Dated: December 29, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 05–410 Filed 1–7–05; 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 of Indiana State Plan Amendment 02–021

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

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing to be held on January 20, 2005, at 10 a.m., 233 North Michigan Avenue, Minnesota Room, Chicago, Illinois 60601 to reconsider the decision to disapprove Indiana State Plan Amendment (SPA) 02–021.

Closing Date: Requests to participate in the hearing as a party must be received by the presiding officer by January 25, 2005.

FOR FURTHER INFORMATION CONTACT: Kathleen Scully-Hayes, Presiding Officer, CMS, LB–23–20, Lord Baltimore Drive, Baltimore, Maryland 21244, Telephone: (410) 786–2055.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider the decision to disapprove Indiana Medicaid State Plan Amendment (SPA) 02–021, which was submitted on December 27, 2002.

In SPA 02–021, Indiana proposed to expand the State's Medicaid mental health rehabilitation benefit to include services furnished by five types of child care facilities to inpatients in the facilities. The State incorporated into the SPA portions of the Indiana State code (470 IAC 3–11, 470 IAC 3–12, 470 IAC 3–13, 470 IAC 3–14, and 470 IAC 3–15) that govern the operation of these facilities.

At issue in this reconsideration is whether SPA 02–021 is consistent with the requirements contained in sections 1902(a)(10), 1902(a)(19), 1902(a)(30)(A), and 1902(a)(4) of the Social Security Act (the Act) as described in more detail below. In general, the Centers for Medicare & Medicaid Services (CMS) found that the SPA had four basic problems: (1) The proposed services would be provided to individuals under age 65 who are patients in institutions for mental diseases (IMDs) (that are not juvenile psychiatric hospitals) and who have not been determined eligible for Medicaid; (2) the proposed services would be provided on order of individuals who are neither physicians nor licensed practitioners; (3) the proposed services would be provided in facilities which permit use of mechanical restraints and provide for seclusion of children and which, therefore, cannot be considered to be ''in the best interests'' of the recipients; and (4) the proposed payment methodology includes items not encompassed in the definition of Medicaid rehabilitation services and improperly includes payment for state administrative costs.

More specifically, at issue is whether the proposed SPA complies with the requirements of section 1902(a)(10) of the Act, which provides generally that state plans must make ''medical assistance'' as defined in section 1905(a) of the Act, available to eligible individuals. The definition of medical assistance at section 1905(a)(27), excludes payment for care and services for individuals under age 65 who are patients in institutions for mental diseases (IMDs), except payment for juvenile psychiatric hospital services pursuant to section 1905(a)(16) of the Act. Indiana proposed to furnish services to individuals who are under age 65 in institutions that appear to meet the definition of an IMD at section 1905(i) of the Act and applicable Federal regulations at 42 CFR 435.1009. However, these facilities do not provide services that meet the definition of inpatient psychiatric hospital services contained in section 1905(h) of the Act and do not comply with the regulatory requirements for providers of inpatient psychiatric hospital services set forth at 42 CFR 483 Subpart G (concerning use of restraint or seclusion). Thus, the State has failed to establish that the services are within the scope of medical assistance that is authorized under the Act.

In addition, section 1905(a)(13) of the Act defines rehabilitative services as those that are recommended by a physician or other licensed practitioner of the healing arts. The proposed SPA would include services that are recommended by individuals who are neither physicians nor licensed practitioners, but who are operating under the supervision of these individuals. Nor do the proposed services meet the requirements or services in any inpatient setting within the scope of medical assistance (hospitals, nursing facilities, psychiatric hospital services for juveniles, or intermediate care facilities for the mentally retarded).

Finally, section 1905(a) of the Act defines the term ''medical assistance'' as payment of part or all of the cost of care and services furnished to eligible individuals. The reimbursement section of this amendment, detailed at section 4.2.2 of the Indiana Residential Care Reimbursement Rate Establishment document, and included in Attachment 4.19B of this amendment, would provide payment for services furnished to individuals who have not been determined eligible for Medicaid.

In addition, at issue is whether the proposed SPA is consistent with the requirement in section 1902(a)(19) of the Act that services be provided ''in the best interests of the recipients.'' Indiana permits the use of mechanical restraints and provides for extended periods of seclusion of children in the facilities covered by this amendment. CMS has determined that these policies, defined in the Indiana Administrative Code (470 IAC 3–11, 470 IAC 3–12, and 470 IAC 3–13) and incorporated in this amendment by reference, would endanger the health and welfare of the victims of these procedures, and cannot be considered to be in the best interests of the children affected.

Finally, at issue is whether the proposed payment methodology complies with section 1902(a)(30)(A) of the Act, which requires that payments for services under the plan be ''consistent with efficiency, economy, and quality of care,'' and with section 1902(a)(4) which requires that the State use methods of administration that are found by the Secretary to be ''necessary for the proper and efficient operation of the plan.'' The payment methodology proposed by the State includes payment for numerous cost items, including elements of room and board and transportation services, that are not encompassed in the definition of Medicaid rehabilitation services. For this reason, CMS found that the State has not documented that the proposed payment methodology would be efficient or economical, as required by section 1902(a)(30)(A) of the Act. Furthermore, CMS determined that the payment methodology improperly includes payment for State administrative costs as medical assistance. The amendment would include Medicaid administrative costs as part of the payment to providers and thus would likely result in incorrect payment of FFP. Because the proposed payment methodology commingles medical assistance and administrative costs, it is not consistent with the requirement for proper and efficient

plan administration contained in section 1902(a)(4) of the Act. Therefore, based on the reasoning set forth above, and after consultation with the Secretary as required under 42 CFR 430.15(c)(2), CMS disapproved Indiana SPA 02–021.

Section 1116 of the Act and 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 Indiana announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Ms. Melanie Bella, Assistant Secretary, Medicaid Policy, 402 West Washington Street, Indianapolis, IN 46204.

Dear Ms. Bella: I am responding to your request for reconsideration of the decision to disapprove Indiana Medicaid State Plan Amendment (SPA) 02–021 submitted on December 27, 2002.

In SPA 02–021, Indiana proposed to expand the State's Medicaid mental health rehabilitation benefit to include services furnished by five types of child care facilities to inpatients in the facilities. The State incorporated into the SPA portions of the Indiana State code (470 IAC 3–11, 470 IAC 3–12, 470 IAC 3–13, 470 IAC 3–14, and 470 IAC 3–15) that govern the operation of these facilities.

We do not find the proposed SPA to be consistent with section 1902(a) of the Social Security Act (the Act), which provides generally that state plans must make ''medical assistance,'' as defined in section 1905(a) of the Act, available to eligible individuals. The proposed SPA would provide a facility-based benefit that within the scope of ''medical assistance'' as that term is used in section 1902(a) of the Act and defined in section 1905(a) of the Act. The definition of medical assistance at section 1905(a) of the Act excludes payment for care and services to individuals under age 65 who are patients in institutions for mental diseases (IMDs), except payment for juvenile psychiatric hospital services pursuant to section 1905(a)(16) of the Act. The services proposed under this SPA would be furnished to individuals who are under age 65 in institutions that appear to meet the definition of an IMD at section 1905(i) of the Act and applicable Federal regulations at 42 CFR 435.1009. (In responses to Centers for Medicare & Medicaid Services (CMS) inquiries, the State itself indicated that the facilities can have over 16 beds, and that the patients reside in the facility in order to receive treatment for mental illness.) But, the proposed services are not within the scope of juvenile psychiatric hospital services which, pursuant to section 1905(h) of the Act, includes services provided to individuals under age 21 in psychiatric residential treatment facilities. It appears that the proposed services would be furnished in facilities that do not meet the regulatory requirements for providers of inpatient psychiatric hospital services set forth at 42 CFR 483 Subpart G (concerning use of restraint or seclusion). Thus, CMS does not find that the State has established that the services are within the scope of medical assistance that is authorized under the Act.

Even if the State were to demonstrate that the individuals were not inpatients in IMDs, CMS does not believe the State has demonstrated that the proposed services are within the proper scope of medical assistance. The proposed services do not meet the requirement under section 1905(a)(13) of the Act that rehabilitation services be recommended by a physician or other licensed practitioner of the healing arts. The proposed SPA would include services that are recommended by individuals who are neither physicians nor licensed practitioners, but who are operating under the supervision of these individuals. Nor has the State shown that the proposed services meet the requirements for any inpatient setting within the scope of medical assistance, including hospitals, nursing facilities, psychiatric hospital services for juveniles, or intermediate care facilities for the mentally retarded.

In addition, the proposed SPA, does not appear to be consistent with the requirement in section 1902(a)(19) of the Act that services be provided ''in the best interests of the recipients.'' Indiana permits the use of mechanical restraints and provides for extended periods of seclusion of children in the facilities covered by this amendment. CMS believes that these policies, defined in the Indiana Administrative Code (470 IAC 3–11, 470 IAC 3–12, and 470 IAC 3–13) and incorporated in this amendment by reference, would endanger the health and welfare of the victims of these procedures, and cannot be considered to be in the best interests of the children affected.

CMS found that the State has not demonstrated that the proposed payment methodology would comply with section 1902(a)(30)(A) of the Act, which requires that payments for services under the plan be ''consistent with efficiency, economy, and quality of care.'' The payment methodology proposed by the State includes payment for numerous cost items, including elements of room and board and transportation services, that are not encompassed in the definition of Medicaid rehabilitation services. For this reason, CMS found that the State has not documented that the proposed payment methodology would be efficient or economical.

Furthermore, the proposed payment methodology does not appear to comply with the requirement for methods of administration that are found by the Secretary to be ''proper and efficient'' for the operation of the State plan, because the payment methodology improperly includes payment for State administrative costs as medical assistance. Section 1903(a) of the Act provides for FFP for medical assistance at the Federal medical assistance percentage rate, which is currently 62.32 percent in Indiana. Section 1903(a) of the Act provides for FFP at the 50 percent match rate for activities that have been found to be in support of the proper and efficient administration of the state plan. The amendment would include Medicaid administrative costs as part of the payment to providers and thus would likely result in incorrect payment of FFP. Because the proposed payment methodology commingles medical assistance and administrative costs, CMS finds that the payment methodology is not consistent with the requirement for proper and efficient plan administration.

Equally important, section 1905(a) of the Act defines the term ''medical assistance'' as payment of part or all of the cost of care and services furnished to eligible individuals. The reimbursement section of this amendment, detailed at section 4.2.2 of the Indiana Residential Care Reimbursement Rate Establishment document, and included in Attachment 4.19B of this amendment, would appear to provide payment for services furnished to individuals who have not been determined eligible for Medicaid.

Based on the reasoning set forth above, and after consulting with the Secretary as required by 42 CFR 430.15(c)(2), CMS disapproved Indiana Medicaid SPA 02–021.

I am scheduling a hearing on your request for reconsideration to be held January 20, 2005, at 10:00 a.m., 233 North Michigan Avenue, Minnesota Room, Chicago, Illinois 60601 to reconsider the decision to disapprove Indiana SPA 02–021.

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. 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. The presiding officer may be reached at (410) 786–2055.

Sincerely,

Mark B. McClellan, M.D., Ph.D.

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: January 5, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–445 Filed 1–7–05; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues. The committee also advises and makes recommendations to the Secretary of Health and Human Services under 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services, when that research is also regulated by FDA.

Date and Time: The meeting will be held on February 14, 2005, from 2 p.m. to 6 p.m. and on February 15, 2005, from 8 a.m. to 4:30 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Jan N. Johannessen, Office of Science and Health Coordination of the Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, rm. 14C–06) Rockville, MD 20857, 301–827–6687, e-mail: *jjohannessen@fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732310001. Please call the Information Line for up-to-date information on this meeting.

Agenda: On Monday, February 14, 2005, the committee will discuss an agency report on Adverse Event Reporting, as mandated in Section 17 of the Best Pharmaceuticals for Children Act (BPCA), for LOTENSIN (benazepril), BREVIBLOC (esmolol), MALARONE (atovaquone/proguanil), VIRACEPT (nelfinavir), XENICAL (orlistat), and GLUCOVANCE (glyburide/metformin). The committee will also be asked to advise the agency on how to improve the process and content of the adverse event reviews and reporting as mandated by BPCA.

On Tuesday, February 15, 2005, the committee will discuss risk evaluation, labeling, risk communication, and dissemination of information on potential cancer risk among pediatric patients treated for atopic dermatitis with topical dermatological immunosuppressants.

The background material will become available no later than the day before the meeting and will be posted under the Pediatric Advisory Committee (PAC) docket Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm* (click on the year 2005 and scroll down to PAC meetings).

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 7, 2005. Oral presentations from the public will be scheduled on Monday, February 14, 2005, between approximately 4 p.m. and 4:30 p.m. and on Tuesday, February 15, 2005, between approximately 12 noon and 12:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by February 7, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please notify Jan Johannessen at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 30, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 05–382 Filed 1–7–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000P–1378]

Guidance for Industry: Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients.'' The guidance recommends content for a labeling statement for cosmetic products containing alpha hydroxy acids (AHAs) as ingredients. This action was prompted by a citizen petition filed by the Cosmetic, Toiletry, and Fragrance Association, which requested that FDA issue a regulation establishing labeling requirements relating to sun protection with use of cosmetic products containing AHAs.

DATES: You may submit written or electronic comments on the guidance document at any time.

ADDRESSES: Submit written requests for single copies of the guidance document to the Office of Cosmetics and Colors, Center for Food Safety and Applied Nutrition (HFS–100), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835. Include a self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent.

Submit written comments on the guidance document to the Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Julie N. Barrows, Center for Food Safety and Applied Nutrition (HFS–125), Food and