DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services

Notice of Opportunity for Hearing on Compliance of Texas Calculation of Post-Eligibility Treatment of Income With Titles XI and XIX (Medicaid) of the Social Security Act

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice of opportunity for a hearing; Compliance of Texas calculation of post-eligibility treatment of income for institutionalized individuals and certain participants in home and community-based services waivers.

DATES: Requests to participate in the hearing as a party must be received by the presiding officer by March 18, 2019.

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

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 Texas Health and Human Services Commission (HHSC) is not properly calculating the post-eligibility treatment of income (PETI) for institutionalized individuals and certain participants in home and community-based services (HCBS) waivers.

Section 1902(r)(1) of the Social Security Act (the Act), codified at 42 U.S.C. 1396a(r)(1), mandates that, in applying the PETI calculation against institutionalized individuals and certain participants of HCBS waivers to determine how much of their income must be contributed to the cost of their institutional or HCBS waiver services, states must deduct from their incomes ''amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including . . . necessary medical or remedial care recognized under State law but *not covered under the State plan*[.]'' (Emphasis added.) This statutory mandate is incorporated in the federal regulations at 42 CFR 435.725(c)(4)(ii) and 435.733(c)(4)(ii) (for the categorically needy in non-209(b) states).

CMS has consistently interpreted the phrase ''not covered under the state plan'' as meaning *not paid for* by the state Medicaid program. (See *Maryland Dept. of Health and Mental Hygiene* v. *Centers for Medicare and Medicaid Services,* 542 F.3d 424, 432–433 (3rd Cir. 2008)). Thus, deductions must be made in the PETI calculation for incurred medical or remedial expenses for services that are not included in the state plan, or that are included in the state plan but were not paid for by the state Medicaid agency because the individual was not eligible for Medicaid when the services were delivered. States are permitted to limit past medical expenses to those incurred within three months of an individual applying for Medicaid. 42 CFR 435.831. However, the Texas HHSC has acknowledged that it limits the mandatory incurred medical expense deduction in the PETI calculation to those that were incurred when an individual was eligible under the state plan. This practice has the effect of excluding services that are covered under the state plan but which were not paid for by the Texas HHSC because the individual was not eligible for Medicaid when they were delivered.

Throughout 2017, CMS and the Texas HHSC engaged in several discussions during which CMS explained its longstanding interpretation of section 1902(r)(1) of the Act. CMS also provided several documents supporting that interpretation, including a 2008 decision from the U.S. Court of Appeals for the Fourth Circuit, in which the court upheld CMS's disapproval of a Maryland state plan amendment (SPA) that proposed a PETI calculation method nearly identical to the one that the Texas HHSC presently imposes. On May 1, 2018, CMS issued a corrective action letter, informing the Texas HHSC that, if it did not demonstrate compliance with these requirements within 30 days of the date of the letter, CMS would initiate formal compliance proceedings. Texas HHSC asked for several extensions and ultimately submitted a formal response on August 10, 2018. The August 10, 2018, response did not evidence compliance with section 1902(r)(1) of the Act.

Absent a hearing request or if, following a hearing requested, the Administrator determines that the Texas HHSC is not in compliance with federal Medicaid law and regulations, CMS will begin withholding federal financial participation (FFP). The FFP withholding will continue until the Texas HHSC comes into compliance with the requirement in section 1902(r)(1) of the Act to deduct incurred medical or remedial expenses for services that are included in the state plan but were not paid for by the state Medicaid agency in its PETI calculations.

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

Dear Ms. Muth:

This letter provides notice that the Centers for Medicare & Medicaid Services (CMS) has determined the Texas Health and Human Services Commission (HHSC) to be out of compliance with federal Medicaid law in the manner in which it conducts its post-eligibility treatment of income (PETI) calculations for institutionalized individuals and certain individuals receiving home and community-based services (HCBS). The Texas HHSC policy and practice violates section 1902(r)(1) of the Social Security Act (the Act), codified at 42 U.S.C. 1396a(r)(1), which requires generally that incurred medical expenses not covered by a third party must be taken into account in making the PETI calculations.

Pursuant to section 1904 of the Act, codified at 42 U.S.C. 1396c, and 42 CFR 430.35, a portion of the federal financial participation (FFP) of the administrative costs associated with the operation of the Texas Medicaid program will be withheld. However, CMS is first providing the Texas HHSC with an opportunity for a hearing on this withholding decision. Absent a hearing request or if, following a hearing requested, the Administrator determines that the Texas HHSC is not in compliance with federal Medicaid law and regulations, CMS will begin this FFP withholding. The FFP withholding will continue until the Texas HHSC comes into compliance with the requirement in section 1902(r)(1) of the Act to deduct incurred medical or remedial expenses for services that are included in the state plan but were not paid for by the state Medicaid agency in its PETI calculations. The details of the finding, proposed withholding, opportunity for Texas to request a hearing on the finding, and possibility of postponing, and ultimately avoiding, withholding by coming into compliance are described below.

I. The Finding

Section 1902(r)(1) of the Act mandates that, in applying the PETI calculation against institutionalized individuals and certain participants of HCBS waivers to determine how much of their income must be contributed to the cost of their institutional or HCBS waiver services, states must deduct from an individual's income ''amounts for incurred expenses

for medical or remedial care that are not subject to payment by a third party, including . . . necessary medical or remedial care recognized under State law *but not covered under the State plan*[.]'' (Emphasis added.) This statutory mandate is incorporated in the federal regulations at 42 CFR 435.725(c)(4)(ii) and 435.733(c)(4)(ii) (for the categorically needy in non-209(b) states).

CMS has consistently interpreted the phrase ''not covered under the state plan'' as meaning *not paid for* by the state Medicaid program. (See *Maryland Dept. of Health and Mental Hygiene v. Centers for Medicare and Medicaid Services*, 542 F.3d 424, 432–433 (3rd Cir. 2008)). Thus, deductions must be made in the PETI calculation for incurred medical or remedial expenses for services that are not included in the state plan, or that are included in the state plan but were not paid for by the state Medicaid agency because the individual was not eligible for Medicaid when the services were delivered. States are permitted to limit past medical expenses to those incurred within three months of an individual applying for Medicaid. 42 CFR 435.831. However, the Texas HHSC has acknowledged that it limits the incurred medical expense deduction in the PETI calculation to only those expenses incurred on or after the date on which the individual met all eligibility requirements for Medicaid. This practice has the effect of excluding services that are covered under the state plan but which were not paid for by the Texas HHSC because the individual was not eligible for Medicaid when they were delivered, regardless of how recently the services were provided.

Throughout 2017, CMS and the Texas HHSC engaged in several discussions, during which CMS explained its longstanding interpretation of section 1902(r)(1) of the Act. CMS also provided several documents supporting that interpretation, including a 2008 decision from the U.S. Court of Appeals for the Fourth Circuit, in which the court upheld CMS's disapproval of a Maryland state plan amendment (SPA) that proposed a PETI calculation method nearly identical to the one the Texas HHSC presently imposes. On May 1, 2018, CMS issued a corrective action letter informing the Texas HHSC that, if it did not demonstrate compliance with these requirements within 30 days of the date of the letter, CMS would initiate formal compliance proceedings. The Texas HHSC asked for several extensions and ultimately submitted a formal response on August 10, 2018. The August 10, 2018, response did not evidence compliance with section 1902(r)(1) of the Act.

The Texas HHSC'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. However, at this time, CMS has not received information from the Texas HHSC providing evidence of compliance with section 1902(r)(1) of the Act.

II. Proposed Withholding

In light of the Texas HHSC's non-compliance with section 1902(r)(1) of the Act, CMS is moving forward with a formal determination of substantial noncompliance with federal requirements described in section 1902(r)(1) of the Act to deduct amounts for incurred expenses for medical or remedial care recognized under state law but not covered under the state plan in the PETI calculation. Subject to the Texas HHSC's opportunity to request a hearing, CMS will withhold a portion of FFP from the Texas HHSC's quarterly claim of expenditures for administrative costs until such time as the Texas HHSC is and continues to be in compliance with the federal requirements. 42 CFR 430.35. The withholding will initially be 4 percent of the federal share of the Texas HHSC's quarterly claim for administrative expenditures, an amount that was developed based on the proportion of total state Medicaid expenditures that are used for expenditures for eligibility determinations, as reported on Form CMS-64.10 Line 50. The withholding percentage will increase by 2 percentage points for every quarter in which the Texas HHSC remains out of compliance, up to a maximum withholding percentage of 100 percent (of total administrative expenditures). The withholding will end when the Texas HHSC demonstrates that it has implemented a corrective action plan bringing its procedures to process eligibility determinations under its Medicaid program into compliance with the federal requirements found at section 1902(r)(1) of the Act.

III. Opportunity to Request a Hearing

Hearing procedures are found at 42 C.F.R. Part 430 Subpart D. As specified in the accompanying **Federal Register** notice, the Texas HHSC may request an administrative hearing within 30 days of the date of this letter prior to this determination becoming final. 42 CFR 430.70; 42 CFR 430.72(a). Upon receipt of a timely hearing request, the hearing will be convened by the Hearing Officer designated below no later than 60 days from the date of this letter, unless a later date is agreed to by the state and CMS. 42 CFR 430.72(a). The hearing will take place at the CMS Regional Office in Dallas, Texas. 42 CFR 430.72(a). The issue in any such hearing will be whether, in applying the PETI calculation against institutionalized individuals and certain participants of HCBS waiver, Texas HHSC properly deducts from their incomes amounts for incurred expenses for medical or remedial care recognized under State law but not covered under the state plan, in accordance with section 1902(r)(1) of the Act. Please note that additional issues may be considered at the hearing, provided that the additional issues are sent to the state in writing and published in the **Federal Register**. 42 CFR 430.74.

Any request for such a hearing should be sent to the designated Hearing Officer. The Hearing Officer also should be notified if the Texas HHSC requests a hearing but cannot meet the timeframe expressed in this notice. The Hearing Officer designated for this matter is:

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

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.

IV. Submission of Plan to Come into Compliance

If the Texas HHSC intends to come into compliance with its approved state plan and section 1915(c) waivers, the Texas HHSC should submit, within 30 days of the date of this letter, an explanation of how it plans to come into compliance with federal requirements and the timeframe for doing so. If that explanation is satisfactory, CMS may consider postponing any requested hearing, which could also delay the imposition of the withholding of funds as described above. Our goal is to have the Texas HHSC come into compliance with federal law, and CMS continues to be available to provide technical assistance to the Texas HHSC to achieve this outcome.

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

Bill Brooks
Associate Regional Administrator
Division of Medicaid and Children's Health Operations
CMS Dallas Regional Office, 1301 Young Street, Suite 714

Dallas, TX 75202
214-767-4461

Sincerely,

Seema Verma

cc: Benjamin R. Cohen

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: February 11, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019–02401 Filed 2–14–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0801]

Agency Information Collection Activities; Proposed Collection; Comment Request; Exports: Notification and Recordkeeping Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 export notification and recordkeeping requirements for persons exporting human drugs, biological products, devices, animal drugs, food, cosmetics, and tobacco that may not be marketed or sold in the United States.

DATES: Submit either electronic or written comments on the collection of information by April 16, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 16, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 16, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2014–N–0801 for ''Agency Information Collection Activities; Proposed Collection: Comment Request; Exports: Notification and Recordkeeping Requirements.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@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