

security of United States citizens living abroad and that involves EV-D68.

III. Declaration of the Secretary of Health and Human Services

Also on February 6, 2015, on the basis of my determination of a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves EV-D68, I declared that circumstances exist justifying the authorization of emergency use of new in vitro diagnostics for detection of EV-D68 pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Notice of the EUAs issued by the FDA Commissioner pursuant to this determination and declaration will be provided promptly in the **Federal Register** as required under section 564 of the FD&C Act.

Dated: February 6, 2015.

Sylvia M. Burwell,
Secretary.

[FR Doc. 2015-04121 Filed 2-26-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the SACHRP Web site at: <http://www.dhhs.gov/ohrp/sachrp/mtgngs/index.html>.

DATES: The meeting will be held on Tuesday, March 24, 2015, from 8:30 a.m. until 5:00 p.m. and Wednesday, March 25, 2015, from 8:30 a.m. until 4:30 p.m.

ADDRESSES: Fishers Lane Conference Center, Terrace Level, 5635 Fishers Lane, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections (OHRP), or

Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; 240-453-8141; fax: 240-453-6909; email address: SACHRP@hhs.gov.

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The meeting will open to the public at 8:30 a.m., on Tuesday, March 24. Following opening remarks from Dr. Jerry Menikoff, Executive Secretary of SACHRP and OHRP Director, and Dr. Jeffrey Botkin, SACHRP Chair, Dr. Botkin and invited speakers will discuss issues surrounding the use of newborn dried bloodspots in research. The Subpart A Subcommittee (SAS) report will follow; SAS will discuss draft recommendations on the research uses of newborn dried bloodspots and the Newborn Screening Saves Lives Reauthorization Act of 2014. SAS was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

In the afternoon of March 24, the Subcommittee on Harmonization (SOH) will present their report; SOH was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination. SOH will present recommendations on the research use of "big data" and the intersection of the HHS and FDA regulations.

On March 25, the SOH will discuss the return of individual research results with special considerations regarding HIPAA and CLIA; this will be followed by presentation of SOH recommendations on the FDA draft guidance "General Clinical Pharmacology Considerations for Pediatric Studies for Drugs and Biologics." The meeting will adjourn at 4:30 p.m. March 25, 2015. Time for public comment sessions will be allotted both days.

Public attendance at the meeting is limited to space available. Individuals

who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify one of the designated SACHRP points of contact at the address/phone number listed above at least one week prior to the meeting. Pre-registration is required for participation in the on-site public comment session; individuals may pre-register the day of the meeting. Individuals who would like to submit written statements should email or fax their comments to SACHRP at SACHRP@hhs.gov at least five business days prior to the meeting.

Dated: February 23, 2015.

Jerry Menikoff,

Executive Secretary, Secretary's Advisory Committee on Human Research Protections, Director, Office for Human Research Protections.

[FR Doc. 2015-04120 Filed 2-26-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-1696 and CMS-10417]

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 April 28, 2015.

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-1696 Appointment of Representative

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 currently approved collection; *Title of Information Collection:* Appointment of Representative; *Use:* The Appointment of Representative form is completed by beneficiaries, providers and suppliers, and any party seeking to appoint a representative to assist them with their initial determinations and filing appeals. This extension request proposes non-substantive changes to the form. *Form Number:* CMS-1696 (OMB control number 0938-0950); *Frequency:* Once; *Affected Public:* Individuals and households and the Private sector (Business or other for-profits); *Number of Respondents:* 4,073,960; *Total Annual Responses:* 407,396; *Total Annual Hours:* 101,849. (For policy questions regarding this collection contact Katherine Hosna at 410-786-4993).

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Fee-for-Service Prepayment Medical Review; *Use:* The information required under this collection is requested by Medicare contractors to determine proper payment or if there is a suspicion of fraud. Medicare contractors request the information from providers or suppliers submitting claims for payment from the Medicare program when data analysis indicates aberrant billing patterns or other information which may present a vulnerability to the Medicare program. *Form Number:* CMS-10417 (OMB control number: 0938-0969); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 3,211,800; *Total Annual Responses:* 3,211,800; *Total Annual Hours:* 1,597,950. (For policy questions regarding this collection contact Debbie Skinner at 410-786-7480.)

Dated: February 24, 2015.

William N. Parham, III

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

[FR Doc. 2015-04115 Filed 2-26-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-10341 and CMS-10522]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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 (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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by March 30, 2015.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 or Email: OIRA_submission@omb.eop.gov.

To obtain copies of a supporting statement and any related forms for the