

Information Collection: Annual Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Participation Report; **Use:** The baseline data collected is used to assess the effectiveness of state early and periodic screening, diagnostic and treatment (EPSDT) programs in reaching eligible children, by age group and basis of Medicaid eligibility, who are provided initial and periodic child health screening services, referred for corrective treatment, and receiving dental, hearing, and vision services. This assessment is coupled with the state's results in attaining the participation goals set for the state. The information gathered from this report, permits federal and state managers to evaluate the effectiveness of the EPSDT law on the basic aspects of the program. **Form Number:** CMS-416 (OCN#: 0938-0354); **Frequency:** Yearly; **Affected Public:** State, Local, or Tribal Governments; **Number of Respondents:** 56; **Total Annual Responses:** 56; **Total Annual Hours:** 1,568. (For policy questions regarding this collection contact Marsha Lillie-Blanton at 410-786-8856.)

2. **Type of Information Collection Request:** Reinstatement with change of a previously approved collection; **Title of Information Collection:** Quality Improvement Organization (QIO) Assumption of Responsibilities and Supporting Regulations; **Use:** The Peer Review Improvement Act of 1982 amended Title XI of the Social Security Act to create the Utilization and Quality Control Peer Review Organization (PRO) program which replaces the Professional Standards Review Organization (PSRO) program and streamlines peer review activities. The term PRO has been renamed Quality Improvement Organization (QIO). This information collection describes the review functions to be performed by the QIO. It outlines relationships among QIOs, providers, practitioners, beneficiaries, intermediaries, and carriers. **Form Number:** CMS-R-71 (OCN#: 0938-0445); **Frequency:** Yearly; **Affected Public:** Business or other for-profit and Not-for-profit institutions; **Number of Respondents:** 6,939; **Total Annual Responses:** 50,377; **Total Annual Hours:** 158,993. (For policy questions regarding this collection contact Coles Mercier at 410-786-2112.)

3. **Type of Information Collection Request:** Reinstatement without change of a previously approved collection; **Title of Information Collection:** Collection of Drug Pricing and Network Pharmacy Data from Medicare Prescription Drug Plans (PDPs and MA-PDs) and Supporting Regulations; **Use:** Both stand alone prescription drug

plans (PDPs) and Medicare Advantage Prescription Drug (MA-PDs) plans are required to submit drug pricing and pharmacy network data to us. These data are made publicly available to people with Medicare through the Medicare Prescription Drug Plan Finder web tool on <http://www.medicare.gov>. Drug prices vary across a plans pharmacy network based on the contracts that each plan negotiates with each pharmacy or pharmacy chain in their networks. The pharmacy networks can change during the course of the year as new pharmacies open, close, change ownership, or plans negotiate new contracts with pharmacies resulting in different dispensing fees for prescriptions. Drug prices also change frequently due to the daily fluctuation of the Average Wholesale Price (AWP), thus plans increase or decrease their drug prices to reflect these changes.

The purpose of the data is to enable prospective and current Medicare beneficiaries to compare, learn, select and enroll in a plan that best meets their needs. The database structure provides the necessary drug pricing and pharmacy network information to accurately communicate plan information in a comparative format. **Form Number:** CMS-10150 (OCN#: 0938-0951); **Frequency:** Yearly; **Affected Public:** Business or other for-profit and Not-for-profit institutions; **Number of Respondents:** 680; **Total Annual Responses:** 17,680; **Total Annual Hours:** 70,720. (For policy questions regarding this collection contact Jay Dobbs at 410-786-1182.)

Dated: August 6, 2013.

Martique Jones,

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

[FR Doc. 2013-19321 Filed 8-8-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-5506-N3]

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 Comprehensive ESRD Care Initiative

Letters of Intent submission period and extends the deadlines for the submission of the Comprehensive ESRD Care Initiative Letters of Intent and Applications to August 30, 2013. All potential applicants must submit a Letter of Intent to be eligible to submit an application.

DATES: *Letter of Intent Submission*

Deadline: Interested organizations must submit a non-binding letter of intent on or before August 30, 2013, by an online form at: <https://cms.gov.secure.force.com/cec>.

Application Submission Deadline: Interested organizations must submit an application on or before August 30, 2013, as described on the Innovation Center Web site at: <http://innovation.cms.gov/initiatives/comprehensive-ESRD-care/apply.html>. Updates on this initiative will also be posted to the Web site.

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.

On July 17, 2013, we published a notice in the **Federal Register** announcing an extension of deadlines. The new deadlines were July 19, 2013 for the Letter of Intent and August 1, 2013 for the application.

II. Provisions of the Notice

Since the publication of the July 17, 2013 notice, several stakeholders have requested additional time to prepare their applications and form partnerships. Therefore, for the Comprehensive ESRD Care Initiative, the Innovation Center is reopening the Letters of Intent submission period and extending the deadlines for submission of both the Letters of Intent and the Applications to August 30, 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: August 5, 2013.

Marilyn Tavenner,
Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013–19351 Filed 8–8–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Home Visiting: Approaches to Father Engagement and Father’s Experiences.

OMB No.: New Collection.

Description: The Office of Planning, Research, and Evaluation (OPRE) in the Administration for Children and Families (ACF) is proposing an information collection activity for the

Home Visiting: Approaches to Father Engagement and Father’s Experiences Study.

This study will document strategies used by home visiting programs to engage and serve fathers and the perceptions of the fathers regarding the programs. The findings will be of broad interest to many home visiting programs that desire to increase the active engagement of fathers.

Data collection will involve semi-structured discussions and interviews with administrators and managers of select home visiting programs as well as staff about the objectives, experiences, and specific methods and approaches used by program operators that have successfully engaged fathers.

Data collection will also include semi-structured discussions and interviews with invited and/or participating fathers about their expectations, perceptions, and opinions of the home visiting program and experiences with the program.

Respondents: Administrators and managers of select home visiting programs, home visiting staff, and participating and invited fathers.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Discussion Guide for use with Fathers	250	83	1	2	166
Discussion Guide for use with Home Visiting Program Administrators, Managers, and Staff	50	17	1	2	34

Estimated Total Annual Burden Hours: 200.

In compliance with the requirements of Section 3506(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: OPRE Reports Clearance Officer. Email address: OPREinfocollection@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 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, Administration for Children and Families.

[FR Doc. 2013–19337 Filed 8–8–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0471]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Prescription Drug User Fee Cover Sheet; Form FDA 3397

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Prescription Drug User Fee Cover Sheet; Form FDA 3397” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, 1350 Piccard