

the Act, and implementing regulations at 42 CFR 440.230(b), which CMS has interpreted to mean that the state provides reasonable coverage of the benefit that meets the needs of most beneficiaries who need the outpatient hospital services. While the state provided information on emergency room services, it did not provide information on outpatient hospital services.

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 Florida announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Stuart F. Williams, Esq., General Counsel, Agency for Health Care Administration, Office of the General Counsel, 2727 Mahan Drive, Building 3, MS #3, Tallahassee, FL 323008

Dear Mr. Williams:

I am responding to your request for reconsideration of the decision to disapprove the Florida State Plan Amendment (SPA) 12-015 which was submitted on September 14, 2012, and disapproved on December 13, 2012. The SPAs reflects a Florida state law that would limit outpatient hospital emergency room visits to six per fiscal year for non-pregnant adults, 21 years of age and older, effective August 1, 2012.

I disapproved Florida SPA 12-015 because it appeared to impose a limitation on outpatient hospital services that was based on the individual's diagnosis, illness, or condition and because the state failed to demonstrate that the limitation is consistent with the provision of a

sufficient amount, duration and scope to reasonably achieve the purpose of the benefit. At issue in this appeal are the following issues, which are more detailed than set out in the disapproval letter:

- Whether the exceptions to the proposed general service limitations on outpatient hospital services violate comparability requirements under section 1902(a)(10)(B) of the Act and implementing regulations at 42 CFR 440.230(c) because they provide that some individuals described in section 1902(a)(10)(A) of the Act, who have particular diagnoses or conditions, will receive benefits that individuals with other diagnoses and conditions will not receive.

- Whether the imposition of a limit specifically on emergency outpatient hospital visits would violate those comparability requirements because the limitation would be imposed only on outpatient hospital visits that are warranted to address acute and immediate conditions, which means that the limitation is based on the diagnosis or condition.

- Whether the exception to the limitation on emergency room visits for "aliens" would violate section 1902(a)(10)(B) of the Act because it would provide that aliens would receive a greater amount, duration and scope of emergency outpatient hospital benefits than other individuals described in section 1902(a)(10)(A) of the Act.

- Whether the state has demonstrated that the resulting outpatient hospital benefits are of a sufficient amount, duration and scope to reasonably achieve the purpose of the benefit, consistent with the requirements of sections 1902(a)(10)(A) and 1905(a)(2) of the Act, and implementing regulations at 42 CFR 440.230(b), which CMS has interpreted to mean that the state provides reasonable coverage of the benefit that meets the needs of most beneficiaries who need the outpatient hospital services. While the state provided information on emergency room services, it did not provide information on outpatient hospital services.

I am scheduling a hearing on your request for reconsideration to be held on April 30, 2013, at the CMS Atlanta Regional Office, Atlanta Federal Center, 3rdrd Floor, 61 Forsyth Street, SW., Suite 3B52, Atlanta, Georgia 30303-8909, to reconsider CMS' decision to disapprove Florida SPA 12-015.

If this date is not acceptable, I would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the

procedures prescribed by Federal regulations at 42 CFR Part 430.

I am designating Mr. Benjamin Cohen as the presiding officer. If these arrangements present any problems, please contact the 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 scheduled hearing date and provide names of the individuals who will represent the state at the hearing.

Sincerely,
Marilyn Tavenner
Acting Administrator

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: March 8, 2013.

Marilyn Tavenner,
Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-64, CMS-10295, CMS-10302 and CMS-10185]

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:** Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program. **Use:** Form CMS-64 has been used since January 1980 by Medicaid state agencies to report their actual program benefit costs and administrative expenses. CMS uses this information to compute the federal financial participation for the state's Medicaid program costs. Certain schedules of the CMS-64 form are used by states to report budget, expenditure and related statistical information required for implementation of the Medicaid portion of the State Children's Health Insurance Programs, Title XXI of the Social Security Act, established by the Balanced Budget Act of 1997. **Form Number:** CMS-64 (OCN: 0938-0067). **Frequency:** Quarterly. **Affected Public:** State, Local, or Tribal Governments. **Number of Respondents:** 56. **Total Annual Responses:** 224. **Total Annual Hours:** 16,464. (For policy questions regarding this collection contact Abraham John at 410-786-4518. For all other issues call 410-786-1326.)

2. Type of Information Collection

Request: Revision of a currently approved collection. **Title of Information Collection:** Reporting Requirements for States Under Transitional Medical Assistance (TMA) Provisions. **Use:** The HHS Secretary is required to submit annual reports to Congress with information collected from states in accordance with section 5004(d) of the American Recovery and Reinvestment Act of 2009. Medicaid agencies in 50 states complete the reports while CMS reviews the information to determine if each state has met all of the reporting requirements specified under section 5004(d). We are revising this package to remove the requirement to report the Medicaid Federal Medical Assistance Percentage since it no longer needs to be collected from states. **Form Number:** CMS-10295 (OCN: 0938-1073). **Frequency:** Quarterly. **Affected Public:** State, Local, or Tribal Governments. **Number of Respondents:** 50. **Total Annual Responses:** 200. **Total Annual Hours:** 400. (For policy questions regarding this collection contact Rhonda Simms at 410-786-1200. For all other issues call 410-786-1326.)

3. Type of Information Collection

Request: Extension of a currently approved collection; **Title of Information Collection:** Collection Requirements for Compendia for Determination of Medically-accepted Indications for Off-label Uses of Drugs and Biologicals in an Anti-cancer

Chemotherapeutic Regimen Use:

Section 182(b) of the Medicare Improvement of Patients and Providers Act (MIPPA) amended Section 1861(t)(2)(B) of the Social Security Act (42 U.S.C. 1395x(t)(2)(B)) by adding at the end the following new sentence: 'On and after January 1, 2010, no compendia may be included on the list of compendia under this subparagraph unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interest.' We believe that the implementation of this statutory provision that compendia have a "publicly transparent process for evaluating therapies and for identifying potential conflicts of interests" is best accomplished by amending 42 CFR 414.930 to include the MIPPA requirements and by defining the key components of publicly transparent processes for evaluating therapies and for identifying potential conflicts of interests.

All currently listed compendia will be required to comply with these provisions, as of January 1, 2010, to remain on the list of recognized compendia. In addition, any compendium that is the subject of a future request for inclusion on the list of recognized compendia will be required to comply with these provisions. No compendium can be on the list if it does not fully meet the standard described in section 1861(t)(2)(B) of the Act, as revised by section 182(b) of the MIPPA. **Form Number:** CMS-10302 (OCN: 0938-1078); **Frequency:** Reporting, Recordkeeping and Third-party disclosure; **Affected Public:** Business and other for-profits and Not-for-profit institutions; **Number of Respondents:** 845; **Total Annual Responses:** 900; **Total Annual Hours:** 5,135. (For policy questions regarding this collection contact Brijet Coachman at 410-786-7364. For all other issues call 410-786-1326.)

4. Type of Information Collection

Request: Revision of a currently approved collection; **Title of Information Collection:** Medicare Part D Reporting Requirements; **Use:** Title I, Part 423, § 423.514 describes CMS' regulatory authority to establish reporting requirements for Part D sponsors. It is noted that each Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, statistics in the following areas: the cost of its operations; the patterns of utilization of its services; the

availability, accessibility, and acceptability of its services; information demonstrating that the Part D plan sponsor has a fiscally sound operation; and other matters that CMS may require. CMS has identified the appropriate data needed to effectively monitor plan performance. Changes to the currently approved data collection instrument reflect new executive orders, legislation, as well as recent changes to Agency policy and guidance. **Form Number:** CMS-10185 (OCN: 0938-0992); **Frequency:** Reporting, Recordkeeping and Third-party disclosure; **Affected Public:** Business and other for-profits; **Number of Respondents:** 690; **Total Annual Responses:** 8,067; **Total Annual Hours:** 12,658. (For policy questions regarding this collection contact Latoyia Grant at 410-786-5434. 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 Email 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 May 14, 2013:

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: March 12, 2013.

Martique Jones,

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

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