Frequency of Response: Once per request.

Annual Responses: 1,680.

Average Minutes Per Response: 22 (rounded to nearest whole minute).

Burden Hours: 615.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number assigned to the FTC to conduct past activities under this program is 3084–0159.

Request for Comment: Under the PRA, 44 U.S.C. 3501–3521, federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' means agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3); 5 CFR 1320.3(c). As required by section 3506(c)(2)(A) of the PRA, the FTC is providing this opportunity for public comment before requesting that OMB extend the existing paperwork clearance for the regulations noted herein.

Pursuant to Section 3506(c)(2)(A) of the PRA, the FTC invites comments on: (1) Whether the proposed information collection is necessary, including whether the information will be practically useful; (2) the accuracy of our burden estimates, including whether the methodology and assumptions used are valid; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information. All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before April 7, 2014.

You can file a comment online or on paper. For the FTC to consider your comment, we must receive it on or before April 7, 2014. Write ''FTC Generic Clearance ICR, Project No. P035201'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment doesn't include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment doesn't include any sensitive health information, like medical records or other individually identifiable health information. In addition, don't include any ''[t]rade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential . . .,'' as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[5] Your comment will be kept confidential only if the FTC General Counsel grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online, or to send them to the Commission by courier or overnight service. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/genericclearance* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home*, you also may file a comment through that Web site.

If you file your comment on paper, write ''FTC Generic Clearance ICR, Project No. P035201'' on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex J), 600 Pennsylvania Avenue NW., Washington, DC 20580. If possible, submit your paper comment to the Commission by courier or overnight service.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before April 7, 2014. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

David C. Shonka,

Principal Deputy General Counsel.

[FR Doc. 2014–02216 Filed 2–3–14; 8:45 am]

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response; (2) Six focus groups per year, 10 respondents each (to test education products and Web sites), 2 hours per response; and (3) Ten usability sessions per year, 12 respondents per Web site (to test the usability of FTC Web sites by inviting people to complete common tasks on those sites), 1 hour per response.

[5] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c), 16 CFR 4.9(c).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–5511–N]

Medicare and Medicaid Programs; Solicitation for Proposals for the Frontier Community Health Integration Project Demonstration

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

ACTION: Notice.

SUMMARY: This notice provides eligible entities with the information necessary to apply for participation in the Frontier Community Health Integration Project (FCHIP) demonstration. The demonstration is designed to better integrate the delivery of acute care, extended care and other health care services, and improve access to care for Medicare and Medicaid beneficiaries residing in very sparsely populated areas. A competitive application process will be used to select eligible entities for participation in this demonstration. The demonstration is planned for up to 3 years.

DATES: Applications will be considered timely if we receive them on or before 5 p.m., eastern standard time (E.S.T.) on May 5, 2014.

ADDRESSES: Mail one unbound original and two copies to: Centers for Medicare & Medicaid Services, Attention: Steven Johnson, 7500 Security Boulevard, Mail Stop: WB–06–05, Baltimore, Maryland 21244–1850.

In addition, an email copy in MS Word or PDF must be sent to: *FCHIP@cms.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Steven Johnson, (410) 786–3332 or *FCHIP@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: Please refer to file code CMS–5511–N on the application. Applicants are required to submit one unbound original and two copies to the address listed in the **ADDRESSES** section of this notice. In addition, an email copy in MS Word or PDF must be sent to: *FCHIP@cms.hhs.gov*. Because of staffing and resource limitations, we cannot accept applications by facsimile (FAX) transmission. Applications postmarked after the closing date, or postmarked on or before the closing date but not received in time, will be considered late.

I. Background

A. Legislative Authority

Section 123 of the Medicare Improvements for Patients and Providers Act of 2008, (MIPPA) (Pub. L. 110–275) as amended by section 3126 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), authorizes a demonstration project on community health integration models in certain rural counties to develop and test new models for the delivery of health care services to better integrate the delivery of acute care, extended care and other health care services, and improve access to care for Medicare and Medicaid beneficiaries residing in very sparsely populated areas.

The authorizing legislation defines distinct roles for this demonstration for the Centers for Medicare & Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA) in developing and implementing this project. HRSA was charged with awarding grants to eligible entities for the purpose of technical assistance and informing the Secretary of the Department of Health and Human Services (Secretary) on the specific needs of frontier communities, while CMS is to conduct a demonstration testing alternative reimbursement and administrative strategies.

This demonstration is commonly known as the Frontier Community Health Integration Project (FCHIP). CMS is hereby requesting applications for participation in this demonstration from eligible entities as defined in Section 123(d)(1)(B) of MIPPA. CMS interprets the eligible entity definition as meaning critical access hospitals (CAHs) that receive funding through the Rural Hospital Flexibility Program. The statute limits the Demonstration to no more than 4 States; it also restricts eligibility to CAHs within States with at least 65 percent of counties with 6 or less persons per square mile. With respect to these requirements, CMS is limiting applications to CAHs in Alaska, Montana, Nevada, North Dakota, and Wyoming.

The authorizing legislation mandates that the project last for 3 years. The law authorizes waiver of such provisions of the Medicare and Medicaid programs as are necessary to conduct the demonstration project. The authorizing legislation also requires the demonstration to be budget neutral, that is, to be structured such that Medicare expenditures under the demonstration do not to exceed the amount which the Secretary estimates would have been paid if the demonstration project were not implemented. This notice references CMS's request for proposals for the FCHIP demonstration, which sets forth project guidelines, conditions of participation, payment methodology, and application instructions.

The FCHIP demonstration is designed to improve access to certain services, the delivery of which is often not feasible at low volumes under current Medicare reimbursement but if integrated into the local delivery system, would lead to improved outcomes and greater efficiency in health care service delivery. Integration of services is intended as an intervention that is directed by the various providers serving the community so that the specific health care needs of residents are addressed in appropriate settings—either inpatient, outpatient, or at home. The desired outcome is to increase access to health care services, with the objective of supporting certain services so as to allow them to be financially feasible given the low patient volumes of a remote and sparsely populated area. Another objective is to decrease the number of avoidable hospital admissions, readmissions, and avoidable transfers to tertiary facilities, such that there is no net increase in Medicare spending for the affected population. To address the goal of increasing access with no net cost increase, we have identified four types of services for which this demonstration will provide financial support, and promote community health integration—these are: Nursing facility care within the CAH, telemedicine, ambulance, and home health. We have selected these services on the basis of research and literature review. Applicants should identify additional services of one or more of these types, beyond what is currently available. Applicants must address the need for these services, including how they enhance patient care options and the ability of beneficiaries to remain in their communities; and how quality of these services will be maintained, to assure care can safely be provided locally. We will also work in the development process of this project with State Medicaid agencies on their proposals for Medicaid-specific reimbursement mechanisms to support access to community-based health care services.

B. FCHIP Applications

In keeping with the authorizing legislation in section 123 of MIPPA, entities that meet the eligibility requirements will be able to apply for the demonstration. Specifically, an eligible entity must be located in either Alaska, Montana, Nevada, North Dakota, or Wyoming although CMS will select no more than 4 States to participate in the demonstration. Each entity in its application will be required to describe a proposal to enhance health-related services so as to complement those currently provided within the community and reimbursed by Medicare, Medicaid, or other third-party payers. The applicant must describe an integrated system of services and explain how these will better serve the community's health-related needs.

An entity applying for the demonstration will be required to demonstrate linkages (either ownership or contractual) with the providers of the identified additional services, such as nursing home, telemedicine, home health agency, or ambulance service. Specifically, to be approved for payment of telemedicine services under the demonstration's payment methodology, the applicant must demonstrate effective arrangements with distant site specialists who will participate in telemedicine linkages with providers within the communities. In addition, to be approved for ambulance services, the applicants must show transfer arrangements with essential providers.

Each applicant will be asked to submit an analysis of how its proposed project will be budget neutral and/or achieve cost savings. This will include projections of the number of patients that will gain access to services within the community that are supported by the demonstration, the cost of these services, and the resulting cost savings from averting transfers to out-of-area hospitals and/or avoidable hospitalizations. The applicant will be evaluated on the plausibility of this analysis, the ability to support projections with clinical evidence and the sensitivity of cost outcomes to the stated assumptions of change in services and patient behavior.

Interested and eligible parties can obtain complete solicitation and supporting information on the CMS

Web site at: *http://innovation.cms.gov/initiatives/index.html.* Paper copies can be obtained by writing to Steven Johnson at the address listed in the **ADDRESSES** section of this notice.

II. Collection of Information Requirements

The information collection requirements associated with this notice are subject to the Paperwork Reduction Act of 1995; however, the information collection requirements are currently approved under the information collection request associated with OMB control number 0938–0880 entitled ''Medicare Waiver Demonstration Applicant.'' Applicants must submit the Medicare Waiver Demonstration Application to be considered for this program.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 20, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–02062 Filed 1–31–14; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0053]

Designation of High-Risk Foods for Tracing; Request for Comments and for Scientific Data and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments and for scientific data and information.

SUMMARY: The Food and Drug Administration (''FDA'' or ''we'') is announcing the opening of a docket to obtain comments and scientific data and information that will help us to implement the section of the FDA Food Safety Modernization Act (FSMA) that requires FDA to designate high-risk foods. We are providing an opportunity for interested parties to submit comments and scientific data and information that will help us develop our process for implementing this provision.

DATES: Submit electronic or written comments and scientific data and information by April 7, 2014.

ADDRESSES: You may submit comments and scientific data and information, identified by Docket No. FDA–2014–N–0053, by any of the following methods:

Electronic Submissions

Submit electronic comments and scientific data and information in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments and scientific data and information.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2014–N–0053 for this notice. All comments and scientific data and information received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments and scientific data and information, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments and scientific data and information received, go to *http://www.regulations.gov* and insert the docket number found in brackets in the heading of this document into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sherri Dennis, Center for Food Safety and Applied Nutrition (HFS–005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1914.

SUPPLEMENTARY INFORMATION:

I. Background

A. FDA Food Safety Modernization Act Provision Requiring Designation of High-Risk Foods

On January 4, 2011, the President signed the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) into law. Section 204 of FSMA requires, among other things, the designation of high-risk foods. Specifically, section 204(d)(2)(A) of FSMA requires FDA to designate high-risk foods for which additional recordkeeping requirements are appropriate and necessary to protect the public health, and to do so not later than 1 year after the date of enactment of FSMA (and thereafter, if necessary). Section 204(d)(2)(B) requires FDA to publish the list of high-risk foods on the Internet Web site of FDA at the time when FDA issues final rules to establish the additional recordkeeping requirements for high-risk foods.

Section 204(d)(2)(A) of FSMA specifically states that the designation of high-risk foods must be based on the: (1) Known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to such food, taking into consideration foodborne illness data collected by the Centers for Disease Control and Prevention; (2) likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce such food; (3) point in the manufacturing process of the food where contamination is most likely to occur; (4) likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination; (5) likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food; and (6) likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.

Through this notice, we are establishing a docket to provide an opportunity for interested parties to provide comments and scientific data and information that will help us refine our draft approach to identifying high-risk foods, as required by section 204(d)(2) of FSMA. Section I.B summarizes our tentative draft approach for the review and evaluation of data to designate high-risk foods. Attached as a reference to this notice is a draft approach document in which we describe the process and methodology we are considering using for designating high-risk foods. After reviewing comments received in response to this notice on the draft approach described here, we plan to further revise the approach as necessary. We also anticipate that the approach will be reviewed by scientific experts (''peer reviewed'').

While section 204(d)(2)(A) of FSMA includes a statutory deadline within 1 year of the enactment of FSMA, FDA is issuing this notice to solicit comments and scientific data and information that will help us refine our draft approach to identifying high-risk foods. In section II.B, there are a number of specific