February 15, 2017

Melinda Campopiano, MD
Chief Medical Officer, Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane, 13E49
Rockville, MD 20852

RE: Docket No. [SAMHSA-2016-0004]

Dear Dr. Campopiano,

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty society representing more than 4,300 physicians and allied health professionals who specialize in the treatment of addiction, I would like to thank you for the opportunity to provide comments on the Protecting Our Infants Act: Report to Congress.

ASAM commends SAMHSA for an excellent report that recognizes the nuances and complexities of prenatal substance exposure. ASAM agrees that strategies to reduce prenatal substance exposure should account for the numerous biological, environmental, and social variables that drive disparities in access to treatment for pregnant and parenting women with addiction involving opioid use, and differences in prenatal opioid use and use disorders in pregnant women between demographic groups. The report also rightly recognizes that there needs to be a life-course perspective on opioid addiction and that contraceptive services for all women, including women with addiction involving opioid use, should be integrated into a complete health care plan.

At the same time, ASAM recommends the following revisions to strengthen the report and improve the Strategy to Protect Our Infants. ASAM understands that SAMHSA has solicited comments only on Part 4 of the Report (Strategy to Protect Our Infants). However, we respectfully offer comments on the earlier sections of the report for SAMHSA's consideration. Our comments are detailed by Part and page or table number below.

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Executive Summary

Page 3: Women who become pregnant while struggling with opioid use disorder (OUD) may expose the fetus to both licitly and illicitly obtained opioids. The final sentence of the third paragraph should be revised accordingly.

Part 2: Review of Programs

Page 18: SBIRT has an important implementation gap. The "RT" part of it often does not happen due to providers not knowing local resources, not ensuring a warm hand-off to treatment, or the unavailability of appropriate treatment (either total lack of treatment options or a mismatch between the woman's needs and the type of treatment available). The recommendation to expand implementation of SBIRT should include a special emphasis on referral to treatment and educating providers on resources available, treatment locators, and what to do when the type of treatment a woman needs is not available.

Page 25: There is a critical gap that must be acknowledged and addressed. Often, women who are being prescribed opioids for pain and taking that medication as prescribed are abruptly cut off from treatment when they become pregnant for fear of exposing the fetus. These women are left in desperate situations and some women are forced to buy pain medication off the street to avoid withdrawal and cope with their pain.

Part 3: Recommendations for Prevention and Treatment of Prenatal Opioid Exposure

Page 38: ASAM recommends removing selective serotonin reuptake inhibitors (SSRIs) from the list of medications that are misused. Our members do not report misuse of SSRIs as a significant problem, and many women who need them stop using them during pregnancy because they worry about effects on the fetus. To say that they are misused may serve to further stigmatize their use. They do increase the risk of NAS, but women shouldn't be encouraged to discontinue for that reason.

Page 39: The sentence "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" could be revised for clarity to say, "The safety of naltrexone in pregnancy is not established, but the risk of discontinuing naltrexone or an agonist completely needs to be weighed carefully against the risks associated with relapse to opioid use in the context of pregnancy." One important risk that needs explicit mention is that any change in medication creates the context of vulnerability to relapse, especially during the transition between medications.

Page 41: The sentence "Any toxicology screening of the mother must be done with her informed consent" would benefit from a clarification that includes the need for confirmatory testing of any positive test to avoid unintended consequences for children and mothers.

Part 4: Strategy to Protect Our Infants

Tables 11 and 12: ASAM encourages SAMHSA to expand the recommendation "Determine the safety and effectiveness of naltrexone use during pregnancy" to include naloxone as well. The use of both medications during pregnancy requires additional research.

Table 11: ASAM recommends revising the recommendation “Provide ready access to effective SUD treatment, including tobacco cessation counseling/treatment, prior to conception and during pregnancy” to say “Provide ready access to effective SUD treatment, including tobacco cessation counseling/treatment, *prior to conception, during pregnancy and for a year post-partum*.” It is well-documented that the risk of relapse increases postpartum if treatment is not continued.

Further, ASAM recommends this statement be expanded (or another statement added) to call for ready access to effective and alternative treatment options for pain prior to conception and during pregnancy. In both statements, the Report should be explicit in addressing the role that insurance plays in facilitating or hampering access to treatment. Our members report it is often easier to get a prescription for a short-acting opioid covered by insurance than it is to get alternative pain therapies (such as physical therapy or acupuncture) or medications for opioid addiction treatment covered.

Table 12: ASAM recommends the strategy to ““Research effective non-pharmacologic and non-opioid pharmacotherapies for pain management during pregnancy and breastfeeding” be expanded to include pain management during pregnancy, labor and delivery, and in the post-partum period, as there are no evidence-based protocols for pain management during these periods for women with OUD.

Table 13: There is a non-evidence based assumption that removing children from women who use substances during pregnancy protects the child. In fact, there are limited data (at best) to support this notion. We desperately need data to look at the risks and benefits of child removal due to prenatal substance exposure, and this research need should absolutely be added to the report. We need data to answer research questions about what happens to children when they are in “the system” versus remaining with the mother who then has system or other support to help care for her children.

ASAM could not agree more with the Report’s conclusion that “prejudice remains perhaps the greatest barrier to the adoption and dissemination of effective, evidence-based interventions.” Stigma against patients with addiction, and heightened stigma against pregnant or parenting women with addiction, lead to policies and approaches to treatment, criminal justice, and child welfare that not only lack an evidence base but likely do more harm than good. ASAM stands ready to work with SAMHSA and other federal and state partners to develop, disseminate and promote best practices in obstetric addiction treatment and pediatric care to maximize the health of women and their children.

Sincerely,

R. Jeffrey Goldsmith, MD, DLFAPA, DFASAM
President, American Society of Addiction Medicine