

percent of Sumner Bank & Trust, Gallatin, Tennessee.

2. *The McGehee Bank Employee Stock Ownership Plan*, McGehee, Arkansas; to acquire up to 35 percent of the voting shares of Southeast Financial Bankstock Corp., and thereby indirectly acquire voting shares of McGehee Bank, both in McGehee, Arkansas.

Board of Governors of the Federal Reserve System, July 12, 2013.

Margaret McCloskey Shanks,
Deputy Secretary of the Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10494]

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 *August 14, 2013*:

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) 395-6974 or Email: *OIRA_submission@omb.eop.gov*.

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: 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. 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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Patient Protection and Affordable Care Act; Exchange Functions: Standards for Navigators and Non-Navigator Assistance Personnel; Consumer Assistance Tools and Programs of an Exchange and Certified Application Counselors; *Use:* Section 1413 of the Affordable Care Act directs the Secretary of HHS to establish, subject to minimum requirements, a streamlined enrollment system for qualified health plans offered through the Exchange and insurance affordability programs. In addition, section 1321(a)(1) of the Affordable Care Act directs and authorizes the Secretary to issue

regulations setting standards for meeting the requirements under title I of the Affordable Care Act, with respect to, among other things, the establishment and operation of Exchanges. Pursuant to this authority, regulations establishing the certified application counselor program are being finalized at 45 CFR 155.225. Specifically, 45 CFR 155.225(a) requires an Exchange to establish a certified application counselor program that complies with the requirements of the rule. Section 155.225(b)(1) allows each Exchange to designate certain organizations, including organizations designated by state Medicaid or CHIP agencies, which will certify their staff and volunteers to act as certified application counselors. In accordance with 45 CFR 155.225(b)(2), Exchanges may choose to certify directly individuals who seek to act as certified application counselors, designate certain organizations which will certify staff or volunteers to perform application services, or do both. *Form Number:* CMS-10494 (OCN: 0938-NEW); *Frequency:* Yearly, annually; *Affected Public:* Private sector (not-for-profit institutions), individuals or households, State, Local, or Tribal Governments; *Number of Respondents:* 8,720; *Total Annual Responses:* 8,720; *Total Annual Hours:* 5,536. (For policy questions regarding this collection contact Tricia Beckmann at 301-492-4328.)

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013-17149 Filed 7-15-13; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-5506-N2]

Medicare Program; Comprehensive ESRD Care Initiative; Extension of the Submission Deadlines for the Letters of Intent and Applications

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

ACTION: Notice of extension of deadlines.

SUMMARY: This notice reopens the Letter of Intent submission period for the Comprehensive ESRD Care initiative letters of intent. Letters of Intent are now due on or before July 19, 2013. All potential applicants must submit a Letter of Intent to be eligible to submit

an application. The submission deadline for the application has been extended to August 1, 2013.

DATES: Letter of Intent Submission Deadline: Interested organizations must submit a non-binding letter of intent on or before July 19, 2013, by an online form at: <https://cmsgov.secure.force.com/cec>.

Application Submission Deadline: Interested organizations must submit an application on or before August 1, 2013, as described on the Innovation Center Web site at: <http://innovation.cms.gov/initiatives/comprehensive-ESRD-care/apply.html>. Interested organizations should also continue to check the Web site for updates on this initiative.

FOR FURTHER INFORMATION CONTACT: Melissa Cohen, (410) 786-1829 or ESRD-CMMI@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Center for Medicare and Medicaid Innovation (Innovation Center) is interested in identifying models designed to improve care for beneficiaries with end-stage renal disease (ESRD). To promote seamless and integrated care for beneficiaries with ESRD, we are developing a comprehensive care delivery model to emphasize coordination of a full-range of clinical and non-clinical services across providers, suppliers, and settings. Through the Comprehensive ESRD Care Model, we seek to identify ways to improve the coordination and quality of care for this population, while lowering total per-capita expenditures under the Medicare program. We anticipate that the Comprehensive ESRD Care Model would result in improved health outcomes for beneficiaries with ESRD regarding the functional status, quality of life, and overall well-being, as well as increased beneficiary and caregiver engagement, and lower costs to Medicare through improved care coordination.

On February 6, 2013, we published a notice in the **Federal Register** announcing a request for applications from organizations to participate in the testing of the Comprehensive ESRD Care Model, for a period beginning in 2013 and ending in 2016, with a possible extension into subsequent years.

In that notice, we stated that organizations interested in applying to participate in the testing of the Comprehensive ESRD Care Model must submit a non-binding letter of intent by March 15, 2013, and an application by May 1, 2013.

II. Provisions of the Notice

Since the publication of the February 6, 2013 notice, several stakeholders have requested additional time to prepare their applications and form partnerships. Therefore, the Innovation Center is extending the following deadlines relating to the Comprehensive ESRD Care initiative: (1) The letter of intent submission period has been reopened. The deadline for submission of the letter of intent has been extended to July 19, 2013; and (2) the deadline for submission of the application has been extended to August 1, 2013.

In the **DATES** section of this notice, we are including the new submissions deadlines. For additional information on the Comprehensive ESRD Care Model and how to apply, we refer readers to click on the Request for Applications located on the Innovation Center Web site at: <http://innovation.cms.gov/initiatives/comprehensive-ESRD-care>.

(No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare-Supplementary Medical Insurance Program)

Dated: July 9, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013-17131 Filed 7-16-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0754]

Authorization of Emergency Use of an In Vitro Diagnostic for Detection of Middle East Respiratory Syndrome Coronavirus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for an in vitro diagnostic device for detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV), formerly known as Novel Coronavirus 2012 or NCV-2012. FDA is issuing this Authorization under the Federal Food, Drug, and Cosmetic (the FD&C) Act, as requested by the Centers for Disease Control and Prevention (CDC). The Authorization contains, among other things, conditions on the emergency use of the authorized in vitro diagnostic device. The Authorization follows the

determination by the Secretary of Health and Human Services (HHS) that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves MERS-CoV. On the basis of such determination, the Secretary also declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of MERS-CoV subject to the terms of any authorization issued under the FD&C Act. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of June 5, 2013.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4121, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Luciana Borio, Assistant Commissioner for Counterterrorism Policy, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4118, Silver Spring, MD 20993-0002, telephone 301-796-8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3), as amended by the Project BioShield Act of 2004 (Pub. L. 108-276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5), allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help assure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.