

all applicants. In addition, eliminating the error correction window will help NIH reduce the time needed to process applications and forward them through the peer review process.

The error correction window was established at a time when an application could take multiple days to get processed by Grants.gov and NIH's eRA systems. The lengthy processing time meant that applicants who applied on time might not receive feedback on the status of their submissions in time to address system identified errors/warnings until after the due date, unless they applied well in advance.

During the initial transition the error correction window also provided an opportunity for applicants to become familiar with the use of the new SF424 (R&R) applications and the new way that long standing business rules would be enforced by electronic systems upon submission.

Since 2005, combined system processing times have improved dramatically, with applications now taking minutes to process through both systems on average instead of days. This improvement provides applicants timely feedback on the status of their applications and allows them to address any system identified errors and warnings immediately, as the systems can process multiple submissions within a short period of time. NIH also has policies in place that do not rely on the error correction window to ensure that applicants are protected from possible eRA Commons or Grants.gov system issues that might keep an application from being received by the submission deadline.

Additionally, elimination of the error correction window will not affect an applicant's ability to submit late applications under the existing NIH Policy on Late Submission of Grant Applications (NOT-OD-06-086 available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-086.html>) or for those who have provided substantial review service to NIH to take advantage of NIH's continuous submission policy (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-026.html>).

NIH is accepting comments from individuals and organizations on the impact of this change. We are also interested in feedback on possible timing of the change. Is there support for making the change in the next 3-6 months, a year, or is more time needed to make the change should the agencies decide to move forward?

Date: March 9, 2010.

Sally J. Rockett,

Acting Deputy Director for Extramural Research, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10146]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Notice of Denial of Medicare Prescription Drug Coverage; *Use:* Section 1860D-4(g)(1) of the Social Security Act requires Part D plan sponsors that deny prescription drug coverage to provide a written notice of the denial to the enrollee. The purpose of this notice is to provide information to enrollees when prescription drug coverage has been denied, in whole or in part, by their Part D plans. The notice must be readable, understandable, and state the specific reasons for the denial. The notice must also remind enrollees about their rights and protections related to requests for prescription drug coverage and include an explanation of both the standard and expedited redetermination processes and the rest of the appeal process. For a list of changes, refer to the summary of changes document. *Form Number:*

CMS-10146 (OMB#: 0938-0976); *Frequency:* Daily; *Affected Public:* Business or other for-profits; *Number of Respondents:* 456; *Total Annual Responses:* 290,344; *Total Annual Hours:* 145,172. (For policy questions regarding this collection contact Kathryn M. Smith at 410-786-7623. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *May 11, 2010*:

1. *Electronically.* You may submit 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) 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.

Dated: March 8, 2010.

Michelle Shortt,

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

[FR Doc. 2010-5429 Filed 3-11-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-2744, CMS-10304 and CMS-10282]

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

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the

Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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 function; (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.

1. Type of Information Collection

Request: Reinstatement without change of a previously approved collection; **Title of Information Collection:** End Stage Renal Disease (ESRD) Medical Information Facility Survey; **Form Number:** CMS-2744 (OMB#: 0938-0447); **Use:** The End Stage Renal Disease (ESRD) Medical Information Facility Survey form (CMS-2744) is completed annually by Medicare-approved providers of dialysis and transplant services. The CMS-2744 is designed to collect information concerning treatment trends, utilization of services and patterns of practice in treating ESRD patients. The information is used to assess and evaluate the local, regional and national levels of medical and social impact of ESRD care and is used extensively by researchers and suppliers of services for trend analysis. The information is available on the CMS Dialysis Facility Compare Web site and will enable patients to make informed decisions about their care by comparing dialysis facilities in their area.

Frequency: Yearly; **Affected Public:** Business or other for-profit, not-for-profit institutions; **Number of Respondents:** 5,465; **Total Annual Responses:** 5,465; **Total Annual Hours:** 43,720. (For policy questions regarding this collection contact Connie Cole at 410-786-0257. For all other issues call 410-786-1326.)

2. Type of Information Collection

Request: New collection; **Title of Information Collection:** Information Collection Requirements and Supporting Information for Chronic Kidney Disease Surveys under the 9th Scope of Work; **Form Number:** CMS-10304 (OMB#: 0938-New); **Use:** The Centers for Medicare & Medicaid Services (CMS) and the U.S. Department of Health and Human Services (DHHS)

are requesting OMB clearance for the Chronic Kidney Disease (CKD) Partner Survey and the Chronic Kidney Disease (CKD) Provider Survey. The Prevention CKD Theme is a component of the Prevention Theme of the Quality Improvement Organization (QIO) Program's 9th Scope of Work (SOW). The statutory authority for this scope of work is found in Part B of Title XI of the Social Security Act (the Act) as amended by the Peer Review Improvement Act of 1982. The Act established the Utilization and Quality Control Peer Review Organization Program, now known as the Quality Improvement Organization (QIO) Program.

The goal of the Prevention CKD Theme is to detect the incidence, decrease the progression of CKD, and improve care among Medicare beneficiaries through provider adoption of timely and effective quality of care interventions; participation in quality incentive initiatives; beneficiary education; and key linkages and collaborations for system change at the state and local level. In addition to improving the quality of care for the elderly and frail-elderly, this Theme aims to reduce the rate of Medicare entitlement by disability through the delay and prevention of end-stage renal disease (ESRD); thus resulting in higher quality care and significant savings to the Medicare Trust Fund.

The CKD Partner Survey constitutes a new information collection to be used by CMS to obtain information on how QIO collaboration with partners facilitates systems change within the QIO's respective state. The CKD Partner Survey will be a census administered to 350 collaborative partners in the 9th SOW. The CKD Partner Survey will be administered via telephone. Responses will be entered into a pre-programmed Computer-Assisted Telephone Interviewing (CATI) interface. The results of the survey shall be used for inpatient quality indicators (IQI) by the QIO. CMS will also use the results to assess how partner organizations and their perspective of the QIO's role are implementing system change.

Similarly, the CKD Provider Survey constitutes a new information collection to be used by CMS to obtain information on how QIO collaboration with physician practices facilitates systems change within the QIO's respective state. The CKD Provider Survey will be administered via telephone and the Web. Responses collected by phone will be entered into a pre-programmed Computer-Assisted Telephone Interviewing (CATI) interface. Responses collected by Web will be

housed on a secure server and database. The results of the survey shall be used for inpatient quality indicators (IQI) by the QIO. CMS will also use the results to assess how physicians' practices and their perspective of the QIO's role are implementing system change.

Frequency: Yearly; **Affected Public:** Private Sector—business or other for-profits and not-for profit institutions; **Number of Respondents:** 1,350; **Total Annual Responses:** 1,350; **Total Annual Hours:** 337.5. (For policy questions regarding this collection contact Robert Kambic at 410-786-1515. For all other issues call 410-786-1326.)

3. Type of Information Collection

Request: New collection; **Title of Information Collection:** Conditions of Participation for Comprehensive Outpatient Rehabilitation Facilities (CORFs) and supporting regulations in 485.50, 485.51, 485.54, 485.56, 485.58, 485.60, 485.62, 485.64, 485.66, 485.70, and 485.74.; **Form Number:** CMS-10282 (OMB#: 0938-New); **Use:** The Conditions of Participation (CoPs) and accompanying requirements specified in the regulations are used by our surveyors as a basis for determining whether a comprehensive outpatient rehabilitation facility (CORF) qualifies to be awarded a Medicare provider agreement. CMS believes the health care industry practice demonstrates that the patient clinical records and general content of records are necessary to ensure the well-being and safety of patients and that professional treatment and accountability are a normal part of industry practice. **Frequency:** Yearly; **Affected Public:** Business or other for-profit, not-for-profit institutions; **Number of Respondents:** 446; **Total Annual Responses:** 446; **Total Annual Hours:** 30,105. (For policy questions regarding this collection contact Monique Howard 410-786-3869. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on April 12, 2010:

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk

Officer, Fax Number: (202) 395-6974, E-mail: OIRA_submission@omb.eop.gov.

Dated: March 8, 2010.

Michelle Shortt,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Proposed Project: Substance Abuse Prevention and Treatment Block Grant Synar Report Format, FFY 2011-2013— (OMB No. 0930-0222)—Revision

Section 1926 of the Public Health Service Act [42 U.S.C. 300x-26] stipulates that funding Substance Abuse Prevention and Treatment (SAPT) Block Grant agreements for alcohol and drug abuse programs for fiscal year 1994 and subsequent fiscal years require States to have in effect a law providing that it is unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18. This section further requires that States conduct annual, random, unannounced inspections to ensure compliance with the law; that the State submit annually a report describing the results of the inspections, describing the activities carried out by the State to enforce the required law, describing the success the State has achieved in reducing the availability of tobacco products to individuals under the age of 18, and describing the strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought.

Before making an award to a State under the SAPT Block Grant, the Secretary must make a determination that the State has maintained compliance with these requirements. If a determination is made that the State is not in compliance, penalties shall be

applied. Penalties ranged from 10 percent of the Block Grant in applicable year 1 (FFY 1997 SAPT Block Grant Applications) to 40 percent in applicable year 4 (FFY 2000 SAPT Block Grant Applications) and subsequent years. Respondents include the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, Palau, Micronesia, and the Marshall Islands.

Regulations that implement this legislation are at 45 CFR 96.130, are approved by OMB under control number 0930-0163, and require that each State submit an annual Synar report to the Secretary describing their progress in complying with section 1926 of the PHS Act. The Synar report, due December 31 following the fiscal year for which the State is reporting, describes the results of the inspections and the activities carried out by the State to enforce the required law; the success the State has achieved in reducing the availability of tobacco products to individuals under the age of 18; and the strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought.

SAMHSA's Center for Substance Abuse Prevention will request OMB approval of revisions to the current report format associated with Section 1926 (42 U.S.C. 300x-26). The report format is minimally changing. Any changes in either formatting or content are being made to simplify the reporting process for the States and to clarify the information as the States report it; both outcomes will facilitate consistent, credible, and efficient monitoring of Synar compliance across the States and will reduce the reporting burden by the States. All of the information required in the new report format is already being collected by the States. Most of the specific revisions appear in Section I (Compliance Progress) of the report format and include clarifications to Questions 4a, 5b, 5e and 5f. Additionally, three new questions (5c, 5d and 5g) have been added and two items have been added to Question 7b. Information on these additions appears below:

Question 5c: Level of Enforcement—This question, which asks the State to select whether enforcement is conducted only at those outlets randomly selected for the Synar survey, only at a subset of outlets not randomly selected for the Synar survey, or a combination of the two, has been newly added to the ASR format. It has been added to provide additional information

about State enforcement programs, which is frequently requested by partner agencies and can also be used to target technical assistance.

Question 5d: Frequency of Enforcement—This question, which asks the State to select whether every tobacco outlet in the State did or did not receive at least one enforcement compliance check in the last year, has been newly added to the ASR format. It has been added to provide additional information about State enforcement programs, which is frequently requested by partner agencies and can also be used to target technical assistance.

Question 5g: Relationship of State Synar Program to FDA-Funded Enforcement Program—This question, which asks the State to describe the relationship between the State's Synar program and the Food and Drug Administration (FDA)-funded enforcement program, has been added to the ASR format. The Family Smoking Prevention and Tobacco Control Act, recently signed into law by President Obama, requires the FDA to reissue the 1996 regulation aimed at reducing young people's access to tobacco products and curbing the appeal of tobacco to the young. This regulation must be reissued by April 2010. As part of the implementation of this regulation, FDA will be contracting with States to enforce new Federal youth access provisions. This question asks the State to describe the relationship and coordination between its Synar program and the enforcement program funded by FDA.

Question 7b. Synar Survey Results for States that Do Not Use the Synar Survey Estimation System (SSES)—Two items have been added to this question (accuracy rate and completion rate). These items were added to ensure that the same statistical parameters are asked of both States that do and do not use the SSES to analyze their Synar survey results.

Additionally, in Appendix B (Synar Survey Sampling Methodology), the following changes are being made with respect to the Annual Synar Report:

Question 10. Provide the following information about sample size calculation for the current FFY Synar survey. This question has been added to Appendix B and asks the State to provide information about the specific input values used to calculate the effective, target and original sample sizes for the current FFY Synar survey. This question will reduce the need for SAMHSA/CSAP to request additional clarifying information from the State when SAMHSA/CSAP is unable to