

## Modifiers/Subgroups of Interest

- Race, ethnicity
- Maternal age, parity, singleton/multiple pregnancy, mode of delivery (e.g., cesarean versus vaginal delivery, preterm versus term)
- Co-occurring disorders (e.g., obesity, diabetes)
- Subgroups defined by potential indicators of social determinants of health (e.g., insurance coverage, English proficiency, income, educational attainment)
- Timing of MgSO<sub>4</sub> administration or onset of preeclampsia with severe features with respect to delivery
  - Antepartum
  - Intrapartum
  - Postpartum
- Individuals with reduced kidney function

## Interventions

- Peripartum MgSO<sub>4</sub> administration
  - Any dose, route (except oral), timing, duration of treatment, concomitant treatment, or regimen
- **Exclude:** Oral magnesium supplementation

## Comparators

- Alternative MgSO<sub>4</sub> regimens
  - Different criteria for initiation of treatment
  - Different criteria for stopping (or continuing) treatment
  - Different criteria for altering dosing during treatment
  - Different loading dose
  - Different planned total dose
  - Different route
  - Different planned duration of treatment
  - Tailored interventions based on pharmacokinetic monitoring (i.e., based on serum Mg levels)
  - Combined treatment with antihypertensive medications (including regimens with alternative antihypertensive medications)
  - Other variations in regimens
- **Exclude:** No MgSO<sub>4</sub> treatment (either placebo, no treatment, or non-MgSO<sub>4</sub> comparators)
  - Except retain RCTs with placebo, no treatment, or non-MgSO<sub>4</sub> comparators and NRCs comparing MgSO<sub>4</sub> with no MgSO<sub>4</sub> for postpartum preeclampsia with severe features. These may be included in network meta-analyses to indirectly compare alternative MgSO<sub>4</sub> regimens.

Outcomes (prioritized outcomes have an asterisk and are in bold font)

- Severe maternal health outcomes
  - **Maternal mortality, including**

**pregnancy-related mortality \***

- **Severe maternal morbidity \*** (e.g., eclampsia \*, stroke)
- Newborn/child outcomes
  - **Infant morbidities \*** (e.g., respiratory depression, Apgar score)
  - **Breastfeeding outcomes \*** (e.g., initiation, success, duration)
  - Fetal/neonatal mortality
  - Cognitive function
- Healthcare utilization and functional status
  - Length of postpartum hospital stay
  - Time to ambulation
- Patient reported outcomes
  - Patient reported experience measures (PREMs), for example
    - **Satisfaction with care \***
    - Quality of communication
    - Support to manage preeclampsia treatment
  - Patient reported outcome measures (PROMs), for example
    - **Global Quality of life \***, e.g., SF-36
    - **Specific to postpartum population \***, e.g., Mother-Generated Index, Functional Status After Childbirth scales
    - Psychosocial distress
  - **Anxiety \***, e.g., State-Trait Anxiety Inventory (STAI)
  - **Depression \***, e.g., Edinburgh Postnatal Depression Score (EPDS)
  - **Stress \***, e.g., Impact of Event Scale
  - **Maternal-neonatal bonding \***, e.g., Postpartum Bonding Questionnaire
- **Reduction of health disparities \*** (increase in disparities included under Harms)
- Maternal harms/adverse events
  - **Magnesium-related toxicity \*** (respiratory depression, loss of reflexes, reduced urine output, need for calcium infusion) \*
  - **Other clinically important adverse events \*** (e.g., hypotension, neuromuscular blockade)
  - **Adverse drug interactions \*** (e.g., with antihypertensive medications)
  - **Generation or exacerbation of health disparities \***
  - Other serious (e.g., severe flushing)

## Study Design

- Comparative studies (comparisons of different interventions)
  - Randomized controlled trials N ≥ 10 per group
    - Comparisons between MgSO<sub>4</sub> and placebo/no treatment or non-MgSO<sub>4</sub> treatments must be randomized (for potential network meta-analyses)
  - Nonrandomized comparative studies (prospective or retrospective) that use statistical techniques (e.g., regression adjustment, propensity score matching, inverse probability weighting) to reduce bias due to

## confounding

- Any publication language (unless cannot be translated)
- **Exclude**
  - Single group (noncomparative) studies
  - Case-control studies
  - Claims database analyses
  - Feasibility studies
  - Qualitative studies
  - Conference abstracts prior to 2020 (without subsequent, eligible peer-reviewed publication)

## Timing

- Intervention: Peripartum (antenatal, during delivery hospitalization, postpartum)
- Outcomes: Any

## Setting

- Inpatient management
- Any publication date
- Any country

Dated: March 23, 2022.

Marquita Cullom,  
Associate Director.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Agency for Healthcare Research and Quality

## Meeting of the National Advisory Council for Healthcare Research and Quality

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ).

**ACTION:** Notice of public meeting.

**SUMMARY:** This notice announces a meeting of the National Advisory Council for Healthcare Research and Quality.

**DATES:** The meeting will be held on Thursday, May 12, 2022, from 10:00 a.m. to 3:00 p.m.

**ADDRESSES:** The meeting will be held virtually.

**FOR FURTHER INFORMATION CONTACT:**

Jaime Zimmerman, Designated Management Official, at the Agency for Healthcare Research and Quality, 5600 Fishers Lane, Mail Stop 06E37A, Rockville, Maryland 20857, (301) 427-1456. For press-related information, please contact Bruce Seeman at (301) 427-1998 or [Bruce.Seeman@AHRQ.hhs.gov](mailto:Bruce.Seeman@AHRQ.hhs.gov).

Closed captioning will be provided during the meeting. If another reasonable accommodation for a disability is needed, please contact the

Food and Drug Administration (FDA) Office of Equal Employment Opportunity and Diversity Management on (301) 827-4840, no later than Monday, May 2, 2022. The agenda, roster, and minutes will be available from Ms. Heather Phelps, Committee Management Officer, Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, Maryland 20857. Ms. Phelps' phone number is (301) 427-1128.

#### SUPPLEMENTARY INFORMATION:

##### I. Purpose

In accordance with section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. app., this notice announces a meeting of the National Advisory Council for Healthcare Research and Quality (the Council). The Council is authorized by Section 941 of the Public Health Service Act, 42 U.S.C. 299c. In accordance with its statutory mandate, the Council is to advise the Secretary of the Department of Health and Human Services and the Director of AHRQ on matters related to AHRQ's conduct of its mission including providing guidance on (A) priorities for health care research, (B) the field of health care research including training needs and information dissemination on health care quality and (C) the role of the Agency in light of private sector activity and opportunities for public private partnerships. The Council is composed of members of the public, appointed by the Secretary, and Federal ex-officio members specified in the authorizing legislation.

##### II. Agenda

On Thursday, May 12, 2022, the Council meeting will convene at 10:00 a.m., with the call to order by the Council Chair and approval of previous Council summary notes. The meeting will begin with an introduction of NAC members, an update on AHRQ activities, and a discussion about new opportunities with AHRQ's new Director. The agenda will also include discussions about AHRQ and the Patient-Centered Outcomes Research (PCOR) Trust Fund and AHRQ's role in conducting and supporting health services research, analysis and evaluations focused on understanding the effects of healthcare financing policies. The meeting will adjourn at 3:00 p.m. The meeting is open to the public. For information regarding how to access the meeting as well as other meeting details, including information on how to make a public comment, please go to <https://www.ahrq.gov/news/events/nac/>. The final agenda will be

available on the AHRQ website no later than Thursday, May 5, 2022.

Dated: March 23, 2022.

**Marquita Cullom,**

*Associate Director.*

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**BILLING CODE 4160-90-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Notice of Meetings

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), HHS.

**ACTION:** Notice of five AHRQ subcommittee meetings.

**SUMMARY:** The subcommittees listed below are part of AHRQ's Health Services Research Initial Review Group Committee. Grant applications are to be reviewed and discussed at these meetings. Each subcommittee meeting will be closed to the public.

**DATES:** See below for dates of meetings:

1. *Healthcare Research Training (HCRT)*  
Dates: May 19–20, 23, 2022  
July 15, 2022
2. *Healthcare Effectiveness and Outcomes Research (HEOR)*  
Date: June 8–9, 2022
3. *Healthcare Information Technology Research (HITR)*  
Date: June 9–10, 2022
4. *Healthcare Safety and Quality Improvement Research (HSQR)*  
Date: June 15–16, 2022
5. *Health System and Value Research (HSVR)*  
Date: June 16–17, 2022

**ADDRESSES:** Agency for Healthcare Research and Quality (Virtual Review), 5600 Fishers Lane, Rockville, Maryland 20857.

**FOR FURTHER INFORMATION CONTACT:** (To obtain a roster of members, agenda or minutes of the non-confidential portions of the meetings.)

Jenny Griffith, Committee Management Officer, Office of Extramural Research Education and Priority Populations, Agency for Healthcare Research and Quality (AHRQ), 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 427-1557.

**SUPPLEMENTARY INFORMATION:** In accordance with section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), AHRQ announces meetings of the above-listed scientific peer review groups, which are subcommittees of AHRQ's Health

Services Research Initial Review Group Committee. The subcommittee meetings will be closed to the public in accordance with the provisions set forth in 5 U.S.C. app. 2 section 10(d), 5 U.S.C. 552b(c)(4), and 5 U.S.C. 552b(c)(6). The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Agenda items for these meetings are subject to change as priorities dictate.

Dated: March 23, 2022.

**Marquita Cullom,**

*Associate Director.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10398 #74 and #76]

#### Medicaid and Children's Health Insurance Program (CHIP) Generic Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** On May 28, 2010, the Office of Management and Budget (OMB) issued Paperwork Reduction Act (PRA) guidance related to the "generic" clearance process. Generally, this is an expedited process by which agencies may obtain OMB's approval of collection of information requests that are "usually voluntary, low-burden, and uncontroversial collections," do not raise any substantive or policy issues, and do not require policy or methodological review. The process requires the submission of an overarching plan that defines the scope of the individual collections that would fall under its umbrella. On October 23, 2011, OMB approved our initial request to use the generic clearance process under control number 0938-1148 (CMS-10398). It was last approved on April 26, 2021, via the standard PRA process which included the publication of 60- and 30-day **Federal Register** notices. The scope of the April 2021 umbrella accounts for Medicaid and