids (InCK) Model to reduce expenditures and improve the quality of care for children covered by Medicaid and CHIP.

Overview: Summary of Progress – FY19 Q2

o FDA is developing a multi-component systems model of opioid use, misuse, abuse, and overdose. The goal is a tool that can assess the potential effects of policies and identify areas where interventions by FDA and others may have the greatest impact on stemming overdose deaths. To support this work, FDA hosted the first ever Inter-Agency Opioid Systems modeling meeting with NIH and CDC on April 29, 2019 to ensure close collaboration and alignment amongst data modeling teams, federal partners, data experts, and other stakeholders.

o In April of 2019, FDA issued a safety announcement identifying reports of harm from sudden discontinuation of opioid pain medicines and announced required label changes to guide prescribers on gradual, individualized tapering. The Office of the Assistant Secretary for Health convened a working group with representatives from AHRQ, ASPE, CDC, CMS, FDA, NIDA, and SAMHSA to develop a guide for clinicians on appropriate dosage reduction or discontinuation of opioids.

o NIH HEAL (Helping to End Addiction Long-term[SM]) Initiative supports cutting-edge research to speed scientific solutions for the national opioid public health crisis. Research priorities include development of new non-addictive pain medications, more flexible medication options and behavioral interventions to treat OUD, comparison of different treatments for neonatal abstinence syndrome, and implementation science to develop and test OUD treatment models. NIH plans to award more than $850 million in support of NIH HEAL Initiative[SM] research in FY 2019.

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

Key Indicators: FY19 Q2

Indicator	Target Value Q2FY19	Actual Value Q2FY19	Final Target Value* Q4FY19
Total morphine milligram equivalents dispensed	29 billion	28 billion	27 billion
Morphine milligram equivalents /prescription	737	730	718
Naloxone prescriptions	214,425	233,896	257,310**
Unique buprenorphine patients	688,396	697,220	728,890
Long-acting injectable or implantable buprenorphine prescriptions	2,545	4,283	5,086**
Extended release naltrexone prescriptions	71,757	72,416	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.

**Naloxone and long-acting buprenorphine goals were revised to be more ambitious. Naloxone: based on a linear projection of 2017-2018 data, the new goal is 150 percent increase in prescriptions in FY 2019. Long-acting buprenorphine: based on a quadratic projection of data since introduction of Sublocade, the new goal is a 3.13 fold increase in FY 2019.
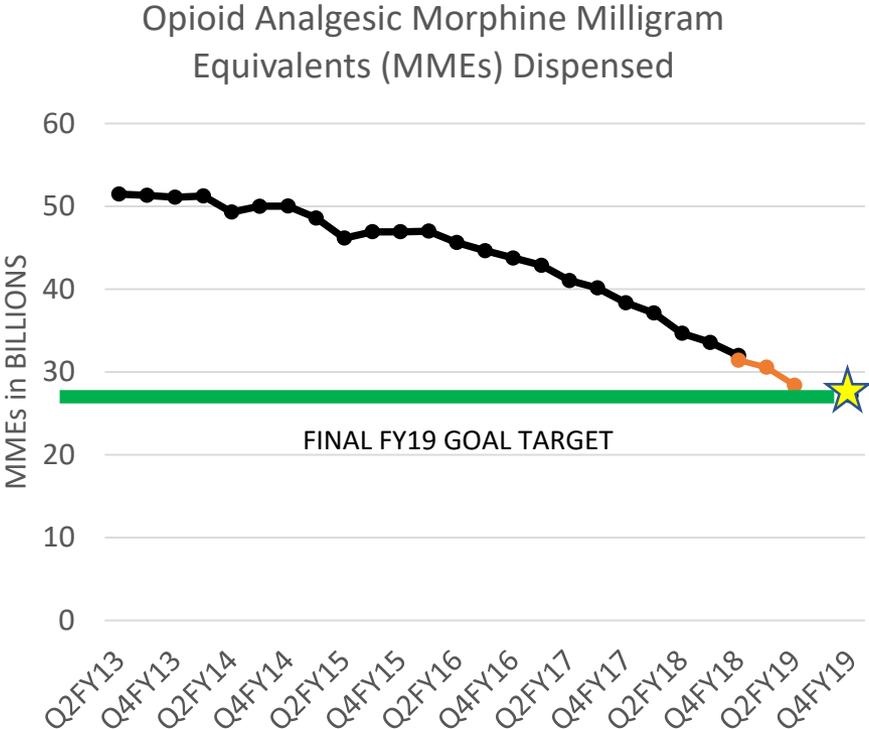
Key Indicators

o 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

Q4FY18	31
Q1FY19	31
Q2FY19	28

Opioid Analgesic Morphine Milligram Equivalents (MMEs) Dispensed

FINAL FY19 GOAL TARGET

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

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Key Indicators

o 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

Q4FY18	756
Q1FY19	749
Q2FY19	730
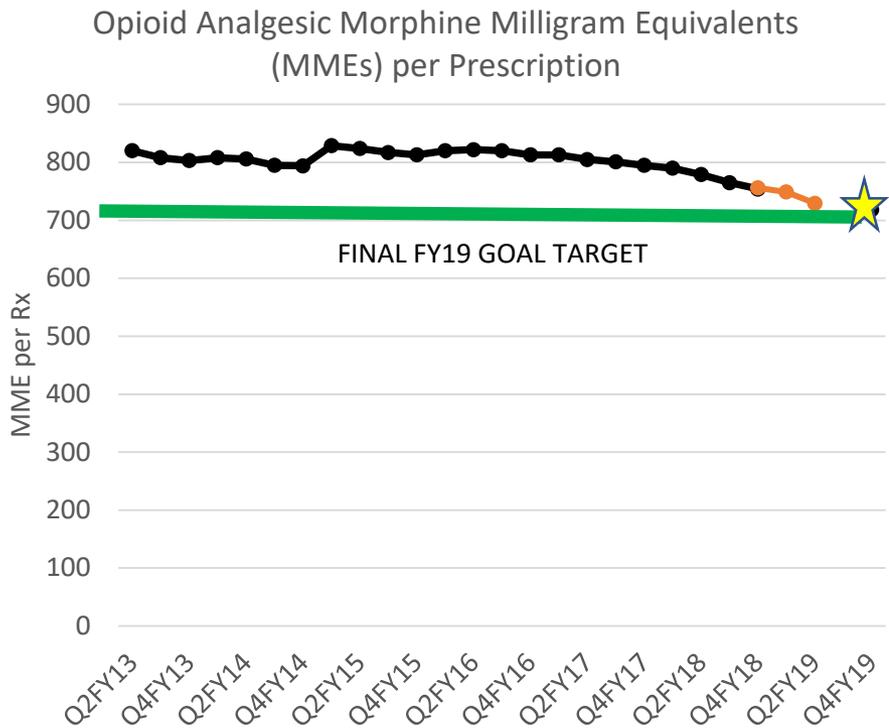
Opioid Analgesic Morphine Milligram Equivalents (MMEs) per Prescription

FINAL FY19 GOAL TARGET

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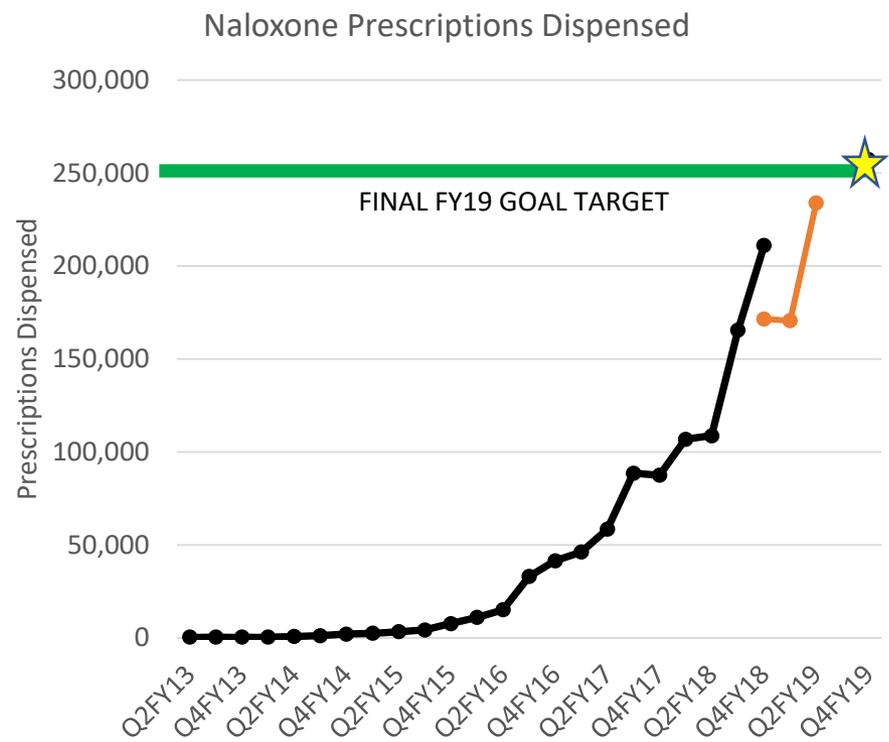
Key Indicators

o 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

Q4FY18	171,540
Q1FY19	170,575
Q2FY19	233,896

Naloxone Prescriptions Dispensed

FINAL FY19 GOAL TARGET

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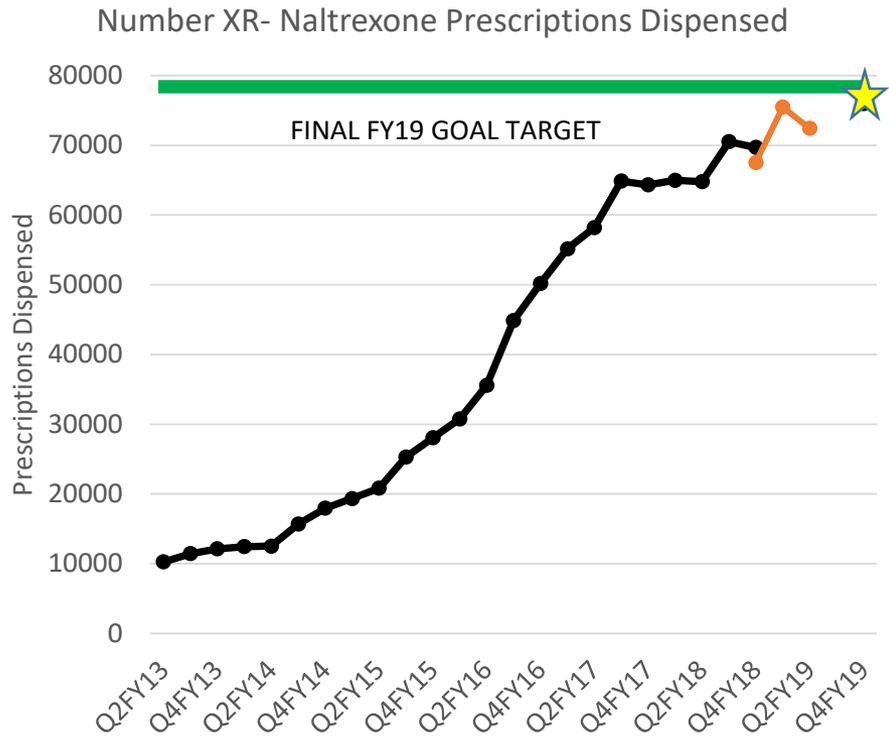
Key Indicators

o 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

Q4FY18	67,536
Q1FY19	75,480
Q2FY19	72,416

Number XR- Naltrexone Prescriptions Dispensed

FINAL FY19 GOAL TARGET

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

Key Indicators

o 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
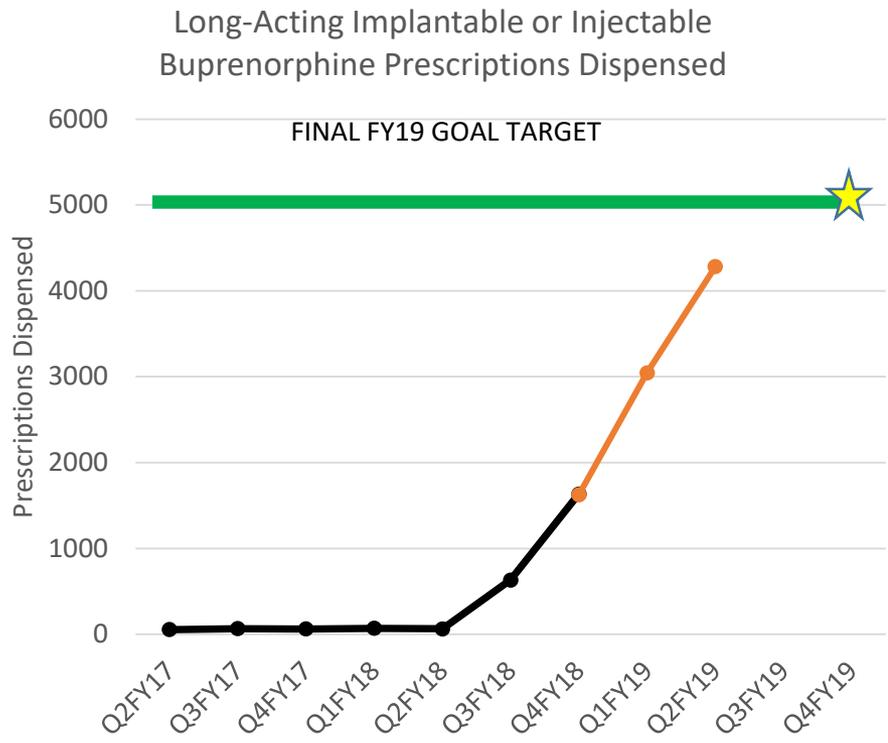
Long-Acting Implantable or Injectable Buprenorphine Prescriptions Dispensed

FINAL FY19 GOAL TARGET

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

Key Indicators

o Number of unique patients receiving buprenorphine

Unique Patients Receiving Buprenorphine

FINAL FY19 GOAL TARGET
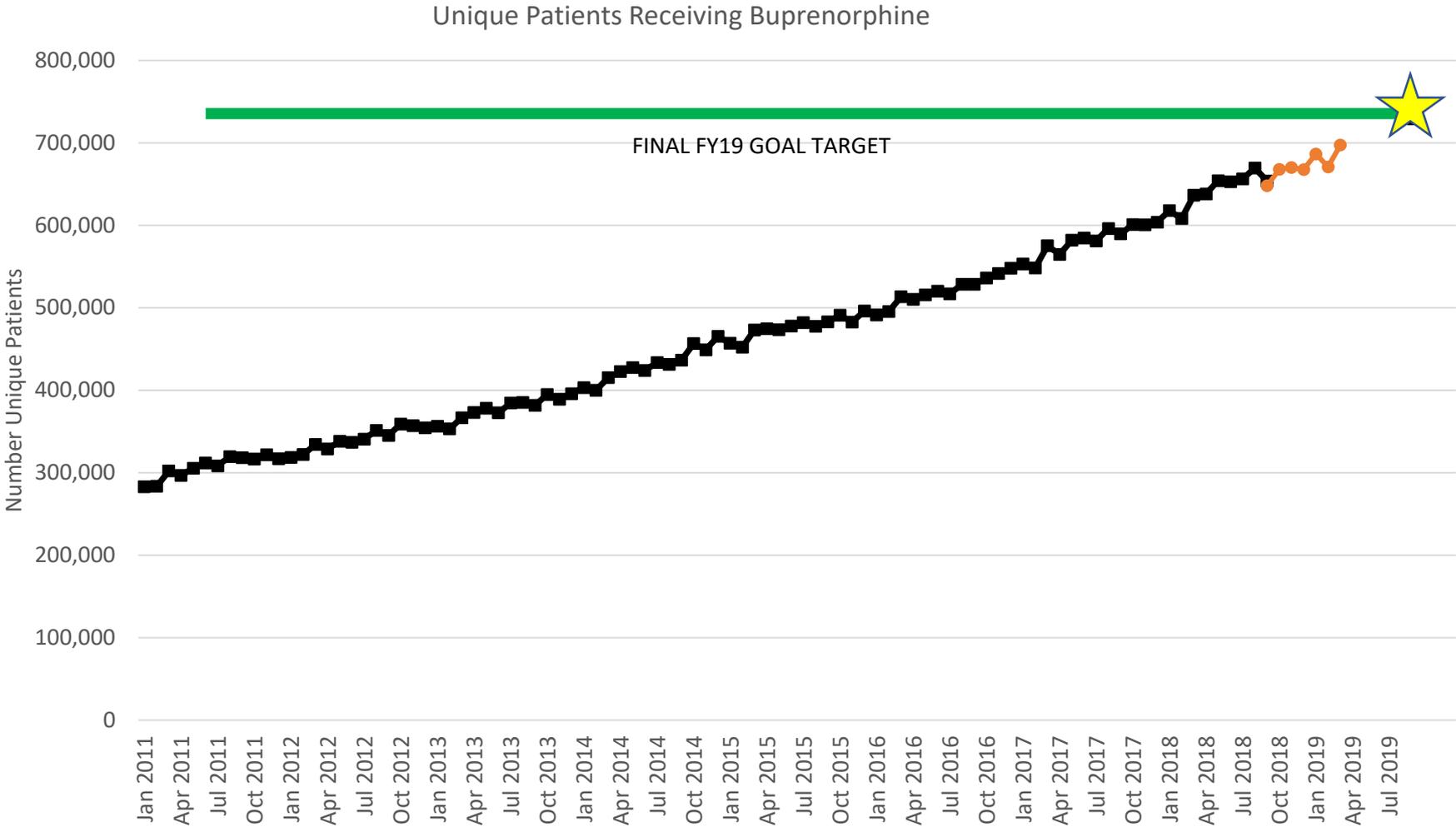
Source: IQVIA Total Patient Tracker. Retrieved October 2018 and April 2019.

Key Indicators

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

Original Dataset

Jan 2011	282,680	Jan 2013	356,217	Jan 2015	456,933	Jan 2017	553,127
Feb 2011	283,299	Feb 2013	352,936	Feb 2015	451,952	Feb 2017	548,236
Mar 2011	302,038	Mar 2013	366,672	Mar 2015	472,956	Mar 2017	575,146
Apr 2011	296,560	Apr 2013	373,083	Apr 2015	474,673	Apr 2017	564,749
May 2011	305,414	May 2013	378,071	May 2015	473,289	May 2017	581,884
Jun 2011	311,828	Jun 2013	372,519	Jun 2015	477,787	Jun 2017	584,361
Jul 2011	308,331	Jul 2013	384,453	Jul 2015	482,037	Jul 2017	581,081
Aug 2011	319,571	Aug 2013	385,154	Aug 2015	477,343	Aug 2017	596,044
Sept 2011	318,069	Sept 2013	381,482	Sept 2015	482,757	Sept 2017	589,540
Oct 2011	316,515	Oct 2013	394,861	Oct 2015	490,729	Oct 2017	600,979
Nov 2011	321,562	Nov 2013	388,896	Nov 2015	482,648	Nov 2017	600,495
Dec 2011	316,717	Dec 2013	395,822	Dec 2015	495,938	Dec 2017	603,720
Jan 2012	318,347	Jan 2014	403,103	Jan 2016	491,135	Jan 2018	617,767
Feb 2012	321,877	Feb 2014	400,008	Feb 2016	495,341	Feb 2018	608,144
Mar 2012	334,108	Mar 2014	415,101	Mar 2016	513,216	Mar 2018	636,506
Apr 2012	328,860	Apr 2014	422,673	Apr 2016	510,109	Apr 2018	638,066
May 2012	337,959	May 2014	427,300	May 2016	515,682	May 2018	654,147
Jun 2012	336,796	Jun 2014	423,909	Jun 2016	520,109	Jun 2018	652,682
Jul 2012	340,684	Jul 2014	433,507	Jul 2016	516,827	July 2018	656,350
Aug 2012	351,043	Aug 2014	431,412	Aug 2016	528,396	Aug 2018	669,400
Sept 2012	345,195	Sept 2014	436,368	Sept 2016	528,292	Sept 2018	653,737
Oct 2012	358,867	Oct 2014	456,588	Oct 2016	536,006		
Nov 2012	356,973	Nov 2014	448,999	Nov 2016	541,688		
Dec 2012	354,349	Dec 2014	465,204	Dec 2016	547,869		

New Dataset

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

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

Summary of Progress – FY19 Q1

CDC

o Prescribing Estimates Project: the CDC has completed meetings of the federal advisory workgroup established by the NCIPC's Board of Scientific Counselors (BSC). The BSC met in December 2018 to provide providing guidance to the CDC based on the results of the workgroup. CDC will analyze medical claims data from Optum and Marketscan to assess current opioid prescribing patterns among patients with Medicare, Medicaid, and private insurance.

o Overdose Deaths Morbidity and Mortality Weekly Report published: Drug and Opioid-Involved Overdose Deaths—United States, 2013-2017 confirms that the drug overdose epidemic continues to be driven by sharp increases in deaths involving synthetic opioids (other than methadone), such as illicitly manufactured fentanyl. The report highlights the expanding geographic reach and significant impact of synthetic opioids, which is notable given that death rates from heroin and prescription opioids were stable from 2016 to 2017.

o New Opioid Trainings for Providers: Initiating Opioid Therapy and Implementing the CDC Guideline CDC launched two new opioid trainings that support providers in safer prescribing of opioids for chronic pain. The modules are part of a series of interactive online trainings that feature recommendations from the *CDC Guideline for Prescribing Opioids for Chronic Pain.*

o *Determining Whether to Initiate Opioids for Chronic Pain*

o *Implementing CDC's Opioid Prescribing Guideline into Clinical Practice*

o Combating Opioid Overdose Through Community-level Intervention Initiatives (COOCLI): In partnership with the Office of National Drug Control Policy (ONDCP), CDC provided $3.5 million dollars in FY 2019 to ONDCP to develop public health/public safety interventions at the local level.

Summary of Progress – FY19 Q2

CDC

- Overdose Data to Action Notice of Funding: Posted on Grants.gov on Feb 1, applications will be accepted until May 2. Funding will support states, eligible territories, and select cities/counties in enhancing the quality and timeliness of data on opioid prescribing, morbidity and mortality, and then to use data to inform and target prevention and response initiatives at the state and local level. CDC hosted five informational webinars in February and March.

- Fentanyl Submissions: Published Notes from the Field: Fentanyl Drug Submissions — United States, 2010–2017, summarizing trends in number of drug products obtained by law enforcement testing positive for fentanyl; indicated number of fentanyl submissions may be stabilizing for the first time in 4 years.

- Overdose Deaths Among Women: Published MMWR on Drug Overdose Deaths Among Women Aged 30–64 Years — United States, 1999–2017, finding the crude rate of drug overdose deaths among women aged 30–64 years in the United States increased by 260 percent during this time period for all drug categories examined, with a notable increase in rates of deaths involving synthetic opioids (1,643 percent) and heroin (915 percent).

Summary of Progress – FY19 Q2

CDC (Q2 cont)

o County-Level Opioid Prescribing: Published in JAMA on [County-Level Opioid Prescribing in the United States, 2015 and 2017](#) finding that the reduction in opioid prescribing that began in 2012 has accelerated in the United States; amount of opioids prescribed decreased an average of 10.0 percent annually with reductions in 74.7 percent of counties from 2015 to 2017, compared with 3.6 percent annually with reductions in 49.6 percent of counties from 2010 to 2015. However, opioids continued to be prescribed at 512.6 MME per capita in 2017, nearly triple the amount prescribed in 1999, and the duration of opioid prescriptions continues to increase nationally.

o National Academies of Sciences Engineering Medicine Workshop: Presented on CDC's efforts with regard to prescribing guidelines for opioids, particularly with regard to acute pain at NASEM Workshop on Applying Clinical Practice Guidelines for Prescribing Opioids for Acute Pain.

o 2019 ESOOS Partners Meeting: Collaborated with Association of State and Territorial Health Officials to host partner organizations for a 1.5 day Enhanced State Opioid Overdose Surveillance (ESOOS) national partnership meeting to explore how CDC ESOOS strategies interact with and complement partners' current opioid work and how we might achieve common goals.

Summary of Progress – FY19 Q1/Q2

NIH

o NIH HEAL Initiative[SM]: NIH is continuing to support cutting-edge research through the NIH HEAL (Helping to End Addiction Long-term[SM]) Initiative, an aggressive effort to speed scientific solutions to stem the national opioid public health crisis. Research priorities include the development of new non-addictive pain medications, more flexible medication options and behavioral interventions for treating OUD, the comparison of different treatments for neonatal abstinence syndrome, and implementation science to develop and test OUD treatment models. NIH plans to award more than $850 million in support of NIH HEAL Initiative[SM] research in FY 2019 (from funds appropriated in FY 2018 and FY 2019). This adds to a substantial investment made by NIH Institutes and Centers in the areas of pain, addiction, complementary medicine, and much more.

Summary of Progress – FY19 Q1/Q2

NIH (cont)

- To date, HEAL has awarded new research grants and contracts in the following areas:

    - Development of opioid addiction and overdose medications
    - Implementation science for preventing and treating addiction
    - New models for the development of pain medications.
    - Novel and optimized addiction prevention and treatment strategies
    - Preclinical research on pain
    - Clinical trials on pain management
    - Improving outcomes in infants and children exposed to opioids

- The HEALing Communities Study, in collaboration with SAMHSA, will test the effect of integrating evidence-based interventions for OUD, such as medications for addiction treatment, in an array of community-based settings in select communities hardest hit by the opioid crisis (SEE COLLABORATIVE MILESTONES).

Summary of Progress – FY19 Q1/Q2

NIH (cont)

- In FY 2019 alone, HEAL has issued new funding opportunities calling for research to enhance pain management through:
    - Developing novel devices and non-addictive medications for the treatment of pain
    - Building a clinical network to test new pain medications
    - Testing novel approaches for managing pain associated with specific conditions, including hemodialysis and back pain
    - Creating preclinical models to study pain, opioid use disorder, and opioid overdose
    - Carrying out studies of pain management in real-world settings to reduce opioid prescribing and inform policies
    - Identifying and validating new targets for the treatment of pain, using innovative modeling and imaging technologies

Summary of Progress – FY19 Q1/Q2

NIH (cont)

- o Improve prevention and treatment of opioid misuse, addiction, and overdose through:
  - Improving the treatment of OUD in the justice system
  - Developing effective OUD prevention interventions for adolescents and young adults
  - Determining the factors related to sleep and circadian rhythms that contribute to OUD risk and treatment response
  - Conducting effectiveness trials to optimize , implement, scale and sustain the collaborative care model for comorbid OUD and other mental health conditions
  - Enhancement of behavioral and social interventions to improve adherence to medications used in the treatment of OUD
  - Characterizing the long-term effects of prenatal opioid exposure, including the effects on brain development

Summary of Progress – FY19 Q1/Q2

NIH (cont)

o Also in FY 2019, HEAL has issued design challenges and funding opportunities for startups and small businesses in order to spur innovation in development of novel approaches to solving the opioid crisis.

o In Q2 FY 2019, external HEAL advisory groups began convening, including:

▪ The HEAL Multi-Disciplinary Working Group of experts in pain and addiction research, which includes members of NIH advisory councils, scientific, industry, and patient advocacy communities.

▪ The HEAL Partnership Committee, a subgroup of the Multi-Disciplinary Working Group that will assist NIH in the development of new treatments for pain and addiction through HEAL research.

o In Q2 FY 2019, the following HEAL events took place:

▪ Eight technical assistance or pre-application events for potential applicants to HEAL funding opportunities.

▪ A Critical Evaluation of Animal Pain Models Workshop

▪ The Opioid Crisis and the Future of Addiction and Pain Therapeutics: Opportunities, Tools, and Technologies Symposium

Summary of Progress – FY19 Q1/Q2

SAMHSA

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

o SAMHSA's Grants to Prevent Prescription Drug and Opioid Overdose-Related Deaths (PDO), first funded in FY2016, and First Responders Comprehensive Addiction and Recovery Act (FR-CARA) grantees, first funded in FY2017, address prescription drug/opioid overdose-related deaths by providing prevention training to first responders and other key community sectors and improving access to naloxone/other FDA approved opioid-overdose reversal kits.

Summary of Progress – FY19 Q1/Q2

SAMHSA (cont)

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

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

o SAMHSA awarded 57 State Opioid Response (SOR) Supplement grants for a total of $1.5 billion in FY 2018. Part of this funding will be award as Year 2 continuation grants for SOR in FY 2019. The grants increase and enhance the ability to address the opioid crisis by increasing access to MAT using the three Food and Drug Administration (FDA) approved medications for the treatment of OUD, reducing unmet treatment need, and reducing opioid overdose related deaths through the provision of prevention, treatment, and recovery activities for OUD.

Summary of Progress – FY19 Q1

AHRQ

o In November, AHRQ held a workshop with grantees to discuss lessons learned on how to reduce barriers and support rural primary care practices providing MAT. AHRQ will disseminate the findings from these grants, along with tools and a playbook, through the Academy for Integrating Behavioral Health and Primary Care, a web portal targeting primary care practices.

o Also in November, AHRQ sponsored a Patient Safety Organization (PSO) Summit to Address the Opioid Crisis, leading to a PSO Working Group on Opioids and a preliminary Action Plan.

o AHRQ has received a higher than usual volume of inquiries in response to the Special Emphasis Notice on Health Services Research to Address the Opioids Crisis. The first applications will be reviewed in the spring.

o AHRQ continues to work on four systematic reviews to support CDC guidelines on opioids and pain management.

Summary of Progress – FY19 Q2

AHRQ

o The Academy for Integrating Behavioral Health and Primary Care has expanded the MAT for OUD Environmental Scan to more than 400 tools and resources to help providers, patients, and communities implement MAT in rural primary care settings. The collection is divided by topic and contains live links to all of the tools and resources.

o The Patient-Centered Clinical Decision Support Learning Network has released its *Stakeholder-driven Action Plan for Improving Pain Management, Opioid Use, and Opioid Use Disorder Treatment Through Patient-Centered Clinical Decision Support.*

o The Evidence Based Practice Centers posted *Treatment for Acute Pain: An Evidence Map* for public comment on March 28. AHRQ continues to work on four systematic reviews to support CDC guidelines on opioids and pain management.

o Two new statistical briefs have been released; one on Inpatient Stays Involving Mental and Substance Use Disorders and the other on Opioid-Related Hospital Stays Among Women in the United States.

Summary of Progress – FY19 Q1

CMS

o Finalized new Medicare Part D opioid policies for 2019, including drug management programs to better coordinate care when chronic high-risk opioid use is present, and improved safety alerts when opioid prescriptions are filled at the pharmacy.

o Working to implement numerous SUPPORT Act provisions, including a new Medicare benefit category for opioid use disorder treatment services furnished by Opioid Treatment Programs, effective January 1, 2020. Finalized requirements in Medicare rulemaking to implement the telehealth expansion for treatment of substance use disorder in section 2001 of the SUPPORT Act, effective July 1, 2019.

o Approved six additional states' 1115 Medicaid demonstrations (NC, WI, AK, NM, KS, RI) to increase access to medication-assisted treatment, bringing the total up to 21 states with such demonstrations

Summary of Progress – FY19 Q1

CMS (Q1 cont)

- o CMS Quality Improvement Organization (QIO) program contractors provided education and technical assistance on opioid use and management to over 7,000 providers and practitioners across all states. For example, QIOs supported education on the CDC Opioid guideline in all states and naloxone training to partners in 144 communities in 29 states. The CMS QIO program and partners were able to contribute to a reduction in 2,437 opioid adverse drug events in the opioid high risk Medicare FFS population.

CMS

o CMS issued a Bulletin provided information to states looking for ways to promote non-opioid options for chronic pain management in their Medicaid programs. The Bulletin meets the requirements of Section 1010 of the SUPPORT Act, which requires CMS to issue guidance to states on mandatory and optional items and services for non-opioid treatment and management of pain that may be provided in the state Medicaid program. The Bulletin supports the President's Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand and is consistent with HHS' 5-Point Strategy to Combat the Opioid Crisis.

o CMS released an expanded version of the Opioid Prescribing Mapping Tool in February, allowing users to visualize 2016 opioid utilization rates and changes between 2013 and 2016. For the first time, the tool includes data for opioid prescribing in the Medicaid program. Additionally, users can now make geographic comparisons of Medicare Part D opioid prescribing rates over time for urban and rural communities.

CMS (Q2 cont)

o CMS released the Medicaid Integrity Institute Compendium of Promising Practices. This publication was developed by a group of state and federal partners who identified program integrity vulnerabilities and promising practices to address them. Practices include information on access to and sharing of prescription drug monitoring program (PDMP) data, opioid prescribing practices and policy, and education needs.

o CMS released Notice of Funding Opportunity announcements for two models: the Maternal Opioid Misuse (MOM) model is a patient-centered, service-delivery model, which aims to improve the quality of care and reduce costs for pregnant and postpartum Medicaid beneficiaries with OUD and their infants through state-driven care transformation. The Integrated Care for Kids (InCK) Model is a child-centered local service delivery and state payment model aimed at reducing expenditures and improving the quality of care for children covered by Medicaid and CHIP, especially those with or at-risk for developing significant health needs.

Summary of Progress – FY19 Q1

FDA

o FDA conducted an iterative, multi-modal social science research project aimed at obtaining a clearer understanding of current knowledge, attitudes, behaviors, and perceptions about opioid use, misuse, and addiction among health care providers, patients, and the lay public. All data collection has been completed and FDA is currently conducting higher-level statistical analysis of the survey data to be completed by end of fourth quarter 2019.

o On Sept. 28, 2018, FDA awarded a three-year contract for an iterative, mixed-method research project to explore and assess the knowledge, attitudes, and behaviors about abuse-deterrent formulation opioids (ADFs) among opioid prescribers and dispensers/pharmacists, including related to the current terminology and to explore possible alternative language for describing these products. All the materials have been completed for the Phase 1 focus groups, and we have obtained OMB approval. We are still awaiting IRB review in order to start data collection; however, we expect to begin recruiting HCPs and conducting Phase 2 focus groups in mid-2019.

FDA (Q1 cont)

o Beginning in 2012, FDA has provided funding and other support under a cooperative agreement with the Partnership to develop and deploy the "Search and Rescue" prescriber education campaign. 2019 marks the 7th year FDA has collaborated with the non-profit Partnership for Drug-Free Kids to develop and promote a nationwide opioid prescriber education campaign called "Search and Rescue" (S&R) that gives healthcare providers the resources they need to prescribe opioids responsibly and prevent the misuse of medicine in their practices. Traffic to the S&R website increased continually throughout the 2018 campaign outreach, garnering 55K visits between 3/1 and 9/30/18, or 258 per day, the highest yearly rate to date. Nearly half of these visitors (49 percent) downloaded or clicked links to resources posted on the site, which is more than double the proportion of visitors who did so in 2017, and the campaign's targeted email outreach reached more than 415K unique HCP.

o On Dec. 17-18, 2018, FDA convened an advisory committee meeting to discuss naloxone co-prescribing. FDA is actively evaluating the comments received during this meeting as well as written comments to the Docket to determine next steps.

Summary of Progress – FY19 Q1

FDA (Q1 cont)

o On Aug. 22, 2018, FDA awarded a contract to the National Academies of Sciences, Engineering, and Medicine (NASEM) to help advance the development of evidence-based guidelines for appropriate opioid analgesic prescribing for acute pain resulting from specific conditions or procedures. Currently, work is underway to understand what evidence is needed to ensure that all current and future clinical practice guidelines for opioid analgesic prescribing are sufficient, and what research is needed to generate that evidence in a practical and feasible manner. NASEM held the first public session on November 13, 2018 to gather information and assemble evidence that members will examine and discuss in the course of making the committee's findings, conclusions, and recommendations. A second public workshop was held on February 4, 2019.

Summary of Progress – FY19 Q2

FDA

- On January 17, 2019, FDA announced the results of our Model Drug Facts Label Comprehension Study for OTC Naloxone, including posting the model DFL and the supporting FDA review, to jumpstart the development of OTC naloxone products to promote wider access to this medicine. This is the first time FDA has proactively developed and tested a DFL for a drug to initiate the development of an OTC product.

- FDA is developing a multi-component systems model of opioid use, misuse, abuse, and overdose. The goal is a tool that can assess the potential effects of policies and identify areas where interventions by FDA and others may have the greatest impact on stemming overdose deaths. Such a model has been recommended by NASEM and others. A multidisciplinary team at FDA is applying a quantitative system dynamics modeling approach that can account for complex and dynamic relationships among a diverse set of contributing factors. Completion and beta-testing of a first iteration of the model are planned in 2019. To support this work, FDA is hosting the first ever Inter-Agency Opioid Systems modeling meeting with NIH and CDC on April 29, 2019 to ensure close collaboration and alignment amongst data modeling teams, federal partners, data experts, and other stakeholders.

Summary of Progress – FY19 Q2

FDA (Q2 cont)

o On March 27, 2019, FDA strengthened Risk Evaluation and Mitigation Strategy (REMS) requirements for transmucosal immediate-release fentanyl (TIRF) products to better ensure the safe use of these products. The required changes to the REMS include:

- Requiring that prescribers document a patient's opioid tolerance concurrently with each prescription of a TIRF medicine for outpatient use.

- Requiring inpatient pharmacies to develop internal policies and procedures to verify opioid tolerance in patients who require TIRF medicines while hospitalized.

- Requiring that a TIRF medicine be dispensed for outpatient use with evidence or other documentation of safe use conditions, including concurrent documentation of opioid tolerance.

- Requiring the development of a new patient registry to monitor for serious adverse events including overdose (both fatal and non-fatal).

Summary of Progress – FY19 Q1

HRSA

o In FY 2019 Q1, HRSA worked to expand the behavioral health workforce and address the opioid crisis through the following notice of funding opportunity (NOFO) announcements, loan repayment programs, and technology innovation challenges:

- The release of FY 2019 Application and Program Guidance for the new National Health Service Corps Substance Use Disorder Workforce Loan Repayment Program. This program provides up to $75,000 per health care professional in exchange for a three-year commitment and expands eligible disciplines and site types eligible for loan repayment.

- The announcement of the Primary Care Training and Enhancement: Integrating Behavioral Health and Primary Care Program NOFO, which will fund 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. Up to 10 grants totaling $4 million will be awarded for this program.

- The announcement of a NOFO for up to 120 award recipients for the Rural Communities Opioid Response Program-Planning to serve rural communities in building capacity for prevention, treatment, and recovery efforts.

HRSA (Q1 cont)

- o The development of a NOFO to fund entities to serve as System Coordination Providers to leverage resources at federal, state, and local levels to ensure people living with HIV (PLWH) who have opioid use disorder have access to appropriate substance use disorder care, treatment, and services. This initiative seeks to strengthen system-level collaborations and networks of care 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 PLWH who have opioid use disorder in 15 states.

- o The review of submissions for the Addressing Opioid Use Disorder in Pregnant Women and New Moms Challenge that will support tech innovations to improve access to care for pregnant women and new moms. HRSA anticipates awarding 7-10 Phase 1 winners by February 2019.

Summary of Progress – FY19 Q2

HRSA

In FY2019 Q2, HRSA worked to expand the behavioral health workforce and address the opioid crisis through several notices of funding opportunities (NOFO), a technology innovation challenge, and a grantee meeting:

NOFO Announcements- Closed

- The HRSA Rural Communities Opioid Response Program (RCORP)-Planning NOFO, which closed on January 15, 2019, received 155 applications. HRSA will award up to 120 grants, totaling $24 million, for this program, which helps rural communities build capacity for prevention, treatment, and recovery efforts. Projects will start on June 1, 2019.

- The HRSA Primary Care Training and Enhancement: Integrating Behavioral Health and Primary Care NOFO, which closed on January 28, 2019, received 89 applications. HRSA will award ten grants totaling up to $4 million, which will fund 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 (OUD). Projects will start on July 1, 2019.

Summary of Progress – FY19 Q2

HRSA (Q2 cont)

NOFO Announcements- Closed

- The HRSA National Health Service Corps (NHSC) Substance Use Disorder (SUD) Workforce Loan Repayment Program NOFO, which closed on February 28, 2019, received over 1,600 applications—representing every U.S. state and territory—from healthcare providers serving in SUD treatment facilities. This program provides up to $75,000 per health care professional in exchange for a three-year commitment and expands eligible disciplines and site types eligible for loan repayment. By the end of FY 2019, the NHSC SUD Workforce Loan Repayment Program will award approx 1,100 health professionals providing SUD treatment to vulnerable communities.

NOFO Announcements- Open

- The HRSA Strengthening Systems of Care for People Living with HIV and Opioid Use Disorder program funds entities to serve as System Coordination Providers to leverage resources at federal, state, and local levels to ensure people living with HIV (PLWH) who have OUD have access to appropriate SUD care, treatment, and services. This initiative seeks to 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 PLWH who have OUD. This NOFO is open until April 16, 2019.

Summary of Progress – FY19 Q2

HRSA (Q2 cont)

NOFO Announcements- Open

- o The HRSA RCORP-Implementation program will fund up to 75 award recipients, totaling $75 million. The program advances the RCORP initiative by strengthening and expanding SUD/OUD prevention, treatment, and recovery service delivery in high-risk rural communities. This NOFO is open until May 6, 2019.

- o The HRSA RCORP-Evaluation NOFO will award one recipient a total of $3 million per year for four years to evaluate the impact of RCORP initiatives including RCORP-Planning and RCORP-Implementation, as well as future RCORP programs. This NOFO is open until May 6, 2019.

- o The HRSA Graduate Psychology Education Program and the Opioid Workforce Expansion Programs will fund training programs that support students in psychology and other mental and behavioral health professionals and paraprofessionals with a focus on the treatment of OUD and SUD. HRSA will fund approximately 62 awards, totaling over $69 million. This NOFO is open until May 7, 2019.

HRSA (Q2 cont)

Technology Innovation Challenge

- A panel of federal judges chose ten winners of Phase 1 of the HRSA-sponsored Addressing OUD in Pregnant Women and New Moms Challenge, who each received a share of a $100,000 prize. The Challenge aims to improve access to quality health care for pregnant and new mothers struggling with OUD and to use technology to provide access to treatment and recovery services to keep women and their children healthy and SUD-free. The Challenge is currently in Phase 2, where Phase 1 winners are developing their innovation ideas and performing small-scale testing. Demonstration Day for Phase 2 will take place on September 12-13, 2019, after which three-to-five Phase 2 winners will receive a share of a $125,000 prize and move to the final phase of the Challenge. One final winner will receive a $150,000 prize.

Grantee Meeting

- Planning efforts are underway, and registration is now open, for the HRSA Responding to the Rural Substance Use Crisis: Promoting Community Action and Tele-Behavioral Health Grantee Meeting taking place on June 18-20, 2019, in Rockville, Maryland. This is a reverse site visit and participants will include grantees from the following cohorts: RCORP-Planning, Rural Health Opioid Program, Evidence-Based Tele-Behavioral Health Network Program, and Substance Abuse Treatment Telehealth Network Grant Program.

Summary of Progress – FY19 Q1

IHS

o Released the "IHS Internet Eligible Controlled Substance Prescriber Designation" policy to expand access to tele-medicine MAT models in remote IHS locations

o The IHS National Pharmacy and Therapeutics Committee added buprenorphine, buprenorphine/naloxone, and naltrexone to the IHS National Core Formulary to ensure patient access to these medications pursuant to a legal prescription order

o Collaborated with the American College of Obstetrics and Gynecology to finalize a guidance document entitled "Recommendations to the Indian Health Service on American Indian/Alaska Native Pregnant Women and Women of Childbearing Age with Opioid Use Disorder" to implement strategies surrounding early detection and treatment of OUD in women of childbearing age. Release delayed.

Summary of Progress – FY19 Q1

IHS (Q1 cont)

- Designed and began implementation of an opioid surveillance strategy that will evaluate opioid-related data on national, regional, and local levels. The data will be used to evaluate population outcomes, target opioid interventions, enhance clinical decision support, and create professional practice evaluation strategies and inform local Opioid Stewardship campaigns.

- Released the IHS "Dental Acute Pain Management Guideline" and provider training for prescribing opioids for acute pain for general dentistry conditions and procedures.

- Convened the inaugural IHS Opioid Strategic Planning meeting and created an IHS Opioid Coordinating Group to combat the opioid epidemic through an expanded, comprehensive opioid strategy that is informed by actionable data and robust surveillance strategies.

Summary of Progress – FY19 Q2

IHS

Improve access to prevention, treatment, and recovery support services

- o Released the "Recommendations to the Indian Health Service on American Indian/Alaska Native Pregnant Women and Women of Childbearing Age with Opioid Use Disorder" guidance document to improve IHS response in the early detection and treatment of OUD in women of childbearing age.

- o Expanded partnership with University of New Mexico ECHO program to offer a monthly online DATA waiver training and a weekly ECHO for MAT to support MAT expansion in Primary Care.

Target the availability and distribution of overdose-reversing drugs

- o Increased naloxone dispensing 57 percent from FY 2017 baseline (data current through July 2018).

Strengthen public health data and reporting

- o Developed update for IHS National Data Warehouse to capture prescription day supply and prescriber to allow calculation of MME for opioid prescriptions. Functionality currently in beta testing. Subsequent opioid prescribing and OUD dashboards in planning discussions.

- o Developed and released EHR enhancements to capture SUD screening results.

- o Developed and submitted two clinical reporting surveillance measures to track implementation status of the perinatal OUD recommendations.

- o IHS received 10 million dollars in the Alcohol and Substance budget line for a new Pilot Program to provide opioid prevention, treatment, and recovery services. IHS will soon announce tribal consultation and confer for these funds to be distributed as grants in FY 2020.

Collaborative Milestones

HEALing Communities

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

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

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

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

- In April 2019, 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. RTI International, based in North Carolina, will serve as the study's coordinating center.

Collaborative Milestones

Non-pharmacological approaches to pain

o CMS and NIH are collaborating to ensure that research efforts are effectively targeted to inform coverage for pain treatments without addiction liability

o In February 2019, CMCS issued an informational bulletin addressing the Medicaid authorities that states may use for coverage of non-opioid pharmacological and non-pharmacological pain management therapies

o As part of its HEAL Initiative, NIH has also initiated research on acupuncture for management of chronic low back pain in older adults, in order to generate evidence needed to inform Medicare coverage of this treatment

Collaborative Milestones

o The Opioid and Controlled Substances Subcommittee (formerly part of the HHS Behavioral Health Coordinating Council) consists of HHS Operating Divisions and Staff Divisions that provides guidance and recommendations on relevant opioid use issues.

o Protecting Our Infants Act Strategy : The Opioids and Controlled Substances Subcommittee is implementing a work plan for the Protecting Our Infants Act Strategy and the Report to Congress under the Substance Use – Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act or the SUPPORT for Patients and Communities Act of 2018 that was recently published in March 2019.

Collaborative Milestones

o The Office of the Assistant Secretary for Health convened a working group with representatives from AHRQ, ASPE, CDC, CMS, FDA, NIDA, and SAMHSA to develop a guide for clinicians on appropriate dosage reduction or discontinuation of opioids.

o In April of 2019, FDA issued a safety announcement identifying reports of harm from sudden discontinuation of opioid pain medicines and announced required label changes to guide prescribers on gradual, individualized tapering.

o The draft HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics provides advice to clinicians and patients who are contemplating or initiating a reduction in opioid dosage or discontinuation of long-term opioid therapy for chronic pain.

o Collaboration with the patient, consideration of individual circumstances, and individualized approaches are emphasized.

Goal Structure & Strategies

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

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

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

Goal Structure & Strategies

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

Goal Structure & Strategies

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

Goal Structure & Strategies

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

Goal Structure & Strategies

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

Goal Structure & Strategies

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

Goal Structure & Strategies

Strategy: Target the availability and distribution of overdose-reversing drugs	
Rationale: Opioid overdose can be reversed by the opioid antagonist naloxone. Naloxone is a vital tool in the fight against opioid overdose, though issues of access and increasing potency of illicit opioids pose practical challenges. The activities below support improved access to overdose reversal medication, and quantitative progress will be reflected in the indicator tracking increased naloxone access.	
AGENCY	**ACTIVITY**
AHRQ	AHRQ will continue to disseminate the findings of their recently completed systematic evidence review on the Management of Suspected Opioid Overdose with Naloxone by Emergency Medical Services Personnel which was released in late November.
FDA	Model Drug Facts Label Comprehension Study for OTC naloxone to be completed by FDA in Spring 2019
IHS	IHS is developing an Indian Health Manual policy to issue naloxone to law enforcement agencies and other first responders and is expanding the number of pharmacist collaborative practice agreements to prescribe naloxone.
NIH	NIH's NIDA supports research to: ● Evaluate naloxone distribution programs ● Develop novel overdose reversal medications
SAMHSA	Continue to provide national leadership and support for naloxone and overdose prevention through the following: ● CARA First Responders grant funding ● State Opioid Response, STR, TOR, and targeted technical assistance ● Preventing Prescription Drug/Opioid Overdose Related Deaths grant funding ● Substance Abuse Prevention and Treatment block grant

Goal Structure & Strategies

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

Goal Structure & Strategies

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

Goal Structure & Strategies

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

Goal Structure & Strategies

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

Goal Structure & Strategies

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

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

Goal Structure & Strategies

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