

Formats in year 3. AHRQ estimates the number of hospitals using Common

Formats will remain level for the next three years at 1,000 hospitals.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Certification for Initial Listing Form *	17	1	18	306
Certification for Continued Listing Form *	16	1	8	128
Two Bona Fide Contracts Requirement Form **	30	1	1	30
Disclosure Statement Form ***	2	1	3	6
Profile Form ****	77	1	3	231
Patient Safety Confidentiality Complaint Form ***	3	1	20/60	1
Change of Listing Information ***	24	1	05/60	2
Common Formats	1,000	1	100	100,000
Total ***	1,169	NA	NA	100,704

* AHRQ expects the number of PSOs to remain relatively stable, with 65% of listed PSOs seeking continued listing. The number of new entities seeking listing as PSOs and PSOs seeking continued listing will be offset by the number of entities that will voluntarily relinquish their status as a PSO, allow their listing to expire, or have their listing revoked for cause by AHRQ.

** The Two Bona Fide Contracts Requirement Form will be completed by each PSO within the 24-month period after listing by the Secretary.

*** The Disclosure Statement Form and the Change of Listing Information form may be submitted by individual PSOs in different years. Due to changes in their operations, a PSO can submit more than one Change of Listing Information in a year. OCR is anticipating considerable variation in the number of complaints per year. Hence, the total for each year is expressed as an average of the expected total over the three year collection period.

**** The Profile Form collects data from listed PSOs each calendar year. The prior version of this form, the PSO Information Form, began collecting data from listed PSOs each calendar year in 2011.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost
Certification for Initial Listing Form	17	306	\$35.93	\$10,994.58
Certification for Continued Listing Form	16	128	35.93	4,599.04
Two Bona Fide Contracts Requirement Form	30	30	35.93	1,077.90
Disclosure Statement Form	2	6	35.93	215.58
Profile Form	77	231	35.93	8,299.83
Patient Safety Confidentiality Complaint Form	3	1	35.93	35.93
Change of Listing Information	24	2	35.93	71.86
Common Formats	1,000	100,000	35.93	3,593,000.00
Total	1,169	100,704	NA	3,618,294.72

* Based upon the mean of the hourly wages for healthcare practitioner and technical occupations, 29-0000, National Compensation Survey, May 2013, "U.S. Department of Labor, Bureau of Labor Statistics." (http://www.bls.gov/oes/current/oes_nat.htm#29-0000).

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: July 1, 2014.

Richard Kronick,

AHRQ Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Management of Postpartum Hemorrhage

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

ACTION: Request for scientific information submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review of Management of Postpartum Hemorrhage, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to

published and unpublished pertinent scientific information will improve the quality of this review. AHRQ is conducting this systematic review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, and Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: Submission Deadline on or before August 18, 2014.

ADDRESSES:

Online submissions: <http://effectivehealthcare.AHRQ.gov/index.cfm/submit-scientific-information-packets/>. Please select the study for which you are submitting information from the list to upload your documents.

Email submissions: SIPS@epc-src.org.

Print Submissions

Mailing Address

Portland VA Research Foundation,
Scientific Resource Center, ATTN:
Scientific Information Packet
Coordinator, P.O. Box 69539,
Portland, OR 97239.

Shipping Address (FedEx, UPS, etc.)

Portland VA Research Foundation,
Scientific Resource Center, ATTN:
Scientific Information Packet
Coordinator, 3710 SW U.S. Veterans
Hospital Road, Mail Code: R&D 71,
Portland, OR 97239.

FOR FURTHER INFORMATION CONTACT:

Ryan McKenna, Telephone: 503–220–8262 ext. 58653 or Email: SIPS@epc-src.org.

SUPPLEMENTARY INFORMATION: AHRQ has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a review of the evidence for Management of Postpartum Hemorrhage.

The EHC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on Management of Postpartum Hemorrhage, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: <http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1918>.

This notice is to notify the public that the EHC program would find the following information on Management of Postpartum Hemorrhage helpful:

- A list of completed studies that your company has sponsored for this indication. In the list, please indicate whether results are available on *ClinicalTrials.gov* along with the *ClinicalTrials.gov* trial number.

- For completed studies that do not have results on *ClinicalTrials.gov*, please provide a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.

- A list of ongoing studies that your company has sponsored for this indication. In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

- Description of whether the above studies constitute ALL Phase II and above clinical trials sponsored by your company for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EHC Program. Since the contents of all submissions will be made available to the public upon request, materials submitted must be publicly available or can be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EHC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EHC program Web site and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: <http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/>.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions. The entire research protocol, is also available online at: <http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1918>.

The Key Questions (KQ)

KQ1. What is the evidence for the comparative effectiveness of interventions for management of postpartum hemorrhage?

a. What is the comparative effectiveness of interventions intended to treat postpartum hemorrhage likely due to atony?

b. What is the comparative effectiveness of interventions intended to treat postpartum hemorrhage likely due to retained placenta?

c. What is the comparative effectiveness of interventions intended to treat postpartum hemorrhage likely due to genital tract trauma?

d. What is the comparative effectiveness of interventions intended to treat postpartum hemorrhage likely due to uncommon causes (e.g., coagulopathies, uterine inversion, subinvolution)?

KQ2. What is the evidence for choosing one intervention over another and when to proceed to subsequent interventions for management of postpartum hemorrhage?

KQ3. What are the comparative harms, including adverse events, associated with interventions for management of postpartum hemorrhage?

KQ4. What is the comparative effectiveness of interventions to treat acute blood loss anemia after stabilization of postpartum hemorrhage?

KQ5. What systems-level interventions are effective in improving management of postpartum hemorrhage?

PICOTS (Population, Intervention, Comparator, Outcomes, Timing, and Setting)

Population

- KQ1–3: Women with postpartum hemorrhage (PPH) immediately post-birth to 12 weeks postpartum following pregnancy >24 weeks gestation.
- KQ4: Women with stabilized PPH and acute blood loss anemia
- KQ 1–5: All modes of birth

Intervention(s)

- KQ1–3, 5
 - Compression techniques (external uterine massage, bimanual compression, aortic compression)
 - Medications (oxytocin [Pitocin], prostaglandin E1 [Misoprostol, Cytotec], methylergonovine [Methergine], prostaglandin 15-methyl F2a [Hemabate], prostaglandin E2 [Dinoprostone], recombinant factor VIIIa [NovoSeven], and tranexamic acid [Cyklokapron])

- Devices (Bakri postpartum balloon, Foley catheter, Sengstaken-Blakemore tube, Rusch balloon)
- Procedures (manual removal of placenta, manual evacuation of clot, uterine tamponade, uterine artery embolization, laceration repair)
- Surgeries (curettage, uterine artery ligation, uterine hemostatic compression suturing, hysterectomy)
- Blood and fluid products
- Anti-shock garment
- Systems-level interventions (e.g., implementation of protocols, training)

● KQ4

- Interventions for acute blood loss anemia (e.g., iron replacement, erythropoietin)

Comparator

- Different intervention (any intervention compared with any other intervention)
- Placebo

Outcomes

- Intermediate outcomes
 - Blood loss
 - Transfusion
 - ICU admission
 - Anemia
 - Length of stay
- Final outcomes
 - Mortality
 - Uterine preservation
 - Future fertility
 - Breastfeeding
 - Psychological impact
 - Harms

Timing

- Immediately post-birth to 12 weeks postpartum
- Primary (< 24 hours postpartum) or secondary (≥ 24 hours postpartum)

Setting

All birth settings (hospital, birth center, home)

Dated: July 1, 2014.

Richard Kronick,
AHRQ Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10477, CMS-R-185 and CMS-10343]

Agency Information Collection Activities: Proposed Collection; 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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by *September 16, 2014*.

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4-26-05,

7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10477 Medicaid Incentives for Prevention of Chronic Disease (MIPCD) Demonstration

CMS-R-185 Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and of State Exemption Under State Laboratory Programs and Supporting Regulations

CMS-10343 State Plan Preprint for Medicaid Recovery Audit Contractors (RAC) Program

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Medicaid Incentives for Prevention of Chronic