



BILLING CODE: 4162-20-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

[Docket No. SAMHSA-2016-0002]

Request for comment on report entitled: Advancing the Care of Pregnant and Parenting Women with Opioid Use Disorder and their Infants: A Foundation for Clinical Guidance.

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

ACTION: Request for Comment

SUMMARY: Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment, in the Department of Health and Human Services (HHS) announces the opening of a docket to obtain public comment on a report entitled: Advancing the Care of Pregnant and Parenting Women with Opioid Use Disorder and their Infants: A Foundation for Clinical Guidance. The report is available at: <http://www.regulations.gov/docket?D=SAMHSA-2016-0002>.

This report describes the formal process agreed on and followed under the guidance of the federal steering committee (FSC). It explains the RAND Corporation (RAND)/University of California Los Angeles (UCLA) Appropriateness Method (RAM), justifies its adoption, and reports the outcomes of its application that will form the basis for the development of clinical guidance. This report will serve as the foundation for the development of clinical guidance to be used by providers caring for women with opioid use disorder and their infants.

DATES: *Comment Close Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. no later than 30 days after date of publication in the Federal Register.

ADDRESSES: You may submit comments identified by **Docket No. [SAMHSA-2016-0002]** by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Electronically:* You may submit electronic comments to samhsa.ppdaoram@samhsa.hhs.gov.
- *By regular mail:* You may mail written comments to the following address ONLY: Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment, Division of Pharmacologic Therapies, 5600 Fishers Lane, 13E24, Rockville, MD 20852 Attn: **Docket No. [SAMHSA-2016-0002]**. Please allow sufficient time for mailed comments to be received before the close of the comment period.
- *By express or overnight mail.* You may send written comments to the following address ONLY: Substance Abuse and Mental Health Services Administration, Attention: DPT Federal Register Representative, Division of Pharmacologic Therapies, 5600 Fishers Lane, 13E24, Rockville, MD 20852 Attn: **Docket No. [SAMHSA-2016-0002]**.
- *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following address prior to the close of the comment period: For delivery in Rockville, MD: Substance Abuse and Mental Health Services Administration, Attention: DPT Federal Register Representative, Division of Pharmacologic Therapies, 5600 Fishers Lane, 13E24, Rockville, MD 20852. To deliver

your comments to the Rockville address, call telephone number (240) 276-2700 in advance to schedule your delivery with one of our staff members.

Instructions: To avoid duplication, please submit only one copy of your comments by only one method. All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For access to the report or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Melinda Campopiano, MD, Medical Officer, Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment, Division of Pharmacologic Therapies, 5600 Fishers Lane, 13E24, Rockville, MD 20852, Email: samhsa.ppdaoram@samhsa.hhs.gov.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. Comments received by the deadline will be available for public inspection at the Substance Abuse and Mental Health Services Administration, Division of Pharmacologic Therapies, 5600 Fishers Lane, 13E24, Rockville, MD 20852, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, phone (240) 276-2700.

Background: SAMHSA led a federal steering committee in overseeing the application of the RAND/UCLA Appropriateness Method (RAM) to the available evidence concerning the optimal management of opioid use disorder for women who are pregnant or parenting and the management of their infants. After completion of the literature review, generation of the

indications, and the expert panel RAM rating process—all described in this report—this report was generated for the purpose of producing a clinical guide that will be written to facilitate optimal management of pregnant and parenting women with opioid use disorder and their infants across disciplines and treatment settings. The guide will have a dual purpose: first, to serve as a tool that will increase provider willingness and confidence to manage pregnant and parenting women with opioid use disorder and their infants; and second to help assure the care provided this population optimizes the outcomes for both mother and infant.

The purpose of this effort is to produce a patient-centered guide to be used in a range of clinical settings. SAMHSA plans to organize the results described in this report around clinical scenarios and interventions consistent with the range of ways that women with opioid use disorder may access substance use treatment or maternity care. The guide will provide options for clinical interventions that recognize the complexities of patients' lives. The guide will also include discussion of any conflicting evidence and clinician, treatment or patient characteristics that directly influence the appropriateness or effectiveness of a given clinical intervention. The paucity of the evidence to support specific interventions will be addressed in the guide. As such, the guide will present options based on current clinical practice, paired with the risks and benefits of each option as currently understood.

Public comment is sought in two general areas: the outcomes of the RAM process and the strategy to translate these findings into a clinical guide. Relevant public comment will inform the development and final appearance of the guide. Members of the expert panel, FSC, and a variety of professional societies will be asked to provide input into the guide outline and drafting of the guide which will then be subject to a formal federal clearance process including scientific review.

Supporting and Related Material in the Docket

The report contains the materials to help inform public comment. The appendices include listings of participants, more detailed information about the literature search, citations of primary references and data tables that were used by SAMHSA to develop the findings in the report. The information provided includes:

(1) The REPORT

(2) Supporting appendices: Appendix A: RAM Process Participants; Appendix B: Literature Review Methods; Appendix C: RAM Reference List and Appendices D-E7: Rated Indications

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[FR Doc. 2016-19187 Filed: 8/11/2016 8:45 am; Publication Date: 8/12/2016]