

# **Protecting Our Infants Act: Final Strategy**

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

## 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 was required to conduct a review of HHS agencies' planning and coordination of activities related to prenatal opioid exposure and neonatal abstinence syndrome (NAS). Second, the Act mandated 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 required 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. "The Protecting Our Infants Act: Report to Congress" (the report) covered all three of the above elements. Upon its transmission to Congress, and as the Act requires, public comment was solicited on the strategy to address gaps in research; gaps, overlap or duplication in relevant federal programs; and coordination of federal efforts to address NAS. Public comment was received via docket number SAMHSA-2016-0004-0001 (<https://www.regulations.gov/docket?D=SAMHSA-2016-0004>) from January 17, 2015 through February 21, 2017. These comments and corresponding changes to the strategy were summarized in a Federal Register Notice published on May 25, 2017 at <https://www.federalregister.gov/documents/2017/05/25/2017-10735/protecting-our-infants-act-report-to-congress-summary-of-public-comment-and-final-strategy>.

This document "Protecting Our Infants Act: Final Strategy" (Final Strategy) retains the overall structure of the original strategy and, for convenience, the summary of the findings of the original report with regard to prevention, treatment and services. Each section has a corresponding table of recommendations, revised based on public comment, which encapsulates the strategy. The Final Strategy will be used to inform planning and policy across HHS, although full implementation will be contingent upon funding. As the Act requires, the Final Strategy is publicly available at: <https://www.samhsa.gov/specific-populations/age-gender-based#poia>.

## Prevention Strategy

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 medication assisted treatment (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 substance use disorder (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. The numbering of the tables in the original document has been preserved here to facilitate cross-reference.

**Table 11: Prevention Strategy - Final**

	<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>	<ul style="list-style-type: none"> <li>• Define and understand the elements of an effective risk–benefit assessment in order to counsel pregnant women with pain regarding their management.</li> <li>• Research consequences of unrelieved pain on women and their pregnancies.</li> <li>• Determine the safety and effectiveness of naltrexone and naloxone when combined with buprenorphine use during pregnancy and breastfeeding.</li> </ul>	Conduct research to support effective and safe non-opioid pharmacotherapy and non-pharmacologic pain relief strategies during pregnancy and breastfeeding.

	<b>Maternal</b>	<b>Child</b>
<b>Programs &amp; Services</b>	<ul style="list-style-type: none"> <li>• Increase access to the full range of contraceptive options for women at risk of experiencing a substance-exposed pregnancy, including barrier free access to long-acting reversible contraception.</li> <li>• Provide ready access to effective SUD treatment, including tobacco cessation counseling/treatment, prior to conception and during pregnancy.</li> <li>• Make available family-friendly relapse prevention and recovery support for parents in recovery.</li> <li>• Provide ready access to family-friendly SUD treatment for parents.</li> <li>• Expand the use of SBIRT to identify hazardous and harmful substance use and intervene to change behavior prior to conception.</li> <li>• Provide access to effective and alternative treatment options for pain prior to conception and during pregnancy and breastfeeding.</li> </ul>	Provide ready access to parental support and early intervention services.
<b>Education</b>	<ul style="list-style-type: none"> <li>• Promote general public awareness of the effectiveness of SUD treatment to reduce barriers to seeking treatment prior to conception and in early pregnancy.</li> <li>• 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.</li> </ul>	

## Treatment Strategy

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 neonatal opioid withdrawal syndrome (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 International Classification of Disease (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 non-pharmacologic 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 non-pharmacologic interventions, such as rooming in,<sup>1</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. The numbering of the tables in the original document has been preserved here to facilitate cross-reference.

**Table 12: Treatment Strategy -Final**

	<b>Maternal</b>	<b>Child</b>
<b>Data &amp; Surveillance</b>	<ul style="list-style-type: none"> <li>• Develop easy to implement and valid screening instruments for SUD in pregnancy.</li> <li>• Collect substance- and diagnosis-specific data about prenatal substance use in order to develop adequate treatment capacity.</li> </ul>	<p>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.</p>
<b>Research &amp; Evaluation</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Study prenatal opioid treatment for pain and develop an objective risk–benefit analysis for providers and patients to use in making pain management decisions.</li> <li>• Determine the safety and effectiveness of naltrexone and naloxone when combined with buprenorphine use during pregnancy and breastfeeding.</li> <li>• Research effective non-pharmacologic and non-opioid pharmacotherapies for pain management during pregnancy, labor and delivery, the post-partum care, and breastfeeding for women with chronic pain or OUD.</li> </ul>	<ul style="list-style-type: none"> <li>• Establish evidence-based protocols for identifying and managing NAS and NOWS.</li> <li>• Determine optimal toxicology screening of the opioid-exposed infant to support effective management with or without NAS/NOWS.</li> </ul>
<b>Programs &amp; Services</b>	<ul style="list-style-type: none"> <li>• Support continuation of treatment for SUD from preconception through pregnancy and one year postpartum and tailor MAT according to parental need.</li> <li>• Develop effective strategies to support informed decision making around pain management or SUD treatment when these conditions are identified prenatally.</li> </ul>	<p>Promote non-pharmacologic interventions, such as rooming in, for managing mild to moderate NAS/NOWS.</p>

	<b>Maternal</b>	<b>Child</b>
<b>Education</b>	<ul style="list-style-type: none"> <li>• Promote breastfeeding for women who receive opioids for pain or the treatment of OUD when not otherwise contraindicated and consistent with appropriate guidelines.</li> <li>• Provide continuing medical education to the provider for managing pain in the pregnant woman with OUD.</li> </ul>	<ul style="list-style-type: none"> <li>• Promote breastfeeding of infants of women who receive opioids for pain or OUD when not otherwise contraindicated and consistent with appropriate guidelines.</li> <li>• Provide continuing medical education to the provider for managing the infant with NAS symptoms.</li> </ul>

**Services Strategy**

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>2</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 of the report 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 through these programs. 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, often multiple substances, and treat withdrawal symptoms from different substances appropriately. Protocols need to be developed, validated, standardized, and adopted to guide the treatment of infants with NWS based on existing evidence in order to prevent the use of non-evidence-based pharmacotherapies and promote the use of evidence-based non-pharmacologic interventions, such as rooming in,<sup>1</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 an adequate number 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. The numbering of the tables in the original document has been preserved here to facilitate cross-reference.

**Table 13: Services Strategy - Final**

	<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.	<ul style="list-style-type: none"> <li>• Identify a history of prenatal substance exposure and NAS/NOWS when children receive developmental assessment, early intervention services or enter child welfare.</li> <li>• Collect data on the welfare of substance exposed children who are removed from their families versus those remaining with a mother receiving supportive interventions.</li> </ul>
<b>Research &amp; Evaluation</b>		<ul style="list-style-type: none"> <li>• Assess and determine optimal family and development support services for the child who experienced prenatal substance exposure or NAS/NOWS.</li> <li>• Research the long-term developmental effects of prenatal substance exposure so that services can be developed to mitigate any effects.</li> </ul>
<b>Programs &amp; Services</b>	Provide easily accessible, family-friendly, SUD treatment for pregnant and parenting women.	<ul style="list-style-type: none"> <li>• Provide developmental assessment and early intervention services for substance-exposed children with or without a history of NAS/NOWS.</li> <li>• Promote non-pharmacologic interventions, such as rooming in, for managing mild to moderate NAS/NOWS.</li> </ul>
<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.	Promote training and resources for child welfare workers to effectively address SUD and prenatal substance exposure, facilitate linkages to treatment, and promote recovery for mothers with SUD.

## 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.

## References

<sup>1</sup> Holmes AV, Atwood EC, Whalen B, et al. Rooming-in to treat neonatal abstinence syndrome: Improved family-centered care at lower cost. *Pediatrics*. 2016. 137(6).

<sup>2</sup> Jones CM, Campopiano M, Baldwin G, McCance-Katz E. (2015). National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment. *Am J Public Health*. 2015; 105(8):e55-63.

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