

MATTERS FOR DISCUSSION: The meeting will include the initial review, discussion, and evaluation of applications received in response to “Understanding the Epidemiology of Syphilis in the United States”, PS17-002.

CONTACT PERSON FOR MORE INFORMATION: Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road NE., Mailstop E60, Atlanta, Georgia 30329, Telephone: (404) 718-8833.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-10, CMS-10487, CMS-10116, CMS-10219 and CMS-10275]

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: The necessity and utility of the proposed information collection for the proper performance of the agency's functions; the accuracy of the estimated burden;

ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by February 7, 2017.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. 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-R-10 Advance Directives (Medicare and Medicaid) and Supporting Regulations
 CMS-10487 Medicaid Emergency Psychiatric Demonstration (MEPD) Evaluation
 CMS-10116 Conditions for Payment of Power Mobility Devices, including Power Wheelchairs and Power-Operated Vehicles

CMS-10219 Healthcare Effectiveness Data and Information Set (HEDIS®) Data Collection for Medicare Advantage

CMS-10275 CAHPS Home Health Care Survey

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:* Extension of a previously approved collection; *Title of Information Collection:* Advance Directives (Medicare and Medicaid) and Supporting Regulations; *Use:* The advance directives requirement was enacted because Congress wanted individuals to know that they have a right to make health care decisions and to refuse treatment even when they are unable to communicate. Steps have been taken at both the Federal and State level, to afford greater opportunity for the individual to participate in decisions made concerning the medical treatment to be received by an adult patient in the event that the patient is unable to communicate to others, a preference about medical treatment. The individual may make his preference known through the use of an advance directive, which is a written instruction prepared in advance, such as a living will or durable power of attorney. This information is documented in a prominent part of the individual's medical record. Advance directives as described in the Patient Self-Determination Act have increased the individual's control over decisions concerning medical treatment. Sections 4206 of the Omnibus Budget Reconciliation Act of 1990 defined an advance directive as a written instruction recognized under State law relating to the provision of health care when an individual is incapacitated

(those persons unable to communicate their wishes regarding medical treatment).

All states have enacted legislation defining a patient's right to make decisions regarding medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives. Participating hospitals, skilled nursing facilities, nursing facilities, home health agencies, providers of home health care, hospices, religious nonmedical health care institutions, and prepaid or eligible organizations (including Health Care Prepayment Plans (HCPPs) and Medicare Advantage Organizations (MAOs) such as Coordinated Care Plans, Demonstration Projects, Chronic Care Demonstration Projects, Program of All Inclusive Care for the Elderly, Private Fee for Service, and Medical Savings Accounts must provide written information, at explicit time frames, to all adult individuals about: (a) The right to accept or refuse medical or surgical treatments; (b) the right to formulate an advance directive; (c) a description of applicable State law (provided by the State); and (d) the provider's or organization's policies and procedures for implementing an advance directive. *Form Number:* CMS-R-10 (OMB control number: 0938-0610); *Frequency:* Yearly; *Affected Public:* Business or other for-profits; *Number of Respondents:* 39,479; *Total Annual Responses:* 39,479; *Total Annual Hours:* 2,836,441. (For policy questions regarding this collection contact Jeannine Cramer at 410-786-5664.)

2. Type of Information Collection
Request: Extension of a previously approved collection; *Title of Information Collection:* Medicaid Emergency Psychiatric Demonstration (MEPD) Evaluation; *Use:* Since the inception of Medicaid, inpatient care provided to adults ages 21 to 64 in institutions for mental disease (IMDs) has been excluded from federal matching funds. The Emergency Medical Treatment and Active Labor Act (EMTALA), however, requires IMDs that participate in Medicare to provide treatment for psychiatric emergency medical conditions (EMCs), even for Medicaid patients for whose services cannot be reimbursed. Section 2707 of the Affordable Care Act (ACA) directs the Secretary of Health and Human Services to conduct and evaluate a demonstration project to determine the impact of providing payment under Medicaid for inpatient services provided by private IMDs to individuals with emergency psychiatric conditions between the ages of 21 and 64. We will use the data to evaluate the Medicaid

Emergency Psychiatric Demonstration (MEPD) in accordance with the ACA mandates. This evaluation in turn will be used by Congress to determine whether to continue or expand the demonstration. If the decision is made to expand the demonstration, the data collected will help to inform both CMS and its stakeholders about possible effects of contextual factors and important procedural issues to consider in the expansion, as well as the likelihood of various outcomes. *Form Number:* CMS-10487 (OMB control number: 0938-NEW); *Frequency:* Annually; *Affected Public:* Individuals and households; State, Local and Tribal governments; Business and other for-profits and Not-for-profits; *Number of Respondents:* 93; *Total Annual Responses:* 1,944; *Total Annual Hours:* 2,046. (For policy questions regarding this collection contact Vetisha McClair at 410-786-4923.)

3. Type of Information Collection
Request: Extension of a currently approved collection; *Title of Information Collection:* Conditions for Payment of Power Mobility Devices, including Power Wheelchairs and Power-Operated Vehicles; *Use:* We are renewing our request for approval for the collection requirements associated with the final rule, CMS-3017-F (71 FR 17021), which published on April 5, 2006, and required a face-to-face examination of the beneficiary by the physician or treating practitioner, a written prescription, and receipt of pertinent parts of the medical record by the supplier within 45 days after the face-to-face examination that the durable medical equipment (DME) suppliers maintain in their records and make available to CMS and its agents upon request. *Form Number:* CMS-10116 (OMB control number: 0938-0971); *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other for-profits; *Number of Respondents:* 46,000; *Number of Responses:* 72,500; *Total Annual Hours:* 14,434. (For policy questions regarding this collection contact Stuart Caplan at 410-786-8564.)

4. Type of Information Collection
Request: Extension of a currently approved collection; *Title of Information Collection:* Healthcare Effectiveness Data and Information Set (HEDIS®) Data Collection for Medicare Advantage; *Use:* We use the collected data to: Monitor Medicare Advantage organization performance, inform audit strategies, and inform beneficiary choice through their display in our consumer-oriented public compare tools and Web sites. Medicare Advantage organizations use the data for quality assessment and

as part of their quality improvement programs and activities. Quality Improvement Organizations and our contractors use HEDIS® data in conjunction with their statutory authority to improve quality of care. Consumers use the information to help make informed health care choices. In addition, the data is made available to researchers and others as public use files at www.cms.hhs.gov. *Form Number:* CMS-10219 (OMB control number: 0938-1028); *Frequency:* Yearly; *Affected Public:* Private sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 576; *Total Annual Responses:* 576; *Total Annual Hours:* 184,320. (For policy questions regarding this collection contact Lori Teichman at 410-786-6684.)

5. Type of Information Collection
Request: Revision of a currently approved collection; *Title of Information Collection:* CAHPS Home Health Care Survey; *Use:* The national implementation of the Home Health Care Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Survey is designed to collect ongoing data from samples of home health care patients who receive skilled services from Medicare-certified home health agencies. The data collected from the national implementation of the Home Health Care CAHPS Survey will be used for the following purposes: (1) To produce comparable data on the patients' perspectives of the care they receive from home health agencies, (2) to create incentives for agencies to improve the quality of care they provide through public reporting of survey results, and (3) to enhance public accountability in health care by increasing the transparency of the quality of care provided in return for the public investment. Sampling and data collection will be conducted on a monthly basis. Survey results will be analyzed and reported on a quarterly basis, with publicly reported results based on one year's worth of data.

As part of this information collection request for the national implementation of Home Health Care CAHPS, CMS is also requesting approval to conduct a randomized mode experiment with a sample of home health agencies. The mode experiment compared the responses to the survey across the three proposed modes to determine whether adjustments are needed to ensure that the data collection mode does not influence the survey results. In addition, data from the mode experiment will be used to determine which, if any, patient characteristics may affect the patients' rating of the care they receive and, if so,

develop an adjustment model of those data based on those factors. CMS worked with RTI, the federal contractor to recruit approximately 100 home health agencies to participate in the mode experiment. The mode experiment included approximately 23,000 home health care patients.

Form Number: CMS-10275 (OMB control number: 0938-1066); *Frequency:* Quarterly; *Affected Public:* Individuals and households and the Private sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 2,715,890; *Total Annual Responses:* 2,715,890; *Total Annual Hours:* 699,440. (For policy questions regarding this collection contact Lori Teichman at 410-786-6684.)

Dated: December 6, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016-29584 Filed 12-8-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2431-N]

Zika Health Care Services Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the November 9, 2016 publication of a funding opportunity providing up to \$66.1 million available to support prevention activities and treatment services for health conditions related to the Zika virus. The funding opportunity solicited single source emergency applications for a cooperative agreement aimed at supporting prevention activities and treatment services for women (including pregnant women), children, and men adversely or potentially impacted by the Zika virus. Entities eligible to apply for this funding opportunity are states, territories, tribes or tribal organizations, with active or local transmission of the Zika virus, as confirmed by the Centers for Disease Control and Prevention (CDC). As of October 12, 2016, the CDC designated American Samoa, Puerto Rico, the U.S. Virgin Islands, and Florida as areas with laboratory-confirmed active or local Zika virus transmission. As such, this emergency funding opportunity is currently available to the territorial and state health departments in these areas.

DATES: The project period of performance for the Cooperative Agreement will be 36 months from the date of award.

FOR FURTHER INFORMATION CONTACT: Elizabeth Garbarczyk, 410-786-0426.

SUPPLEMENTARY INFORMATION:

I. Background

The Zika Response and Preparedness Act (Pub. L. 114-223) provides \$387,000,000 in funding to prevent, prepare for, and respond to the Zika virus. Of the funds appropriated by Public Law 114-223, Congress designated \$75 million to support states, territories, tribes, or tribal organizations with active or local transmission cases of the Zika virus, as confirmed by the Centers for Disease Control and Prevention (CDC), to reimburse the costs of health care for health conditions related to the Zika virus not covered by private insurance. No less than \$60 million of this funding is for territories with the highest rates of Zika transmission.

II. Provisions of the Notice

In accordance with the Zika Response and Preparedness Act (Pub. L. 114-223), entities eligible to apply for this funding opportunity include states, territories, tribes or tribal organizations with active or local transmission of the Zika virus, as confirmed by the Centers for Disease Control and Prevention (CDC). As of October 12, 2016, the CDC reports that American Samoa, Puerto Rico, the U.S. Virgin Islands, and Florida are the only areas with laboratory-confirmed active or local transmission of the Zika virus, and therefore, these are the only territories and state eligible to receive funding as authorized under the legislation. Funding available under the "Zika Health Care Services Program" may be used to address the following four critical components of a comprehensive response to Zika. Applicant needs may vary and some applicants may not have unmet needs across each of the four areas. If approved by CMS, recipients may use grant funds for additional health care services for health conditions related to the Zika virus that are not listed in the following section.

1. Increase Access to Contraceptive Services for Women and Men

Contraceptive services for women and men can reduce the risk of unintended pregnancy, as well as sexual transmission of Zika. Preventing unintended pregnancy in areas affected by the Zika virus outbreak among people who may have been exposed is a primary strategy to reduce the number

of pregnancies affected by Zika virus. To increase access to all FDA-approved contraceptive methods, a territory or state must use grant funds to provide client-centered contraceptive counseling to educate women (including women who are pregnant and post-partum) and men on effective contraception methods, increase contraceptive supplies in provider offices, increase family planning delivery sites, train providers on the full range of contraceptive methods and their use, including insertion and removal of long-acting reversible contraception (LARC), and to remove a patient's financial barriers to use of effective contraception through methods such as cost sharing assistance for contraceptive services.

2. Reduce Barriers to Diagnostic Testing, Screening, and Counseling for Pregnant Women and Newborns

Uninsured or underinsured pregnant women may not seek testing and medical follow-up if Zika testing does not begin at the initial point of prenatal care or if it presents financial hardship. Testing should be performed as a part of routine prenatal care. However, additional unscheduled prenatal visits may be necessary to complete the testing protocol (for example, reflex testing) and to provide pre- and post-test counseling on the interpretation of results. Funds designated for diagnostic testing, screening, and counseling will be used to ensure access to diagnostic services to test for Zika infection wherever a pregnant woman initially presents for care. This will increase the identification of pregnant women infected with Zika, who require increased monitoring and prenatal care services, and will lead to early diagnosis of infants with special medical needs.

3. Increase Access to Appropriate Specialized Healthcare Services for Pregnant Women, Children Born to Mothers With Maternal Zika Virus Infection, and Their Families

Complex clinical and psychosocial needs associated with maternal Zika virus infection require access to comprehensive and appropriate specialized healthcare, and a coordinated suite of services that serves mother, child, and their families. Increased access to prenatal care is critical to plan for post-natal care, particularly access to ultrasounds which can detect abnormalities in fetal development. In addition, high-risk pregnancies and pregnancy loss, can be stressful for both the pregnant woman and her family and require psychosocial support. Moreover, the infants themselves require enhanced follow-up,