ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Pathologist	Pathology Report—No standard form	5	1	5/60
Next-of-kin for deceased miner	2.6	5	1	15/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–06160 Filed 3–17–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval Louisiana Medicaid State Plan Amendment (SPA) 12–66–B

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of hearing: Reconsideration of disapproval.

SUMMARY: This notice announces an administrative hearing to be held on April 30, 2015, at the Department of Health and Human Services, Centers for Medicare and Medicaid Services, Division of Medicaid & Children's Health, Dallas Regional Office, 1301 Young Street, Room 730, Dallas, TX 75202, to reconsider CMS' decision to disapprove Louisiana's Medicaid SPA 12–66–B.

Closing Date: Requests to participate in the hearing as a party must be received by the presiding officer by April 2, 2015.

FOR FURTHER INFORMATION CONTACT: Benjamin R. Cohen, Presiding Officer, CMS, 2520 Lord Baltimore Drive, Suite L, Baltimore, Maryland 21244, Telephone: (410) 786–3169.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider CMS' decision to disapprove Louisiana's Medicaid SPA 12–66B which was submitted to the Centers for Medicare and Medicaid Services (CMS) on December 20, 2012 and disapproved on December 11, 2014. In part, this SPA requested CMS approval to revise the current pharmacy reimbursement methodology for estimated acquisition cost (EAC) which is currently calculated as average acquisition cost (AAC) of the drug dispensed to a new calculation of AAC adjusted by a multiplier of 1.1 for multiple source drugs and 1.01 for single source drugs. In addition, propose a reimbursement methodology of wholesale acquisition cost (WAC) adjusted by a multiplier of 1.05 for state-defined specialty therapeutic classes of drugs.

The issues to be considered at the hearing are:

- Whether the state's proposed increased payment methodology under Louisiana Medicaid SPA 12–66–B complies with the requirements of section 1902(a)(30)(A) of the Act which requires, in part, that states have methods and procedures to assure that payment rates are consistent with efficiency, economy, and quality of care.
- Whether the state demonstrated that the proposed payment increases are consistent with the aggregate upper payment limits set in implementing regulations at 42 CFR 447.512 which provide that payments for drugs are to be based on the lower of: (1) The ingredient EAC of the drug and a reasonable dispensing fee; or (2) the provider's usual and customary charges to the general public.
- Whether the proposed calculation of EAC used in calculating upper payment limits (based on a multiple of the AAC) is consistent with the definition of EAC in 42 CFR 447.502, which defines EAC as ''the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.''

Section 1116 of the Act and federal regulations at 42 CFR part 430, establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a state plan or plan amendment. CMS is required to publish a copy of the notice to a state Medicaid agency that informs the agency of the time and place of the hearing, and the issues to be considered. If we subsequently notify the agency of additional issues that will be considered at the hearing, we will also publish that notice.

Any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as *amicus curiae* must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

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

J. Ruth Kennedy
State Medicaid Director
Louisiana Department of Health and Hospitals
628 N. 4th Street
P.O. Box 91030
Baton Rouge, LA 70821

Dear Ms. Kennedy:

I am responding to your request for reconsideration of the decision to disapprove Louisiana's Medicaid state plan amendment (SPA) 12–66B, which was submitted to the Centers for Medicare and Medicaid Services (CMS) on December 20, 2012, and disapproved on December 11, 2014. I am scheduling a hearing on your request for reconsideration to be held on April 30, 2015, at the Department of Health and Human Services, Centers for Medicare and Medicaid Services, Division of Medicaid & Children's Health, Dallas Regional Office, 1301 Young Street, Room 730, Dallas, TX 75202.

I am designating Mr. Benjamin R. Cohen as the presiding officer. If these arrangements present any problems, please contact Mr. Cohen at (410) 786–3169. In order to facilitate any communication that may be necessary between the parties prior 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. If the hearing date is not acceptable, Mr. Cohen can set another date mutually agreeable to the parties. The hearing will be governed by the procedures prescribed by federal regulations at 42 CFR part 430.

In part, this SPA would revise the current pharmacy reimbursement methodology for estimated acquisition cost (EAC) which is currently calculated as average acquisition cost (AAC) of the drug dispensed to a new

calculation of AAC adjusted by a multiplier of 1.1 for multiple source drugs and 1.01 for single source drugs. In addition, this SPA would apply a reimbursement methodology of wholesale acquisition cost (WAC) adjusted by a multiplier of 1.05 for state-defined specialty therapeutic classes of drugs.

The issues to be considered at the hearing are:

- Whether the state's proposed increased payment methodology under Louisiana Medicaid SPA 12–66–B complies with the requirements of section 1902(a)(30)(A) of the Act which requires, in part, that states have methods and procedures to assure that payment rates are consistent with efficiency, economy, and quality of care.
- Whether the state demonstrated that the proposed payment increases are consistent with the aggregate upper payment limits set in implementing regulations at 42 CFR 447.512 which provide that payments for drugs are to be based on the lower of: 1) the ingredient EAC of the drug and a reasonable dispensing fee; or 2) the provider's usual and customary charges to the general public.
- Whether the proposed calculation of EAC used in calculating upper payment limits (based on a multiple of the AAC) is consistent with the definition of EAC in 42 CFR 447.502, which defines EAC as ''the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.''

In the event that CMS and the state come to agreement on resolution of the issues which formed the basis for disapproval, this SPA may be moved to approval prior to the scheduled hearing.

Sincerely,

Andrew M. Slavitt

Section 1116 of the Social Security Act (42 U.S.C. 1316; 42 CFR 430.18) (Catalog of Federal Domestic Assistance program No. 13.714. Medicaid Assistance Program.)

Dated: March 13, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–06226 Filed 3–17–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0684]

Identification of Alternative In Vitro Bioequivalence Pathways Which Can Reliably Ensure In Vivo Bioequivalence of Product Performance and Quality of Non-Systemically Absorbed Drug Products for Animals; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Identification of Alternative In Vitro Bioequivalence Pathways Which Can Reliably Ensure In Vivo Bioequivalence of Product Performance and Quality of Non-Systemically Absorbed Drug Products for Animals''. The purpose of the public meeting is to discuss the use of in vitro methods as a mechanism for assessing the in vivo product bioequivalence (BE) of non-systemically absorbed drug products intended for use in veterinary species. FDA is seeking additional public comment to the docket, and is requesting that any written comments be submitted by May 18, 2015.

Date and Time: The public meeting will be held on April 16, 2015, from 9 a.m. to 4 p.m.

Location: The public meeting will be held at the Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., 3rd Floor, Conference Room A, Rockville, MD 20855. Parking is free.

Contact Person: Aleta Sindelar, CVM, Food and Drug Administration, 7519 Standish Pl., Rm. 144, Rockville, MD 20855, 240–276–9230, FAX: 240–276–9241, email: *BioequivalencePublic MeetingRegistration@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in requesting an opportunity to speak during the open public comment period must register by April 8, 2015, and must include a brief summary of comments with their registration. Those individuals will be contacted prior to the meeting regarding their participation. Persons interested in attending this meeting who are not requesting an opportunity to speak at the meeting must register by April 14, 2015. For general questions about the meeting, for assistance registering for the meeting, to request an opportunity to make an oral presentation, or to request special accommodations due to a disability, contact Aleta Sindelar (see *Contact Person*). Please include your name, organization, and contact information. Early registration for the meeting is encouraged due to limited time and space.

SUPPLEMENTARY INFORMATION:

I. Background

Given the imprecision and logistic challenges associated with clinical endpoint BE studies, FDA is exploring alternative pathways that can be applied to help ensure the equivalence of product performance and quality for those products that are non-systemically absorbed (locally acting).

The assessment of in vivo BE of non-systemically absorbed drug products has been a longstanding challenge facing drug manufacturers and regulators of human and animal health products. Although blood level BE trials remain the standard for comparing drug products that are systemically absorbed and that act at a target site reached via the blood (systemic circulation), such studies cannot confirm product in vivo BE when a drug is either not systemically absorbed or when it is associated with therapeutic effects occurring proximal to the site of absorption. To date, unless the active pharmaceutical ingredient met the criteria for highly soluble, as defined in CVM Guidance #171 entitled ''Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles,'' clinical endpoint BE trials have provided the only option for generating inter-product comparisons. FDA is exploring whether an alternative in vitro BE approach may be considered when blood level BE studies are either not feasible or not appropriate, and when products do not meet the criteria for applying a Guidance #171-based biowaiver.

The assumption underlying the application of the in vitro BE approach is that equivalence in product physicochemical attributes and in vitro product performance translates to equivalence in product in vivo behavior. For sponsors with a right of reference to underlying safety and effectiveness data, the criteria for similarity of physicochemical attributes would be defined on the basis of the underlying dataset to confirm the comparability of the original formulation and pre- and post-approval changes in formulation or method of product manufacture. In the case of generic products, a more rigid approach to sameness would be used in terms of product composition and physicochemical characteristics. In both situations, physicochemical comparisons would be based upon a battery of in vitro test procedures, including a comparison of in vitro dissolution behavior under a range of physiologically-relevant conditions.

Examples of the kinds of products where in vitro bioequivalence concepts can potentially be applied include some orally administered products (*e.g.,* Type A medicated articles), solutions, emulsions, ointments, creams, suspensions, transdermal products, and intra-mammary formulations. Due to unique issues raised by products