430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

The notice to Missouri announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Mr. Steven E. Renne, Interim Director, Missouri, Department of Social Services, P.O. Box 1527, Broadway State Office Building, Jefferson City, MO 65102–1527.

Dear Mr. Renne: I am responding to your request for reconsideration of the decision to disapprove the Missouri State plan amendment (SPA) 05–11, which was submitted on September 27, 2005, and disapproved on June 16, 2006.

Under SPA 05–11, Missouri was proposing to alter the provider qualifications and payment methodology for personal care assistance services by transferring administrative responsibility for such providers from one State agency to another.

At issue in this reconsideration is: (1) whether SPA 05–11 complied with the requirements of section 1902(a) of the Social Security Act (the Act) generally, and 1902(a)(30) of the Act specifically, in providing for coverage of services for which the State plan did not contain a clear payment methodology that the State had shown was consistent with efficiency and economy; (2) whether the proposed coverage of personal care services in SPA 05–11 was consistent with the definition of personal care services in section 1905(a)(24) of the Act (which is integral to the definition of ''medical assistance'' at sections 1905(a) and 1902(a)(10) of the Act), and applicable regulations, including services of registered nurses.

This amendment was disapproved because it did not comport with the requirements of section 1902(a) generally, section 1902(a)(30)(A) specifically, and section 1905(a)(24) of the Act and implementing regulations.

Section 1902(a)(30)(A) of the Act requires that State plans have methods and procedures to assure that payments are consistent with economy, efficiency, and quality of care. While this SPA would have provided for coverage of personal care services, the methodology for paying for such services was not clearly set forth in the State plan. Moreover, Missouri provided information that personal care services and personal care assistance services are reimbursed based on a 15-minute service unit. However, the State did not provide to the Centers for Medicare & Medicaid Services (CMS) the rate for the 15-minute service unit or any rate derivation information to conclude that this payment is economic or efficient. In light of this, CMS cannot conclude that coverage of the proposed services would be accomplished through an efficient and economical payment methodology in compliance with the requirements of section 1902(a)(30)(A).

Further, the overall requirement in section 1902(a) for a State plan, and the specific requirement at section 1902(a)(30)(A) for methods and procedures related to payment, as implemented by Federal regulations at 42 CFR §§ 430.10 and 447.252(b) require that the State plan include a comprehensive description of the methods and standards used to set payment rates. Payment methodologies should be understandable and auditable. In addition, since the plan is the basis for Federal financial participation, it is important that the plan language be clear and unambiguous. The proposed methodology does not provide sufficient information for providers to determine the payment amount to which they are entitled.

Additionally, the Medicaid personal care services benefit does not include registered nurse services in the definitions at section 1905(a)(24) of the Act and Federal regulations at 42 CFR 440.167, and thus such coverage is not within the scope of ''medical assistance'' defined under section 1905(a) and 1902(a)(10) of the Act. As CMS had indicated in the State Medicaid Manual Part 4, section 4480(C), although personal care services may be similar to, or overlap, some services furnished by home health aides, ''skilled services that may be performed only by a health professional are not considered personal care services.'' It would not be consistent with efficiency and economy for a State to pay higher rates to attract overqualified individuals (registered nurses) to provide personal care services. Registered nurse services may instead be furnished as a home health service under 42 CFR 440.70(b)(1), or as private duty nursing services as defined at 42 CFR 440.80(a). Furthermore, there is no provision in Medicaid for payment for training of personal care providers, including the ''training and supervision'' of the ''qualified staff licensed by the Department of Mental Health'' or supervision visits by a registered nurse.

For these reasons, and after consulting with the Secretary as required by Federal regulations at 42 CFR section 430.15(c)(2), I disapproved this SPA on June 16, 2006.

I am scheduling a hearing on your request for reconsideration to be held on November 15, 2006, at the Richard Bolling Federal Building, 601 E. 12th Street, Kansas City, MO 64106–2898, the Kansas City Room, to reconsider the decision to disapprove SPA 05–11. If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed at 42 CFR part 430.

I am designating Ms. Kathleen Scully-Hayes as the presiding officer. If these arrangements present any problems, please contact the presiding officer at (410) 786–2055. In order to facilitate any communication which may be necessary between the parties to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing.

Sincerely,

Mark B. McClellan, M.D., PhD

(Section 1116 of the Social Security Act (42 U.S.C. section 1316); 42 CFR section 430.18)

(Catalog of Federal Domestic Assistance program No. 13.714, Medicaid Assistance Program)

Dated: September 20, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E6–15780 Filed 9–26–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Title IV–E Foster Care Eligibility Reviews; Child and Family Services Reviews; Anti-Discrimination Enforcement.

OMB No.: 0970–0214.

Description: The following five separate activities are associated with this information collection:

- Foster Care Eligibility Review (FCER) Program Improvement Plan;
- Child and Family Services Reviews (CFSR) State agency Statewide Assessment;
- CFSR On-site review;
- CFSR Program Improvement Plan; and
- Anti-Discrimination Enforcement Corrective Action Plan.

The collection of information for review of Federal payments to States for foster care maintenance payments (45 CFR 1356.71(i)) is authorized by title IV–E of the social Security Act (the Act), section 474 [42 U.S.C. 674]. The Foster Care Eligibility Reviews (FCER) ensure that States claim title IV–E funds on behalf of title IV–E eligible children.

The collection of informaiton for review of State child and family services programs (45 CFR 1355.33(b), 1355.33(c) and 1355.35(a)) to determine whether such programs are in substantial conformity with State plan requirements under parts B and E of the Act is authorized by section 1123(a) [42 U.S.C 1320a–1a] of the Act. The CFSR looks at both the outcomes related to safety, permanency and well-being of children served by the child welfare system and at seven systemic factors that support the outcomes.

Section 474(d) of the Act [42 U.S.C 674] deploys enforcement provisions (45 CFR 1355.38(b) and (c)) for the requirements at section 4371(a)(18) [42 U.S.C 671], which prohibit the delay or denial of foster and adoptive placements based on the race, color, or national origin of any of the individuals involved. The enforcement provisions include the execution and completion of corrective action plans when a State is in violation of section 471(a)(18).

The information collection is needed: (1) To ensure compliance with title IV–E foster care eligibility requirements; (2) to monitor State plan requirements under titles IV–B and IV–E of the Act, as required by Federal statute; and (3) to enforce the title IV–E anti-discrimination requirements through State corrective action plans. The resultant information will allow ACF to determine if States are in compliance with State plan requirements and are achieving desired outcomes for children and families, help ensure that claims by States for title IV–E funds are made on behalf of title IV–E eligible children, and require States to revise applicable statutes, rules, policies and procedures, and provide proper training to staff, through the development and implementation of corrective action plans. These reviews not only address compliance with eligibility requirements but also assist States in enhancing the capacities to serve children and families. In computing the number of burden hours for this information collection, ACF based the annual burden estimates on ACF's and States' experiences in conducting reviews and developing program improvement plans.

Respondents: State Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
45 CFR 1356.7 (i) Program Improvement Plan (FCER)	7	1	90	630
45 CFR 1366.33 (b) Statewide Assessment (CFSR)	13	1	240	3,120
45 CFR 1355.33 (c) On-site Review (CFSR)	13	1	1,170	15,210
45 CFR 1355.35 (a) Program Improvement Plan (CFSR)	13	1	240	3,120
45 CFR 1355.38 (b) and (c) Corrective Action Plan (Anti-discrimination enforcement)	1	1	780	780

Estimated Total Annual Burden Hours: 22,860.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Office for ACF, E-mail address: *Katherine_T._Astrich@omb.eop.gov.*

Dated: September 20, 2006.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 06–8272 Filed 9–26–06; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0006]

Determination of Regulatory Review Period for Purposes of Patent Extension; LYRICA (New Drug Application 21–446)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LYRICA (new drug application (NDA) 21–446) 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 written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

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 human drug product 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 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 LYRICA (NDA 21–446) (pregabalin). LYRICA (NDA 21–446) is indicated for management of neuropathic pain associated with