specifically required the Secretary to establish and implement programs under which competitive bidding areas are established throughout the United States for contract award purposes for the furnishing of certain competitively priced items and services for which payment is made under Medicare Part B. This program is commonly known as the ''Medicare DMEPOS Competitive Bidding Program.''

CMS conducted its first round of bidding for the Medicare DMEPOS Competitive Bidding Program in 2007 with the help of its contractor, the Competitive Bidding Implementation Contractor. CMS published a Request for Bids instructions and accompanying forms for suppliers to submit their bids to participate in the program. During this first round of bidding, DMEPOS suppliers from across the U.S. submitted bids identifying the MSA(s) to service and the competitively bid item(s) they wished to furnish to Medicare beneficiaries. CMS evaluated these bids and contracted with those suppliers that met all program requirements. The first round of bidding was successfully implemented on July 1, 2008.

On July 15, 2008, however, Congress delayed this program in section 154 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). MIPPA mandated certain changes to the competitive bidding program which included, but are not limited to: a delay of Rounds 1 (competition began in 2009) and 2 of the program (competition began in 2011 in 70 specific MSAs); the exclusion of Puerto Rico and negative pressure wound therapy from Round 1 and group 3 complex rehabilitative power wheelchairs from all rounds of competition; a process for providing feedback to suppliers regarding missing financial documentation; and a requirement for contract suppliers to disclose to CMS information regarding subcontracting relationships. Section 154 of the MIPPA specified that the competition for national mail order items and services may be phased in after 2010 and established a rule requiring that a bidder demonstrate that its bid covers 50 percent (or higher) of the types of diabetic testing strips, based on volume (the ''50 percent rule'') for national mail order competitions. As required by MIPPA, CMS conducted the competition for the Round 1 Rebid in 2009. The Round 1 Rebid contracts and prices became effective on January 1, 2011.

The Affordable Care Act, enacted on March 23, 2010, expanded the Round 2 competition by adding an additional 21 MSAs, bringing the total MSAs for Round 2 to 91. The competition for Round 2 began in December 2011. CMS also began a competition for National Mail Order of Diabetic Testing Supplies at the same time as Round 2. The Round 2 and National Mail-Order contracts and prices have a target implementation date of July 1, 2013.

The MMA requires the Secretary to re-compete contracts not less often than once every 3 years. Most Round 1 Rebid contracts will expire on December 31, 2013. (Round 1 Rebid contracts for mail-order diabetic testing supplies ended on December 31, 2012.) Consequently, we are currently in the process of re-competing the competitive bidding contracts in the Round 1 Rebid areas.

The most recent approval for this information collection request (ICR) was issued by OMB on October 10, 2012. Since then, CMS has decided to sequentially update the paperwork burden necessary to administer the program as it expands nationally and cycles through multiple rounds of competition. Specifically, we are now seeking to update our burden estimates for certain contract maintenance forms for Round 2 and the national mail-order competitions. These include Form C and the Contract Supplier's Disclosure of Subcontractors form. We are also requesting approval of two additional forms: the Change of Ownership (CHOW) Purchaser Form and the CHOW Contract Supplier Notification Form, which will be utilized in all rounds of competition. Finally, we are retaining without change Forms A, B, and D and their associated burden under this ICR. We note that the information collection for Forms A and B is already complete. We intend to continue use of the forms in future rounds of competition.

Form Number: CMS–10169 (OCN: 0938–1016). *Frequency:* Occasionally. *Affected Public:* Private Sector (business or other for-profits) and Individuals or households. *Number of Respondents:* 19,035. *Total Annual Responses:* 19,035. *Total Annual Hours:* 9,311. (For policy questions regarding this collection contact Michael Keane at 410–786–4495. 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 Email 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 June 10, 2013.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer. Fax Number: (202) 395–6974. Email: *OIRA_submission@omb.eop.gov*.

Dated: May 6, 2013.

Martique Jones,

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

[FR Doc. 2013–11033 Filed 5–9–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–R–70, CMS–R–72, CMS–R–247, CMS–10287, CMS–R–43, CMS–855(POH), CMS–2552–10, and CMS–10062]

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:* Reinstatement with a change of a previously approved collection; *Title of Information Collection:* Information Collection Requirements in HSQ–110, Acquisition, Protection and Disclosure of Peer review Organization Information and Supporting Regulations in 42 CFR, Sections 480.104, 480.105, 480.116, and 480.134; *Use:* The Peer Review Improvement Act of 1982 authorizes quality improvement organizations

(QIOs), formally known as peer review organizations (PROs), to acquire information necessary to fulfill their duties and functions and places limits on disclosure of the information. The QIOs are required to provide notices to the affected parties when disclosing information about them. These requirements serve to protect the rights of the affected parties. The information provided in these notices is used by the patients, practitioners and providers to: obtain access to the data maintained and collected on them by the QIOs; add additional data or make changes to existing QIO data; and reflect in the QIO's record the reasons for the QIO's disagreeing with an individual's or provider's request for amendment.: *Form Number:* CMS–R–70 (OCN: 0938–0426); *Frequency:* Reporting—On occasion; *Affected Public:* Business or other for-profits; *Number of Respondents:* 400; *Total Annual Responses:* 21,200; *Total Annual Hours:* 42,400. (For policy questions regarding this collection contact Coles Mercier at 410–786–2112. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Information Collection Requirements in 42 CFR 478.18, 478.34, 478.36, 478.42, QIO Reconsiderations and Appeals; *Use:* In the event that a beneficiary, provider, physician, or other practitioner does not agree with the initial determination of a Quality Improvement Organization (QIO) or a QIO subcontractor, it is within that party's rights to request reconsideration. The information collection requirements at 42 CFR 478.18, 478.34, 478.36, and 478.42, contain procedures for QIOs to use in reconsideration of initial determinations. The information requirements contained in these regulations are imposed on QIOs to provide information to parties requesting the reconsideration. These parties will use the information as guidelines for appeal rights in instances where issues are actively being disputed. *Form Number:* CMS–R–72 (OCN: 0938–0443); *Frequency:* Reporting—On occasion; *Affected Public:* Individuals or Households and Business or other for-profit institutions; *Number of Respondents:* 2,590; *Total Annual Responses:* 5,228; *Total Annual Hours:* 2,822. (For policy questions regarding this collection contact Coles Mercier at 410–786–2112. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* Reinstatement with a change of a previously approved collection; *Title of Information Collection:* Expanded Coverage for Diabetes Outpatient Self-Management Training Services and Supporting Regulations Contained in 42 CFR 410.141, 410.142, 410.143, 410.144, 410.145, 410.146, 414.63; *Use:* According to the National Health and Nutrition Examination Survey (NHANES), as many as 18.7 percent of Americans over age 65 are at risk for developing diabetes. The goals in the management of diabetes are to achieve normal metabolic control and reduce the risk of micro- and macro-vascular complications. Numerous epidemiologic and interventional studies point to the necessity of maintaining good glycemic control to reduce the risk of the complications of diabetes. Despite this knowledge, diabetes remains the leading cause of blindness, lower extremity amputations and kidney disease requiring dialysis. Diabetes and its complications are primary or secondary factors in an estimated 9 percent of hospitalizations (Aubert, RE, et al., Diabetes-related hospitalizations and hospital utilization. In: Diabetes in America. 2nd ed. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Disease, NIH, Pub. No 95–1468–1995: 553–570). Overall, beneficiaries with diabetes are hospitalized 1.5 times more often than beneficiaries without diabetes. HCFA–3002–F ''Expanded Coverage for Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements'', provided for uniform coverage of diabetes outpatient self-management training services. These services include educational and training services furnished to a beneficiary with diabetes by an entity approved to furnish the services. The physician or qualified non-physician practitioner treating the beneficiary's diabetes would certify that these services are needed as part of a comprehensive plan of care. This rule established the quality standards that an entity would be required to meet in order to participate in furnishing diabetes outpatient self-management training services. It set forth payment amounts that have been established in consultation with appropriate diabetes organizations. It implements section 4105 of the Balanced Budget Act of 1997. *Form Number:* CMS–R–247 (OCN: 0938–0818); *Frequency:* Recordkeeping and Reporting—Occasionally; *Affected Public:* Business or other for-profit institutions; *Number of Respondents:* 5327; *Total Annual Responses:* 63,924; *Total Annual Hours:* 197,542. (For policy questions regarding this collection contact Kristin Shifflett at 410–786–4133. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Quality of Care Complaint Form; *Use:* In accordance with Section 1154(a)(14) of the Social Security Act, Quality Improvement Organizations (QIOs) are required to conduct appropriate reviews of all written complaints submitted by beneficiaries concerning the quality of care received. The Medicare Quality of Care Complaint Form will be used by Medicare beneficiaries to submit quality of care complaints. This form will establish a standard form for all beneficiaries to utilize and ensure pertinent information is obtained by QIOs to effectively process these complaints. *Form Number:* CMS–10287 (OCN: 0938–1102); *Frequency:* Reporting—Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 3,500; *Total Annual Responses:* 3,500; *Total Annual Hours:* 583. (For policy questions regarding this collection contact Coles Mercier at 410–786–2112. For all other issues call 410–786–1326.)

5. *Type of Information Collection Request:* Reinstatement with change of a currently approved collection; *Title of Information Collection:* Conditions of Participation for Portable X-ray Suppliers and Supporting Regulations in 42 CFR Sections 486.104, 486.106, 486.110; *Use:* The requirements contained in this information collection request are classified as conditions of participation or conditions for coverage. These conditions are based on a provision specified in law relating to diagnostic X-ray tests ''furnished in a place of residence used as the patient's home,'' and are designed to ensure that each supplier has a properly trained staff to provide the appropriate type and level of care, as well as, a safe physical environment for patients. CMS uses these conditions to certify suppliers of portable X-ray services wishing to participate in the Medicare program. This is standard medical practice and is necessary in order to help to ensure the well-being, safety and quality professional medical treatment accountability for each patient. *Form Number:* CMS–R–43 (OCN: 0938–0338); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 578; *Total Annual Responses:* 578; *Total Annual Hours:* 948. (For policy questions regarding this collections contact Alesia Hovatter at 410–786–6861. For all other issues call 410–786–1326.)

6. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Annual Report of Physician-Owned Hospital Ownership and/or Investment Interest; *Use:* Section 6001 of the Affordable Care Act (ACA) requires Medicare hospitals to report whether they have any physician owners including immediately family members of the physician.

Currently the CMS 855A captures basic ownership/managerial information on providers. The CMS 855A was revised in July 2011 and a specific attachment designed to capture physician-owned hospital ownership and investment interest data was added to the form. The attachment is being removed from the CMS 855A application because the annual reporting requirement for physician-owned hospitals is not required for Medicare enrollment processing. This physician-owned hospital data collection is mandated to be reported on an annual basis. Additionally, the ACA prohibits the expansion of current physician-owned hospitals and banned the establishment of new ones making the CMS 855A the improper method to collect this required annual report.

CMS is requesting the physician-owned hospital ownership information, investment information or both, previously collected in Attachment 1 of the CMS 855A enrollment application to become a stand-alone form with a unique OMB number for the following reasons:

- The physician-owned data collection has a small targeted audience of approximately 140 physician-owned hospitals nationwide.
- The physician-owned data collection is required annually, as noted above.
- The data required under section 6001 is more specific than the data currently collected on the CMS–855A provider enrollment application.
- The data is not required for Medicare provider enrollment purposes.

Form Number: CMS–855 (POH)(OCN: 0938-New); *Frequency:* Reporting—Yearly; *Affected Public:* Private Sector—Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 140; *Total Annual Responses:* 140; *Total Annual Hours:* 140. (For policy questions regarding this collection contact Kim McPhillips at 410–786–5374. For all other issues call 410–786–1326.)

7. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Hospital and Health Care Complexes and Supporting Regulations in 42 CFR 413.20 and 413.24; *Use:* Medicare Part A institutional providers must provide adequate cost data to receive Medicare reimbursement (42 CFR 413.24(a)). Providers must submit the cost data to their Medicare Fiscal Intermediary (FI)/Medicare Administrative Contractor (MAC) through the Medicare cost report (MCR). We are submitting a revision of the Hospital and Hospital Health Care Complex Cost Report, Form CMS–2552–10. Form CMS 2552–10 is used by hospitals participating in the Medicare program to report the health care costs to determine the amount of reimbursable costs for services rendered to Medicare beneficiaries. The revisions were caused by legislative requirements in the Patient Protection and Affordable Care Act of 2010 and the Temporary Payroll Tax Cut Continuation Act of 2011. *Form Number:* CMS–2552–10 (OCN: 0938–0050); *Frequency:* Reporting—Yearly; *Affected Public:* Private Sector—Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 6,171; *Total Annual Responses:* 6,171; *Total Annual Hours:* 4,153,083. (For policy questions regarding this collection contact Nadia Massuda at 410–786–5834. For all other issues call 410–786–1326.)

8. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection. *Title of Information Collection:* Collection of Diagnostic Data from Medicare Advantage Organizations for Risk Adjusted Payments. *Use:* CMS will use the data to make risk adjusted payment under Parts C. MA and MA–PD plans will use the data to develop their Parts C bids. As required by law, CMS also annually publishes the risk adjustment factors for plans and other interested entities in the Advance Notice of Methodological Changes for MA Payment Rates (every February) and the Announcement of Medicare Advantage Payment Rates (every April). Lastly, CMS issues monthly reports to each individual plan that contains the CMS–HCC and RxHCC models' output and the risk scores and reimbursements for each beneficiary that is enrolled in their plan. *Form Number:* CMS–10062 (OMB 0938–0838). *Frequency:* Quarterly. *Affected Public:* Private Sector (business or other for-profit and not-for-profit institutions). *Number of Respondents:* 766. *Total Annual Responses:* 830,000. *Total Annual Hours:* 40,650. (For policy questions regarding this collection contact Michael Massimini at 410–786–1566. 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 Email 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 July 9, 2013:

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: May 6, 2013.

Martique Jones,

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

[FR Doc. 2013–11035 Filed 5–9–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1181]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medicated Feed Mill License Application; Extension

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.