Demonstration grant. The program supports the movement of Medicaid beneficiaries with disabling and chronic conditions from institutions into the community. The award expands already funded tasks related to quality technical assistance provided to State grantees.

DATES: *Effective Date:* The program expansion is effective on the date of award (before September 30, 2011 through April 15, 2013).

FOR FURTHER INFORMATION CONTACT:

Anita Yuskauskas, (410) 786–0268.
Arun Natarajan, (410) 786–7455.

SUPPLEMENTARY INFORMATION:

I. Background

The need for additional funds is the result of an increase in the number of Money Follows the Person (MFP) State Grantees through the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148, enacted on March 23, 2010). Fifteen additional States received new MFP funds in January, 2011 under the Affordable Care Act. The increase in the number of States and programs resulting from the Affordable Care Act place more demand on the need for technical assistance to States developing and implementing quality improvement strategies, particularly given the complexity and vulnerability of the populations being served in MFP and the Congress' commitment to the Grant Program's success. The expansion was not calculated in the original National Quality Enterprise (NQE) budget because at the time of the original award, the Affordable Care Act money was not included in CMS' budget allocation.

The additional resources are necessary to assure the success of the individual placements, specifically, by facilitating sufficient quality mechanisms to address the unique needs of the populations with disabling and chronic conditions. These are the most vulnerable populations and a lack of quality and oversight mechanisms in place, may place individuals at risk.

II. Provisions of the Notice

We solicited a proposal from Thomson Reuters Healthcare to expand the National Home and Community-Based Services (HCBS) Quality Enterprise beyond the grant's present scope. The expansion was created by section 2403 of the Affordable Care Act, which amended section 6071 of the Deficit Reduction Act of 2005, the Money Follows the Person Rebalancing Demonstration. The provision expanded previous legislation to support State and CMS efforts to improve quality in a ''rebalanced'' long-term support system, and to demonstrate the ongoing benefits from and need for an effective HCBS QI Enterprise. The grant offered $1.2 million over 2 years through a program expansion supplement.

We requested that the Thomson Reuters Healthcare submit an abbreviated application addressing the expansion of the existing grant. The Grantee provided an updated quality technical assistance model and work plan focused on the following four major goals:

- Development of a process demonstrating consistency between the Grantee and CMS, and across all Grantee staff and subcontractors for providing technical assistance (Project Management, 1.1).
- The provision of technical assistance to states related to quality in home and community-based services programs (Technical Assistance, 2.1b).
- The provision of technical assistance to CMS staff related to the oversight of quality in HCBS programs (Technical Assistance, 2.1c).
- The ongoing development and maintenance of a national HCBS quality web-based technical assistance site and quality TA manuscripts (Technical Assistance, 2.1d and e).

As part of the application, based on the four major goals listed above, the Grantee submitted a 3 page project narrative describing the activities, and an accompanying budget revision, related to Grant #1LICMS030329/01, entitled ''The National HCBS Quality Enterprise: Assisting States to Achieve Enhanced Quality in a Rebalanced Environment''.

The documents included the following:

- *Cover Letter*—The letter included the current project director's name and a brief summary of the proposed project, submitted and signed by the authorized representative for this grant.
- *SF–424a (Budget Information—Non Construction Programs)*—The applicant provided the total costs for the remainder of the project for $1.2 million, with a break out of those costs in Section B ''Budget Categories'' of the SF–424a form. The costs proposed were for the additional costs only (not the cumulative total costs of the entire grant).
- *Detailed Budget Narrative*—The applicant provided a detailed breakdown of the aggregate numbers for the budget recorded on the Standard Form 424a ''Budget Information—Non Constructions Programs,'' including allocations for each major set of activities or proposed tasks. The proposed budget justification clearly described each cost element in the related budget category.
- *Project Narrative*—The project narrative (approximately 3 pages in length) provided a concise and complete description of the proposed project. It contained the information necessary for CMS to fully understand the additional work of the project. It covered all aspects of the project requirements (see criteria for writing the project narrative—four major goals).

Authority: Section 6071 Deficit Reduction Act of 2005.

Dated: September 20, 2011.

Daniel F. Kane,

Chief Grants Management Officer, Office of Acquisition and Grants Management, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–24986 Filed 9–27–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: State Council on Developmental Disabilities Program Performance Report.

OMB No.: 0980–0172.

Description: A Developmental Disabilities Council Program Performance Report is required by federal statute. Each State Developmental Disabilities Council must submit an annual report for the preceding fiscal year of activities and accomplishments. Information provided in the Program Performance Report will be used (1) in the preparation of the biennial Report to the President, the Congress, and the National Council on Disabilities and (2) to provide a national perspective on program accomplishments and continuing challenges. This information will also be used to comply with requirements in the Government Performance and Results Act of 1993.

Respondents: State Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Council on Developmental Disabilities Program Performance Report ..	55	1	138	7,590

Estimated Total Annual Burden Hours: 7,590.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. *E-mail address: infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–24967 Filed 9–27–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0362]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 28, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *Fax:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0139. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals—21CFR Parts 210 and 211 (OMB Control No. 0910–0139)—Extension

Under Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351(a)(2)(B)), a drug is adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with Current Good Manufacturing Practices (CGMPs) to ensure that such drug meets the requirements of the FD&C Act as to safety, and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

The FDA has the authority under Section 701(a) of the FD&C Act (21 U.S.C. 371(a)) to issue regulations for the efficient enforcement of the FD&C Act regarding CGMP procedures for manufacturing, processing, and holding drugs and drug products. The CGMP regulations help ensure that drug products meet the statutory requirements for safety and have their purported or represented identity, strength, quality, and purity characteristics. The information collection requirements in the CGMP regulations provide FDA with the necessary information to perform its duty to protect public health and safety. CGMP requirements establish accountability in the manufacturing and processing of drug products, provide for meaningful FDA inspections, and enable manufacturers to improve the quality of drug products over time. The CGMP recordkeeping requirements also serve preventive and remedial purposes and provide crucial information if it is necessary to recall a drug product.

The general requirements for recordkeeping under part 211 (21 CFR part 211) are set forth in § 211.180. Any production, control, or distribution record associated with a batch and required to be maintained in compliance with part 211 must be retained for at least one year after the expiration date of the batch and, for certain OTC drugs, three years after distribution of the batch (§ 211.180(a)).