TABLE 1—PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, SETTINGS) AND INCLUSION/EXCLUSION CRITERIA—Continued

PICOTS	Inclusion	Exclusion
	○ Harms specific to pregnancy and breastfeeding (infertility, miscarriage, abruption, preterm labor/preterm birth, preeclampsia, gestational hypertensive disorders, glucose intolerance/gestational diabetes mellitus, reduced milk production in breastfeeding/undesired weaning). ○ Danger to self or infant. ○ Misuse of prescription medication. ○ Serious adverse events related to treatment. ○ Death. • Fetal/infant/child harms. ○ Preterm birth/small for gestational age or large for gestational age. ○ Congenital anomalies. ○ Perinatal complications (low APGAR, withdrawal, respiratory distress, neonatal intensive care unit time, persistent pulmonary hypertension). ○ Poor infant attachment/bonding*†. ○ Delayed social, emotional, and cognitive development*. ○ Death.	
Time frame ...	*Followup* KQ 1, KQ 2: From conception up to 1 year postpartum for maternal outcomes. KQ 3, KQ 4: All	*Followup* • KQ 1, KQ 2: More than 12 weeks preconception for maternal preconception outcomes, more than 1 year for maternal postpartum outcomes • KQ 3, KQ 4: None.
Settings§	*Clinical setting* All settings	*Clinical setting* None.
Study design	• RCTs, CCTs, case-control studies, cohort studies with comparison arms. • Reference lists of relevant systematic reviews published in 2013 or later will be used to ensure our search strategies captured all relevant studies.	All other designs and studies using included designs that do not meet the sample size criterion.
Language	Studies published in English	Studies published in languages other than English.

*We will limit included outcomes to those using validated measures. Another potential exclusion, depending on volume of yield, includes studies that fail to control for confounding.
† Drugs such as brexanolone that are awaiting FDA approval will be included in the review once they are approved
‡ We will focus strength of evidence (SOE) grades on outcomes prioritized by the Technical Expert Panel (TEP).
§ Depending on volume, we may limit the primary analysis to studies from geographic settings with resources comparable or applicable to the United States.

Dated: December 4, 2019.

Virginia Mackay-Smith,

Associate Director.

[FR Doc. 2019–26510 Filed 12–9–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

Statement of Organization, Functions, and Delegations of Authority

Part J (Agency for Toxic Substances and Disease Registry) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (50 FR 25129–25130, dated June 17, 1985, as amended most recently at 82 FR 42555, dated September 8, 2017) is amended to reflect the Order of Succession for the Agency for Toxic Substances and Disease Registry.

Section J–C, Order of Succession:

Delete in its entirety the Section J–C, Order of Succession, and insert the following:

During the absence or disability of the Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), or in the event of a vacancy in that office, the first official listed below who is available shall act as Administrator, except during a planned period of absence, the Administrator may specify a different order of succession:

1. Assistant Administrator, ATSDR
2. Deputy Director for Non-Infectious Diseases
3. Principal Deputy Director
4. Chief Medical Officer
5. Director, Center for Preparedness and Response

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10221, CMS–10344 and CMS–10137]

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

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested