## DEPARTMENT OF HEALTH AND HUMAN SERVICE

### Substance Abuse and Mental Health Services Administration

### Protecting Our Infants Act Report to Congress: Summary of Public Comment and Final Strategy

**AGENCY:** Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Substance Abuse and Mental Health Services Administration (SAMHSA) in the Department of Health and Human Services (HHS) announces the release of the ''Protecting Our Infants Act: Final Strategy'' in response to sections 3(a)(2) and 3(b) of the Protecting Our Infants Act of 2015 (POIA). The POIA mandated HHS to: conduct a review of planning and coordination activities related to prenatal opioid exposure and neonatal abstinence syndrome; develop recommendations for the identification, prevention, and treatment of prenatal opioid exposure and neonatal abstinence syndrome; and develop a strategy to address gaps, overlap, and duplication among Federal programs and Federal coordination efforts to address neonatal abstinence syndrome. The Protecting Our Infants Act: Report to Congress which satisfied these requirement was made available January 17, 2017, through February 21, 2017, for public comment in the following docket SAMHSA–2016–0004–0001. As a result of the public comments, summarized below, several recommendations were added to the original strategy and others expanded. The Final Strategy can be read and downloaded at *https://www.samhsa.gov/specific-populations/age-gender-based#poia.*

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**SUPPLEMENTARY INFORMATION:** *Inspection of Public Comments:* All comments, including any personally identifiable or confidential business information that is included in a comment, received during the comment period are available for viewing by the public in the public docket.

*Background:* The POIA mandated HHS to: (1) conduct a review of planning and coordination activities related to prenatal opioid exposure and neonatal abstinence syndrome (Section 2(a) of the Act); (2) develop recommendations for the identification, prevention, and treatment of prenatal opioid exposure and neonatal abstinence syndrome (Section 3 of the Act); and (3) develop a strategy to address gaps, overlap, and duplication among Federal programs and Federal coordination efforts to address neonatal abstinence syndrome (Section 2(b) of the Act). The POIA is available at: *https://www.congress.gov/114/plaws/publ91/PLAW-114publ91.pdf.*

In response to the requirements of the POIA, ''The Protecting Our Infants Act: Report to Congress'' was released January 17, 2017. The report provided background information on prenatal opioid exposure and neonatal abstinence syndrome (Part 1), summarized HHS activities related to prenatal opioid exposure and neonatal abstinence syndrome (Part 2), presented clinical and programmatic evidence and recommendations for preventing and treating neonatal abstinence syndrome (Part 3), and presented a strategy to address the identified gaps, challenges, and recommendations (Part 4).

As required in Section 2(b) of POIA, public comment was sought on ''Part 4: Strategy to Protect Our Infants.'' All comments, including any personally identifiable or confidential business information that is included in a comment, received during the comment period are available for viewing by the public in this docket. The comments and corresponding changes to the strategy are summarized in this notice, below. The Protecting Our Infants Act: Final Strategy can be read and downloaded at *https://www.samhsa.gov/specific-populations/age-gender-based#poia.*

*Summary of Public Comment:* A total of 22 comments were received. The majority were both favorable and relevant. This is a summary of the relevant public comments. It is organized according to the same three sections included in Part 4 of the report: Prevention, Treatment, and Services. It also includes a brief section in which global comments are reviewed. Examples of comments outside the scope of the original FRN that are not included in this summary, include discussion of: The statute itself, current unresolved policy issues related to health care access, decriminalization of drug use, specific state policies or laws outside the purview of the federal government, and comments on sections of the report other than the strategy.

**Prevention**

Prevention-related comments were received on the topic of pain management. These comments urged that education and awareness efforts address opportunities to prevent and treat pain in preconception and pregnancy. Commenters pointed out that the same types of barriers, such as coverage limits and requirements for prior authorization that impede access to substance use disorder treatment, also limit access to alternative treatments for pain. The wider use of these alternatives may ultimately reduce the numbers of opioid-exposed pregnancies and neonatal opioid withdrawal syndrome (NOWS). The following language was added to the programs and services section of the prevention strategy (Table 11 of the final strategy) to address this comment: ''Provide access to effective and alternative treatment options for pain prior to conception and during pregnancy and breastfeeding.''

One comment urged exploration of primary prevention strategies of benefit to women and infants at risk for NOWS and described important elements of primary prevention strategies such as social determinants of health, opioid prescribing practices, the need for care coordination and increased capacity for behavioral, general medical, and gynecologic health services. Language corresponding to this comment was not added to the strategy because these comments, while relevant to opioid use disorder (OUD) in general, are not directly related to opioid use during pregnancy. Suggestions were provided on ways to strengthen data collection and close existing gaps. Language capturing these suggestions was not added to the document because similar activities are currently underway within HHS, as described in Part 2 of the report.

**Treatment**

Comments with regard to treatment urged that comprehensive, integrated services be emphasized, that services such as smoking cessation be tailored to pregnant women, and that all substance use disorder (SUD) treatment continue for one year postpartum. The words ''from preconception through pregnancy and one year postpartum'' were added to a recommendation in the programs and services section of the treatment strategy (Table 12 of the final strategy) to reflect these comments. The recommendation now reads: ''Support continuation of treatment for SUD from preconception through pregnancy and one year postpartum and tailor

medication assisted treatment according to parental need.''

Commenters reaffirmed the need for research into pain management during pregnancy for women either with or without OUD. One asked that research into pain management during labor and delivery and postpartum for women with OUD be conducted. A recommendation in the research section of the treatment strategy (Table 12 of the final strategy) was revised to reflect these comments. It now reads: ''Research effective non-pharmacologic and non-opioid pharmacotherapies for pain management during pregnancy, labor and delivery, post-partum care and breastfeeding for women with chronic pain or opioid use disorder.''

Another commenter recommended the scope of the recommendation ''Determine the safety and effectiveness of naltrexone use during pregnancy and breastfeeding'' be expanded to include naloxone in both the strategies for prevention and treatment. Language was added to this recommendation in the treatment strategy (Table 12 of the final strategy) but not the prevention strategy. It was not included in the prevention section because naloxone does not have a role in preventing or reducing prenatal substance exposure. The recommendation now reads: ''Determine the safety and effectiveness of naltrexone and naloxone when combined with buprenorphine use during pregnancy and breastfeeding.''

Many commenters sought to reinforce specific elements of the strategy, refine broad research recommendations with more specific research questions, or inform how the recommendations might best be carried out. For example, a group of commenters emphasized ''the need for additional research into the impact on the fetus of drugs taken during pregnancy . . . especially when exposure is concurrent with opioids.'' There was a request for greater research on whether a subgroup of women at sufficiently low risk of relapse could be identified and detoxified safely and reliably and for more research on the impact of detoxification on the fetus. There was also a request for greater research on the most effective pharmacotherapy for infants with neonatal abstinence syndrome (NAS) and or NOWS. These comments reinforced or elaborated upon existing recommendations in the strategy and therefore the strategy was not edited to reflect them.

**Services**

Several commenters raised concerns about criminal penalties experienced by pregnant and parenting women with substance use disorder and the uncertain benefit and unknown consequences of removing children from their parents due to prenatal substance exposure. This comment best summarizes the range of strategies suggested by the various comments:

> The current opioid epidemic is resulting in numerous referrals to and removals by the child welfare system. . . . But, since the primary purpose of the child welfare system is to investigate reports of abuse and neglect, child welfare workers often lack the appropriate training and resources to effectively address substance use disorders. . . . more research and resources are needed to help the child welfare system facilitate linkages to treatment and promote recovery for mothers with addiction.

Another commenter pointed out that there is a ''non-evidence based assumption that removing children from women who use substances during pregnancy protects the child'' and several urged research into the risks and benefits of child removal due to prenatal substance exposure be added to the strategy. Two recommendations were added to the services strategy (Table 13 of the final strategy). First, ''Collect data on the welfare of substance exposed children who are removed from their families versus those remaining with a mother receiving supportive interventions'' was added to data collection. Second, ''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'' was added to the education section.

**General Comments**

A group of commenters noted that the strategy would be improved by greater synthesis of the recommendations and the definition of clear goals with associated metrics. There are several reasons why goals and metrics are not specified. First, the generally limited and inconsistent data collection described in the report currently precludes establishment of a national baseline upon which metrics can be established. Second, the establishment of goals and metrics is further complicated by the fact that for pregnant women with OUD, the most effective intervention to promote optimal outcomes for both mother and child is the provision of medication assisted treatment with an opioid agonist, which itself carries a risk of NOWS. As a result, reduction in the number of cases of NOWS is not a meaningful goal even if NOWS, as distinct from NAS, could be measured accurately. As a result, no changes were made to the strategy based on these comments.

*Supporting and Related Material in the Docket:* The information provided includes:

(1) The Report
(2) The Final Strategy
(3) Public Comments

**Summer King,**

*Statistician.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

**Project: Participant Feedback on Training Under the Cooperative Agreement for Mental Health Care Provider Education in HIV/AIDS Program (OMB No. 0930–0195)—Extension**

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Mental Health Services (CMHS) intends to continue to conduct a multi-site assessment for the Mental Health Care Provider Education in HIV/AIDS Program. There are no changes to the forms or the burden hours.

The education programs are funded under a cooperative agreement that are designed to disseminate knowledge of the psychological and neuropsychiatric sequelae of HIV/AIDS to both traditional (*e.g.,* psychiatrists, psychologists, nurses, primary care physicians, medical students, and social workers) and non-traditional (*e.g.,* clergy, and alternative health care workers) first-line providers of mental health services, in particular to providers in minority communities.

The multi-site assessment is designed to assess the effectiveness of particular training curricula, document the integrity of training delivery formats, and assess the effectiveness of the various training delivery formats. Analyses will assist CMHS in