

information. In addition, do not include any “[t]rade secret or any commercial or financial information which is . . . privileged or confidential” as provided in Section 6(f) of the FTC Act 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c).¹² Your comment will be kept confidential only if the FTC General Counsel grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/rbprulepra>, by following the instructions on the web-based form. If this Notice appears at <http://www.regulations.gov/#/home>, you also may file a comment through that Web site.

If you file your comment on paper, write “RBP Rule, PRA Comment, P145403,” on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex J), 600 Pennsylvania Avenue NW., Washington, DC 20580. If possible, submit your paper comment to the Commission by courier or overnight service.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before April 28, 2014. You can find more information, including routine uses permitted by the Privacy Act, in

the Commission’s privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

David C. Shonka,

Principal Deputy General Counsel.

[FR Doc. 2014-04235 Filed 2-26-14; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Notice of Opportunity for Hearing on Compliance of Florida State Plan Provisions Concerning Payment for Outpatient Hospital Services With Title XIX (Medicaid) of the Social Security Act

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

ACTION: Notice of Opportunity for a Hearing; Compliance of Florida Medicaid State Plan Outpatient Hospital Benefit.

SUMMARY: This notice announces the opportunity for an administrative hearing to be held by April 28, 2014 at the CMS Atlanta Regional Office, 61 Forsyth Street SW., Suite 4T20, Atlanta, GA 30303-8909, to consider whether Florida provisions concerning payments for outpatient hospital services comply with the requirements of the Social Security Act as discussed in the [date of publication] letter sent to the state and published herein.

Closing Date: Requests to participate in the hearing as a party must be received by the presiding officer by March 31, 2014.

FOR FURTHER INFORMATION CONTACT: Benjamin R. Cohen, Hearing Officer, Centers for Medicare & Medicaid Services, 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244, (301) 869-3169.

SUPPLEMENTARY INFORMATION: This notice announces the opportunity for an administrative hearing concerning the finding of the Administrator of the Centers for Medicare & Medicaid Services (CMS) that the state of Florida is not operating their outpatient hospital services in compliance with their approved state plan, or in compliance with the provisions of the Social Security Act (the Act), and the proposed withholding of Federal reimbursement of a portion of Florida’s administrative dollars proportionate to outpatient hospital services. In particular, CMS has found that Florida has continued to implement a limit on the number of times a Medicaid beneficiary may visit

an emergency department, even though CMS disapproved an amendment to add this limit to the Florida state plan. Consequently, Federal payments for a portion of the Federal funding of administrative costs will be withheld, subject for the opportunity for a hearing described below. This notice is being provided pursuant to the requirements of section 1904 of the Act, as implemented at 42 CFR 430.35 and 42 CFR 430, Subpart D.

Under section 1902(a)(10)(A) of the Act, a state plan must provide for making medical assistance available to eligible individuals, including for most eligible individuals the medical assistance specified in section 1905(a)(2) of the Act. This provision includes in the definition of medical assistance “outpatient hospital services.” Section 1902(a)(17) of the Act requires the state plan to include reasonable standards for determining the extent of medical assistance, and under section 1902(a)(19) of the Act, the state plan must assure that eligibility for care and services are provided in the best interest of the recipients. As the implementing regulations at 42 CFR 440.230(b) require, a state plan must “specify the amount, duration, and scope of each service that it provides,” and “each service must be sufficient in amount, duration, and scope to reasonably achieve its purpose.” While states may place “appropriate limits on a service based on such criteria as medical necessity or utilization control procedures” under CFR 440.230(d), 42 CFR 440.230(c) specifies that a state may not arbitrarily deny or reduce the amount, duration, or scope of required services, including physicians’ services, solely because of the diagnosis, type of illness, or condition.

The proposed limitation on certain outpatient hospital services appeared to be based on the diagnosis, illness, or condition because it is limited to outpatient services furnished at a hospital emergency room, which are designed to address acute and immediate conditions. Thus, the limitation appeared to violate the requirements of 42 CFR 440.230(c). Even if that were not the case, the state did not demonstrate that the limitation is consistent with provision of a sufficient amount, duration, and scope to reasonably achieve the purpose of the benefit, which in this case would be providing reasonable coverage that meets the needs of most beneficiaries who need the outpatient hospital services, consistent with 42 CFR 440.230(b).

In disapproving SPA 12-015, CMS staff suggested to the state some

¹² In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c), 16 CFR 4.9(c).

alternate methods to address inappropriate utilization of hospital emergency rooms, including the development of payment rates for hospital emergency rooms that are lower if the individual does not require care for an acute and immediate condition, or the use of the alternative cost sharing authority available to states under section 1916(d) of the Act, permitting higher beneficiary cost sharing for elective non-emergency use of the emergency room. CMS offered to work with the state on these options and technical assistance.

The state requested reconsideration of the denial of the state plan amendment.

During the course of the reconsideration proceedings, CMS became aware of Florida's continued implementation of the limitation on emergency department visits.

The notice to Florida containing the details concerning the compliance issue, the proposed withholding, opportunity for a hearing, and possibility of postponing and ultimately avoiding withholding by coming into compliance, reads as follows:

Justin M. Senior
Deputy Secretary for Medicaid
Florida Agency for Health Care
Administration
2727 Mahan Drive, MS #8
Tallahassee, Florida 32308

Dear Mr. Senior:

This letter provides notice that the Centers for Medicare & Medicaid Services (CMS) has found that Florida is not providing all Medicaid beneficiaries with outpatient hospital benefits required under title XIX of the Social Security Act (the Act) and that until this deficiency is corrected (by making outpatient hospital services available to all beneficiaries entitled to such services), a portion of the Federal funding of the administrative costs associated with the operation of the Florida Medicaid program will be withheld, subject to the opportunity for Florida to request a hearing on this finding. The details of the finding, proposed withholding, opportunity for a hearing, and possibility of postponing and ultimately avoiding withholding by coming into compliance, are described in detail below.

Specifically, CMS has found that Florida is not providing beneficiaries with medical assistance for outpatient hospital services in accordance with the approved Florida State Plan, specifically by imposing numeric limits (six visits annually) on coverage of outpatient hospital visits furnished in hospital emergency departments. The approved state plan does not contain any numeric

limitation on coverage of outpatient hospital services or services of a hospital emergency department. It is our understanding that Florida is nevertheless imposing a numeric limitation on such coverage.

This issue is related to the disapproval of a proposed state plan amendment that would have placed numeric limitations on outpatient hospital visits furnished in a hospital emergency department. Florida submitted the proposed amendment to the coverage provisions of the Medicaid state plan on September 14, 2012, to impose a limit of 6 visits per year to emergency departments. The proposed state plan amendment would have been effective on August 1, 2012. CMS disapproved the amendment on December 13, 2012, indicating that the limitation on outpatient services was not consistent with the requirements of section 1902 of the Social Security Act and implementing regulations because the limitation: 1) would not be consistent with the mandatory nature of the outpatient hospital services benefit under section 1902(a)(10)(A); 2) would not be a reasonable standard consistent with section 1902(a)(17) of the Act because it would arbitrarily deny coverage of outpatient hospital services, a mandatory benefit, based on the (emergency) condition of the patient; and 3) would not be consistent with the best interests of beneficiaries as required by section 1902(a)(19).

In disapproving the amendment, CMS suggested to the state some alternate methods to address inappropriate utilization of hospital emergency rooms, including the development of payment rates for hospital emergency rooms that are lower if the individual does not require care for an acute and immediate condition, or the use of the alternative cost sharing authority available to states under section 1916(d) of the Act, permitting higher beneficiary cost sharing for elective non-emergency use of the emergency room. CMS offered to work with the state on these options and technical assistance.

Florida requested reconsideration of the CMS disapproval of the amendment in February 2013. In the CMS response, CMS noted that the disapproval was also supported because the proposed coverage limitations has an exception to the limitation on emergency room visits for "aliens" that would violate the "comparability" requirements of 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.

During the course of the reconsideration process, CMS learned that Florida had implemented the six visit limit on hospital emergency department visits and was still applying the limit after the proposed amendment was disapproved. This means that Florida is not operating its program in accordance with the approved state plan. It should also be mentioned that Florida's submission of its quarterly expenditure reports through the CMS-64, includes a certification that the state is operating under the authority of its approved Medicaid state plan.

In light of our obligation to ensure that beneficiaries receive services to which they are entitled under the approved state plan, I am taking this compliance action to withhold a portion of the Federal Financial Participation (FFP) in state expenditures for administrative costs necessary to administer the Florida Medicaid program, subject to the opportunity for a hearing described below, until such time as I am satisfied that the state is complying with the Federal requirements described above. The withholding will initially be 10 percent of the Federal share of the state's quarterly claim for administrative expenditures allocable to outpatient hospital services, using an allocation method based on the proportion of total State Medicaid expenditures that were for outpatient hospital expenditures, as reported on Form CMS-64. The withholding percentage will increase by 5 percentage points (i.e. 15%, 20%, etc.) for every quarter in which the state remains out of compliance, up to a maximum withholding percentage of 100 percent (of administrative expenditures allocable to outpatient hospital services). The withholding will end when Florida implements a corrective action plan to bring its Medicaid program into compliance with Federal requirements.

The state has 30 days from the date of this letter to request a hearing. As specified in the accompanying Federal Register notice, we are providing an opportunity for an administrative hearing to ensure that you have an opportunity for a hearing prior to this determination becoming final. However, it is up to the state whether to go forward with this hearing. If a request for a hearing is timely submitted, the hearing will be convened by the Hearing Officer designated below no later than 60 days after the date of the Federal Register notice, or a later date by agreement of the parties and the Hearing Officer, at the CMS Regional Office in Atlanta, Georgia, in accordance with the procedures set forth in Federal

regulations at 42 CFR Part 430, Subpart D. The overall issue in any such appeal will be whether the Florida outpatient hospital benefit is consistent with Federal requirements. Any request for such a hearing should be sent to the designated Hearing Officer. The Hearing Officer also should be notified if you request a hearing but cannot meet the timeframe expressed in this notice. Your Hearing Officer is:

Benjamin R. Cohen, Hearing Officer
Centers for Medicare & Medicaid Services
2520 Lord Baltimore Drive, Suite L
Baltimore, MD 21244

If the state requests a hearing but nevertheless plans to come into compliance with the approved state plan, please submit within 30 days of the date of this letter an explanation of how the state plans to come into compliance with Federal requirements and the timeframe for doing so. If that explanation is satisfactory, we may consider postponing the timing of the scheduled hearing (which would also delay the imposition of the withholding of funds). Our goal is to ensure compliance. We are available to provide further information or assistance on the steps necessary to bring the state into compliance with its approved state plan.

Should you not request a hearing within 30 days, a notice of withholding will be sent to you and the withholding of Federal funds will begin as described above.

If you have any questions or wish to discuss this determination further, please contact:

Jackie Glaze
Associate Regional Administrator
Division of Medicaid and Children's Health Operations
CMS Atlanta Regional Office
61 Forsyth Street SW., Suite 4T20
Atlanta, GA 30303-8909

Sincerely,

Marilynn Tavenner,
Administrator.

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

Dated: February 20, 2014.

Marilynn Tavenner,
Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014-04290 Filed 2-26-14; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0717]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Evaluation of the Food and Drug Administration's General Market Youth Tobacco Prevention Campaign

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Evaluation of the Food and Drug Administration's General Market Youth Tobacco Prevention Campaign" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On February 7, 2014, the Agency submitted a proposed collection of information entitled "Evaluation of the Food and Drug Administration's General Market Youth Tobacco Prevention Campaign" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0753. The approval expires on October 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: February 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-04271 Filed 2-26-14; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0110]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements, including third party disclosure, contained in FDA's current regulations on prescription drug advertisements.

DATES: Submit either electronic or written comments on the collection of information by April 28, 2014.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane., Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in