

# **Protecting Our Infants Act: Report to Congress**

**Submitted by the Behavioral Health Coordinating Council  
Subcommittee on Prescription Drug Abuse**

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## Executive Summary

The Protecting Our Infants Act (Public Law 114-91), enacted on November 25, 2015, mandated that the U.S. Department of Health and Human Services (HHS):

- Conduct a review of planning and coordination of HHS activities related to prenatal opioid exposure and neonatal abstinence syndrome (NAS).
- Develop recommendations for the prevention of prenatal opioid exposure; treatment of opioid use disorder (OUD); and prevention, identification, and treatment of NAS, as well as any long-term consequences thereof.
- Develop a strategy to address these issues, gaps, overlap, and duplication among federal programs, and coordination of federal efforts to address NAS.

In response to this Act, this report provides background information on prenatal opioid exposure and NAS, summarizes HHS activities related to prenatal opioid exposure and NAS, presents clinical and programmatic evidence and recommendations for preventing and treating NAS, and presents a strategy to address the identified gaps, challenges, and recommendations. Full implementation of the recommendations included in this report will be contingent upon adequate funding. This document encompasses both reports required by the Act, but will be subject to public comment and revision of the strategy based on these comments.

## Background on Opioid Use Disorder and Neonatal Abstinence Syndrome

Prenatal opioid exposure may result from pain treatment or OUD. In some cases, women of reproductive age may not realize they are pregnant and, consequently, they unknowingly expose their fetuses to opioids. In other circumstances, women are aware of their pregnancies, but may be advised to continue using an opioid to treat pain or as an effective way to use medication-assisted treatment (MAT) which is the standard of care for treating OUD during pregnancy. In addition, some women become pregnant while struggling with OUD and expose the fetus to illicitly obtained opioids.

OUD is a growing problem and is associated with numerous adverse outcomes, including infectious diseases, drug overdose, and trauma. Treatment needs often exceed treatment capacity, making it difficult for individuals to access treatment, the negative consequences of untreated OUD on the pregnancy and fetus are numerous and well documented.

Prenatal maternal opioid use, whether related to pain management or OUD, has increased considerably in recent years. This increase has contributed to a significant rise in the rate of NAS, a constellation of symptoms in newborns exposed to any of a variety of substances in utero, including opioids. When it is possible to determine that the withdrawal symptoms are specifically associated with opioids, the more precise term “Neonatal Opioid Withdrawal Syndrome” (NOWS) is used. However, because opioid use often does not occur in isolation from other risk factors or other substance use, it can be difficult to identify NOWS. For this reason, the term “NAS” will be used throughout this report, unless NOWS is used in the source being referenced.

## Review of Programs (Section 2(a) of the Act)

HHS agencies participate in numerous activities related to studying, preventing, and treating prenatal opioid exposure and NAS. They have also identified relevant gaps and recommendations for addressing many of these gaps, as outlined below.

### *Data and Surveillance*

HHS administers and maintains several data collection and survey instruments that collect data relevant to NAS, including:

- The Substance Abuse and Mental Health Services Administration (SAMHSA)'s National Survey on Drug Use and Health<sup>1</sup>, (NSDUH) Treatment Episode Data Set (TEDS), and National Survey of Substance Abuse Treatment Services (N-SSATS)
- The Administration for Children & Families (ACF)'s National Child Abuse and Neglect Data System (NCANDS) and Adoption and Foster Care Analysis and Reporting System (AFCARS)
- The Agency for Healthcare Research and Quality (AHRQ)'s Health Care Utilization Project Nationwide Inpatient Sample
- The Centers for Disease Control and Prevention (CDC)'s Pregnancy Risk Assessment Monitoring System (PRAMS)
- Several smaller-scale, one-time data collection efforts

The data collected from these surveys have enabled HHS to produce numerous tabulations and publications.

Gaps related to data and surveillance include:

- The limited and inadequate adoption of screening instruments and methodologies to identify the prevalence of substance use disorder (SUD) and pain
- Misinformation and bias about SUD that dissuade women from disclosing their substance use
- The subjective nature of current methods of assessing infants for NAS
- Inconsistent use of International Classification of Diseases (ICD) codes
- Different reporting requirements across jurisdictions
- Inconsistent use of terminology across data collection instruments
- Challenges with comparing data across different datasets

### *HHS Recommendations:*

- Standardize data collection and survey activities to ensure consistency and a more systematic approach to building a fuller and more nuanced picture of prenatal substance exposure, the multiple social and environmental variables involved in access to treatment for pregnant and parenting women with OUD, disparities in access, and differences in prenatal opioid use and use disorders in pregnant women between demographic groups.
- Expand implementation of Screening, Brief Intervention, and Referral to Treatment (SBIRT) to allow hazardous and harmful substance use to be addressed and SUD to be

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<sup>1</sup> Underlined text indicates that a hyperlink is included in the electronic copy of this report

treated prior to conception, and to provide women at risk with access to the full range of contraceptive options.

- Place greater emphasis on collecting high-quality data, as well as developing and adopting strong, validated screening instruments for substance use among pregnant women and NAS in infants.
- Establish a clear definition of NAS and NOWS and more consistent use of this terminology.
- Increase the likelihood that women who use opioids will obtain needed prenatal care and be comfortable disclosing opioid misuse to their health care providers.

### *Research and Evaluation*

The CDC, the Food and Drug Administration (FDA), the National Institute of Child Health and Human Development (NICHD), and the National Institute on Drug Abuse (NIDA) have funded and/or conducted numerous research projects on prenatal opioid exposure and NAS. Much of this work has been published in peer-reviewed scientific journals.

Gaps related to research and evaluation result from:

- The unique challenges associated with studying this population
- The high likelihood of polysubstance use among this population
- Inconsistent use of terminology
- Inconsistent use of ICD codes

### *HHS Recommendations:*

- Improve data collection so that the differences and scope of prenatal substance exposure, access to treatment, barriers to access, and disparities in access can be fully understood and inform the development of targeted and effective research agendas.
- Conduct further research to define and understand the elements of an effective risk–benefit assessment in order to counsel pregnant women with pain about the use of opioids for pain versus other pharmacotherapies, nonpharmacologic interventions, and the use of these interventions for themselves, their pregnancy, and their infants.
- Conduct studies to examine the extent and impact of polysubstance use on the outcomes of opioid exposure in pregnancy and NAS/NOWS, and the effects of prenatal opioid exposure through childhood.
- Facilitate and coordinate data sharing and data analysis activities across HHS agencies so that findings will be more comprehensive and bring a more robust understanding to substance use and its impact on children/youth and families.
- Undertake research to identify behaviors that can mitigate the risk of NAS for infants of women who, for medical reasons, receive prescription opioid therapy or MAT during pregnancy.
- Undertake research to distinguish between the needs and outcomes of women of different ages, and between women who become pregnant while being treated with an opioid for pain, women on MAT and women with untreated SUD.
- Undertake research on how best to make NAS and NOWS assessment more objective and reliable.
- Conduct policy analysis and implementation studies to determine how to overcome institutional, social, legal, and other system barriers to the adoption of MAT and

determine the most effective means of delivering MAT to women who are pregnant or parenting.

- Improve access to the full range of contraceptive options for women who receive opioids
- Improve access to early intervention services for substance-exposed infants.

### *Programs/Service Delivery*

HHS supports the provision of a number of services targeting pregnant and parenting women and infants. These include:

- The Indian Health Service's (IHS) Centering Pregnancy® program
- The Health Resources and Services Administration (HRSA) and ACF's Federal Home Visiting Program
- The ACF Early Head Start and Early Head Start-Child Care Partnership Programs
- CDC's Perinatal Quality Collaboratives
- ACF, HRSA, and Centers for Medicare & Medicaid Services' (CMS) Strong Start for Mothers
- The Baby Friendly program, in which a number of HHS agencies participate
- Several grant opportunities and training programs supported by numerous HHS agencies

Gaps related to programs and service delivery result from:

- Concerns among pregnant women about the legal ramifications associated with disclosing substance use
- Limited knowledge about how to identify opioid use among pregnant women
- Barriers in accessing MAT
- Workforce shortages
- The limited availability of family-friendly services that address the full continuum of care
- The fact that many programs do not specifically target women with OUD or infants at risk for NAS, and no programs currently target pain management for pregnant women

### *HHS Recommendations:*

- Improve data collection so that the scope of the prenatal substance exposure, access to treatment, barriers to access, and disparities in access can be fully understood and inform the development of targeted and accessible programs and services for pregnant and parenting women with OUD and substance-exposed infants.
- Expand services for women with opioid use and their children and ensure more consistent evidence-based resource allocation.
- Develop more family-friendly OUD treatment programs providing appropriate services for women during pregnancy and for mothers and infants following childbirth.
- Work to remove deterrents to treatment for women and promote the adoption of evidence-based practices, including MAT.

### *Education*

HHS has several educational initiatives that target state and local jurisdictions and providers:

- SAMHSA and ACF jointly fund the National Center on Substance Abuse and Child Welfare (NCSACW)
- CDC provides technical assistance to states and tribal governments on maternal substance use and NAS

- HRSA funds a cooperative agreement supplement on opioids and HIV/hepatitis C with the Association of State and Territorial Health Officials
- SAMHSA funds the Addiction Technology Transfer Center Network (ATTC), the Providers' Clinical Support System for Medication Assisted Treatment and the Providers' Clinical Support System for Opioid Therapies
- IHS has a health professions scholarship program
- CMS funds the Innovation Accelerator Program (IAP) and has developed toolkits to assist providers in identifying SUD
- CDC leads the Treating for Two: Safer Medication Use in Pregnancy initiative

HHS has also developed several guidance documents to support state and local jurisdictions and providers. Additionally, FDA has made label changes related to the use of opioids during pregnancy and has participated in ongoing communications about abuse-deterrent formulations of opioids. Finally, there have been numerous efforts aimed at addressing the public about prenatal opioid exposure and NAS.

Education-related gaps include:

- Limited resources and strategies to support the adoption and implementation of existing guidance by health systems and providers
- The lack of evidence-based, reproducible strategies for identifying and managing infants at risk of NAS
- Misinformation about the nature and causes of SUD and its treatment
- Misconceptions about MAT

#### *HHS Recommendations*

- Promote improved public and health professional understanding of OUD as a brain disease responsive to treatment, and of NAS/NOWS as a medical condition that can be prevented, minimized, and effectively treated with available interventions.
- Increase efforts to train obstetricians, emergency department personnel, and community-based primary care providers on the need to take the cultural and social perspectives of at-risk and pregnant women into account when providing them with SUD treatment guidance, with special consideration for reducing the potential impact of NAS.
- Ensure prescribing providers, in particular obstetrician-gynecologists, family physicians, orthopedists, general surgeons, and dentists, are well trained in appropriate pain management during pregnancy, including the appropriate prescribing practices for opioids when needed.

#### *Coordination*

HHS engages in many coordination efforts in order to avoid duplication and overlap and to ensure that efforts undertaken by various agencies are adopted, promoted, and put to maximum use.

Gaps in coordination include:

- The social and medical complexity of opioid use and its impact on children
- Limited outreach to women at risk of experiencing a substance-exposed pregnancy to improve access to the full range of contraceptive options

- Early identification of NAS
- The extensive range of government entities, stakeholders, professional disciplines and specialties involved in addressing these issues

*HHS Recommendations:*

- Continue to focus on strengthening interagency communication and coordination while minimizing overlap.
- Promote opportunities for cross-agency idea exchange and discussion of the broader context of key issues.
- Improve cross promotion of agency efforts and activities to the public.

### **Prevention and Treatment of Prenatal Opioid Exposure (Section 3 of the Act)**

In 2016, CDC published its *Guideline for Prescribing Opioids for Chronic Pain*. Later in 2016, SAMHSA developed *Advancing the Care of Pregnant and Parenting Women with Opioid Use Disorder and Their Infants: A Foundation for Clinical Guidance*, which will result in the production of a guide for clinicians. Both of these documents include a comprehensive review of existing research by expert professionals and reflect interagency and stakeholder input. Both initiatives found much of the available research to be limited in quality and clinical utility, and revealed gaps and deficiencies in the overall evidence base. However, they produced sound guidance for immediate use by health care providers.

These documents provide key recommendations for women of reproductive age, pregnant women, peripartum women, breastfeeding women, parenting women, and infants. They also highlight special considerations in the context of OUD, including comorbid illnesses, comorbid substance use, MAT dose changes, and the safety and efficacy of naltrexone for pregnant and breastfeeding women and their infants. These recommendations consistently emphasize the need for individualized, risk–benefit-based clinical decision-making, and the need to ensure the health and well-being of the mother to promote an optimal outcome for the infant.

*Key Recommendations:*

- Improved access to the full range of contraceptive options for women at risk of experiencing a substance-exposed pregnancy
- Adoption and implementation of the CDC guideline on opioid prescribing for chronic pain
- Appropriate identification of OUD and NAS
- Early engagement in MAT
- Protocol-driven screening, assessment, monitoring, and treatment of NAS/NOWS
- Careful discharge planning
- In-home supports

### **Strategy To Protect Our Infants (Section 2(b) of the Act)**

HHS developed a strategy aimed at filling identified gaps in the field and improving treatment and clinical care. This strategy addresses the prevention, treatment, and service delivery needs of women and children. Because the strategy (Section 2(b) of the Act) was informed by the



evidence base on clinical guidelines (Section 3 of the Act), Section 3 precedes Section 2(b) in this report. Public comment on this report is being solicited and recommendations will be incorporated into the strategy as appropriate. Once finalized, the strategy will be used to inform planning and policy across HHS, although full implementation will be contingent upon funding.

*HHS Recommendations to Prevent Opioid-Exposed Pregnancy and NAS/NOWS:*

- Improve and expand the use of SBIRT to identify women in need of intervention or treatment.
- Better define the elements of an effective risk–benefit assessment in order to counsel pregnant women with pain regarding the appropriate use of opioids.
- Research the consequences of unrelieved pain and the safety and effectiveness of naltrexone use for OUD in pregnancy.
- Increase access to the full range of contraceptive options and SUD treatment for women at risk of experiencing a substance-exposed pregnancy
- Develop family-friendly services.
- Promote public awareness of SUD as a disease and the effectiveness of treatment.

*HHS Recommendations to Prevent Prenatal Opioid Exposure:*

- Standardize terminology and promote a unified approach to data collection and reporting.
- Conduct research on effective and safe non-opioid pharmacotherapy and non-pharmacologic pain relief strategies during pregnancy and breastfeeding.
- Improve access to parental support and early intervention services.

*HHS Recommendations to Meet the Treatment Needs of Women:*

- Develop valid screening instruments.
- Collect substance- and diagnosis-specific data.
- Conduct research on maternal risk and protective factors, prenatal prescription opioid use for pain relief, effective and safe non-opioid pharmacotherapy and non-pharmacologic pain relief strategies during pregnancy and breastfeeding, and the safety and effectiveness of naltrexone, which has not been studied for use during pregnancy or breastfeeding and so has uncertain safety and efficacy.
- Support the continuation of treatment for SUD postpartum.
- Develop effective strategies to support informed decision making around pain management or SUD treatment.
- Promote breastfeeding, if no contraindications exist.
- Provide continuing medical education for providers.

*HHS Recommendations to Meet the Treatment Needs of Children:*

- Establish clear definitions of NAS and NOWS.
- Standardize the use of relevant ICD codes.
- Establish evidence-based protocols to identify and manage NAS and NOWS.
- Determine optimal toxicology screening of infants.
- Promote nonpharmacologic interventions.
- Promote breastfeeding, if no contraindications exist.
- Provide continuing medical education for providers.

*HHS Recommendations to Meet the Service-Delivery Needs of Women:*

- Collect substance- and diagnosis-specific data.
- Provide family-friendly SUD treatment.
- Promote public and health-professional awareness of OUD and strategies to meet the unique needs of women who required SUD treatment.

*HHS Recommendations to Meet the Service-Delivery Needs of Children:*

- Identify a history of prenatal opioid exposure and NAS or NOWS during developmental assessments, early interventions, or entrance into the child welfare system.
- Determine and promote optimal family and developmental support services.
- Conduct research on the long-term developmental effects of prenatal substance exposure.
- Provide developmental assessment and early intervention services.
- Promote nonpharmacologic interventions, such as rooming in, for managing mild to moderate NAS/NOWS.

Together, these proposed approaches can lead to significant advancements in data and surveillance, research and evaluation, programs and service delivery, and education. Ultimately, these advancements can improve outcomes and well-being among women with OUD and infants with NAS.

## Introduction

The Protecting Our Infants Act of 2015 (the Act) became law on November 25, 2015. The Act (Public Law 114-91) addresses problems related to prenatal opioid exposure and includes several mandates for the U.S. Department of Health and Human Services (HHS). First, HHS must conduct a review of HHS agencies' planning and coordination of activities related to prenatal opioid exposure and neonatal abstinence syndrome (NAS). Second, the Act mandates that HHS study, and develop recommendations for preventing prenatal opioid exposure; treating opioid use disorder (OUD) in pregnant women; and preventing, identifying, and treating NAS, as well as any long-term consequences thereof. Lastly, the Act requires development of a strategy to address gaps in research; gaps, overlap, or duplication in relevant federal programs; and coordination of federal efforts to address NAS. All three of these elements must be informed by and address the 2015 Government Accountability Office report *Prenatal Drug Use and Newborn Health*. The *Protecting Our Infants Act: Report to Congress* (the report) covers all three of the above elements and encompasses both required reports. After this report is released, public comment will be solicited, and comments will be addressed and incorporated into the strategy, as appropriate. The updated report will be made available for review via an HHS website within 18 months of the enactment of the Act.

The report is organized as follows:

- Part 1, "Background," provides a brief overview of prenatal opioid exposure and NAS.
- Part 2, "Review of Programs," corresponds to Section 2(a) of the Act and summarizes HHS activities relating to NAS, including data and surveillance, research and evaluation, program and service delivery (including treatment), education, and coordination. Gaps, duplication, and overlap in each area are discussed.
- Part 3, "Prevention and Treatment of Prenatal Opioid Exposure," corresponds to Section 3 of the Act and presents the study of, and resulting clinical and programmatic recommendations for prevention of prenatal opioid exposure; treatment of OUD; and prevention, identification, and treatment of NAS and any long-term consequences. This Section includes gaps in the evidence base regarding these issues.
- Part 4, "Strategy To Protect Our Infants," corresponds to Section 2(b) and presents a unified strategy to address the gaps, overlap, and duplication across HHS activities based on the review of the evidence and actual delivery of care reported in Parts 2 and 3. Because this strategy was informed by the evidence base on clinical guidelines (Section 3 of the Act), Section 3 precedes Section 2(b) in this report. As noted above, HHS will solicit public comment on this report and incorporate recommendations from the public into the strategy as appropriate. The final strategy will be posted on an HHS website.

## Part 1: Background on Opioid Use Disorder and Neonatal Abstinence Syndrome

Opioid exposure in pregnancy is a result of two conditions affecting women: pain and OUD. Between 2008 and 2012, approximately one-third of women ages 15–44 filled a prescription for at least 5 days of an opioid medication.<sup>1</sup> Opioid exposure during pregnancy may occur because women of reproductive age with acute or chronic pain do not realize they are pregnant, so they unknowingly expose their fetuses to opioids. In other cases, women know they are pregnant, but are advised by their providers to continue using opioids for pain relief or as part of medication-assisted treatment (MAT) for OUD which is the standard of care for treating OUD during pregnancy. In addition, some women become pregnant while struggling with OUD and expose the fetus to illicitly obtained opioids.

OUD is a chronic disease with potentially serious negative consequences for the individual, the family, and society, including HIV, hepatitis B and C, syphilis, gonorrhea, chlamydia, overdose, and trauma.<sup>2,3,4,5,6</sup> OUD is also a growing problem. In 2014, 4.3 million people reported using opioid pain medications for nonmedical reasons in the previous 30 days, and 435,000 people 12 years of age or older used heroin in the previous 30 days.<sup>7</sup> Further, approximately 2.2 million people had an OUD related to prescription opioids and/or heroin.<sup>7</sup> The ability to treat individuals with OUD has also exceeded treatment capacity each year. The limited availability of treatment is multifactorial, and may be related to both the overall number of providers and the reluctance of some providers to provide MAT.<sup>5,7</sup> The number of people needing treatment has increased from 634.1 per 100,000 in 2003 to 891.8 per 100,000 in 2012.<sup>8</sup>

Treatment of the underlying condition, whether pain or OUD, may expose the fetus to opioids. Not receiving treatment has multiple impacts on pregnant women with OUD, women using prescription opioids for pain relief, and their infants. Women with untreated OUD face significant risks, such as risk of fetal death,<sup>9</sup> preterm delivery, and low birth weight.<sup>10</sup> In addition, mothers who inject drugs are at risk of transmitting HIV and hepatitis B and C to infants.<sup>2,3</sup> Another challenge that parenting women with OUD face is the need to care for an infant with opioid exposure, often while coping with underlying mental health problems, violence, unstable housing, limited income, and few social supports.<sup>11,12,13</sup> Other children in the household may be affected by these difficulties. Despite the longstanding scientific consensus that OUD is a chronic brain disease, laws and policies based on criminalization of drug use may be deterrents to treatment and prenatal care for some women.

Between 2000 and 2009, reported prenatal maternal opioid use because of prescribed pain management, OUD, or the treatment of OUD with opioid agonist MAT (buprenorphine, buprenorphine/naloxone, or methadone), increased from 1.19 to 5.63 per 1,000 hospital births per year.<sup>14</sup> The wide use of opioids and the expanding opioid epidemic are having a proportional effect on the NAS rate. From 2009 to 2012, the incidence of NAS increased nearly twofold, from 3.4 to 5.8 per 1,000 hospital births per year.<sup>15</sup> NAS occurs with considerable variability, with anywhere from 55 to 94 percent of exposed infants exhibiting some degree of symptoms in various studies.<sup>16</sup> NAS is a constellation of symptoms, including hypersensitivity and hyperirritability, tremors, vomiting, respiratory difficulties, poor sleep, and low-grade fevers.<sup>17</sup> It occurs in newborns who are exposed to a range of substances in utero, including prescription medications that may be life-sustaining for the mother, and results from withdrawal from these

substances.<sup>18,19,20</sup> NAS is most often associated with opioid withdrawal, but can occur because of withdrawal from other substances as well. The more specific term, NOWS, is gaining wider use to indicate that symptoms are due to opioid withdrawal (when this has been clearly isolated).

NOWS can be difficult to identify, describe, and study, in part because it often does not occur in isolation from other risk factors or substance use. Consequently, the term “NAS” will be used throughout the report to avoid misrepresenting or misapplying existing research findings.

“NOWS” is the preferred and most specific term for the syndrome being discussed in this report. Accordingly, this report will use “NOWS” only when the source being referenced does so.

## Part 2: Review of Programs (Section 2(a) of the Act)

A review of HHS agencies reveals numerous activities related to prenatal opioid exposure and NAS, including data and surveillance, research and evaluation, service delivery, education, and coordination. Gaps in each of these areas were identified, and HHS agencies have provided recommendations for addressing many of these gaps. Below is an overview of these activities, gaps, and recommendations. It should be noted that there are many HHS activities that reach pregnant women, but do not specifically target this population. These activities fall outside the scope of this report and are not included in this overview.

### Data and Surveillance

The first step in providing effective interventions is accurately measuring the scope and intensity of the problem. Data collected for this purpose can also include individual and community characteristics that help shape effective prevention and interventions. To be most meaningful, data need to be collected using terms and tools that are consistently defined and applied across data collection instruments. Raw data can then be subject to a range of analyses to understand risk and protective factors, assist with planning and implementation of prevention efforts, and develop effective interventions.

#### Data Collection

HHS administers and maintains several data collection and survey instruments. Large data sets overseen by the Substance Abuse and Mental Health Services Administration (SAMHSA) provide population-, patient-, and facility-level measures of opioid use among pregnant women. These data sets include the National Survey on Drug Use and Health (NSDUH), which consists of population-level survey data on substance use and mental health; the Treatment Episode Data Set (TEDS), which collects patient-level data on substance use disorder (SUD) treatment admissions; and the National Survey of Substance Abuse Treatment Services (N-SSATS), which consists of facility-level data on SUD treatment. All of these data sets are updated annually via surveys.

The Administration for Children & Families (ACF) maintains two data sets, which provide information on prenatal substance exposure, parental substance use, and child substance use. The National Child Abuse and Neglect Data System (NCANDS) is a voluntary national reporting system that annually collects case-level data on reports of child abuse and neglect from state child protective service agencies. The data are submitted by the 50 states, the District of Columbia, and the Commonwealth of Puerto Rico. NCANDS data include information on whether the child or caregiver had a risk factor of “alcohol abuse” or “drug abuse.” The Adoption and Foster Care Analysis and Reporting System (AFCARS) collects case-level information from state and tribal agencies under the Title IV-E Federal Foster Care Programs for all children/youth in foster care and those whose adoptive parents or guardians have a title IV-E adoption or guardianship assistance agreement with the reporting Title IV-E agency. AFCARS data contain information on the reasons children were removed from the home, which include whether the child or parent had “alcohol abuse” or “drug abuse” as a condition associated with

the removal.<sup>ii</sup> Additionally, as of Oct. 1, 2019, Title IV-E agencies will also be required to separately indicate whether “prenatal exposure” to alcohol or drugs contributed to the child being removed from the home.

The Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample, a publically available all-payer health care database yielding national estimate of hospital inpatient stays, can be used to identify trends in deliveries with an indicator of NAS. Finally, the Centers for Disease Control and Prevention (CDC) collects annual data through the Pregnancy Risk Assessment Monitoring System, which provides state-specific, population-based data about health behaviors and experiences before, during, and after pregnancy among women who recently had a live birth. CDC has developed standardized questions related to maternal opioid use and NAS for PRAMS. These questions are available to be added optionally by participating PRAMS states. Additionally, CDC is working to provide a few states with supplemental funding in 2017 to add these standardized questions to their PRAMS survey.

HHS agencies have participated in smaller-scale, one-time data collection efforts targeting providers, pregnant and postpartum women, and infants. For example, CDC is collaborating with the American College of Obstetricians and Gynecologists to develop a survey on obstetrician-gynecologists’ interactions with pregnant women who misuse opioids. The instrument will collect information on a number of clinical practices. These include provider knowledge, attitudes, and beliefs regarding maternal opioid use; screening and referral practices for pregnant and postpartum patients with OUD; barriers to screening and treating pregnant and postpartum patients for opioid misuse; coordination with pediatric staff to manage infants with NAS; and resources needed to improve treatment and referral. The National Institutes of Health (NIH) supports surveillance research as part of its grant program. For instance, work by NIH-supported work at of Vanderbilt University has provided important summaries of rates of NAS in admissions to neonatal intensive care units (NICUs), and of health care expenditure on NAS.<sup>14,15</sup>

**Analytic Reporting**

SAMHSA and CDC oversee several survey and surveillance efforts that provide a high-level overview of trends in prenatal opioid exposure and NAS. These efforts have resulted in numerous work products, including tabulations of data and narrative publications describing the implications of these tabulations. Lists of the tabulations and the publications are presented in Tables 1 and 2, respectively.

**Table 1: Tabulated Data Relevant to Opioid Use Among Women, 2013-2014**

Agency	Title
SAMHSA	Tabulation of types of illicit drug use in the past month among females ages 15 to 44, by pregnancy status. Available at <a href="http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs2014/NSDUH-DetTabs2014.htm#tab6-71a">http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs2014/NSDUH-DetTabs2014.htm#tab6-71a</a>

<sup>ii</sup> This terminology is what is used in this particular instrument. However, clinical guidance encourages use of the term substance misuse.

SAMHSA	Tabulation of illicit drug use in the past month among females ages 15 to 44, by pregnancy and demographic characteristics. Available at <a href="http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs2014/NSDUH-DetTabs2014.htm#tab6-71a">http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs2014/NSDUH-DetTabs2014.htm#tab6-71a</a>
SAMHSA	Tabulation of marital status, living arrangements, pregnancy status, and veteran status among substance use disorder treatment admissions ages 12 and older, by primary substance of abuse. Available at <a href="http://www.samhsa.gov/data/sites/default/files/2013_Treatment_Episode_Data_Set_National/2013_Treatment_Episode_Data_Set_National.pdf">http://www.samhsa.gov/data/sites/default/files/2013_Treatment_Episode_Data_Set_National/2013_Treatment_Episode_Data_Set_National.pdf</a>
SAMHSA	Tabulation of substance use disorder treatment facilities offering specifically tailored programs or groups, by facility operation and client type. Available at <a href="http://www.samhsa.gov/data/sites/default/files/2013_N-SSATS_National_Survey_of_Substance_Abuse_Treatment_Services/2013_N-SSATS_National_Survey_of_Substance_Abuse_Treatment_Services.pdf">http://www.samhsa.gov/data/sites/default/files/2013_N-SSATS_National_Survey_of_Substance_Abuse_Treatment_Services/2013_N-SSATS_National_Survey_of_Substance_Abuse_Treatment_Services.pdf</a>
SAMHSA	Tabulation of substance use disorder treatment facilities offering specifically tailored programs or groups for specific client types, by state or jurisdiction. Available at <a href="http://www.samhsa.gov/data/sites/default/files/2013_N-SSATS_National_Survey_of_Substance_Abuse_Treatment_Services/2013_N-SSATS_National_Survey_of_Substance_Abuse_Treatment_Services.pdf">http://www.samhsa.gov/data/sites/default/files/2013_N-SSATS_National_Survey_of_Substance_Abuse_Treatment_Services/2013_N-SSATS_National_Survey_of_Substance_Abuse_Treatment_Services.pdf</a>

**Table 2: Publications Relevant to Prenatal Opioid Exposure and Neonatal Abstinence Syndrome, 2009-2016**

Agency	Title
<i>Reports on women of reproductive age</i>	
CDC	“Opioid Prescription Claims Among Women of Reproductive Age — United States, 2008–2012.” Available at <a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6402a1.htm">http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6402a1.htm</a>
SAMHSA	<i>The NSDUH Report: Substance Use Among Women During Pregnancy and Following Childbirth.</i> Available at <a href="http://archive.samhsa.gov/data/2k9/135/PregWoSubUse.htm">http://archive.samhsa.gov/data/2k9/135/PregWoSubUse.htm</a>
<i>Report on women of reproductive age and infants</i>	
CDC	“Infant and Maternal Characteristics in Neonatal Abstinence Syndrome — Selected Hospitals in Florida, 2010–2011.” Available at <a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6408a3.htm">http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6408a3.htm</a>
<i>Report on infants</i>	
CDC	“Incidence of Neonatal Abstinence Syndrome – 28 States, 1999-2013.” Available at <a href="http://www.cdc.gov/mmwr/volumes/65/wr/mm6531a2.htm">http://www.cdc.gov/mmwr/volumes/65/wr/mm6531a2.htm</a>

### Gaps, Overlap, Duplication

Challenges to data collection and surveillance efforts have resulted in some notable gaps in the understanding of the scope, severity, and characteristics of opioid exposure in pregnancy and NAS or neonatal opioid withdrawal syndrome (NOWS). In particular, many of the surveys examining substance use and treatment do not ask women about pregnancy status, thus reducing the potential of these surveys to be used for identifying the prevalence of substance exposure among infants. Previously, the National Hospital Discharge Survey provided nationally representative estimates of NAS, but this survey was discontinued. The identification of and



intervention in substance misuse in the population as a whole is also significantly limited by the lack of adoption and consistent application of Screening, Brief Intervention, and Referral to Treatment (SBIRT) a validated screening and intervention modality. SBIRT is also recommended by ACOG, AAP and AMA based on early promising evidence of effectiveness for universal use among pregnant women<sup>21,22</sup> and because substance use is common, and pregnancy is a “state of individual biological and social transformation” during which “most women can be helped to quit or cut back on substance use.”<sup>22</sup> However, the absence of sufficiently flexible screening instruments validated as effective for use in pregnancy limits the wide implementation SBIRT for this population. As a result, it is impossible to meaningfully evaluate access to treatment for pregnant or parenting women with OUD or infants with NOWS. Similarly little can be said about whether disparities to access exist based on demographics and differences in prenatal opioid use and use disorders in pregnant women. Finally, the lack of objective measures and surveillance systems for the prevalence of pain, and the limited adequacy of pain treatment pose additional challenges.

Pregnant women with OUD are often hesitant to come in for prenatal care. Misinformation and bias about SUD has resulted in sometimes punitive or, at the very least, unhelpful responses to the disclosure of substance use in health care settings. For example, in pregnancy, significant social and even criminal penalties can be attached to the identification of SUD or substance exposure of a newborn.<sup>23</sup> Additionally, there is a lack of systematic, protocol-driven screening and assessment of neonates for NAS or NOWS. Further, the need for significant training and retraining to ensure inter-rater reliability of the primary screening and monitoring instruments for NAS is a significant limitation.

Data collection about opioid exposure in pregnancy and NAS is also limited by variable use of International Classification of Diseases (ICD) codes, different reporting requirements across jurisdictions, and inconsistent use of terminology across data collection instruments, all of which may contribute to the underestimation of prenatal opioid exposure and NAS. Many HHS agencies rely upon state-collected data to supplement federal data sets. The utility of such data is limited by the fact that each state has its own reporting requirements. Therefore, it is difficult to compare trends across states and use the data to identify national trends. In cases where national data sets are populated by data reported by states, there are limits on the completeness and comparability of the data. The burden of data collection on the states is substantial, so required reporting is necessarily limited. Additionally, lack of standard definitions for key terms such as “NAS” and “NOWS,” the absence of widely accepted outcome measures for interventions, and the inconsistency of information captured across services and systems impede accurate data collection and tracking across agencies. Finally, some of the available data, such as that from NCANDS and AFCARS, lack specificity about type of prenatal substance exposure.

The fact that several different agencies survey and collect data on this population may give the appearance of overlap, but each data set quantifies a different aspect of the problem. Further, the data are often in discrete, independent sets that only illuminate part of the problem. For example, identifying substance use in parents of children touching the foster care system captures a population of adult caregivers. However, adults seeking treatment may or may not be parents, and may or may not be the parent of a substance-exposed child. Further, families who are involved in the child welfare system often have co-occurring behavioral health disorders, and may have low income and inadequate housing.<sup>24,25,26</sup> Quantifying the full range of prenatal

opioid exposure, from minimal to continuous use, informs the denominator against which diagnosed cases of NOWS/NAS can be compared. The elements of effective surveillance are already present. If the gaps and inconsistencies in data capture and terminology are addressed, an improved surveillance system could then be developed.

### Recommendations

- Standardize data collection and survey activities to ensure consistency and a more systematic approach to building a fuller and more nuanced picture of prenatal substance exposure, the multiple social and environmental variables involved in access to treatment for pregnant and parenting women with OUD, disparities in access, and differences in prenatal opioid use and use disorders in pregnant women between demographic groups.
- Expand implementation of SBIRT to allow hazardous and harmful substance use to be addressed and SUD to be treated prior to conception, and to provide women at risk with access to the full range of contraceptive options.
- Place greater emphasis on collecting high-quality data, as well as developing and adopting strong, validated screening instruments for substance use among pregnant women and NAS in infants.
- Establish a clear definition of NAS and NOWS and more consistent use of this terminology. Doing so can improve specific screening, diagnosis, and assessment guidelines for these conditions, refine how they are managed, and identify differences in outcomes.
- Increase the likelihood that women who use opioids will obtain needed prenatal care and be comfortable disclosing opioid misuse to their health care providers.

### Research and Evaluation

The federal government in general, and HHS in particular, have a unique role in supporting research to address questions and problems that affect public health or that the private sector has insufficient incentive to address. HHS accomplishes this by funding and conducting research, evaluating the effectiveness of interventions, analyzing data, and reporting on and disseminating findings for broader adoption and implementation.

#### Research Activities

CDC, the Food and Drug Administration (FDA), and the National Institutes of Health’s (NIH) Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) and the National Institute on Drug Abuse (NIDA) have funded several research studies on prevention, identification, and treatment of prenatal opioid exposure and NAS. Table 3 lists these studies.

**Table 3: Funded Research Related to Prenatal Opioid Exposure and Neonatal Abstinence Syndrome, 2005-Present**

Agency	Type	Title
<i>Research on women of reproductive age</i>		
NIDA	Extramural	Improving Women’s Sexual Health While in Drug Addiction Treatment
NIDA	Extramural	Improving Effective Contraceptive Use Among Opioid-maintained

		Women: Stage II
NIDA	Extramural	A Novel Approach to Reduce Pain, Prescription Opioid Use & Misuse in Pregnancy
CDC	Extramural	Comparison and Validation of Screening Tools for Substance Use Among Pregnant Women
CDC	Intramural	Trends in Non-medical Use of Prescription Drugs/Pain Relievers Among Pregnant and Non-pregnant Women of Reproductive Age
NICHHD	Extramural	Comparative Safety of Buprenorphine vs. Methadone in Pregnancy
<i>Research on infants</i>		
NICHHD	Extramural	Prevention of Neonatal Abstinence Syndrome
FDA	Extramural	First-trimester Exposure to Opioids and Neural Tube Defects
NIDA	Extramural	Fetal and Infant Neurobehavioral Effects of Maternal Buprenorphine Treatment
CDC	Extramural	Support Activities to Better Ascertain Infants Born with NAS
NIDA	Extramural	Neurodevelopmental Impact of Prenatal Exposure to Prescription Pain Medication
NIDA	Extramural	Neonatal Abstinence Syndrome: Risk of Drug Withdrawal in Opioid-Exposed Infants
NIDA	Extramural	Development of Tools to Assess Neonatal Abstinence Syndrome
NIDA	Extramural	Testing the Reliability and Validity of Pupil Diameter in Opioid-exposed Neonates
NIDA	Extramural	Comparison of Buprenorphine to Morphine in Treatment of Neonatal Abstinence Syndrome
NIDA	Extramural	Optimizing the Use of Methadone in Newborn Infants
NIDA	Extramural	Improving Outcomes in Neonatal Abstinence Syndrome
CDC	Extramural	Understand Long Term Neurodevelopmental Outcomes Associated with Neonatal Abstinence Syndrome (NAS)

## Publications

Most extramural research funded by HHS results in multiple publications. A search of PubMed using the following search terms identified 1,324 peer-reviewed publications written in English on opioid use during pregnancy, as of August 2016: Neonat\* and abstinence syndrome, opioid withdrawal, NOWS, NAS, narcotic withdrawal, heroin withdrawal, codeine withdrawal, oxycodone withdrawal, oxycontin withdrawal, Percocet withdrawal, methadone withdrawal, buprenorphine withdrawal, morphine withdrawal, hydrocodone withdrawal, Vicodin withdrawal, or substance abuse withdrawal.

HHS agencies also author and publish documents as technical assistance for professional or policy audiences and for public education. Collectively, these documents advance understanding of prenatal opioid exposure and NAS. Below is a brief overview of some of this work.

NIH-funded work has explored a wide range of questions related to women of reproductive age who are affected by SUD. These include perceptions of pregnant women who use substances, the SUD treatment needs of pregnant women, and contraceptive use by women in treatment for OUD.

For example, Maternal Opioid Treatment: Human Experimental Research (MOTHER) was a large-scale clinical trial that examined the safety and efficacy of maternal and prenatal exposure to methadone and buprenorphine. This work found that buprenorphine treatment during pregnancy is safe and may have some advantages when compared with methadone. This work has led to numerous publications<sup>27,28,29,30,31,32</sup> that have contributed substantially to the public’s understanding of MAT safety for pregnant women.

Numerous publications<sup>14,15,33,34,35,36</sup> based on NIH-funded research have also explored neonatal complications associated with prenatal opioid exposure, factors that increase the risk for developing NAS, and long-term outcomes for infants diagnosed with NAS.

The NIH-funded Maternal Lifestyle Study explored the effects of substance exposure on neurodevelopmental outcomes. While not directly focused on substance exposure, the related Neonatal Intensive Care Unit (NICU) Network Neurobehavioral Scale, which assesses infant neurobehavioral performance, can be used to identify infants at high risk for abnormal developmental outcomes. This enables the development and delivery of interventions to lessen the impact of prenatal substance exposure, and has resulted in numerous publications.<sup>37,38,39,40</sup>

Staff from CDC, NIDA, and SAMHSA has also had several articles on prenatal opioid exposure published in peer-reviewed journals. Table 4 lists these articles.

**Table 4: Peer-Reviewed Publications Produced by HHS Staff Related to Prenatal Opioid Exposure and Neonatal Abstinence Syndrome, 2009 -2016**

Agency	Publication
<i>Publications about women of reproductive age</i>	
SAMHSA	Muhuri PK, Gfroerer JC. Substance use among women: associations with pregnancy, parenting, and race/ethnicity. <i>Matern Child Health J.</i> 2009;13(3):376-85.
CDC	Maeda A, Bateman BT, Clancy CR, Creanga AA, Leffert LR. Opioid abuse and dependence during pregnancy: temporal trends and obstetrical outcomes. <i>Anesthesiology.</i> 2014;121(6):1158-65.
CDC	Jones HE, Deppen K, Hudak ML, et al. Clinical care for opioid-using pregnant and postpartum women: the role of obstetric providers. <i>Am J Obstet Gynecol.</i> 2014;210(4):302-10.
CDC	Farr SL, Hutchings YL, Ondersma SJ, Creanga AA. Brief interventions for illicit drug use among peripartum women. <i>Am J Obstet Gynecol.</i> 2014;211(4):336-43.
CDC	Wright TW, Terplan M, Ondersma SJ, Boyce C, Yonkers K, Chang G, Creanga AA. The role of Screening, Brief Intervention and Referral to Treatment (SBIRT) in the perinatal period. <i>Am J Obstet Gynecol.</i> 2016;Jul 1. pii: S0002-9378(16)30383-0. doi: 10.1016/j.ajog.2016.06.038.
NIDA	Volkow ND. Opioids in pregnancy. <i>BMJ.</i> 2016;352:i19.
<i>Publication about both women of reproductive age and infants</i>	
CDC	Creanga AA, Sabel JC, Ko JY, Wasserman CR, Shapiro-Mendoza CK, Taylor

P, Barfield W, Cawthon L, Paulozzi LJ. Maternal drug use and its effect on neonates: a population-based study in Washington State. <i>Obstet Gynecol.</i> 2012;119(5)924-33.
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### Gaps, Overlap, Duplication

There are multiple reasons for the limited availability of published work on prenatal opioid exposure and NAS. Ethical and legal considerations regarding treatment of children and pregnant or potentially pregnant research subjects, in addition to the usual challenges involved in conducting trials with human subjects, present special challenges for research on prenatal opioid exposure and NAS.<sup>41</sup> Fear of negative attitudes and of the legal implications associated with pharmacotherapy, substance use in pregnancy, and NAS may limit the willingness of women to disclose their health concerns and behaviors to health professionals and researchers. Women with chronic painful medical conditions or SUD may face additional barriers to access in the form of unstable housing, lack of transportation, limited access to childcare, comorbid physical and behavioral health conditions, and a history of trauma. All of these social and health conditions can interfere with their enrollment and ongoing participation in the often demanding protocols associated with research studies. Further complicating research efforts is the high likelihood of polysubstance use, which makes it difficult to identify and examine the impact of opioids specifically.<sup>42</sup>

To some, there is the appearance of overlap between surveillance and data collection, analysis and reporting, and research and evaluation. It is important to note that surveillance and data collection are population-based, while the research and related evaluation activities described here explore problems and apply interventions to specific groups of individuals. Research, as with data collection and surveillance, is also hampered by inconsistent use of terminology and codification of data elements as well as the absence of reliable data collection regarding access to treatment, disparities across demographics, and differences in prenatal opioid use and use disorders in pregnant women between demographic groups. The broad term “NAS” is used in most research and publications and may fail to make a distinction between NAS caused by various substances and NOWS. Finally, there is a paucity of study designs that control for exposure to multiple substances. These factors make it difficult to understand and compare findings across studies and to apply these findings clinically. The inconsistent use of common ICD codes discussed in the previous section on data and surveillance also affects consistency and the interpretation of research from existing data sets and administrative claims.

### Recommendations

- Improve data collection so that the differences and scope of prenatal substance exposure, access to treatment, barriers to access, and disparities in access can be fully understood and inform the development of targeted and effective research agendas.
- Conduct further research to define and understand the elements of an effective risk–benefit assessment in order to counsel pregnant women with pain about the use of opioids for pain versus other pharmacotherapies, nonpharmacologic interventions, and the consequences of untreated pain for themselves, their pregnancy, and their infants.
- Conduct studies to examine the extent and impact of polysubstance use on the outcomes of opioid exposure in pregnancy and NAS/NOWS, and the effects of prenatal opioid exposure through childhood. These effects include the impact on development and

academic performance as compared with exposure to other substances or medications. Such research needs to be carefully controlled for social, familial, and environmental risk and protective factors encountered during childhood. This research should be informed by prior research identifying outcomes at 25 years of follow-up after prenatal cocaine exposure.<sup>43</sup>

- Facilitate and coordinate data sharing and data analysis activities across HHS agencies so that findings will be more comprehensive and bring a more robust understanding to substance use and its impact on children/youth and families.
- Undertake research to identify behaviors that can mitigate the risk of NAS for infants of women who, for medical reasons, receive opioid therapy during pregnancy. Awareness of behaviors in caregiving adults can also help identify other variables that may positively affect the long-term outcome of substance-exposed infants. Such variables may include tobacco cessation and in-home support services.<sup>18,44,45,46</sup>
- Undertake research to distinguish between the needs and outcomes of women of different ages, and between women who become pregnant while being treated with an opioid for pain, women on MAT, and women with untreated SUD.
- Undertake research on how best to make NAS and NOWS assessment more objective and reliable. There is a need to expand the evidence base of nonpharmacologic therapies, and optimize and standardize the full range of pharmacologic therapies available to treat NAS/NOWS. In addition, there is a need to better understand the long-term outcomes of infants treated with pharmacotherapy, and the long-term neurodevelopmental outcomes of opioid-exposed infants.
- Conduct policy analysis and implementation studies to determine how to overcome institutional, social, legal, and other system barriers to the adoption of MAT and determine the most effective means of delivering MAT to women who are pregnant or parenting. Despite an abundance of evidence for its effectiveness, MAT has not been adopted on the scale needed by the population to optimize outcomes for women, children and families. Use these analyses to better understand challenges for women to access evidenced based treatment.
- Improve access to the full range of contraceptive options for women who receive opioids and early intervention services for substance-exposed infants.

## **Programs/Service Delivery**

HHS agencies support the provision of numerous services for women of reproductive age and their children. These programs seek to educate women about opioid use, prevent the nonmedical use and misuse of opioids, and provide treatment for OUD and NAS.

### **Health and Social Services**

HHS supports the direct delivery of a number of health and social services. The Centers for Medicare & Medicaid Services (CMS) covers many services for pregnant women with OUD and infants affected by NAS, including medical, clinical, and SUD treatment services. The Indian Health Service (IHS) operates a Centering Pregnancy® program, which provides group prenatal care facilitated by a nurse midwife. Each patient receives an individual prenatal exam and then participates in a group education program. The group education program includes topics such as substance use, intimate partner violence, depression, and trauma, all of which may be associated

with opioid use during pregnancy. Because the feedback about the program has been so positive, many of the group sessions continue even after women give birth, providing ongoing support for women who misuse or are at risk for misusing opioids.

Several agencies have also been involved with home visitation programs, an intervention for which effectiveness evidence is accumulating.<sup>47,48,49</sup> Such programs provide an important opportunity to deliver health and social services to women of reproductive age and their children. NIH provides support for the primary studies that have documented the potential value of nurse home visitation interventions, and is now supporting work to determine their applicability to an American Indian population.<sup>50</sup> ACF and the Health Resources and Services Administration (HRSA) collaborate on the Federal Home Visiting Program to support parents of young children in at-risk communities. The program helps parents tap the resources and hone the skills they need to raise children who are physically, socially, and emotionally healthy and ready to learn.

IHS public health nurses home visit high-risk prenatal patients and newborns. IHS provider-driven referrals increase the level of contact. Because many Native communities include women who use opioids, other drugs, and alcohol during their pregnancies, IHS contracted with the Johns Hopkins University Center for American Indian Health to provide Community Health Representative training on preventive maternal infant and child health home visiting services in tribal communities. These efforts enabled the provision of valuable education and case management services, which are instrumental in preventing and treating OUD and NAS. IHS also maintains provider resources on NAS best practices on its maternal child health section of the IHS opioid dependence management website. In addition, IHS hosted a six-part provider education series on prenatal illicit substance use, NAS, and breastfeeding considerations.

HRSA's Healthy Start program offers a wide array of services to pregnant and postpartum women and their babies. The program provides depression screening, drug and alcohol screening, health care services, care coordination, public health services such as immunization and health education, and training for community health workers and care coordinators.

A number of HHS agencies also participate in a program called Baby Friendly, which is jointly supported by the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF). The program helps give mothers the information, confidence, and skills necessary to initiate and continue breastfeeding or feeding formula safely. Breastfeeding enhances maternal-infant attachment, and strong attachment is associated with enhanced infant and child mental health.<sup>51</sup>

CDC funds Perinatal Quality Collaboratives, which are networks of perinatal care providers and public health professionals working to improve pregnancy outcomes for women and newborns. Two of the awardees for this program implemented hospital policies related to NAS and have since seen decreases in length of hospital stays among infants with NAS.

Finally, ACF, CMS, and HRSA jointly support the Strong Start for Mothers and Newborns initiative, which aims to reduce preterm births and improve outcomes for newborns and pregnant women. In addition to reducing the rate of early elective deliveries, the program provides a

funding opportunity to test enhanced prenatal care approaches to decrease the frequency of premature births related to health and psychosocial factors.

### **Grant Programs**

SAMHSA has four grant programs that help women of reproductive age who misuse or are at risk for misusing opioids during pregnancy. The Substance Abuse Prevention and Treatment Block Grant, which provides states with formula grants (noncompetitive grants based on a predetermined formula), includes a set-aside for pregnant and postpartum women's services. SAMHSA's annual report on the block grant gives a qualitative summary of state responses to a set of six open-ended questions in order to ascertain each state's activities and strategies to serve pregnant and parenting women. The annual report also highlights states' innovative approaches, which other states may choose to implement as well.

Another SAMHSA grant program, Medication Assisted Treatment – Prescription Drug and Opioid Addiction (MAT-PDOA), provides funding to states to enhance and expand MAT and recovery support services for individuals with OUD. Three grantee states are focusing their efforts on pregnant women with OUD.

SAMHSA's Residential Treatment for Pregnant and Postpartum Women Grant Program provides cost-effective, comprehensive residential SUD treatment services to women and their minor children. These services address the individual needs of women and their children, preserve and support the family unit, and provide a safe and healthy environment for family members.

Project LAUNCH (Linking Actions for Unmet Needs in Children's Health) is a SAMHSA grant program that works in states, tribes, territories, and communities to promote the healthy development of young children, and to strengthen the capacities of families and other caregivers to promote children's social and emotional development and wellbeing. Project LAUNCH grantees offer trainings to providers, including primary care providers and home visitors, on behavioral health issues that impact young children, including parental depression, SUD, and in some cases, NAS specifically. Project LAUNCH grantees integrate preventive mental health supports into obstetrician-gynecology and primary care practices, and engage parents of young children in a variety of family strengthening and parenting education activities. One Project LAUNCH grantee working in a rural county found an increase in infants diagnosed with NAS, and reductions in the length of NICU stays for NAS infants, after the implementation of Project LAUNCH and compared to a similar, neighboring county. Project LAUNCH activities included provider education on NAS diagnosis, pre- and post-natal family supports and education, and in-home family supports following discharge from the NICU. This model is now being implemented across the state.

ACF's competitive Regional Partnership Grants, which are awarded to states, tribes, and communities, have made a significant investment in improving outcomes for children and families affected by parental SUDs. ACF's Child Abuse Prevention and Treatment Act (CAPTA) State Grants are formula grants to improve child protective service systems. The program requires states to provide assurances that they are operating a statewide child abuse and neglect program that provides for the development of plans of safe care to address the needs of infants identified as being affected by substance use. Pursuant to Section 503, "Infant Plan of



Safe Care,” of the Comprehensive Addiction and Recovery Act of 2016 (S. 524), the plan of safe care should address the needs of the child and the parent(s), as appropriate, and make sure that appropriate services are provided to ensure the infant’s safety.

HRSA also administers the Maternal and Child Health Block Grant. States and jurisdictions use their Title V Maternal and Child Health Services Block Grant Program funds to design and implement a wide range of Maternal and Child Health and Children with Special Health Care Needs activities that address the identified national and state needs. Although activities to address the opioid epidemic are not a required focus of the block grant, 23 states (Alaska, Arizona, Colorado, Florida, Kentucky, Louisiana, Maryland, Massachusetts, Missouri, New Hampshire, New Mexico, New York, Oklahoma, Oregon, Pennsylvania, Rhode Island, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin) reported activities to address opioid use in their FY 2016 applications and FY 2014 Annual Reports. In addition, all states are required to provide the rate of infants born with NAS per 1,000 delivery hospitalizations as a National Outcome Measure.<sup>52</sup> The rate has doubled between 2008 and 2012, from 3.9 per 1,000 to 8.2 per 1,000 delivery hospitalizations.

ACF and the Office of Head Start within the Office of Early Childhood Development provides Early Head Start grants which, in turn, provide early, continuous, intensive, and comprehensive child development and family support services to low-income infants and toddlers and their families, and pregnant women and their families. This program places a particular emphasis on prevention activities that both promote healthy development and recognize and address atypical development at the earliest stage possible. Likewise, as Early Head Start-Child Care Partnerships, these same offices allow new or existing Early Head Start programs to partner with local child care centers and family child care providers to offer these same comprehensive services to pregnant women and women with infants or toddlers who previously did not have access to these services.

ACF, in collaboration with HRSA, also administers the Tribal Federal Home Visiting Program, which provides grants to tribal organizations to develop, implement, and evaluate home visiting programs in American Indian and Alaska Native communities.

Together, these grant programs offer numerous opportunities for states and communities to support women of reproductive age and their infants and, ultimately, decrease prenatal opioid exposure and NAS.

### **Gaps, Overlap, Duplication**

Providing services to pregnant women with OUD and infants at risk of NAS carries challenges. Key screening-related challenges affecting service delivery include pregnant women’s concerns about the legal ramifications of disclosing substance use, limited knowledge among providers about how to identify opioid misuse, and the subjectivity of the measures typically used to identify NAS.<sup>53,54</sup> Women who use prescription pain relievers may not realize that they need to alert their providers during pregnancy, which may result in a failure to identify infants at risk of NAS.

Additionally, the impact of the lack of MAT in many rural communities cannot be overstated.<sup>55,56,57</sup> Not enough medical providers in these communities provide MAT, partly

because some hospitals and clinics serving pregnant patients with OUD do not have care coordinators to help keep patients engaged in their MAT. Another significant challenge is the lack of SUD treatment capacity in the rural United States generally.

Many agencies also report that, after pregnant women screen positively for OUD or infants screen positively for NAS, few, if any, specialized services are available to them, particularly in rural areas. Even in areas with greater access to MAT, many programs are reluctant to provide care to pregnant women. Another commonly reported treatment challenge for this population is the limited availability of family-friendly services that provide a full continuum of care and address the social determinants of health.

Although HHS provides and funds many programs to support pregnant and parenting women experiencing or at risk for OUD, HHS does not currently have any programs targeting pain management among pregnant women. The absence of services to support women who either must continue using opioids or need to seek alternative forms of pain relief during their pregnancies may pose significant and potentially avoidable risks to these women and their infants. States and many grantees are not required to provide or ensure access to MAT and, until recently, could exclude patients on MAT from services. Consequently, specialized funding streams have been created to support the development and delivery of MAT.

### **Recommendations**

- Improve data collection so that the scope of the prenatal substance exposure, access to treatment, barriers to access, and disparities in access can be fully understood and inform the development of targeted and accessible programs and services for pregnant and parenting women with OUD and substance-exposed infants.
- Expand services for women with opioid use and their children and ensure more consistent evidence-based resource allocation.
- Develop more family-friendly OUD treatment programs providing appropriate services for women during pregnancy and for mothers and infants following childbirth.
- Work to remove deterrents to treatment for women and promote the adoption of evidence-based practices, including MAT.

### **Education**

Education and awareness are necessary for informed decision making and allocation of community resources that leads to effective prevention and treatment. This section describes educational initiatives targeted at state and local jurisdictions, health care providers and the general public.

### **Training and Technical Assistance**

#### *States and Local Jurisdictions*

HHS agencies provide training and technical assistance through a variety of means. SAMHSA, in partnership with the Administration on Children, Youth and Families (ACF/ACYF), manages the National Center on Substance Abuse and Child Welfare (NCSACW), which provides in depth technical assistance to strengthen the capacity of states and local jurisdictions to improve

the safety, health, and well-being of substance-exposed infants, with an emphasis on women with OUD. The focus of this initiative is to strengthen collaboration and linkages across the child welfare system, the SUD treatment system, and the medical system, in order to improve services for pregnant women with OUD and other SUDs and to improve outcomes for their babies. NCSACW has produced publications, provided online training programs, and responded to hundreds of technical assistance requests. NCSACW offers a series of free recorded webinars on opioid misuse during pregnancy, MAT, and NAS. These webinars target professionals from the child welfare, SUD prevention and treatment, medical, and family court systems.

On August 16, 2016, CDC hosted Public Health Grand Rounds: Primary Prevention and Public Health Strategies to Prevent Neonatal Abstinence Syndrome and continues to provide technical assistance to states and tribal governments on maternal substance use and NAS. Additionally, HRSA has a cooperative agreement that includes an activity on opioids and HIV/hepatitis C with the Association of State and Territorial Health Officials. This cooperative agreement supports state health officials as they develop and implement programs, policy recommendations, and best practices addressing the epidemic of injectable opioids in high-need communities.

In February 2016, ACF, in collaboration with SAMHSA, HRSA and IHS, hosted an expert meeting of tribal leaders, community members, researchers, and advocates to inform ongoing work to support young children and their families who have been impacted by alcohol and substance misuse in tribal communities. As a result, HHS will be releasing a policy statement on *Supporting the Development of Young Children Affected by Alcohol and Substance Exposure in American Indian and Alaska Native Communities*. The purpose of the policy statement is to support early childhood programs and tribal communities by providing recommendations that promote the early development of American Indian and Alaska Native children, prenatal to age 8, who have been exposed to alcohol or substances during pregnancy, or who are affected by parent or caregiver substance misuse during early childhood. Experts agree that a sensitive, responsive, and warm caregiving environment can help reduce and even buffer the effects of exposure to alcohol or substance misuse. The early childhood system, specifically early care and education and home visiting programs, is a critical part of the solution. However, early childhood programs in communities that are affected by this issue do not always have the specialized knowledge, appropriate policies, or a workforce that is trained to address the unique needs of children affected by alcohol or substance exposure and their families. The statement includes recommendations for early childhood programs in tribal communities, tribal and community leaders, and partners of tribal communities, as well as recommendations for building knowledge to advance our understanding of how best to support this population. Resources to support tribal communities in this work are included.

#### *Providers and Health Systems*

SAMHSA has the Addiction Technology Transfer Center (ATTC) Network, a nationwide, multidisciplinary resource for providers of SUD treatment and recovery support, many of whom serve pregnant and postpartum women. SAMHSA also has two national training and mentoring programs developed in response to the opioid epidemic. The Providers' Clinical Support System for Medication Assisted Treatment is a training and mentoring program with the overarching goal of making MAT available to patients in a variety of settings. The Providers' Clinical Support System for Opioid Therapies provides training and continuing medical education

programs on the safe and effective use of opioids for treatment of chronic pain and safe and effective treatment of OUD.

Additionally, IHS has a health professions scholarship program to train nurses, physicians, behavioral health service providers, and other health care providers, further supporting the workforce necessary to effectively identify and treat OUD and NAS.

Through its Innovation Accelerator Program (IAP), which supports state efforts to accelerate Medicaid innovation and delivery system reforms, CMS funded a pilot project with three health systems in one state. The pilot project involved developing a toolkit to increase early identification of mothers at risk for SUD and successfully intervene to engage identified mothers and infants in treatment. CMS also facilitated a learning collaborative and provided webinars on NAS as part of its IAP. CMS provided several learning opportunities for state Medicaid and behavioral health agencies to address NAS and maternal OUD. In 2015, the IAP hosted a webinar for states participating in an intensive SUD learning collaborative; the webinar included information on how to screen and treat children, adolescents, and pregnant women at risk for SUD. In March 2016, the IAP hosted a webinar for all states on SUD services for mothers with SUD and infants affected by NAS. This webinar highlighted different states' experiences dealing with major NAS issues, including providing MAT for pregnant mothers and standardizing postnatal care for infants.

### **Guidance and Information Documents**

In addition to providing training and technical assistance, HHS agencies have produced documents that educate and guide providers and policymakers.

#### *States and Local jurisdictions*

CMS and HRSA in March 2016 jointly released a State Information Bulletin to assist states in designing and funding home visiting services for pregnant women and families with young children. Home visiting programs are critical to preventing and treating OUD among pregnant women. SAMHSA and ACF released a guidance document in August 2016 entitled A Collaborative Approach to the Treatment of Pregnant Women with Opioid Use Disorders. To develop this document, over 40 professionals from the child welfare, substance use treatment, dependency court, and medical fields convened over a 9-month period. The document provides guidance tools that can help facilitate a careful, in-depth analysis of current policies, practices, resources, and training needs for working with pregnant women with OUD. *A Collaborative Approach to the Treatment of Pregnant Women with Opioid Use Disorder* provides specific strategies and guidance for all stakeholders responsible for assuring a plan of safe care is in place for substance-exposed infants and emphasizes the need to coordinate with treatment providers, courts, hospital personnel, the mother's and infant's treatment providers and the child welfare agencies. The document also presents a case study on the Children and Recovering Mothers collaborative, a multidisciplinary group of agencies that serve women with OUD and their families during pregnancy and through infancy.

#### *Providers*

Beginning in March 2015, SAMHSA oversaw a formal process, carried out under the guidance of a federal steering committee (see Table 5), to develop guidance to optimize outcomes for

pregnant and parenting women with OUD and their infants. This activity applied the RAND Corporation (RAND)/University of California Los Angeles (UCLA) Appropriateness Method,<sup>58</sup> hereafter referred to as the RAM process. The RAM process was used to conduct a literature review and convene an expert panel to review the available evidence and then rate the appropriateness of interventions for the treatment of pregnant and parenting women with OUD and their infants. This was carried out via individual review, virtual meetings, and face-to-face meetings. The resulting report, *Advancing the Care of Pregnant and Parenting Women with Opioid Use Disorder and their Infants: A Foundation for Clinical Guidance*, is discussed in Part 3 of this report.

In March 2016, CDC released “*Guideline for Prescribing Opioids for Chronic Pain.*”<sup>59</sup> The guideline includes information for providers regarding the treatment of pain during pregnancy and the use of MAT. The findings are also summarized in Part 3. Additionally, CDC’s *Treating for Two* initiative provides information for providers about medications and pregnancy.

FDA has required label changes related to the use of opioids during pregnancy. For example, in March 2016, FDA announced class-wide safety labeling changes for immediate-release opioid pain medications, including a new boxed warning about the risks of misuse, abuse, addiction, overdose, death, and NOWS. Then, in May 2016, following input from a Risk Communication Advisory Committee, FDA developed and finalized new labeling language communicating the balance of benefits of opioid agonist MAT during pregnancy and risks of NOWS for products indicated for use in opioid agonist MAT. FDA has also participated in ongoing communications about abuse-deterrent formulations of opioids during all stages of the drug development process. Currently seven approved opioid analgesic products have abuse-deterrent properties described in the product labeling. FDA has also approved new formulations of naloxone products for treating opioid overdose, with prescribing information for use in neonates with respiratory depression.

**Table 5: Agencies and Offices Participating in the Federal Steering Committee**

Assistant Secretary for Planning and Evaluation, HHS
Centers for Disease Control and Prevention, HHS
Centers for Medicare & Medicaid Services, HHS
Federal Bureau of Prisons, U.S. Department of Justice
Food and Drug Administration, HHS
Health Resources and Services Administration, HHS
Indian Health Service, HHS
National Institutes of Health, HHS
Office of National Drug Control Policy, The White House
Office of the Assistant Secretary for Health, HHS
Office on Women’s Health, HHS
Substance Abuse and Mental Health Services Administration, HHS
U.S. Department of Defense
U.S. Department of Veterans Affairs

## Public Education

HHS provides public online resources relevant to OUD and NAS. A section of the HHS [website](#) is dedicated to educational information about the use of opioids. It serves as a clearinghouse for information on the opioid epidemic, including types of opioids, ways to access services for individuals needing treatment, overdose response, and proper drug disposal. Through their [Treating for Two](#) initiative, CDC has also produced resources with information about medications and pregnancy for the general public. CDC's [Pregnancy and Opioid Medications](#) factsheet describes the risks associated with opioid exposure and provides recommendations for pregnant and breastfeeding women. SAMHSA's [Methadone Treatment for Pregnant Women](#) brochure urges pregnant women who use heroin or misuse prescription opioids to seek methadone maintenance treatment, and provides information about how methadone therapy works and the unique considerations for pregnant women. Finally, NIDA has a research report series entitled [Substance Use in Women](#) as well as an online guide entitled [Principles of Substance Abuse Prevention for Early Childhood: A Research-Based Guide](#). This guide offers research-based principles addressing how early interventions starting during pregnancy and continuing through age eight that can positively affect a child's self-control and overall mental health development.

## Gaps, Overlap, Duplication

Great strides have been made in providing guidance to health professionals caring for women with OUD and women who experience pain during pregnancy. As the research and data questions described above are addressed, this guidance will need to be refined. Resources and strategies to support the adoption and implementation of the existing guidance are needed. Having multiple tailored messages about these efforts is desirable, because stakeholders include health care professionals of various disciplines, policy makers, members of the public, and patients and their families, and each group needs appropriately designed and targeted resources.

Most notably lacking from federal guidance are evidence-based, reproducible strategies for identifying and managing infants at risk of NAS, both at birth and after discharge from the hospital. This may be the result of the limited research and the lack of specific, systematic screening tools and protocols.

Much misinformation and misunderstanding remains among the public and professionals alike regarding the nature, causes, and treatment of SUD and, in particular, MAT for pregnant and parenting women. No concerted public education campaign exists to address this. Consequently, many pregnant and parenting women with OUD who might otherwise seek or stay on MAT do not participate in treatment.

## Recommendations:

- Promote improved public and health professional understanding of OUD as a brain disease responsive to treatment, and of NAS/NOWS as a medical condition that can be prevented, minimized, and effectively treated with available interventions.
- Increase efforts to train obstetricians, emergency department personnel, and community-based primary care providers on the need to take the cultural and social perspectives of at-risk and pregnant women into account when providing them with SUD treatment guidance, with special consideration for reducing the potential impact of NAS. This should include appropriate, factual, and unbiased messaging, education, outreach, and

engagement activities for women with opioid-exposed pregnancies and for caregivers of opioid-exposed infants.

- Ensure prescribing providers, in particular obstetrician-gynecologists, family physicians, orthopedists, general surgeons, and dentists, are well trained in appropriate pain management during pregnancy, including the use of opioids when needed.

## Coordination

Coordination across HHS is important not just to avoid duplication and overlap, but also to ensure efforts undertaken by various agencies in service of their respective missions are adopted, promoted, and put to maximum use by sister agencies. Coordination also serves to ensure accuracy of scientific information and harmonization of policies and recommendations.

## Collaboration

The February 2015 Government Accountability Office report *Prenatal Drug Use and Newborn Health* helped prompt the Behavioral Health Coordinating Council's (BHCC) subcommittee (BHCC Subcommittee on Prescription Drug Abuse) to focus on prescription drug misuse. The subcommittee, which meets monthly to discuss opioid-related activities in members' agencies, formed a workgroup dedicated to coordinating and reporting NAS-related activities within HHS. BHCC has taken responsibility for producing this report for HHS.

As noted above, the SAMHSA- and ACYF-funded NCSACW has provided a substantial amount of training and technical assistance to providers throughout the country to improve the safety, health, and well-being of substance-exposed infants, with an emphasis on women with OUD.

Several HHS agencies have relevant internal workgroups. CDC has a perinatal drug use and abuse workgroup, IHS has a national prescription drug abuse workgroup, and HRSA has a cross-agency workgroup focused on opioid use, which includes work related to maternal and child health. Work is also being done under the initiative to bridge an existing gap between research and public health practice by providing opportunities to share best practices from around the country. These workgroups each target a unique facet of the opioid epidemic and its implications for pregnant and parenting women, helping to ensure that these issues remain top priorities for HHS. The workgroups enable HHS agencies to be better prepared to implement Departmental initiatives on prenatal opioid exposure and NAS.

Finally, IHS collaborates with the American College of Obstetricians and Gynecologists, the American College of Nurse-Midwives, the Association of Women's Health, Obstetric, and Neonatal Nurses, the American Academy of Pediatrics, and the American Academy of Child and Adolescent Psychiatry to conduct annual site visits to IHS maternity hospitals and pediatric clinics. These site visits provide IHS with objective assessments and recommendations geared to improving the quality of care. They also help to ensure that efforts throughout the field to support mothers and children affected by prenatal opioid exposure are well-coordinated.

## Meetings

HHS agencies have convened or will convene several meetings related to prenatal opioid exposure and NAS. NCSACW is leading one of the Department's major coordination efforts by convening an expert panel focused on treating pregnant and parenting women with OUD, with

the objective of developing clinical guidelines for the combined treatment of these women and their children.

CDC hosted an expert meeting on use of illicit drugs and prescription drug misuse among pregnant women to (1) develop SBIRT algorithms and guidance for use with pregnant and postpartum women, (2) review and discuss key clinical management and psychosocial issues for pregnant and postpartum women who use illicit drugs, and (3) identify research gaps and formulate key research questions.

Additionally, the “Opioid Use in Pregnancy, Neonatal Abstinence Syndrome, and Childhood Outcomes Workshop” was held April 4–5, 2016, under the sponsorship of NICHD, the American Congress of Obstetricians and Gynecologists, the American Academy of Pediatrics, the Society for Maternal-Fetal Medicine, CDC, and the March of Dimes. The goal of this meeting was to identify lessons learned and research gaps in this field.

NCSACW will cosponsor a national conference on substance use and child welfare. The plenary session and many of the workshops will focus on prenatal substance exposure and the opioid epidemic.

The Office on Women’s Health (OWH) convened a national meeting on opioid use, misuse, and overdose in women September 29 and 30, 2016 to build on the work being done under the Secretary’s opioid initiative. This work includes looking at the unique and specific needs of women in the context of the opioid epidemic, and fostering a national conversation on best practices to address opioid-related dependence and death among women in the United States. On October 24–25, 2016, OWH convened a second meeting focused on HHS Region I (the New England states) as a model for other regions of the country. Both meetings will bring together policy experts, program staff, researchers, clinicians, and women with lived experience to foster a conversation on best practices to address opioid use, misuse, and overdose in women.

Finally, SAMHSA convened a policy academy to address the needs of pregnant women with OUD and their infants in July 2016. The meeting targeted state teams interested in improving their capacity to collaborate and develop policies and practices.

### **Gaps, Overlap, Duplication**

Coordination on NAS has improved because of the efforts described above. Challenges remain owing to the social and medical complexity of the issues posed by opioid use. These issues include the use of MAT by pregnant women; effective pain management for pregnant women; effective screening for OUD among pregnant women; access to the full range of contraceptive options for women at risk; and early identification of NAS. The range of government entities, stakeholders, professional disciplines and specialties involved in addressing these issues is extensive, which makes coordination especially challenging. Another identified gap in coordination is the lack of specific goals and measureable outcomes related to the coordination activity.

### **Recommendations**

- Continue to focus on strengthening interagency communication and coordination while minimizing overlap.



- Promote opportunities for cross-agency idea exchange and discussion of the broader context of key issues. In addition, greater recognition of the needs of the mother and fetus or the mother and infant would support more coordinated efforts to assure the best possible outcome for both.
- Improve cross promotion of agency efforts and activities to the public.

## Conclusion

This overview of Departmental activities highlights a broad range of efforts, including data collection, surveillance, research, service provision, grant programs, training, technical assistance, webinars, reports, and meetings. These activities target diverse populations that includes patients, providers, researchers, and the general public.

This overview also sheds light on key areas that warrant further attention. Specifically, a number of activities are limited by screening-related challenges, including limited availability of easy-to-use, validated screening instruments and a lack of knowledge among providers and researchers about how to correctly identify and manage NAS. Therefore, efforts to develop a robust and objective screening instrument for NAS, and to ensure that providers and researchers are adequately trained to use it, would be extremely beneficial.

Additionally, successful prevention and intervention for infants depends on addressing the needs of women with pain or OUD. In particular, efforts to reduce prejudice associated with OUD or licit opioid use during pregnancy and parenting are critical. Fear of medical, social, and legal consequences can prevent women from providing accurate information in both clinical and research settings.

Ensuring that women and their infants have access to effective pain management and treatment for OUD and NAS is also critical. Workforce shortages and limited knowledge and confidence among providers may hinder the ability to provide timely, evidence-based treatment for this patient population, so continuing to offer grant funding, treatment programs, training, and technical assistance will remain important.

Finally, understanding and addressing the magnitude and characteristics of prenatal opioid exposure and NAS depend on high-quality data. The Department has conducted a number of analyses to provide an overview of this issue, but this work is restricted by limited and heterogeneous data sets. Therefore, the Department should continue to give high priority to collecting and analyzing high-quality data that can be used to inform policymakers, researchers, and the general public about the extent of these conditions.

In summary, the Department has engaged in a broad range of activities that help prevent and treat OUD among pregnant women and NAS among infants. Addressing the areas in need of further work will enable the Department to expand its impact on the uniquely interdependent needs of the mother and fetus and the mother and infant.

### Part 3: Recommendations for Prevention and Treatment of Prenatal Opioid Exposure (Section 3 of the Act)

This section presents the clinical and programmatic recommendations for prevention of prenatal opioid exposure; treatment of OUD; and prevention, identification, and treatment of NAS and any long-term consequences. It also covers gaps in the evidence base regarding these issues.

Consistent with the National Pain Strategy,<sup>60</sup> all people with pain should be assured of receiving needed preventive, assessment, treatment, and self-management interventions. Additionally, two important HHS initiatives targeting the national opioid epidemic and informed by the Government Accountability Office report *Prenatal Drug Use and Newborn Health* were carried out in 2015 and 2016. First, CDC developed and published *Guideline for Prescribing Opioids for Chronic Pain*<sup>59</sup> (the CDC Guideline) and SAMHSA developed *Advancing the Care of Pregnant and Parenting Women with Opioid Use Disorder and Their Infants: A Foundation for Clinical Guidance* (the SAMHSA Report). Both of the processes for developing the products, although separate and with different strategies, included a comprehensive research review by expert professionals and benefited from interagency and stakeholder input. The SAMHSA Report included a “comprehensive assessment of existing research with respect to the prevention, identification, treatment, and long-term outcomes of NAS, including the identification and treatment of pregnant women or women who may become pregnant who use opioids or have opioid use disorders,” as required by the Act. It should be noted at this time that since data are not available to support an accurate assessment of any disparities in risk for OUD or access to treatment across demographic groups this cannot be specifically addressed in the report. Both initiatives produced sound guidance for immediate use by health care providers (summarized below) but also revealed gaps and deficiencies in the overall evidence base and population data consistent with those described in Part 2 of this report.

Tables 6–9 below, and the accompanying narrative text, summarize the clinical recommendations in the CDC Guideline and the SAMHSA Report. The recommendations are presented sequentially in the natural course from pregnancy to parenting, with recommendations specific to the opioid-exposed infant at the end.

**Table 6: Recommendations for Reproductive Age Women in the CDC Guideline and the SAMHSA Report**

<b>Opioid Use Disorder</b>	<b>Chronic Pain</b>
<ul style="list-style-type: none"> <li>- A woman with OUD, whether receiving MAT or not, should be counseled about contraception and have immediate, easy access to her contraceptive of choice. Such access will allow her to exert more control and make informed decisions about when and under what circumstances to add to her family.</li> </ul>	<ul style="list-style-type: none"> <li>- Before initiating opioid therapy for chronic pain for reproductive-age women, clinicians should discuss family planning and how long-term opioid use might affect any pregnancy that may occur during the therapy.</li> </ul>

**Table 7: Recommendations for Pregnant Women in the CDC Guideline and the SAMHSA Report**

<b>Opioid Use Disorder</b>	<b>Chronic Pain</b>
<ul style="list-style-type: none"> <li>- Pregnant women with OUD who are not currently receiving MAT should be advised to begin treatment with methadone or buprenorphine.</li>   <li>- Health care providers will need to conduct a careful interview of the patient that includes her pregnancy, drug use, and mental health history, with special attention to high-risk behaviors, such as using drugs by injection. A formal substance use screening instrument may be given to the patient for self-completion, reviewed by the health care providers, and combined with a formal SBIRT protocol to help ensure that information is gathered effectively and in a clinically appropriate and therapeutic manner. Urine toxicology screening and review of the state(s)' prescription drug monitoring program, where available, could be a standard part of the initial visit.</li>   <li>- The patient should be supported in making an informed decision about which pharmacotherapy is most appropriate for her. The patient should be informed of the potential social and medical consequences of each form of therapy, specifically with regard to the risk of NAS. She should also be told that there is no known increased risk of birth defects associated with buprenorphine or methadone in the context of a pregnancy already exposed to opioid due to OUD.</li>   <li>- During the prenatal period a woman with OUD should be educated about how NAS is diagnosed and monitored so she can participate in the assessment</li> </ul>	<ul style="list-style-type: none"> <li>- If opioids will be prescribed to a pregnant woman, she and the clinician together should carefully weigh risks and benefits when deciding whether to initiate opioid therapy.</li>   <li>- If opioid therapy is initiated during pregnancy, all of the CDC Guideline's guidance on dosing and duration of therapy should be followed. The woman and her clinician should apply the same risk-benefit discussion described above to determine whether opioids will be continued.</li>   <li>- For this dialogue and decision making to take place, the patient must be informed that therapy might be associated with additional risks to both her and her fetus, as some studies have shown an association between opioid use in pregnancy and stillbirth, poor fetal growth, preterm delivery, and birth defects.</li>   <li>- In some cases, opioid use during pregnancy leads to NODS. This risk will need to be weighed against the benefits of opioid use.</li>   <li>- Over the course of the pregnancy, regular review of the risk-benefit discussion should take place, as the balance may shift as the woman's pregnancy advances or levels of pain change.</li>   <li>- If the decision is made to discontinue opioids because a woman has become pregnant, clinicians should access appropriate expertise, such as a pain or addiction specialist or toxicologist, if considering tapering opioids, because</li> </ul>

<p>and management of her newborn. She should be made aware of the nonpharmacologic interventions that should be provided to her infant to reduce symptoms of NAS and informed that breastfeeding, if not otherwise contraindicated, may reduce any opioid withdrawal her baby may experience.</p> <ul style="list-style-type: none"><li>- Pregnant women on MAT who report cravings or withdrawal symptoms (which can be caused by the metabolic changes associated with advancing pregnancy) should be assessed for a possible increase in the dose of their medication. They should also receive additional behavioral interventions to prevent relapse and develop effective strategies for coping with triggers.</li><li>- Pregnant women with OUD, with or without a prior history of MAT, should be advised that medically supervised withdrawal from opioids is associated with high rates of relapse and is not recommended. If a pregnant woman not on MAT decides to move forward with detoxification, it can be conducted in a controlled setting at any time in the pregnancy if the benefits outweigh the risks. Such decisions should be made with great care on a case-by-case basis.</li></ul>	<p>of possible risk to the pregnant patient and to the fetus if the patient experiences opioid withdrawal.</p>
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**Table 8: Recommendations for Peripartum Care in the CDC Guideline and the SAMHSA Report**

<b>Opioid Use Disorder</b>	<b>Chronic Pain</b>
<ul style="list-style-type: none"> <li>- Prior to delivery, a pregnant woman with OUD should be informed of her pain relief options. To ensure adequate pain control, her care should be coordinated between the OB/GYN, addiction specialist, and anesthesiologist as appropriate.</li> <li>- Intrapartum pain relief options for a woman with OUD, regardless of whether she is receiving MAT, should include an epidural/spinal anesthesia and the use of a short-acting opioid analgesic.</li> <li>- A woman on MAT will not receive adequate pain relief either intrapartum or postpartum from her regular dose of medication. She may also need a short-acting opioid analgesic in addition to her epidural/spinal anesthesia. In the case of MAT, her buprenorphine or methadone should not be increased for the purposes of short-term intrapartum or postpartum pain control.</li> <li>- Women with OUD, whether on MAT or not, and women who are tolerant to opioids because of chronic use for pain management may require higher doses of opioid analgesics to attain adequate pain relief than women without OUD or chronic pain. The need for higher doses of analgesics may continue into the initial postpartum period regardless of the method of delivery.</li> <li>- At no time should butorphanol, nalbuphine, or pentazocine be administered to a woman with OUD, regardless of whether she is on MAT, nor should these be administered to women who require chronic opioid therapy for pain relief.</li> </ul>	<ul style="list-style-type: none"> <li>- Clinicians caring for pregnant women receiving opioids for pain should arrange for delivery at a facility prepared to monitor, evaluate for, and treat NOWS. In instances when travel to such a facility would present an undue burden on the pregnant woman, it is appropriate to deliver locally, monitor and evaluate the newborn for NOWS, and transfer the newborn for additional treatment if needed.</li> </ul>

**Table 9: Recommendations for Breastfeeding in the CDC Guideline and the SAMHSA Report**

<b>Opioid Use Disorder</b>	<b>Chronic Pain</b>
<ul style="list-style-type: none"> <li>- Upon delivery, women who are stable on buprenorphine or methadone should be advised to breastfeed. While naltrexone has not been studied in breastfeeding mothers, it is generally thought that the benefits of breastfeeding may outweigh any risk from naltrexone exposure. However, the decision to breastfeed while on naltrexone should be made collaboratively with the patient after a full discussion of the lack of research as well as any individual considerations.</li>   <li>- Breastfeeding may need to be discontinued if relapse to benzodiazepine, cocaine, or methamphetamine use occurs. Mothers who relapse to alcohol use should discontinue breastfeeding.</li> </ul>	<ul style="list-style-type: none"> <li>- The CDC Guideline offered the following direction regarding the use of codeine in particular for pain in the context of breastfeeding: neonatal toxicity and death have been reported in breastfeeding infants whose mothers are taking codeine (contextual evidence review); previous guidelines have recommended that codeine be avoided whenever possible among mothers who are breastfeeding and, if used, should be limited to the lowest possible dose, and to a 4-day supply.</li> </ul>

### Special Considerations in the Context of Opioid Use Disorder

#### *Comorbid Illness*

A woman with comorbid mental health conditions that require taking (1) benzodiazepines, (2) selective serotonin reuptake inhibitors (SSRIs), (3) amphetamines, or (4) other pharmacotherapy should receive education and have the opportunity to discuss the known or suspected impact of prenatal exposure to these substances on the baby. Discussion should include whether there is an associated NAS or impact on her choice of breastfeeding or bottle feeding. She should be helped to determine the risks and benefits of continuing versus discontinuing any such pharmacotherapy to her baby and to herself (including to her mental health), with input from expert health professionals as appropriate.

#### *Comorbid Substance Use*

Women who misuse (1) benzodiazepines, (2) SSRIs, (3) amphetamines, or (4) other pharmacotherapies, whether licitly or illicitly obtained, or who have an SUD involving alcohol, cocaine, or tobacco should also receive education. The health care worker should discuss the known or suspected impact on the baby of prenatal exposure to these substances, including whether there is an associated NAS. Any impact on the choice of breastfeeding or bottle feeding should also be discussed. Women with SUDs should be offered appropriate evidence-based behavioral, pharmaceutical, and social services to support the discontinuation of the substances. They should also be supported in attaining abstinence from other substances, including tobacco

and alcohol. A pregnant woman on MAT who is also using one or more other substances should receive behavioral interventions targeting the use of these substances and pharmacotherapy if available for the substance(s) she is using. In the case of relapse to substances other than opioids, she should also be provided with a higher level of care, such as residential treatment, although disruption of her pharmacotherapy should be avoided. A pregnant woman previously on MAT who relapses to opioid use should be restarted on methadone or buprenorphine as appropriate. (See previous page.)

### ***Changing Form of MAT***

Transitioning a woman on buprenorphine to methadone because of cravings should be done only on a case-by-case basis and not as a general policy or standard practice. Decisions about changing from buprenorphine/naloxone to buprenorphine only must be made on a case-by-case basis informed by the patient's specific needs and concerns. The anticipated benefit of any such change must be balanced against the risk of destabilization resulting in relapse to drug use caused by changing the pharmacotherapy of an otherwise stable pregnant patient.

### ***Changing Dose of MAT***

A pregnant woman on MAT who relapses to opioid use should have the effectiveness of her dose of medication evaluated and receive additional behavioral interventions. She should also receive a higher level of care, such as residential treatment, although disruption of her pharmacotherapy should be avoided. Changing the type of pharmacotherapy (e.g., buprenorphine to methadone) is not specifically recommended or advised against but may be considered if the above-recommended interventions are fully implemented but unsuccessful. A woman may wish to decrease her dose of buprenorphine or methadone in the mistaken hope of decreasing the intensity of NAS her newborn may experience. However, the amount of either medication is not strongly associated with the degree of NAS the baby will experience, so there is little evidence to support this decision. In addition, lowering the dose in the presence of the metabolic dynamics of pregnancy may lead to maternal instability and relapse to substance use. Women should be provided with education and the opportunity to discuss concerns about their dose, supported in arriving at a dose that is effective at preventing both withdrawal and relapse, and supported in attaining abstinence from other substances, especially tobacco.

### ***Naltrexone***

Women who become pregnant while using extended-release injectable naltrexone (an opioid antagonist) who wish to continue on MAT could be offered MAT with methadone or buprenorphine. The safety of naltrexone in pregnancy is not established, but the risk of discontinuing MAT completely needs to be weighed carefully against the risks associated with relapse to opioid use in the context of pregnancy. For similar reasons, it is unclear how best to advise women receiving MAT with extended-release injectable naltrexone who wish to become pregnant, but a similar approach could be taken.

### ***SAMHSA Report***

Guidance regarding opioid therapy for parenting women with chronic pain was not specifically provided in the CDC Guideline. The general guidance provided about the appropriate use of opioids for pain would result in primarily only women with chronic pain due to cancer receiving

opioids chronically. The SAMHSA Report’s recommendations for parenting women are in Table 10.

**Table 10: Recommendations for Parenting Women in the SAMHSA Report**

<ul style="list-style-type: none"><li>- In the immediate postpartum period, complaints of drowsiness and somnolence should prompt evaluation of the patient’s dose of agonist therapy. A dose effective in pregnancy may be too high postpartum. Attention should also be given to whether a comorbid medical or psychiatric condition is present or whether relapse to some form of substance use has occurred.</li><li>- Consideration can be given to maternal requests to change the form of pharmacotherapy being used to treat OUD after delivery. However, a careful risk–benefit assessment should be conducted and the decision should be made collaboratively with the patient.</li><li>- Discontinuation of MAT should generally be avoided in the immediate postpartum period but may be entertained later if the patient’s OUD has remained well controlled and the mother and child have a safe, stable social environment and home. Every effort should be made to avoid discontinuing MAT only at the behest of the patient’s family, social service provider, parole or probation officer, or judge.</li><li>- Cravings can occur even when OUD is well managed.</li><li>- Patients who report cravings postpartum or while parenting should receive additional behavioral interventions to address any new or aggravated stressors. The effectiveness of the patient’s dose of MAT should be evaluated and adjusted if needed.</li><li>- A new mother who relapses to any substance use (opioids, benzodiazepines, cocaine, methamphetamine, tobacco, alcohol, or marijuana) should be assessed for possible adjustment of her agonist therapy and receive additional behavioral interventions. In the case of relapse to opioids, there is disagreement about the value of changing the form of pharmacotherapy used to treat the OUD. If it is necessary to change from one pharmacotherapy to another, a careful discussion of the risks of possible further destabilization in the context of relapse should be had with the new mother and no change should be undertaken without fully informed consent.</li><li>- A new mother with OUD should be screened for comorbid mental health conditions prior to discharge from the hospital and again at the postpartum outpatient appointment.</li></ul>
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### **Infants**

Opioid-exposed infants require similar management regardless of the cause of the opioid exposure.



### ***Screening and Assessment for NAS***

Any opioid-exposed infant should be monitored and managed according to a formal protocol for NAS. The monitoring and managing of infants at risk of NAS should be informed by an interview with the mother about other substance and pharmacotherapy use during pregnancy, by the clinical status of the infant and by toxicology screening of the mother and the infant. Any toxicology screening of the mother must be done with her informed consent.

### ***Infants Diagnosed With NAS***

An infant exhibiting mild signs of NAS should be provided with symptom relief primarily with nonpharmacologic interventions and monitored for progression to more severe symptoms according to a formal NAS protocol. Infants with moderate to severe signs of NAS, such as vomiting and excessive crying, should continue to receive nonpharmacologic interventions as for infants with milder NAS, with the addition of liquid oral morphine or liquid oral methadone. Neither tincture of opium nor phenobarbital should be used as first-line agents, but clonidine or phenobarbital may be used as adjuvants for infants with more severe NAS not completely controlled with morphine or methadone. The use of sublingual buprenorphine for the management of moderate to severe NAS is neither recommended nor advised against.

An infant with NAS who cannot maintain adequate hydration or who loses weight despite optimal management should be evaluated to rule out other medical conditions, and consideration should be given to possible transfer to a NICU.

### ***Discharge Planning for Infants With NAS***

The discharge plan for infants treated for NAS should include home visitation and early intervention services, a home nursing consult, a social work consult and referral to a pediatrician knowledgeable about NAS who is accessible to the family immediately upon discharge. An infant treated for NAS who is fussy or having loose stools after discharge home should be promptly evaluated by a medical provider. The caregivers should be educated about the signs of NAS and the benefit of a stable and enriched home environment for the infant.

### ***Counseling for Potential Neurodevelopmental Issues***

All pregnant women with OUD should be taught how NAS is diagnosed and treated, and should be familiarized with standard protocols used to manage it. Caregivers of opioid-exposed infants should be informed that although genetic and social risk factors and protective factors affect the child's eventual risk for developing SUD, prenatal opioid exposure and NAS do not increase this risk. Caregivers should be educated about and supported in providing a stable, healthy home environment to enhance protective factors and reduce social risk factors. Caregivers expressing concerns about the development of a child who was exposed to opioids in-utero or who experienced NAS should be carefully interviewed by a knowledgeable pediatric health professional. The child should have developmental screening and ongoing assessment and should receive early intervention services. The caregiver should be educated about and supported in providing a stable and enriched home environment to promote healthy development of the child.

## **Conclusion**

The clinical recommendations presented above are notable in their consistent emphasis on the need for individualized, risk–benefit-based clinical decision-making and the need to ensure the

health and well-being of the mother to promote an optimal outcome for the infant. Ready access to the full range of contraceptive options is an important strategy to prevent unintended pregnancy in women who require opioids for pain or treatment with OUD, or who have untreated OUD.<sup>31</sup> Appropriate adoption and implementation of the CDC Guideline will also reduce the population of women with chronic pain who risk ongoing prenatal exposure to a small subset for whom opioid therapy is truly the safest and most effective option. Identification of OUD by appropriate screening, assessment, and diagnostic procedures, and engagement in MAT at the earliest opportunity, are also high-yield strategies that should be universally adopted. Opioid-exposed infants should be breastfed unless otherwise contraindicated. Protocol-driven screening, assessment, monitoring, and treatment of NAS/NOWS in substance-exposed infants are imperative, as are careful discharge planning and in-home supports.

## Part 4: Strategy To Protect Our Infants (Section 2(b) of the Act)

The review of federal activities in Part 2 of this report reveals a high degree of collaboration among HHS agencies, with little overlap or duplication. Rather, each agency is exerting every effort to advance the care of pregnant women who have OUD or who require chronic opioid therapy for pain, and their newborns, and the agencies are doing so within the confines of existing budgets. Across the board, the agencies' efforts are hampered by the same gaps in data and research and confront the same barriers to education and service delivery. The most significant of these barriers are biases against SUDs, particularly among women of reproductive age during pregnancy, and against the most effective forms of treatment. Efforts are also affected by the lack of treatment and community resources.

Part 3 of this report summarizes clinical recommendations to reduce opioid exposure during pregnancy and promote optimal outcomes for women who require opioid therapy during pregnancy and their newborns. The impact of the gaps in data and research can be easily seen in limitations in these clinical recommendations. The proposed strategy that follows synthesizes the recommendations to address the gaps identified in Part 2 and to improve treatment and clinical care presented in Part 3, and maps these recommendations onto the prevention, treatment, and service delivery needs of women and children. Public comment on this report is being solicited and recommendations will be incorporated into the strategy as appropriate. Once finalized, the strategy will be used to inform planning and policy across HHS, although full implementation will be contingent upon funding.

### Prevention

Prevention of prenatal opioid exposure must target both women with pain and women with OUD. Data regarding the differences in prenatal opioid use and use disorders in pregnant women between demographic groups needs to be collected and research is needed to improve understanding of when it is clinically appropriate to use opioids to treat chronic pain. Research is also needed to develop effective non-opioid and non-pharmacologic therapies for managing and relieving chronic pain. The goal of such research is to reduce the reliance on opioids for pain relief by health care professionals and by patients whose lives are significantly constricted by pain. A better understanding of pain, pain relief, and the role of opioids will reduce unnecessary or ineffective opioid use. As a result, fewer people, including women of reproductive age and infants, will be exposed to opioids, and fewer opioids will be available for diversion to nonmedical use.

While awaiting clinically applicable research findings and even after such results are available, some women will require chronic opioid therapy for pain management. The CDC *Guideline for Prescribing Opioids for Chronic Pain* articulates the need to conduct a careful risk–benefit analysis when prescribing opioids for women who are pregnant or of childbearing age. For women to be able to make informed decisions about their use of opioids for pain relief, much greater understanding of the long-term impacts of intrauterine opioid exposure, with or without NAS, on infants is needed. To produce meaningful results, such studies need to be large and controlled for a wide range of common comorbid conditions and social and environmental exposures during infancy and childhood. In the meantime, and even when such research is complete, women will need access to the full range of contraceptive options if they require treatment with chronic opioid therapy.

Prevention of opioid-exposed pregnancy among women with OUD would similarly benefit from a sound scientific understanding of the impact of intrauterine opioid exposure and from access to the full range of contraceptive options. A sound evidence base exists for using opioid agonists to treat OUD during pregnancy. More research is needed on the safety of naltrexone for OUD in pregnancy and breastfeeding, and on the comparative effectiveness of all forms of MAT during pregnancy and breastfeeding. Research on how these therapies affect NAS will be discussed below.

Meanwhile, expansion of known effective prevention strategies should be undertaken. Known effective strategies include ready access to the full range of contraceptive options for women at risk, home-based early intervention and parental support services, and widely available treatment and recovery support to prevent relapse are a few well-established examples. Public education about the nature of SUD as a brain disease and promoting acceptance of effective treatment would also help women and parents enter and stay in treatment.

Table 11 lists important elements of an HHS strategy for preventing prenatal and postnatal opioid exposure.

**Table 11: Prevention Strategy**

	<b>Maternal</b>	<b>Child</b>
<b>Data &amp; Surveillance</b>	Improve and expand screening to identify women in need of brief intervention, and referral to treatment.	Standardize terminology and promote a unified approach to data collection and reporting in order to accurately quantify prenatal substance exposure and identify risk and protective factors amenable to preventive efforts.
<b>Research &amp; Evaluation</b>	Define and understand the elements of an effective risk–benefit assessment in order to counsel pregnant women with pain regarding their management.	Conduct research to support effective and safe non-opioid pharmacotherapy and non-pharmacologic pain relief strategies during pregnancy and breastfeeding.
	Research consequences of unrelieved pain on women and their pregnancies.	
	Determine the safety and effectiveness of naltrexone use during pregnancy.	
<b>Programs &amp; Services</b>	Increase access to the full range of contraceptive options for women at	Provide ready access to parental support and early intervention services.

	<p>risk of experiencing a substance-exposed pregnancy, including barrier free access to long-acting reversible contraception.</p> <p>Provide ready access to effective SUD treatment, including tobacco cessation counseling/treatment, prior to conception and during pregnancy.</p> <p>Make available family-friendly relapse prevention and recovery support for parents in recovery.</p> <p>Provide ready access to family-friendly SUD treatment for parents.</p> <p>Expand the use of SBIRT to identify hazardous and harmful substance use and intervene to change behavior prior to conception.</p>	
<b>Education</b>	<p>Promote general public awareness of the effectiveness of SUD treatment, to reduce barriers to seeking treatment prior to conception and in early pregnancy.</p> <p>Promote shift in public perceptions of SUD so that it is regarded as a disease rather than as a criminal or moral problem, to reduce barriers to seeking treatment prior to conception and in early pregnancy.</p>	

## Treatment

Both the mother and the opioid-exposed infant have treatment needs that must be considered. Even under the most optimal circumstances, some women with pain will require opioid treatment. Research is needed to determine what opioid regimens are most effective during pregnancy and whether some regimens are less likely to produce NAS or have as-yet unknown longer term effects on the opioid-exposed infant. Similar comparative outcome studies are needed for women who require opioid MAT for OUD.

The treatment and long-term support of the infant with NAS in general and NOWS in particular lacks a strong evidence base. Much of the research to date has focused on the broader, less specific category of NAS. Research on both NAS and NOWS is confounded by polysubstance exposure and maternal comorbidity. Improved use of ICD codes during hospital management and systematic, uniform data collection are needed for opioid-exposed pregnancies, and for the incidence, management, and outcomes of NAS and NOWS. Also, there is a critical need for objective screening and assessment instruments for NAS/NOWS and treatment protocols that make full use of all pharmacologic and nonpharmacologic therapies to manage these conditions

and minimize further opioid exposure if possible. Many infants at risk of NAS are automatically placed in NICUs, which can be counterproductive environments and which limit mother-infant interaction. Lack of resources in the community may result in infants being discharged with inadequate follow-up or without in-home services. Evidence-based guidance is needed to determine the best interventions in the hospital and the home. Efforts should also focus on promoting nonpharmacologic interventions, such as rooming in,<sup>54</sup> for managing mild to moderate NAS/NOWS.

Research is needed on mitigating or exacerbating factors that may co-exist with the opioid-exposed pregnancy. Greater understanding of mitigating and exacerbating factors, whether modifiable or not, can help the family and its health care providers anticipate the risks and treatment needs of the opioid-exposed infant. Awareness of how factors such as genetics, sex, and gender identity influence the risk associated with specific treatments can inform the shared decision-making by the woman and her health care providers. Some factors, such as alcohol, tobacco, and nicotine use, may be modifiable with targeted education and intervention, if supporting research is available. If subsequent research indicates that mitigating and exacerbating factors can influence longer term outcomes for the child, such findings could encourage prevention and intervention strategies to be put in place in the child’s home.

Table 12 sets out important elements of an HHS strategy for improving treatment of mothers and infants affected by opioids.

**Table 12: Treatment Strategy**

	<b>Maternal</b>	<b>Child</b>
<b>Data &amp; Surveillance</b>	Develop easy to implement and valid screening instruments for SUD in pregnancy.	Establish clear definitions of NAS vs. NOWS and standardize the use of ICD codes in order to collect more meaningful and actionable data on the impact of prenatal substance exposure on infants and children.
	Collect substance- and diagnosis-specific data about prenatal substance use in order to develop adequate treatment capacity.	
<b>Research &amp; Evaluation</b>	Research the modifiable maternal risk and protective factors and most effective interventions to minimize the impact of prenatal substance exposure on the fetus and child.	Establish evidence-based protocols for identifying and managing NAS and NOWS.
	Study prenatal opioid treatment for pain and develop an objective risk–benefit analysis for providers and patients to use in making pain management decisions.	Determine optimal toxicology screening of the opioid-exposed infant to support effective management with or without NAS/NOWS.
	Determine the safety and effectiveness of naltrexone use during pregnancy.	

	Research effective non-pharmacologic and non-opioid pharmacotherapies for pain management during pregnancy and breastfeeding.	
<b>Programs &amp; Services</b>	Support continuation of treatment for SUD postpartum and tailor MAT according to parental need.	Promote nonpharmacologic interventions, such as rooming in, for managing mild to moderate NAS/NOWS.
	Develop effective strategies to support informed decision making around pain management or SUD treatment when these conditions are identified prenatally.	
<b>Education</b>	Promote breastfeeding for women who receive opioids for pain or the treatment of OUD when not otherwise contraindicated and consistent with appropriate guidelines	Promote breastfeeding of infants of women who receive opioids for pain or OUD when not otherwise contraindicated and consistent with appropriate guidelines.
	Provide continuing medical education to the provider for managing pain in the pregnant woman with OUD.	Provide continuing medical education to the provider for managing the infant with NAS symptoms.

## Services

MAT capacity is currently inadequate to meet the treatment needs of the population with OUD. In 2012, only an estimated 1 million of the approximately 2.5 million Americans who needed treatment actually received it.<sup>8</sup> Pregnant women are identified as priority populations in MAT regulations and federal block grant programs, but if programs and providers are not available in a community, being a priority population is of limited benefit. Efforts to expand access to MAT described in Part 2 are underway but are limited by resistance to MAT from the greater treatment community, where only a portion of programs provide any form of MAT for OUD. Other limiting factors include the perception that regulation of MAT is burdensome and the persistent lack of acceptance of SUD as a chronic brain disease despite abundant supporting research and extensive public education. Rejection of the evidence for MAT by abstinence-based programs results in the exclusion of persons receiving MAT from social and behavioral services available to others. This situation is further complicated for women who are excluded from services because their infants or older children cannot be accommodated.

Health care professionals lack the evidence base to distinguish between withdrawal symptoms caused by various and often multiple substances and to treat withdrawal symptoms from different substances appropriately. Protocols need to be developed, validated, standardized, and adopted to guide the treatment of infants with NOWS based on existing evidence in order to prevent the use of non-evidence-based pharmacotherapies and promote the use of evidence-based nonpharmacologic interventions, such as rooming in,<sup>54</sup> as appropriate. Protocol development would allow delivery of care in community hospitals, where appropriate, instead of in tertiary care centers and NICUs. Training needs to be provided to adequate numbers of health

care professionals of all disciplines involved in caring for and following the development of opioid-exposed infants.

Table 13 lists elements of a HHS strategy for improving services to mothers and infants affected by opioids.

**Table 13: Services Strategy**

	<b>Maternal</b>	<b>Child</b>
<b>Data &amp; Surveillance</b>	Collect substance and diagnosis specific data about prenatal substance use in order to identify unmet service and care-coordination needs and any disparities in access.	Identify a history of prenatal substance exposure and NAS/NOWS when children receive developmental assessment, early intervention services or enter child welfare.
<b>Research &amp; Evaluation</b>		Assess and determine optimal family and development support services for the child who experienced prenatal substance exposure or NAS/NOWS.
		Research the long-term developmental effects of prenatal substance exposure so that services can be developed to mitigate any effects.
<b>Programs &amp; Services</b>	Provide easily accessible, family-friendly, SUD treatment for pregnant and parenting women.	Provide developmental assessment and early intervention services for substance-exposed children with or without a history of NAS/NOWS.
		Promote nonpharmacologic interventions, such as rooming in, for managing mild to moderate NAS/NOWS.
<b>Education</b>	Promote public and health professional awareness of ongoing parental treatment engagement, recovery support, and early-intervention services in family function and mitigation of consequences of prenatal substance exposure and NAS/NOWS.	

## Conclusion

Much of what women with pain or OUD need to have healthy pregnancies and infants is already known. Unfortunately, access to the treatment and services is often limited for these women and their families. In the face of rising costs related to the care of substance-exposed infants, access to effective prevention and treatment services is of increasing importance. Improvements leveraged across the federal domains of data and surveillance, research and evaluation, programs and services, and education can result in real gains with immediate benefits for opioid-exposed



infants. Currently available recommendations, such as CDC's *Guideline for Prescribing Opioids for Chronic Pain* and SAMHSA's *Advancing the Care of Pregnant and Parenting Women with Opioid Use Disorder and Their Infants: A Foundation for Clinical Guidance*, should be built upon and used to unify federal efforts and messaging.

Prejudice remains perhaps the greatest barrier to the adoption and dissemination of effective, evidence-based interventions, with compartmentalization of data, knowledge, and skills across levels of government, service providers, and professional disciplines in second place. Consequently, coordination across HHS and consistency in messaging must continue to be priority activities to overcome these barriers.

**Table 14: Acronyms Used in This Report**

<b>Acronym</b>	<b>Definition</b>
ACF	Administration for Children & Families
ACYF	Administration on Children, Youth and Families
AFCARS	Adoption and Foster Care Analysis and Reporting System
AHRQ	Agency for Healthcare Research and Quality
ATTC	Addiction Technology Transfer Center
BHCC	Behavioral Health Coordinating Council
CAPTA	Child Abuse Prevention and Treatment Act
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
FDA	Food and Drug Administration
HCUP	Healthcare Cost and Utilization Project
HHS	U.S. Department of Health and Human Services
HRSA	Health Resources and Services Administration
IAP	Innovation Accelerator Program
ICD-CM	International Classification of Diseases, Clinical Modification
IHS	Indian Health Service
MAT	Medication-assisted treatment
MAT-PDOA	Medication Assisted Treatment – Prescription Drug and Opioid Addiction
MOTHER	Maternal Opioid Treatment: Human Experimental Research
NAS	Neonatal abstinence syndrome
NCANDS	National Child Abuse and Neglect Data System
NCSACW	National Center on Substance Abuse and Child Welfare
NICHD	National Institute of Child Health and Human Development
NICU	Neonatal intensive care unit
NIDA	National Institute on Drug Abuse
NIH	National Institutes of Health
NOWS	Neonatal opioid withdrawal syndrome
NSDUH	National Survey on Drug Use and Health
N-SSATS	National Survey on Substance Abuse Treatment Services
ODU	Opioid use disorder
OWH	Office on Women’s Health
RAM	RAND/UCLA Appropriateness Method
SAMHSA	Substance Abuse and Mental Health Services Administration
SBIRT	Screening, Brief Intervention, and Referral to Treatment
SSRI	Selective serotonin reuptake inhibitor
SUD	Substance use disorder
TEDS	Treatment Episode Data Set
UNICEF	United Nations Children’s Fund
WHO	World Health Organization

## Appendix

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