under the Medicare and Medicaid programs. An OPO must be certified and designated by the Secretary as an OPO and must meet performance-related standards prescribed by the Secretary. The corresponding regulations are found at 42 CFR Part 486 (Conditions for Coverage of Specialized Services Furnished by Suppliers) under subpart G (Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations).

Since each OPO has a monopoly on organ procurement within its donation service area, CMS must hold OPOs to high standards. Collection of this information is necessary for CMS to assess the effectiveness of each OPO and determine whether it should continue to be certified as an OPO and designated for a particular donation service area by the Secretary or replaced by an OPO that can more effectively procure organs within the donation service area. *Form Number:* CMS–R–13 (OMB#: 0938–0688); *Frequency:* Occasionally; *Affected Public:* Not-for-profit institutions; *Number of Respondents:* 79; *Total Annual Responses:* 79; *Total Annual Hours:* 15,178. (For policy questions regarding this collection contact Diane Corning at 410–786–8486. For all other issues call 410–786–1326.)

7. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration; *Use:* The End Stage Renal Disease (ESRD) Medical Evidence Report is completed for all ESRD patients either by the first treatment facility or by a Medicare-approved ESRD facility when it is determined by a physician that the patient's condition has reached that stage of renal impairment that a regular course of kidney dialysis or a kidney transplant is necessary to maintain life. The data reported on the CMS–2728 is used by the Federal Government, ESRD Networks, treatment facilities, researchers and others to monitor and assess the quality and type of care provided to end stage renal disease beneficiaries. The data collection captures the specific medical information required to determine the Medicare medical eligibility of End Stage Renal Disease claimants. *Form Number:* CMS–2728 (OMB#: 0938–0046); *Frequency:* Occasionally; *Affected Public:* Individuals or households; *Number of Respondents:* 100,000; *Total Annual Responses:* 100,000; *Total Annual Hours:* 75,000. (For policy questions regarding this collection contact Connie Cole at 410–786–0257. 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 August 17, 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: June 15, 2010.

Michelle Shortt,

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

[FR Doc. 2010–14781 Filed 6–17–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10179, CMS–R–234, CMS–2540–10, CMS–10108, CMS–10315, CMS–10302, CMS–2744 and CMS–2746]

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. T*ype of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Requests by Hospitals for an Alternative Cost-to-Charge Ratio. *Use:* Section 1886(d)(5)(A) of the Act provides for additional Medicare payments to Inpatient Prospective Payment System (IPPS) hospitals for cases that incur extraordinarily high costs. To qualify for outlier payments, a case must have costs above a predetermined threshold amount (a dollar amount by which the estimated cost of a case must exceed the Medicare payment). Hospital-specific cost-to-charge ratios are applied to the covered charges for a case to determine the estimated cost of the case. In general, additional outlier payments for eligible cases are made based on a marginal cost factor of 80 percent, i.e. a fixed percentage of the costs. Therefore, if the estimated cost of the case exceeds the Medicare payment for that discharge plus the outlier threshold, generally Medicare will pay the hospital 80 percent of the excess amount. The outlier threshold is updated annually at the beginning of the Federal Fiscal Year. *Form Number:* CMS–10179 (OMB#: 0938–1020); *Frequency:* Occasionally; *Affected Public:* Private Sector and Business or other for-profits, Not-for-profit institutions; *Number of Respondents:* 18; *Total Annual Responses:* 18; *Total Annual Hours:* 144. (For policy questions regarding this collection contact Michael Treitel at 410–786–4552. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Subpart D—Private Contracts and Supporting Regulations contained in 42 CFR 405.410, 405.430, 405.435, 405.440, 405.445, and 405.455. *Use:* Section 4507

of Balancing Budget Act (BBA) 1997 amended section 1802 of the Social Security Act to permit certain physicians and practitioners to opt-out of Medicare and to provide through private contracts services that would otherwise be covered by Medicare. Under such contracts the mandatory claims submission and limiting charge rules of section 1848(g) of the Act would not apply. Subpart D and the Supporting Regulations contained in 42 CFR 405.410, 405.430, 405.435, 405.440, 405.445, and 405.455, counters the effect of certain provisions of Medicare law that, absent section 4507 of BBA 1997, preclude physicians and practitioners from contracting privately with Medicare beneficiaries to pay without regard to Medicare limits. *Form Number:* CMS–R–234 (OMB#: 0938–0730); *Frequency:* Biennially; *Affected Public:* Private Sector and Business or other for-profits; *Number of Respondents:* 26,820; *Total Annual Responses:* 26,820; *Total Annual Hours:* 7,197. (For policy questions regarding this collection contact Fred Grabau at 410–786–0206. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Skilled Nursing Facility Health Care Complex Cost Report. *Use:* Providers of services participating in the Medicare program are required under sections 1815(a), and 1861(v)(1)(A) of the Social Security Act to submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries. The CMS–2540–10 cost report is needed to determine the amount of reimbursement that is due to these providers furnishing medical services to Medicare beneficiaries.

CMS is requesting review and approval of revisions made to the Skilled Nursing Facility (SNF) Cost Report FORM CMS–2540–10, (for cost reporting periods beginning on or after December 1, 2010) which replaces the existing FORM CMS 2540–96. Revisions made to update the forms currently in use are incorporated within this request for approval. Refer to the supporting documents for a list of revision to the cost reporting forms. *Form Number:* CMS–2540–10 (OMB#: 0938–0463); *Frequency:* Yearly; *Affected Public:* Private Sector and Business or other for-profits; *Number of Respondents:* 15,037; *Total Annual Responses:* 15,037; *Total Annual Hours:* 2,706,660. (For policy questions regarding this collection contact Edwin Gill at 410–786–4525. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Managed Care Regulations for 42 CFR 438.6, 438.8, 438.10, 438.12, 438.50, 438.56, 438.102, 438.114, 438.202, 438.204, 438.206, 438.207, 438.240, 438.242, 438.402, 438.404, 438.406, 438.408, 438.410, 438.414, 438.416, 438.604, 437.710, 438.722, 438.724, and 438.810; *Use:* These information collection requirements implement regulations that allow States greater flexibility to implement mandatory managed care program, implement new beneficiary protections, and eliminate certain requirements viewed by State agencies as impediments to the growth of managed care programs. Information collected includes information about managed care programs, grievances and appeals, enrollment broker contracts, and managed care organizational capacity to provide health care services. *Form Number:* CMS–10108 (OMB#: 0938–0920); *Frequency:* Reporting: Occasionally; *Affected Public:* State, Local, or Tribal Government; *Number of Respondents:* 39,114,558; *Total Annual Responses:* 4,640,344; *Total Annual Hours:* 3,930,093.5. (For policy questions regarding this collection contact Angela Garner at 410–786–7062. For all other issues call 410–786–1326.)

5. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Patient Safety Survey Under the 9th Scope of Work: Nursing Home in Need (NHIN). *Use:* The Centers for Medicare & Medicaid Services (CMS) is requesting OMB clearance for the Nursing Homes in Need (NHIN) Survey. The NHIN is a component of the Patient Safety 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 QIO in each State will provide special technical assistance to a small number of nursing homes in need of assistance with quality improvement efforts. This special technical assistance will be for the QIO to conduct a root cause analysis (RCA) with one nursing home in its state per year (three over three years). Under this component, it is expected that within the first quarter of the contract period, CMS will assign one nursing home to each QIO. The determination of which nursing homes are eligible under this component will be made by CMS. Some of these facilities may meet criteria for Special Focus Facilities (SFF). The intent of this component is that each State QIO will work with three nursing homes over the three-year contract period; these assignments are expected to be spaced out so that each State QIO will get one nursing home assigned approximately every 12 months.

The NHIN Survey is a new information collection to be used by CMS to obtain information on nursing home satisfaction with technical assistance strategies delivered as a component of the NHIN. The NHIN Survey will be a census of 53 nursing homes working with their respective QIOs. The survey will be conducted one time for each of the nursing homes assisted in the first two years under the 9th SOW and it will be conducted twice with nursing homes assisted in the third year. The information collected through this survey will allow CMS to help focus the NHIN task to maximize the benefit to participating nursing homes. The NHIN Survey will be administered via telephone by trained and experienced interviewers. Responses will be entered into a pre-programmed Computer-Assisted Telephone Interviewing (CATI) interface.

The NHIN Survey will include questions to determine if the QIO has conducted a root cause analysis and developed an action plan. These will be followed by questions about their satisfaction with the QIO and their perceived value of the QIO's assistance. The NHIN Survey will address the following:

- Background information;
- Current work—information and assessment;
- Satisfaction with QIOs;
- Value of QIO assistance;
- Sources of information; and
- Respondent comments.

All survey protocol and correspondence will be translated into Spanish and bi-lingual telephone interviewers will be used as needed. *Form Number:* CMS–10315 (OMB#: 0938–New); *Frequency:* Occasionally; *Affected Public:* Businesses and other for-profit and not-for-profit institutions; *Number of Respondents:* 53; *Total Annual Responses:* 106; *Total Annual Hours:* 17.5 hours (years 1 and 2), 35 hours (year 3). (For policy questions regarding this collection contact Bob Kambic 410–786–1515. For all other issues call 410–786–1326.)

6. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of*

Information Collection: Collection Requirements for Compendia for Determination of Medically-accepted Indications for Off-label Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen *Use:* Congress enacted the Medicare Improvement of Patients and Providers Act (MIPPA). Section 182(b) of MIPPA amended Section 1861(t)(2)(B) of the Social Security Act (42 U.S.C. 1395x(t)(2)(B)) by adding at the end the following new sentence: 'On and after January 1, 2010, no compendia may be included on the list of compendia under this subparagraph unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interest.' We believe that the implementation of this statutory provision that compendia have a "publicly transparent process for evaluating therapies and for identifying potential conflicts of interests" is best accomplished by amending 42 CFR 414.930 to include the MIPPA requirements and by defining the key components of publicly transparent processes for evaluating therapies and for identifying potential conflicts of interests.

All currently listed compendia will be required to comply with these provisions, as of January 1, 2010, to remain on the list of recognized compendia. In addition, any compendium that is the subject of a future request for inclusion on the list of recognized compendia will be required to comply with these provisions. No compendium can be on the list if it does not fully meet the standard described in section 1861(t)(2)(B) of the Act, as revised by section 182(b) of the MIPPA. *Form Number:* CMS–10302 (OMB#: 0938–1078); *Frequency:* Reporting, Recordkeeping and Third-party disclosure; *Affected Public:* Business and other for-profits and Not-for-profit institutions; *Number of Respondents:* 845; *Total Annual Responses:* 900; *Total Annual Hours:* 5,135. (For policy questions regarding this collection contact Brijet Burton at 410–786–7364. For all other issues call 410–786–1326.)

7. *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 website 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.)

8. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* End Stage Renal Disease Death Notification P.L. 95–292; 42 CFR 405.2133, 45 CFR 5–5b; 20 CFR Parts 401 and 422E *Use:* The ESRD Death Notification (CMS–2746) is completed by all Medicare-approved ESRD facilities upon the death of an ESRD patient. Its primary purpose is to collect fact of death and cause of death of ESRD patients. Certain other identifying information (e.g., name, Medicare claim number, and date of birth) is required for matching purposes. Federal regulations require that the ESRD Networks examine the mortality rates of every Medicare-approved facility within its area of responsibility. The Death Form provides the necessary data to assist the ESRD Networks in making decisions that result in improved patient care and in cost-effective distribution of ESRD resources. The data is used by the ESRD Networks to verify facility deaths and to monitor facility performance. *Form Number:* CMS–2746 (OMB#: 0938–0448); *Frequency:* On occasion; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 5,173; *Total Annual Responses:* 82,768; *Total Annual Hours:* 41,384. (For policy questions regarding this collection contact Connie Cole at 410–786–0257. 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 July 19, 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: June 15, 2010.

Michelle Shortt,

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

[FR Doc. 2010–14780 Filed 6–17–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0083]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed

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 July 19, 2010.

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 0910–0339. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr.,