# Reducing Opioid Morbidity and Mortality

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# *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 pharmacies
     b. Decrease by 10% the morphine milligram equivalents (MME) in opioid analgesic prescriptions dispensed in U.S. outpatient retail pharmacies.
  2. Increase naloxone access:
     a. Increase by 30% the number of prescriptions dispensed for naloxone in U.S. outpatient retail 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-order 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*

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

# 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

| Strategy: Improve access to prevention, treatment, and recovery support services (continued) | |
| --- | --- |
| AGENCY | ACTIVITY |
| CDC | CDC will help communities prevent and combat infectious diseases stemming from the opioid crisis by tracking disease patterns, alerting states to risks of disease outbreaks, and supporting proven prevention strategies, including those for engaging people who inject drugs into treatment. |
| CDC | CDC will continue to provide guidance to emergency responders to prevent occupational exposure to fentanyl including through the Health Hazard Evaluations (HHE) Program. |
| CMS | CMS will continue to work with states to support and to improve opioid use prevention and treatment efforts, including medication-assisted treatment and alternative treatments (e.g. 1115 demonstration waivers, 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: <br>● 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. <br>● 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:<br>● Telemedicine models through adoption of an IHS Internet Eligible Controlled Substance Prescriber policy<br>● Tracking of IHS prescribers authorized to prescribe buprenorphine<br>● 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/NIDA | NIDA supports a portfolio of implementation science research to improve the dissemination, use, and sustainability of evidence- based treatment of OUD. |
| NIH/NIDA | NIDA supports a portfolio of clinical research for rigorous study of:<br>● Comparative effectiveness of treatments for OUD<br>● Clinical decision support for OUD management in general healthcare settings<br>● Emergency department linkage to care for OUD<br>● 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/NIDA | 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:<br>● State Targeted Response grant funding and targeted technical assistance<br>● Substance Abuse Prevention and Treatment block grant prevention set aside<br>● Strategic Prevention Framework Partnership for Success (SPF-PFS) and Strategic Prevention Framework for Prescription Drugs (SPF-Rx)<br>● 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:<br>● State Targeted Response grant funding and targeted technical assistance<br>● Substance Abuse Prevention and Treatment block grant<br>● MAT for Prescription Drug and Opioid Addiction (MAT PDOA) grants<br>● Targeted funding such as the Pregnant and Postpartum Women treatment grants and Drug Court grants<br>● Oversight of Opioid Treatment Programs and the DATA waiver process<br>● Provision of education and training via PCSS-MAT<br>● Leveraging the Addiction Technology Transfer Centers<br>● Publication of TIP 63 "Medications for Opioid Use Disorder" |
| SAMHSA | Continue to provide national leadership and support for the broader dissemination and implementation of recovery support services through the following:<br>● Building Communities of Recovery grants<br>● State Targeted Response grant funding and targeted technical assistance<br>● Dissemination of Best Practices from the SAMHSA Policy Lab<br>● Leveraging the Addiction Technology Transfer Centers |

# 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 2018 |
| 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/NIDA | NIDA supports research to: <br>● Evaluate naloxone distribution programs <br>● Develop novel overdose reversal medications |
| SAMHSA | Continue to provide national leadership and support for naloxone and overdose prevention through the following: <br>● CARA First Responders grant funding <br>● State Targeted Response grant funding and targeted technical assistance <br>● Preventing Prescription Drug/Opioid Overdose Related Deaths grant funding <br>● 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:<br>● 1,178 health centers grantees who received $200 million from HRSA in September 2017 to increase access to substance abuse and mental health services.<br>● 13 rural health organizations who received nearly $3.3 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/NIDA | 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/NIDA | 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:<br>● National Survey on Drug Use and Health<br>● Treatment Episode Data Set<br>● 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 will also continue to disseminate 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<br>● Support development of innovative ADFs, data to inform benefit-risk assessment<br>● Ensure ADF label nomenclature enables providers to adequately distinguish between the risk of abuse and the risk of addiction |
| NIH/NIDA | To provide scientific solutions to help end the opioid crisis, NIH/NIDA is 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

| Strategy: Support cutting-edge research (continued) | |
| --- | --- |
| **AGENCY** | **ACTIVITY** |
| NIH/NIDA | The NIH has launched an Opioid Initiative featuring a public-private partnership to identify areas of opportunity where the NIH, FDA, academia, and biopharmaceutical companies can combine efforts and resources to accelerate the development of better pharmacological 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 will be leading research efforts for SAMHSA.  Additionally, the National Mental Health and Substance Use Policy Laboratory will assist in addressing 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

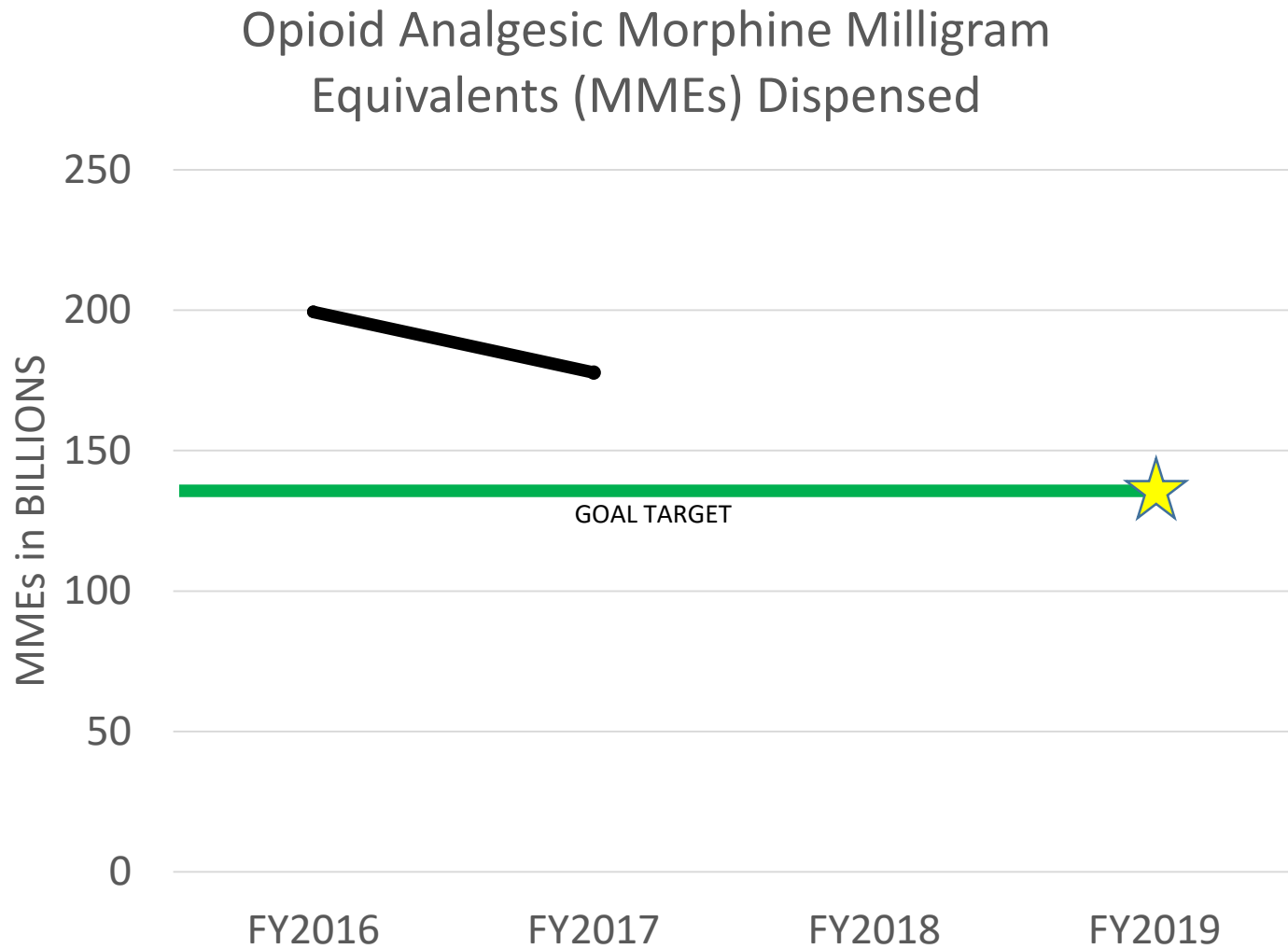| AGENCY | ACTIVITY |
|---|---|
| | **Strategy: Advance the practice of pain management (continued)** |
| NIH/NIDA | The NIH Pain Consortium is involved with implementation of the National Pain Strategy and has published three educational modules from the Centers of Excellence in Pain Education on better pain treatment, with and without opioids. |
| NIH/NIDA | NIH/NIDA 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 Opioid Initiative public-private partnership. |
| SAMHSA | SAMHSA's National Mental Health and Substance Use Policy Laboratory and the Office of the Chief Medical Officer will be 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. |

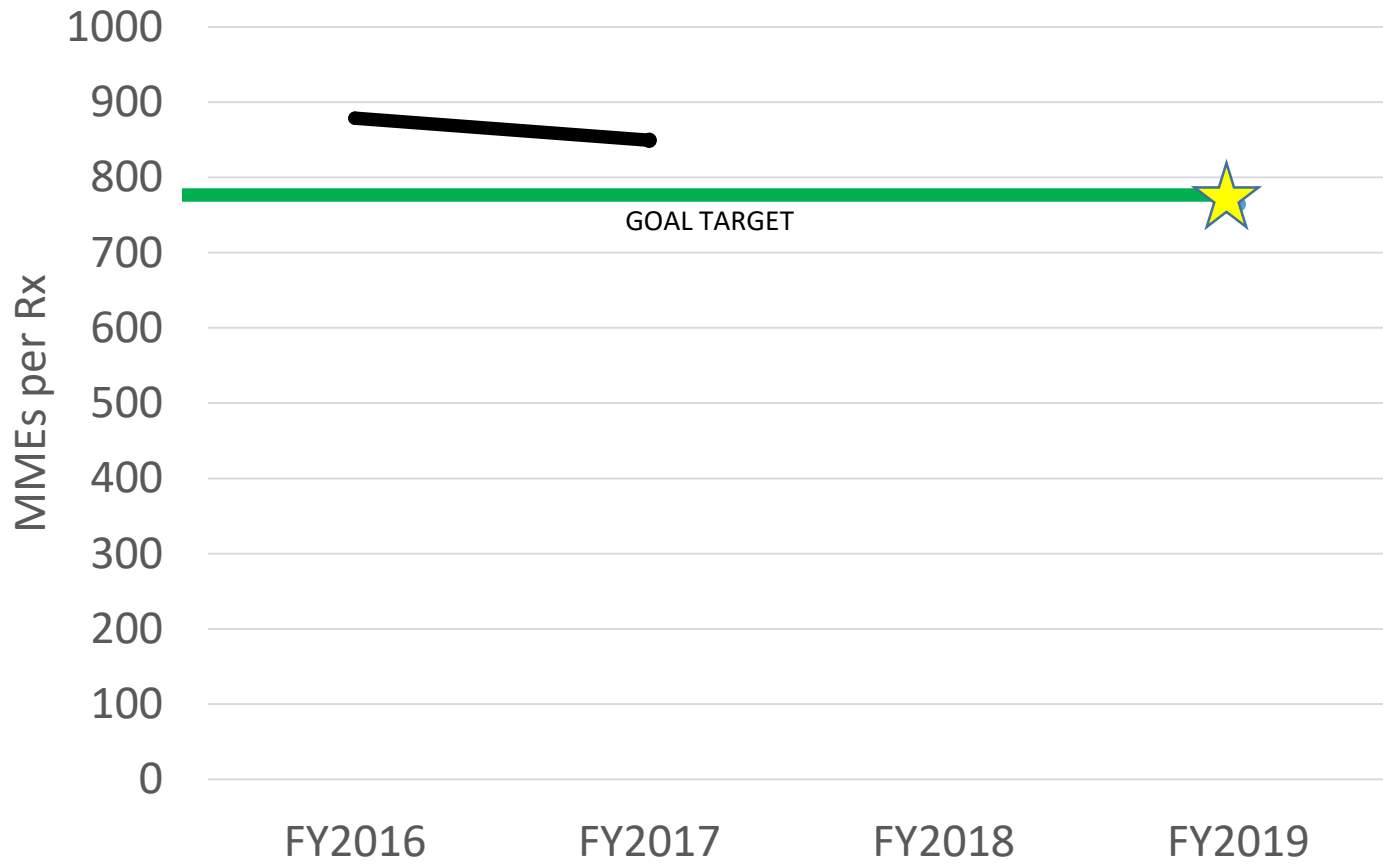# Key Indicators

## Fiscal Years 2018-2019

| Indicator | Target Value | Actual Value |
|---|---|---|
| Total morphine milligram equivalents dispensed | 133 billion | |
| Morphine milligram equivalents /prescription | 764 | |
| Naloxone prescriptions | 401,487 | |
| Unique buprenorphine patients | 979,929 | |
| Long-acting injectable or implantable buprenorphine prescriptions | 504 | |
| Extended release naltrexone prescriptions | 302,706 | |

# Key Indicators



Opioid Analgesic Morphine Milligram Equivalents (MMEs) Dispensed

MMEs in BILLIONS

250
200
150
100
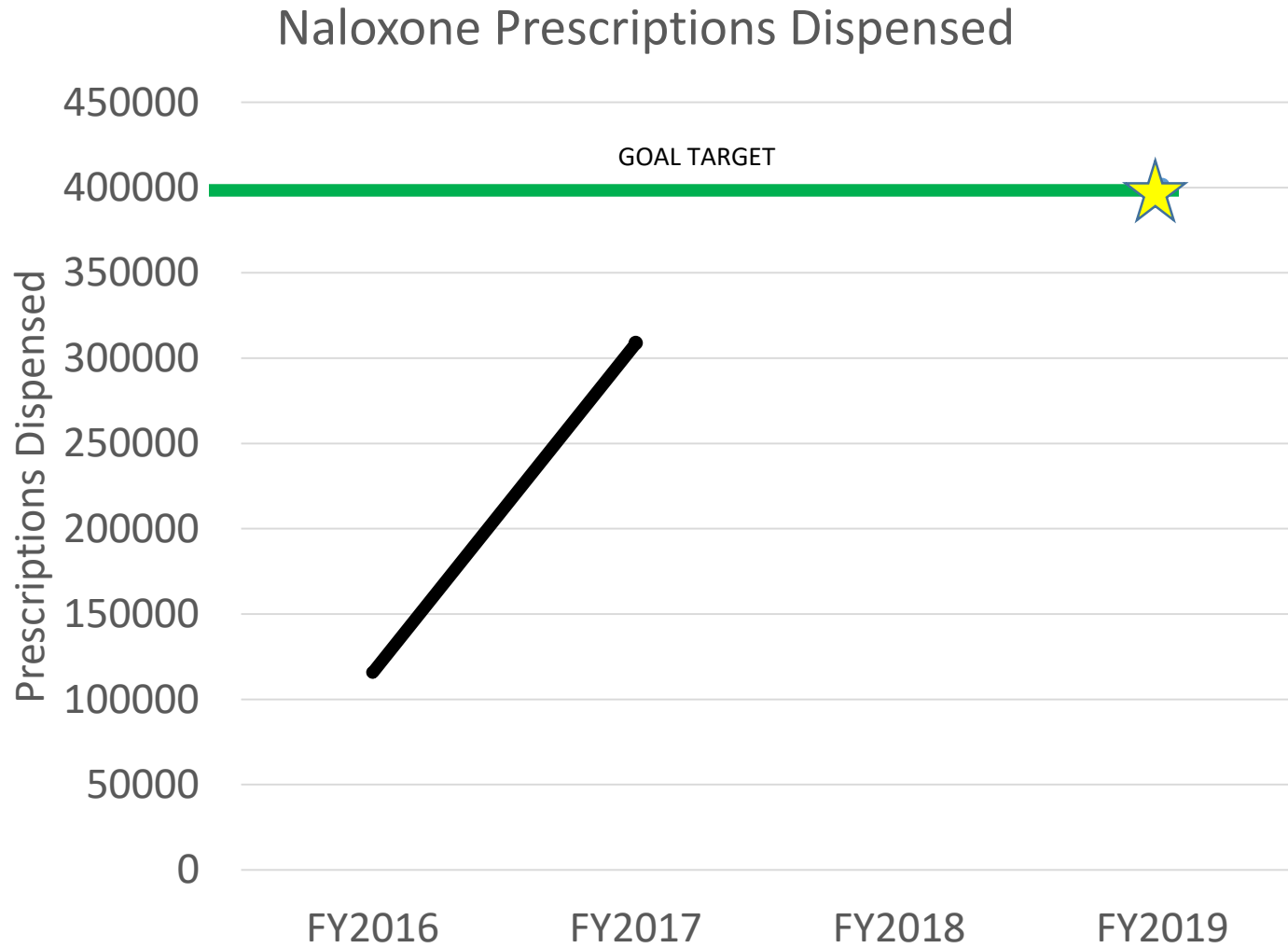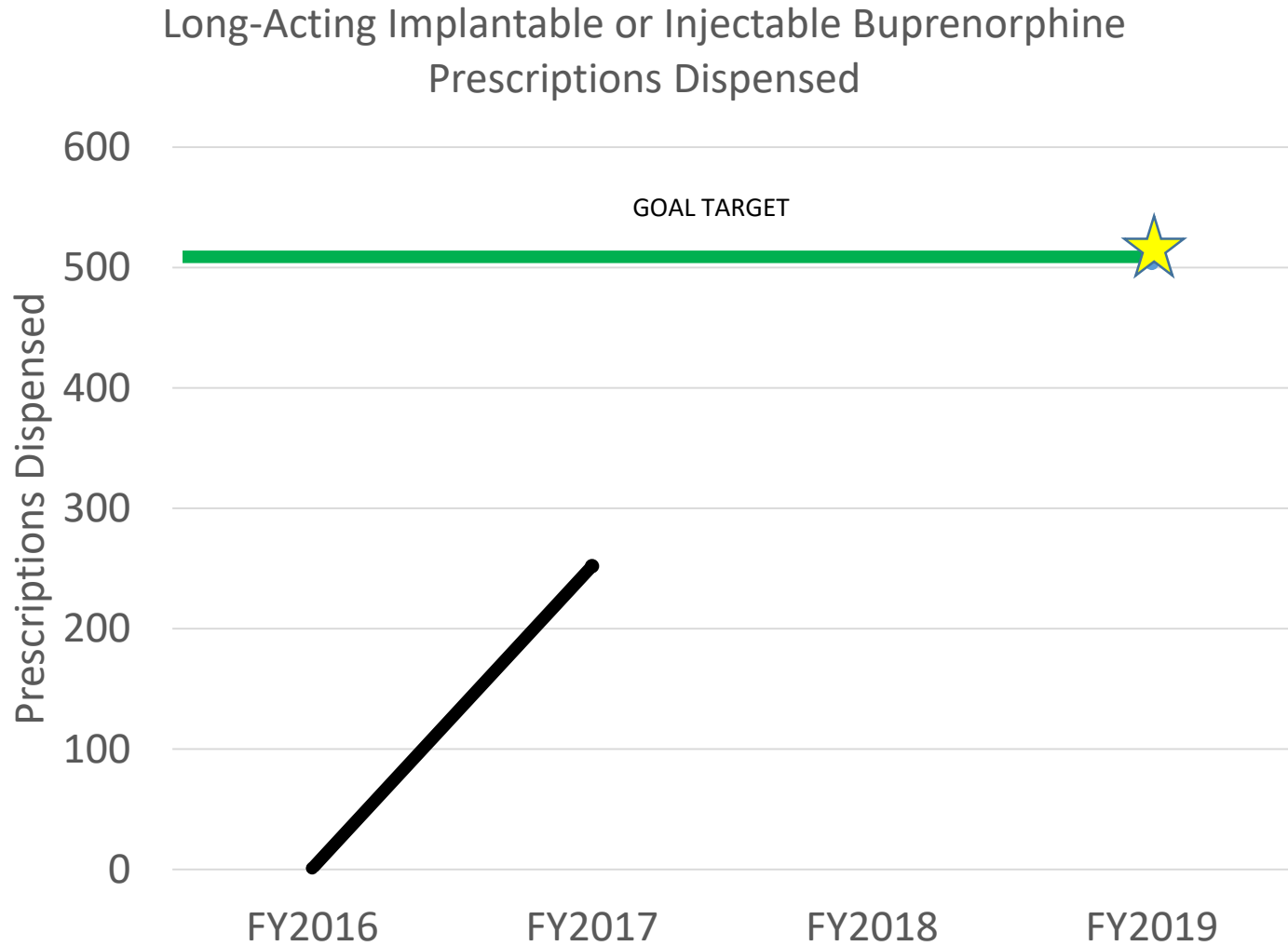50
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GOAL TARGET

FY2016    FY2017    FY2018    FY2019

# Key Indicators



Opioid Analgesic Morphine Milligram Equivalents MMEs per Prescription Dispensed

# Key Indicators



Naloxone Prescriptions Dispensed
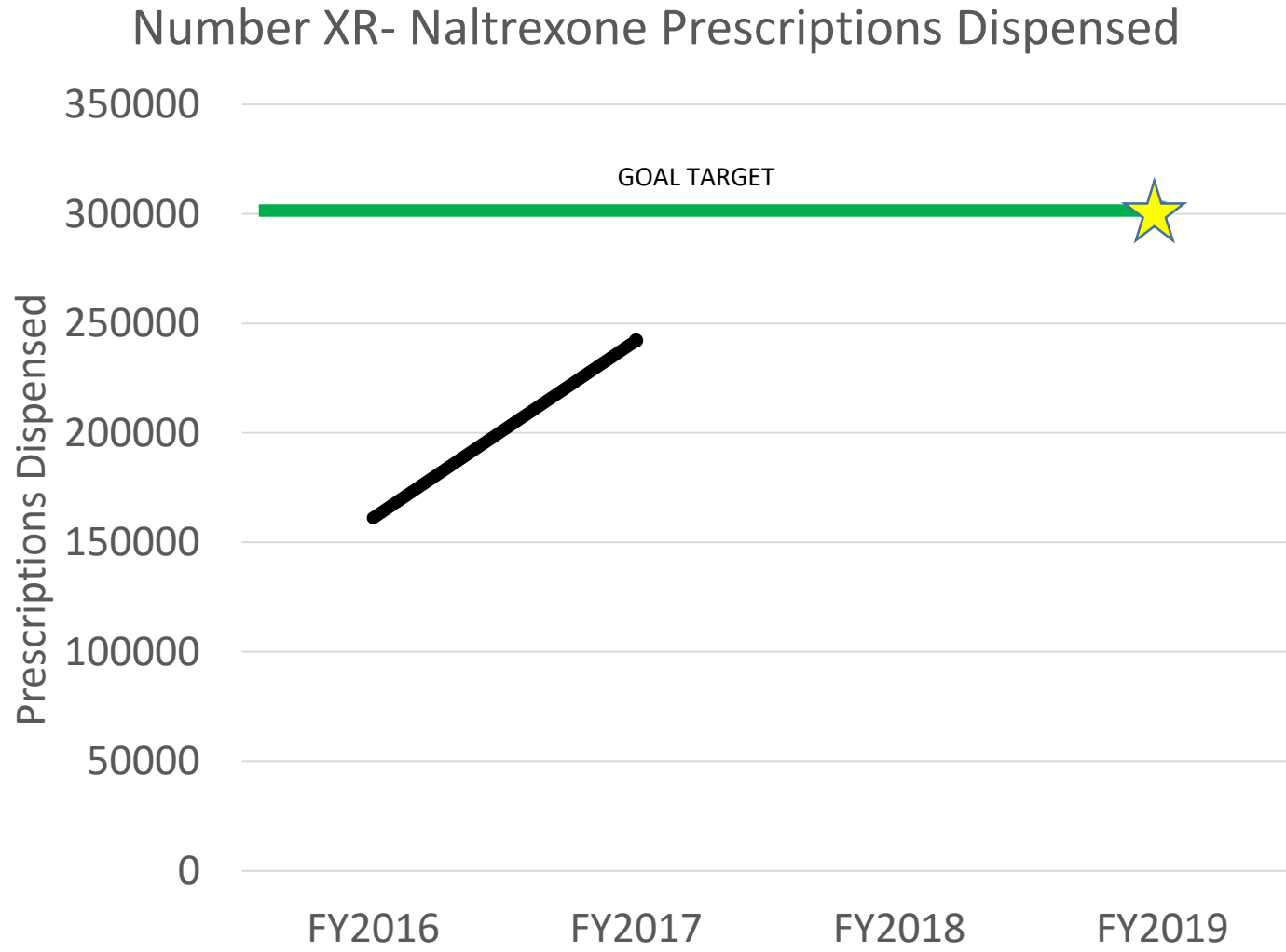
# Key Indicators



Long-Acting Implantable or Injectable Buprenorphine Prescriptions Dispensed

GOAL TARGET

Prescriptions Dispensed

600
500
400
300
200
100
0

FY2016    FY2017    FY2018    FY2019

# Key Indicators

## Average Quarterly Unique Patients Receiving Buprenorphine



GOAL TARGET

Y-axis: Unique Patients (0 – 1200000)
X-axis: FY2016, FY2017, FY2018, FY2019

# Key Indicators

## Number XR- Naltrexone Prescriptions Dispensed
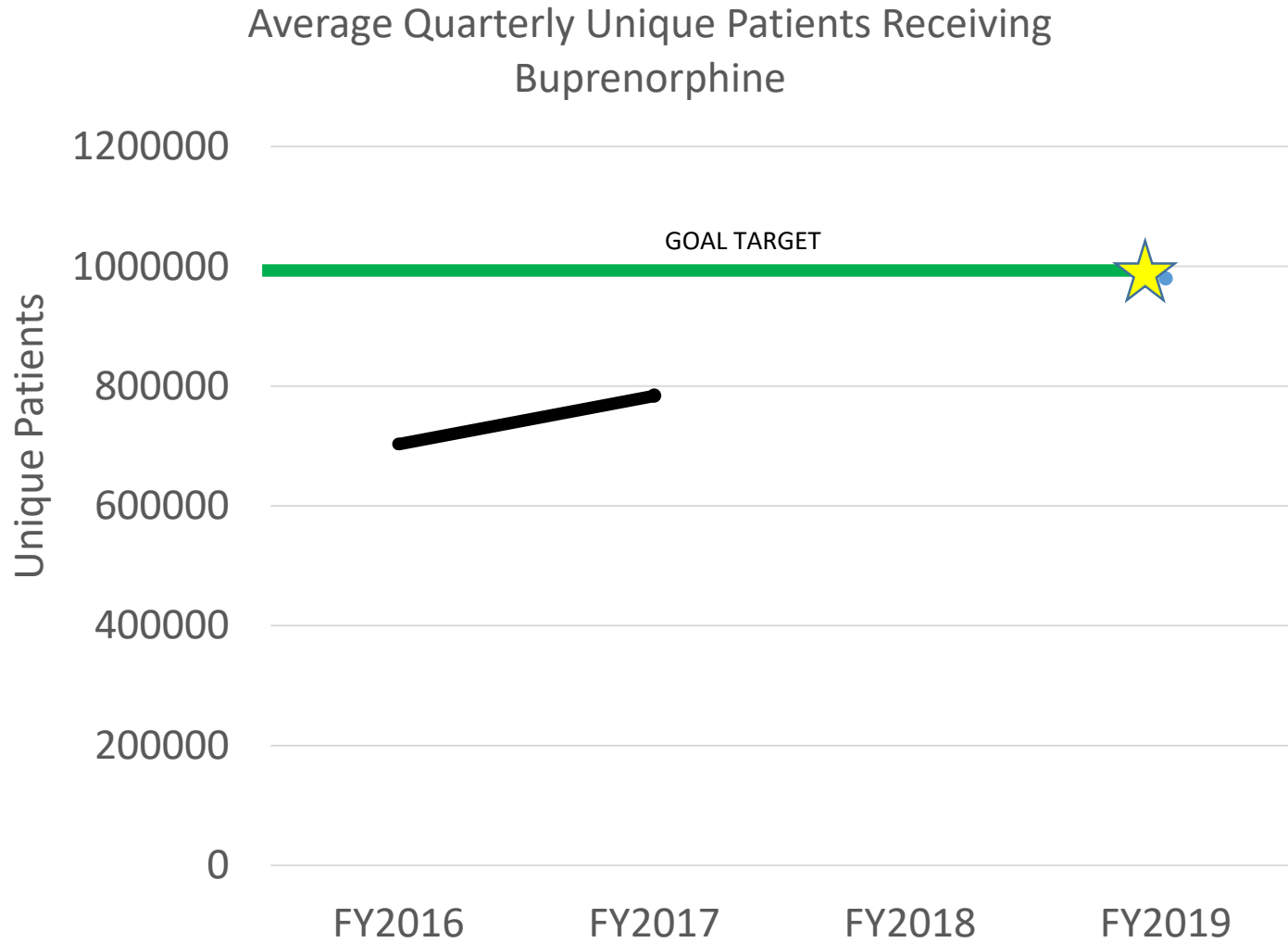
# Data Accuracy and Reliability

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

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