

postpartum depression, new-onset diabetes)

- **Exclude:**
  - *Individuals with specific health conditions not typically managed by providers of pregnancy and postpartum care, (e.g., multiple sclerosis, HIV, cancer, substance use disorders other than tobacco).*
  - *Individuals with diagnosed chronic conditions—pre-existing (non-gestational) diabetes, cardiac disease/risk factors (e.g., cardiomyopathy, pre-existing [non-gestational] hypertension), mood disorders (e.g., major depression, anxiety), stress urinary incontinence, and dyspareunia.*

#### Interventions

- More comprehensive insurance coverage
- Extended duration of insurance coverage
- More continuous insurance coverage
- Better/more continuous access to care as the result of a targeted program at the state, system, or provider level (e.g., Medicaid expansion)

#### Comparators

- Less comprehensive level of or no insurance coverage
- Less continuous insurance coverage
- Worse, less continuous, or no access to healthcare

*Outcomes* (\* and bold font denotes important outcomes that will be used when developing Strength of Evidence tables)

- **Intermediate and healthcare utilization outcomes**
  - Attendance at postpartum visits \*
  - Unplanned care utilization (e.g., readmissions, emergency room visits) \*
  - Adherence to condition-specific screening/testing (e.g., blood pressure monitoring, glucose tolerance testing) or treatment \*
  - Transition to primary care provider for long-term care \*
- **Clinical outcomes** (as appropriate, outcomes include incidence, prevalence/continuation, severity, and resolution)
  - Maternal mortality \*
  - Symptoms or diagnosis of mental health conditions (e.g., anxiety, depression, substance use) \*
  - Patient-reported outcomes
    - Quality of life (using validated measures) \*
    - Perceived stress \*
    - Pain
    - Sleep quality
    - Fatigue
    - Sexual well-being and satisfaction
    - Awareness of risk factors for long-

term ill health

- Physical health/medical outcomes
  - Postpartum onset of preeclampsia or hypertension
  - Infections (e.g., mastitis, wound infections)
  - Severe maternal morbidity
- Cardiovascular disorders (e.g., cardiomyopathy)
- Cerebrovascular disorders (e.g., stroke)
- Bleeding
- Venous thromboembolism
- Other
- Interpregnancy interval
- Unintended pregnancies
- Contraceptive initiation and continuation
- Breastfeeding intention, initiation, duration, and exclusivity
- Reduction in health inequities (e.g., by race, ethnicity, geography, disability status)
- **Harms**
  - Health inequities \*
  - Perceived discrimination \*
  - Over-utilization of healthcare
  - Patient burden regarding postpartum care

#### Potential Effect Modifiers

- **Patient-level factors**
  - Age
  - Race/ethnicity
  - Gender identity
  - Sexual identity
  - Physical disability status
  - Socioeconomic status
  - Immigration status
  - Barriers to transportation to healthcare facility
  - Paid family leave policies (e.g., presence versus absence, different durations of leave)
  - Substance use/substance use disorder
  - Type of insurance coverage (insured versus uninsured, private versus public [e.g., Medicaid], insurance coverage of postpartum care, Medicaid insurance coverage extension or expansion)
  - Presence versus absence of disorders of pregnancy (e.g., hypertensive, cardiovascular, gestational diabetes mellitus) or peripartum complications that increase risk of postpartum complications
  - Preterm versus term delivery
  - Live birth versus stillbirth/spontaneous abortion/induced abortion
  - Number of infants (singleton versus twins/triplets, etc.)
  - Presence versus absence of a supportive partner
  - Infant health (e.g., neonatal intensive care unit [NICU]

admission, congenital anomalies)

- **Setting factors**
  - Geographic location (urban versus suburban versus rural)
  - Different levels of neighborhood vulnerability (e.g., social vulnerability index)
  - Volume of facility/hospital (high versus low)
  - Type of facility/hospital (private versus public)
  - Racial/ethnic concordance between provider and patient
  - Language concordance between provider and patient

#### Timing

- **Interventions and Comparators:** Within 1 year after giving birth
- **Outcome measurement:** Up to 1 year after giving birth (except interpregnancy interval, unintended pregnancies, and chronic diseases [e.g., diabetes, hypertension], which can be later)

#### Settings

- U.S. only
- Outpatient care
- **Exclude: Institutionalized settings (e.g., prisons)**

#### Design

- Randomized controlled trials (N ≥10 participants per group)
- Nonrandomized comparative studies, longitudinal (prospective or retrospective) or cross-sectional (N ≥30 participants per group)
- Case-control studies (N ≥30 participants per group)
- **Exclude: Single-group (noncomparative) studies, comparative cross-sectional studies (without a discernable time-period between intervention and measurement of outcomes), qualitative studies**

Dated: March 7, 2022.

**Marquita Cullom,**

*Associate Director.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Patient Safety Organizations: Voluntary Relinquishment for the QCMetrix PSO

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

**ACTION:** Notice of delisting.

**SUMMARY:** The Patient Safety and Quality Improvement Final Rule (Patient Safety Rule) authorizes AHRQ, on behalf of the Secretary of HHS, to list as a patient safety organization (PSO) an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be “delisted” by the Secretary if it is found to no longer meet the requirements of the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO’s listing expires. AHRQ accepted a notification of proposed voluntary relinquishment from the QCMetrix PSO, PSO number P0166, of its status as a PSO, and has delisted the PSO accordingly.

**DATES:** The delisting was effective at 12:00 Midnight ET (2400) on February 11, 2022.

**ADDRESSES:** The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. Both directories can be accessed electronically at the following HHS website: <http://www.pso.ahrq.gov/listed>.

**FOR FURTHER INFORMATION CONTACT:** Cathryn Bach, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, MS 06N100B, Rockville, MD 20857; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; Email: [psa@ahrq.hhs.gov](mailto:psa@ahrq.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**Background**

The Patient Safety Act, 42 U.S.C. 299b–21 to 299b–26, and the related Patient Safety Rule, 42 CFR part 3, published in the **Federal Register** on November 21, 2008 (73 FR 70732–70814), establish a framework by which individuals and entities that meet the definition of provider in the Patient Safety Rule may voluntarily report information to PSOs listed by AHRQ, on a privileged and confidential basis, for the aggregation and analysis of patient safety work product.

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule

authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be “delisted” if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO’s listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of PSOs.

AHRQ has accepted a notification of proposed voluntary relinquishment from the QCMetrix PSO to voluntarily relinquish its status as a PSO. Accordingly, the QCMetrix PSO, PSO number P0166, was delisted effective at 12:00 Midnight ET (2400) on February 11, 2022.

QCMetrix PSO has patient safety work product (PSWP) in its possession. The PSO will meet the requirements of section 3.108(c)(2)(i) of the Patient Safety Rule regarding notification to providers that have reported to the PSO and of section 3.108(c)(2)(ii) regarding disposition of PSWP consistent with section 3.108(b)(3). According to section 3.108(b)(3) of the Patient Safety Rule, the PSO has 90 days from the effective date of delisting and revocation to complete the disposition of PSWP that is currently in the PSO’s possession.

More information on PSOs can be obtained through AHRQ’s PSO website at <http://www.pso.ahrq.gov>.

Dated: March 7, 2022.

**Marquita Cullom,**

*Associate Director.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Plan for Foster Care and Adoption Assistance—Title IV–E (OMB #0970–0433)**

**AGENCY:** Children’s Bureau, Administration for Children and Families, HHS.

**ACTION:** Request for public comment.

**SUMMARY:** The Children’s Bureau (CB), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting a 3-year extension of the Plan for Foster Care and Adoption Assistance—Title IV–E, (OMB#: 0970–

0433, expiration 11/30/2022). This plan also incorporates the plan requirements for the optional Guardianship Assistance Program, the Title IV–E prevention services plan and the Title IV–E Kinship Navigator program. There are no changes requested to the form.

**DATES:** *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

**ADDRESSES:** You can obtain copies of the proposed collection of information and submit comments by emailing [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). Identify all requests by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* A title IV–E plan is required by section 471, Part IV–E of the Social Security Act (the Act) for each public child welfare agency requesting federal funding for foster care, adoption assistance, and guardianship assistance under the Act. Section 479B of the Act provides for an Indian tribe, tribal organization, or tribal consortium (tribe) to operate a title IV–E program in the same manner as a state with minimal exceptions. The tribe must have an approved Title IV–E Plan. The Title IV–E Plan provides assurances the programs will be administered in conformity with the specific requirements stipulated in Title IV–E. The plan must include all applicable state or tribal statutory, regulatory, or policy references and citations for each requirement as well as supporting documentation. A title IV–E agency may use the pre-print format prepared by CB, or a different format, on the condition that the format used includes all of the Title IV–E Plan requirements.

Title IV–E of the Act was amended by Public Law 115–123, which included the Family First Prevention Services Act (FFPSA). FFPSA authorized new optional Title IV–E funding for time-limited (1 year) prevention services for mental health/substance abuse and in-home parent skill-based programs for (1) a child who is a candidate for foster care (as defined in section 475(13) of the Act), (2) pregnant/parenting foster youth, and (3) the parents/kin caregivers of those children and youth (sections 471(e), 474(a)(6), and 475(13) of the Act). Title IV–E prevention services must be rated as promising, supported, or well supported in accordance with HHS criteria and be approved by HHS (section 471(e)(4)(C) of the Act) as part of the Title IV–E Prevention Services Clearinghouse (section 476(d)(2) of the