determine the following for each candidate product:

a. Product package insert or detailed instructions for use

b. Detailed information to determine if the product is calibrated to a recognized standard

c. Preliminary data demonstrating suitability for validation studies

Organizations that have products selected by CDC for this comparative analysis will be required to enter into an appropriate agreement prior to the transfer of any material to CDC. Sample agreements may be viewed at the following Web site: *http://www.cdc.gov/od/ads/techtran/forms.htm.*

All information submitted to CDC will be kept confidential as allowed by relevant federal law, including the Freedom of Information Act (5 U.S.C. 552) and the Trade Secrets Act (18 U.S.C. 1905). Only information submitted within thirty days of publication of this notice will be reviewed to determine if the offered product(s) will be acceptable for possible inclusion in this comparative analysis.

Responses are preferred in electronic format and can be e-mailed to the attention of Jacqueline Goolsby *jgoolsby@cdc.gov.* Mailed responses can be sent to the following address: Jackie Goolsby, Branch Manager, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, Division of Bacterial Diseases, 404–639–1319 (Phone), 404–639–3059 (Fax), 1600 Clifton Rd. NE., Mail Stop C–09, Atlanta, GA 30333.

FOR FURTHER INFORMATION CONTACT:

Technical

Dr. M. Lucia Tondella, Division of Bacterial Diseases, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road NE., Mail Stop D–11, Atlanta, GA 30333. Telephone (404) 639–1239, E-Mail at *mtondella@cdc.gov.*

Business

Lisa Blake-DiSpigna, Technology Development Coordinator, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road NE., Mail Stop A–42, Atlanta, GA 30333. Telephone (404) 639–2620, E-Mail at *LBlake-DiSpigna@cdc.gov.*

Dated: December 3, 2008.

James D. Seligman,

Chief Information Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–29580 Filed 12–12–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10272, CMS–R–254, CMS–29/30, CMS–372, CMS–10001, CMS–10009, CMS–10242 and CMS–R–52]

Agency Information Collection Activities: Submission for OMB Review; 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), 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:* New collection; *Title of Information Collection:* Hospital Leadership Quality Assessment Tool (HLQAT); *Use:* In 2006, the Hospital Leadership Collaborative (HLC) launched a public-private partnership to develop a CMS-endorsed self-assessment tool, ''The Hospital Leadership and Quality Assessment Tool'' (HLQAT) to assist hospitals in the improvement of quality through enhanced hospital governance, executive, physician, and clinical engagement. Hospitals leaders will take the HLQAT instrument via Web-based technology. This function will be carried out in conjunction with CMS and the Quality Improvement Organization (QIO) 9th Scope of Work (SOW), to convey the importance of this effort in relation to Medicare and other public priorities. This administration of the HLQAT seeks responses from approximately a dozen leaders in each hospital, including physicians (*e.g.*, CEO, CMO), board members, director-level, and mid-level clinical managers—these responses can provide a multi-level representation of hospital leadership showing its commitment to institutional change. *Form Number:* CMS–10272 (OMB# 0938–New); *Frequency:* Occasionally; *Affected Public:* Private Sector—Business or Other for-profits; *Number of Respondents:* 18,000; *Total Annual Responses:* 36,000; *Total Annual Hours:* 44,820.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* National Medicare & You Education Program (NMEP) Survey of Medicare Beneficiaries *Use:* The Centers for Medicare and Medicaid Services is requesting a revision of this information collection request to continue to collect information from Medicare beneficiaries, caregivers, health care providers, and health information providers. It is critical for this agency to obtain feedback from the aforementioned groups so that the agency can accurately assess the needs of the Medicare audience. Using random digit dial and/or an administrative sample, members of the Medicare audience will be called and asked to complete the survey via telephone. The results of this survey will be compiled and studied so that communication may be amended to benefit Medicare's audience. The survey has the following objectives: To assess satisfaction with and knowledge of the Medicare program; to gather information on health behaviors and quality of health care; to determine the most used source for Medicare information; and to gather information from health care provider and health information providers. *Form Number:* CMS–R–254 (OMB# 0938–0738); *Frequency:* Once; *Affected Public:* Individuals and Households, Private Sector—Business or other for-profits; *Number of Respondents:* 7,000; *Total Annual Responses:* 7,000; *Total Annual Hours:* 1,750.

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Request for Certification as Rural Health Clinic (RHC) and RHC Survey Report Form and Supporting Regulations in 42 CFR 491.1–491.11; *Use:* The CMS–29 is utilized as an application to be completed by suppliers of RHC services requesting participation in the

Medicare/Medicaid programs. This form initiates the process of obtaining a decision as to whether the conditions for certification are met as a supplier of RHC services. It also promotes data reduction or introduction to and retrieval from the Automated Survey Process Environment (ASPEN) and related survey and certification databases by the CMS Regional Offices. *Form Number:* CMS–29/30 (OMB# 0938–0074); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 766; *Total Annual Responses:* 766; *Total Annual Hours:* 192.

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Annual Report on Home and Community Based Services Waivers and Supporting Regulations in 42 CFR 440.180 and 441.300–310.; *Use:* States within an approved waiver under section 1915(c) of the act are required to submit a report annually in order for CMS to: (1) Verify that State assurances regarding waiver cost-neutrality are met; and, (2) Determine the waiver's impact on the type, amount, and cost of services provided under the State Plan and health welfare of recipients. *Form Number:* CMS–372 (OMB# 0938–0272); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 49; *Total Annual Responses:* 305; *Total Annual Hours:* 13,115.

5. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Health Insurance Portability and Accountability Act (HIPAA) Nondiscrimination Provisions and Supporting Regulations in 45 CFR 146.121(h) and 121(i)(2)(i); *Use:* If coverage has been denied to any individual because the sponsor of a self-funded non-Federal governmental plan had exempt the plan from the nondiscrimination requirements under 45 CFR 146.180 ''Treatment of Non-Federal Governmental Plans'', and the plan sponsor subsequently chooses to bring the plan into compliance, the plan sponsor must comply with the requirements under 45 CFR 146.121(i)(2)(i) ''Special Transitional Rule for Self-Funded Non-Federal Governmental Plans Exempted under 45 CFR 146.180''. To bring the plan into compliance with the requirements, the plan must notify the individual that the plan will be coming into compliance, afford the individual an opportunity to enroll, specify the effective date of compliance, and inform the individual regarding any enrollment restrictions that may apply under the terms of the plan once the plan is in compliance. *Form Number:* CMS–10001 (OMB# 0938–0827); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 18; *Total Annual Responses:* 18; *Total Annual Hours:* 194.

6. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Health Insurance Portability and Accountability Act (HIPAA) Nondiscrimination Provisions and Supporting Regulations in 45 CFR 146.121 (f)(2)(v)(A); *Use:* Section 146.121 of the regulations requires Health plans or issuers to disclose in all plan materials the terms of certain wellness programs including the availability of a reasonable alternative standard. Plan participants and their dependents need this information to understand the rights they have under HIPAA. States and the Federal government may need the information supplied by issuers to properly perform their regulatory functions. *Form Number:* CMS–10009 (OMB# 0938–0819); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 2,600; *Total Annual Responses:* 2,600; *Total Annual Hours:* 1,300.

7. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Emergency and Non-Emergency Ambulance Transports and Beneficiary Signature Requirements in 42 CFR 424.36(b); *Use:* In the CY 2008 Physician Fee Schedule (PFS) final rule with comment period, we created an additional exception to the beneficiary signature requirements in § 424.36(b) for emergency ambulance transports (72 FR 66406). The exception allows ambulance providers and suppliers to sign the claim on behalf of the beneficiary, at the time of transport, provided that certain documentation requirements are met. Following publication of the CY 2008 PFS final rule with comment period, ambulance provider and supplier stakeholders requested that we extend the exception in § 424.36(b)(6) to non-emergency ambulance transports, in instances where the beneficiary is physically or mentally incapable of signing the claim form.

The current submission of this information collection request relates to the collection of documentation pertaining to non-emergency ambulance transports. In addition, we are updating the collection of information that relates to the collection of documentation pertaining to emergency ambulance transports. *Form Number:* CMS–10242 (OMB# 0938–1049); *Frequency:* Occasionally; *Affected Public:* Private Sector—Business or Other for-profits and Not-for-profit institutions; *Number of Respondents:* 9,000; *Total Annual Responses:* 13,185,835; *Total Annual Hours:* 1,098,819.

8. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Conditions for Coverage of Suppliers of End Stage Renal Disease (ESRD) Services and Supporting Regulations Contained in 42 CFR 405.2100–405.2171; *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: Recordkeeping requirements and reporting requirements. With regard to the recordkeeping requirements, CMS uses 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 (OMB#: 0938–0386); *Frequency:* Recordkeeping and Reporting—Annually; *Affected Public:* Business or other for-profit and Federal government; *Number of Respondents:* 5,415; *Total Annual Responses:* 5,415; *Total Annual Hours:* 131,720.

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 *January 14, 2009.*

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974.

Date: *December 5, 2008.*

Michelle Shortt,

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

[FR Doc. E8–29542 Filed 12–12–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10110, CMS–R–250 and CMS–668B]

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:* Manufacturer Submission of Average Sales Price (ASP) data for Medicare Part B Drugs and Biologicals; *Use:* Section 1847A of the Social Security Act requires that the Medicare Part B payment amounts for covered drugs and biologicals not paid on a cost or prospective payment basis be based upon manufacturers' average sales price data submitted to CMS. CMS will utilize the ASP data to determine the Medicare Part B drug payment amounts. *Form Number:* CMS–10110 (OMB# 0938–0921); *Frequency:* Quarterly; *Affected Public:* Business or other for-profits; *Number of Respondents:* 180; *Total Annual Responses:* 720; *Total Annual Hours:* 28,800.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* MPAF Data and Supporting Regulations in 42 CFR 413.337, 413.343, 424.32 and 483.20; *Use:* Resident assessment information that Skilled Nursing Facilities (SNFs) are required to submit is described under section 42 CFR 413.343 and 483.20. The manner necessary to administer the payment rate methodology is described under section 42 CFR 413.337. An assessment form comprised of a subset of resident assessment information has been developed for use by SNFs to satisfy Medicare payment requirements, in lieu of a full Minimum Data Set. The associated burden is the time the SNF staff is required to complete the Medicare PPS Assessment Form (MPAF), SNF staff time to encode, and SNF staff time spent in transmitting the data. *Form Number:* CMS–R–250 (OMB# 0938–0739); *Frequency:* Occasionally; *Affected Public:* Business or other for-profits and Not-for-profit institutions, State, Local, or Tribal Governments, and Federal Governments; *Number of Respondents:* 15,039; *Total Annual Responses:* 3,834,945; *Total Annual Hours:* 2,704,764.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Post Clinical Laboratory Survey Questionnaire and Supporting Regulations in 42 CFR 493.1771, 493.1773, and 493.1777; *Use:* This form is used by the State agency to determine a laboratory's compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This information is needed for a laboratory's CLIA certification and recertification. *Form Number:* CMS–668B (OMB# 0938–0653); *Frequency:* Biennially; *Affected Public:* Business or other for-profits and Not-for-profit institutions. State, Local, or Tribal Government, Federal Government; *Number of Respondents:* 21,000; *Total Annual Responses:* 10,500; *Total Annual Hours:* 2,625.

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 *February 13, 2009:*

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: December 5, 2008.

Michelle Shortt,

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

[FR Doc. E8–29543 Filed 12–12–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0602]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of the Impact of Coupons Embedded in Direct-to-Consumer Prescription Drug Print Advertisements on Consumer Perceptions of Product Risks and Benefits

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for