Dated: December 27,2019.

David A. Shive,

Chief Information Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Mixed Methods Review—Integrating Palliative Care With Chronic Disease Management in Ambulatory Care

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

ACTION: Request for Supplemental Evidence and Data 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 on *Mixed Methods Review—Integrating Palliative Care with Chronic Disease Management in Ambulatory Care,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before 30 days after date of publication in the **Federal Register**.

ADDRESSES:

Email Submissions: epc@ahrq.hhs.gov.

Print Submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301–427–1496 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for Mixed Methods Review—Integrating Palliative Care with Chronic Disease Management in Ambulatory Care. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

The EPC 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 *Mixed Methods Review—Integrating Palliative Care with Chronic Disease Management in Ambulatory Care,* including those that describe adverse events. The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/palliative-care-integration/protocol.*

This is to notify the public that the EPC Program would find the following information on *Mixed Methods Review—Integrating Palliative Care with Chronic Disease Management in Ambulatory Care* helpful:

- A list of completed studies that your organization 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,* 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 organization 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 organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to 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 EPC 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 EPC Program website 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: *https://www.effectivehealthcare.ahrq.gov/email-updates.*

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.

Key Questions (KQ)

Five questions about the integration of palliative care in ambulatory care will be addressed:

1. How can we identify those patients who could benefit from palliative care in ambulatory care settings?
2. What educational resources are available for patients and caregivers in ambulatory care about palliative care?
3. What palliative care decision making tools are available for clinicians, patients and caregivers in ambulatory care?
4. What educational resources are available for non-palliative care clinicians about palliative care in ambulatory settings?
5. What are the models for integrating palliative care into ambulatory settings?

For each of these questions, three parts will be addressed:

- What is available? (part a of questions)
- What is the effectiveness? (part b of questions)
- How is it implemented? (part c of questions)

The following are the Key Questions to be addressed in this mixed methods review:

KQ 1:

KQ1a. What prediction models, tools, triggers and guidelines and position statements are available about how to identify when and which patients with serious life-threatening chronic illness or conditions in ambulatory settings could benefit from palliative care?

KQ1b. What is the effectiveness of prediction models, tools and triggers for identifying when and which patients with serious life-threatening chronic illness or conditions in ambulatory settings could benefit from palliative care?

KQ1c. How have prediction models, tools and triggers for identifying when

and which patients with serious life-threatening chronic illness or conditions in ambulatory settings could benefit from palliative care been implemented? What is the evidence for how, when and for which patients they could best be implemented in care?

KQ 2:

KQ2a. What educational materials and resources are available about palliative care and palliative care options for patients with serious life-threatening chronic illness or conditions in ambulatory settings and their caregivers?

KQ2b. What is the effectiveness of educational materials and resources about palliative care and palliative care options for patients with serious life-threatening chronic illness or conditions and their caregivers in ambulatory settings?

KQ2c. How have educational materials and resources about palliative care and palliative care options for patients with serious life-threatening chronic illness or conditions and their caregivers in ambulatory settings been implemented? What is the evidence for how, when and for which patients and caregivers they could best be implemented in care?

KQ 3:

KQ3a. What palliative care shared decision-making tools are available for patients with serious life-threatening chronic illness or conditions in ambulatory settings and their caregivers?

KQ3b. What is the effectiveness of palliative care shared decision-making tools for patients with serious life-threatening chronic illness or conditions in ambulatory settings and their caregivers?

KQ3c. How have palliative care shared decision-making tools been implemented for patients with serious life-threatening chronic illness or conditions in ambulatory settings and their caregivers? What is the evidence for how, when and for which patients and caregivers they could best be implemented in care?

KQ 4:

KQ4a. What palliative care training and educational materials are available for non-palliative care clinicians caring for patients with serious life-threatening chronic illness or conditions in ambulatory settings?

KQ4b. What is the effectiveness of palliative care training and educational materials (with or without other intervention components) for non-palliative care clinicians caring for patients with serious life-threatening chronic illness or conditions in ambulatory settings?

KQ4c. How have palliative care training and educational materials (with or without other intervention components) for non-palliative care clinicians caring for patients with serious life-threatening chronic illness or conditions in ambulatory settings been implemented? What is the evidence for how, when and for which clinicians they could best be implemented in care?

KQ 5:

KQ5a. What models (*i.e.,* stepped care, consultative care, shared care, collaborative care, coaching, integrating social workers into practice, and palliative care approaches provided by non-palliative care specialists) for integrating palliative care have been developed for patients with serious life-threatening chronic illness or conditions in ambulatory settings?

KQ5b. What is the effectiveness of models (*i.e.,* stepped care, consultative care, shared care, collaborative care, coaching, integrating social workers into practice, and palliative care approaches provided by non-palliative care specialists) or multimodal interventions for integrating palliative care for patients with serious life-threatening chronic illness or conditions in ambulatory settings?

KQ5c. What are components of models for integrating palliative care in ambulatory settings? What models have been implemented for key subpopulations? What components and characteristics of these models contribute to their effective implementation? What is the evidence for how, when and for which patients they could best be implemented in care?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

- *Population(s):*
  - Adults age 18 or older with serious life-threatening chronic illness or conditions (other than those adults only with cancer) and their caregivers, being seen in ambulatory settings (KQ 1,2,3,5)
  - Clinicians practicing in ambulatory settings listed below (KQ 4)
- *Interventions:*
  - *KQ1:* Prediction models, tools or triggers to identify patients for palliative care in ambulatory settings
  - *KQ2:* Educational materials and resources for patients and/or caregivers about palliative care in ambulatory settings
  - *KQ3:* Palliative care shared decision-making tools and resources for clinicians and patients and/or caregivers in ambulatory settings
  - *KQ4:* Palliative care training or educational materials for non-palliative care clinicians in ambulatory settings
  - *KQ5:* Models for integrating palliative care in ambulatory settings
- *Comparators (for part (b) KQ):* Comparators between:
  - *KQ1:* Prediction models, tools or triggers to identify patients for palliative care in ambulatory settings
  - *KQ2:* Educational materials and resources for patients and/or caregivers about palliative care in ambulatory settings
  - *KQ3:* Palliative care shared decision-making tools and resources for clinicians and patients and/or caregivers in ambulatory settings
  - *KQ4:* Palliative care training or educational materials for clinicians in ambulatory settings
  - *KQ5:* Models for integrating palliative care or multimodal interventions in ambulatory settings
  - As well as with usual care for all KQs
- *Outcomes (for part (b) KQ):*
  - Intermediate (Excludes clinician self-report):
    - Knowledge (clinicians, patients, caregivers) (KQ2, KQ4)
    - Awareness (clinicians, patients, caregivers) (KQ2, KQ4)
    - Skills (clinicians) (KQ4)
  - Final (All apply to all KQ) (In hierarchy from patient-centered to clinician to health system. All patient or caregiver-reported outcomes must be measured by a validated instrument. All outcomes must relate to components of care relevant to serious, life-threatening chronic illness or conditions.)
    - Patient or caregiver satisfaction
    - Patient or caregiver health-related quality of life
    - Patient or caregiver symptoms of depression or anxiety or psychological well-being
    - Caregiver burden, caregiver impact or caregiver strain
    - Patient symptoms or symptom burden (includes multidimensional symptom tools and key symptoms of pain, dyspnea, fatigue). This must include patient-reported symptom measurement (or caregiver-reported for patients unable to report).
    - Concordance between patient preferences for care and care received
    - Clinician job satisfaction or burnout, perceptions of teamwork

- Healthcare utilization (use and length of hospice care, hospitalizations, advance directive documentation) and costs and resource use (use of outpatient clinician services, including palliative care)
- Adverse effects
  - Medication side effects
  - Dropouts
- *Timing*
  - Any timing
- *Settings*
  - Ambulatory primary and specialty care, including geriatrics, nephrology, pulmonology, cardiology, and neurology
  - U.S.-based studies, as systems of care differ in other countries

Dated: January 15, 2020.

Virginia L. Mackay-Smith,

Associate Director, Office of the Director, AHRQ.

[FR Doc. 2020–00903 Filed 1–21–20; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[0Day–20–0006; Docket No. CDC–2019–0118]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on Statements in Support of Application of Waiver of Inadmissibility (0920–0006). CDC uses the information collected in 0920–0006 to review Class A medical waiver applications for prospective immigrants to the United States. CDC assists DHS/USCIS in determining whether or not a prospective immigrant with a Class A mental health designation may be admitted into the United States.

DATES: CDC must receive written comments on or before March 23, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0118 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

*Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.*

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, of the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Statements in Support of Application of Waiver of Inadmissibility (OMB Control No. 0920–0006 Exp. 6/30/2020)—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 212(a)(1) of the Immigration and Nationality Act states that aliens with specific health related conditions are ineligible for admission into the United States. The Attorney General may waive application of this inadmissibility on health-related grounds if an application for waiver is filed and approved by the consular office considering the application for visa. CDC uses this application primarily to collect information to establish and maintain records of waiver applicants in order to notify the U.S. Citizenship and Immigration Services when terms, conditions and controls imposed by waiver are not met.

The purpose of this Revision is to remove information collections for form 4.422–1a, because CDC does not receive information about the evaluation report of an applicant who received a waiver. This results in a reduction of 67 burden hours. CDC requests approval for 33 annual burden hours.