achieving its participation goal and to respond to inquiries. Respondents are State Medicaid Agencies. The data is due April 1 of every year so States need to have the form and instructions as soon as possible in order to report timely. *Frequency:* Yearly; *Affected Public:* State, Tribal and Local governments; *Number of Respondents:* 56; *Total Annual Responses:* 112; *Total Annual Hours:* 1,568. (For policy questions regarding this collection contact Cindy Ruff at 410–786–5916. 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 *October 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: September 3, 2010.

Martique Jones,

Director, Regulations Development Division-B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010–22592 Filed 9–9–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–10207, CMS–10244, CMS–10343 and CMS–R–131]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and 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:* Extension of a currently approved collection; *Title of Information Collection:* Physician Self-Referral Exceptions for Electronic Prescribing and Electronic Health Records; *Use:* Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directed the Secretary to create an exception to the physician self-referral prohibition in section 1877 of the Social Security Act for certain arrangements in which a physician receives compensation in the form of items or services (not including cash or cash equivalents) ("nonmonetary remuneration") that is necessary and used solely to receive and transmit electronic prescription information. Also, CMS created a separate regulatory exception for certain arrangements involving the provision of nonmonetary remuneration in the form of electronic health records software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records.

The conditions for both exceptions require that arrangements for the items and services provided must be set forth in a written agreement, be signed by the parties involved, specify the items or services being provided and the cost of those items or services, and cover all of the electronic prescribing and/or electronic health records technology to be provided by the donating entity. CMS would use the collected information for enforcement purposes; specifically, if we were investigating the financial relationships between the donors and the physicians to determine whether the provisions in the exceptions were met. *Form Number:* CMS–10207 (OMB#: 0938–1009); *Frequency:* Occasionally; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 9,796; *Total Annual Responses:* 38,959; *Total Annual Hours:* 12,451.5. (For policy questions regarding this collection contact Kristin Bohl at 410–786–8680. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid State Program Integrity Assessment (SPIA); *Use:* Under the provisions of the Deficit Reduction Act (DRA) of 2005, the Congress directed CMS to establish the Medicaid Integrity Program (MIP), CMS' first national strategy to combat Medicaid fraud, waste, and abuse. CMS has two broad responsibilities under the MIP: (1) Reviewing the actions of individuals or entities providing services or furnishing items under Medicaid; conducting audits of claims submitted for payment; identifying overpayments; and educating providers and others on payment integrity and quality of care; and (2) Providing effective support and assistance to States to combat Medicaid fraud, waste, and abuse.

In order to fulfill the second of these requirements, CMS developed SPIA. CMS uses SPIA to collect data on State Medicaid program integrity activities, develop reports for each State based on these data, determine areas to provide States with technical support and assistance, and develop measures to assess States' performance. *Form Number:* CMS–10244 (OMB#: 0938–1033); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 1,400. (For policy questions regarding this collection contact Mary Jo Cook at 410–786–3231. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* New collection; *Title of Information Collection:* State Plan Preprint for Medicaid Recovery Audit Contractors (RACs); *Use:* Under section 1902(a)(42)(B)(i) of the Social Security Act, States are required to establish programs to contract with one or more Medicaid RACs for the purpose of identifying underpayments and recouping overpayments under the State plan and any waiver of the State plan with respect to all services for which payment is made to any entity under such plan or waiver. Further, the statute requires States to establish programs to contract with Medicaid RACs in a manner consistent with State law, and generally in the same manner as the Secretary contracts with Medicare RACs.

State programs contracted with Medicaid RACs are not required to be fully operational until after December 31, 2010. States may submit, to CMS, a State Plan Amendment (SPA) attesting

that they will establish a Medicaid RAC program. States have broad discretion regarding the Medicaid RAC program design and the number of entities with which they elect to contract. Many States already have experience utilizing contingency-fee-based Third Party Liability recovery contractors. *Form Number:* CMS–10343 (OMB#: 0938–NEW); *Frequency:* Once; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; Total *Annual Responses:* 56; *Total Annual Hours:* 56. (For policy questions regarding this collection contact Mary Jo Cook at 410–786–3231 or Eva Tetteyfio at 410–786–3653. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Advance Beneficiary Notice of Noncoverage (ABN); *Use:* Under section 1879 of the Social Security Act, a physician, provider, practitioner, or supplier of items or services participating in the Medicare program, or taking a claim on assignment, may bill a Medicare beneficiary for items or services usually covered under Medicare, but denied in an individual case under one of the several statutory exclusions, if they inform the beneficiary, prior to furnishing the service, that Medicare is likely to deny payment. Sections 42 CFR 411.404(b) and (c), and 411.408(d)(2) and (f), require written notice be provided to inform beneficiaries in advance of potential liability for payment. *Form Number:* CMS–R–131 (OMB#: 0938–0566); *Frequency:* Reporting: Weekly, Monthly, Yearly, Biennially and Occasionally; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 1,326,282 ; *Total Annual Responses:* 43,725,850; *Total Annual Hours:* 5,099,309. (For policy questions regarding this collection contact Evelyn Blaemire at 410–786–1803. 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 *November 9, 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: September 3, 2010.

Martique Jones,

Director, Regulations Development Division-B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010–22593 Filed 9–9–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–E–0041]

Determination of Regulatory Review Period for Purposes of Patent Extension; SAPHRIS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SAPHRIS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product SAPHRIS (asenapine). SAPHRIS is an atypical antipsychotic indicated for acute treatment of schizophrenia in adults and acute treatment of manic or mixed episodes associated with bipolar I disorder in adults. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SAPHRIS (U.S. Patent No. 5,763,476) from NV Organon, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 3, 2010, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SAPHRIS represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.