DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10190, CMS-R-52, CMS-10492 and CMS-10416]

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by **[Insert date 60 days after date of publication in the Federal Register]**:

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and recommendations must be

submitted in any one of the following ways:

1. Electronically. You may send 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) that are 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.

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. E-mail 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:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see ADDRESSES).

CMS-10190 State Plan Preprints to Implement Sections 6083, 6036, 6041, 6042, 6043, and 6044 of the Deficit Reduction Act (DRA) of 2005

CMS-R-52 Conditions for Coverage of Suppliers of End Stage Renal Disease (ESRD) Services and Supporting Regulations

CMS-10492 Data Submission for the Federally-facilitated Exchange User Fee Adjustment

CMS-10416 Blueprint for Approval of Affordable Health Insurance Marketplaces

Under the Paperwork Reduction Act (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 requires federal agencies to publish a 60-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.

Information Collections

1. Type of Information Collection Request: Reinstatement without change of a previously approved collection; Title of Information Collection: State Plan Preprints to Implement Sections 6083, 6036, 6041, 6042, 6043, and 6044 of the Deficit Reduction Act (DRA) of 2005;

Use: State Medicaid agencies will complete the templates. We will review the information to determine if the state has met all of the DRA requirements that the state has chosen to implement. If the requirements are met, we will approve the amendments to the state's Title XIX plan giving the state the authority to implement the flexibilities. For a state to receive Medicaid Title XIX funding, there must be an approved Title XIX state plan. With respect to section 6043, if a state adopts the cost-sharing provision for the non-emergency use of an emergency room, a hospital will be required to inform a beneficiary of the cost of the copayment and the availability of the service at a lesser or nearly no co-pay facility. That hospital will coordinate the referral. Form Number: CMS-10190 (OCN: 0938-0993); Frequency: Occasionally; Affected Public: Private sector - Business or other for-profits, Not-for-profit institutions, and State, Local, or Tribal Governments; Number of Respondents: 56; Total Annual Responses: 4,016; Total Annual Hours: 699. (For policy questions regarding this collection contact Rhonda Simms at 410-786-1200.)

2. Type of Information Collection Request: Reinstatement with change of a previously approved collection; Title of Information Collection: Conditions for Coverage of Suppliers of End Stage Renal Disease (ESRD) Services and Supporting Regulations; Use: The information collection requirements described herein are part of the Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities. The requirements fall into two categories: record keeping requirements and reporting requirements. With regard to the record keeping requirements, we use these conditions for coverage to certify health care facilities that want to participate in the Medicare or Medicaid programs. For the reporting requirements, the information is needed to assess and ensure proper distribution and effective utilization of ESRD

treatment resources while maintaining or improving quality of care. The recordkeeping requirements imposed by this collection are no different than other conditions for coverage in that they reflect comparable standards developed by industry organizations such as the Renal Physicians Association, American Society of Transplant Surgeons, National Kidney Foundation, and the National Association of Patients on Hemodialysis and Transplantation. Form Number: CMS-R-52 (OCN: 0938-0386); Frequency: Annually; Affected Public: Business or other for-profit; Number of Respondents: 6,464; Total Annual Responses: 139,110; Total Annual Hours: 523,454. (For policy questions regarding this collection contact Lauren Oviatt at 410-786-4683.)

3. Type of Information Collection Request: New collection (Request for a new OMB control number); Title of Information Collection: Data Submission for the Federally-facilitated Exchange User Fee Adjustment; Use: The final rule "Coverage of Certain Preventive Services Under the Affordable Care Act" published by the Departments of Health and Human Services (HHS), the Treasury, and Labor on July 2, 2013 (78FR 39870), sets forth regulations regarding coverage for certain preventive services under section 2713 of the Public Health Service Act, as added by the Patient Protection and Affordable Care Act, as amended, and incorporated into the Employee Retirement Income Security Act of 1974 and the Internal Revenue Code. Section 2713 of the Public Health Service Act requires coverage without cost sharing of certain preventive health services, including certain contraceptive services, in non-exempt, non-grandfathered group health plans and health insurance coverage. The final rule establishes accommodations with respect to group health plans established or maintained by eligible organizations (and group health insurance coverage offered in connection with such plans). Eligible organizations are required to self-certify that they are eligible for this accommodation

and provide a copy of such self-certification to their third party administrators. The final rule also set forth processes and standards to fund the payments for the contraceptive services that are provided for participants and beneficiaries in self-insured plans of eligible organizations under the accommodation described previously, through an adjustment in the Federally-facilitated Exchange (FFE) user fee payable by an issuer participating in an FFE.

In order to facilitate the FFE user fee adjustment, and ensure that these user fee adjustments reflect payments for contraceptive services provided under this accommodation and that the adjustment is applied to the appropriate participating issuer in an FFE, the final rule requires an information collection from applicable participating issuers and third party administrators. In particular, the final regulations at 45 CFR §156.50(d)(2)(i) provides that a participating issuer who seeks an FFE user fee adjustment must submit to HHS in the year following the benefit year in which payments for contraceptive services were made under the previously mentioned accommodation, identifying information for the participating issuer, each third party administrator, and each self-insured group health plan, as well as the total dollar amount of the payments for contraceptive services that were provided during the applicable calendar year under the accommodation. The final regulation at 45 CFR 156.50(d)(2)(iii) also requires the third party administrator to submit to HHS identifying information for the third party administrator, the participating issuer, and each self-insured group health plan, as well as the total number of participants and beneficiaries in each self-insured group health plan during the applicable calendar year, the total dollar amount of payments made for contraceptive services, and an attestation that the payments for contraceptive services were made in compliance with 26 CFR 54.9815-2713A(b)(2) or 29 CFR 2590.715-2713A(b)(2).

Furthermore, to determine the potential number of submissions provided by third party administrators and allow HHS to prepare to receive submissions in calendar year 2015, the final regulation at 45 CFR 156.50(d)(2)(ii) requires third party administrators to submit to HHS a notification that the third party administrator intends for a participating issuer to seek an FFE user fee adjustment, by the later of January 1, 2014, or the 60th calendar day following the date on which the third party administrator receives a copy of a self-certification from an eligible organization.

The burden associated with these processes includes the time for applicable participating issuers and third party administrators to submit identifying information and total payments made for contraceptive services in the prior calendar year. HHS is unable to estimate the number of organizations that will seek user fee adjustments and seeks comments on this number in this notice. We anticipate that participating issuers in an FFE seeking a user fee adjustment and third party administrators with respect to which the FFE user fee adjustment is received will submit this information electronically. Form Number: CMS-10492 (OCN: 0938-NEW); Frequency: Once, Yearly; Affected Public: Private Sector – Business or other for-profits and Not-for-profit institutions; Number of Respondents: 10; Total Annual Responses: 1; Total Annual Hours: 8. (For policy questions regarding this collection contact Ariel Novick at 301-492-4309.)

4. Type of Information Collection Request: Revision of a currently approved collection. Title of Information Collection: Blueprint for Approval of Affordable Health Insurance Marketplaces; Use: All states (including the 50 States, and the District of Columbia herein referred to as states) have the opportunity under Section 1311(b) of the Affordable Care Act to establish an Exchange (referred to herein as Marketplace). The original information collection

request for the State Marketplace Blueprint Data Collection Tool specified a single reporting tool for all the various Marketplace types. This request revises the collection process by having separate collection tools for each type of Marketplace with the goal of reducing the burden. Also, at the time of the original request, the tool was partially paper-based. During the intervening time, we have has completed the on-line implementation of the tool and will transition all future applications to that system.

Given the innovative nature of Marketplaces and the statutorily-prescribed relationship between the secretary and states in their development and operation, it is critical that the Secretary work closely with states to provide necessary guidance and technical assistance to ensure that states can meet the prescribed timelines, federal requirements, and goals of the statute.

States seeking to establish a Marketplace must build a Marketplace that meets the requirements set out in section 1311(d) of the Affordable Care Act and 45 CFR 155.105. In order to ensure that a state seeking approval as a State-based Marketplace, State-based SHOP, or State Partnership Marketplace in the Federally-facilitated Marketplace meet all applicable requirements, the Secretary will require a state to submit a Blueprint for approval and to demonstrate operational readiness through virtual or on-site readiness review. Submission of the Blueprint Application will be online. Form Number: CMS-10416 (OCN: 0938-1172); Frequency: Once; Affected Public: State, Local, or Tribal governments; Number of Respondents: 51; Number of Responses: 63; Total Annual Hours: 11,283. (For policy questions regarding this collection contact Sarah Summer 301-492-4443.)

Dated: August 13, 2013 _____

Martique Jones

Deputy Director, Regulations Development Group

Office of Strategic Operations and Regulatory Affairs

Billing Code: 4120-01-U-P

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