

FTC staff previously estimated that the billing entities would spend approximately 5 hours each to review, revise, and provide the disclosures on an annual basis. The estimated hour burden for the annual notice component of this requirement is 6,250 burden hours (based on 1,250 possible billing entities each requiring 5 hours each), or a total cost of \$334,375.

(e) *Further disclosures related to consumers reporting a billing error.* As in the 2006 PRA submission for this Rule, FTC staff estimates that the incremental disclosure obligations related to consumers reporting a billing error under section 308.7(d) requires, on average, about one hour per each billing error. Previously, staff projected that approximately 5 percent of an estimated 49,980,000 calls made to pay-per-call services each year involves such a billing error. The staff is now reducing its prior estimate of the number of those calls by 6 percent¹⁵ (46,981,200 calls) to reflect recent changes in the amount of pay-per-call services and their billing. Assuming the same apportionment (5 percent) of overall calls to pay-per-call services, this amounts to 2,349,060 hours, cumulatively. Applying the \$53.5/hour blended wage rate, the estimated annual cost is \$125,674,710 annually.

David C. Shonka

Acting General Counsel

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval of Washington State Plan Amendment (SPA) 08-002

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

ACTION: Notice of Hearing.

SUMMARY: This notice announces an administrative hearing to be held on February 5, 2009, at the CMS Seattle Regional Office, 2201 Sixth Avenue, MS/RX-43, Seattle, Washington 98121

percent for skilled clerical workers, and 20 percent for management time.

¹⁵ Six percent is determined by an approximate halving of the above-noted 11% reduction staff has applied to its prior estimate of the number of vendors (see note 5). As in past clearance requests for this Rule, it is halved on the assumption that pay-per-call services do not account for any more than half of all telephone-billed purchases.

to reconsider CMS' decision to disapprove Washington SPA 08-002.

Closing Date: Requests to participate in the hearing as a party must be received by the presiding officer by January 14, 2009.

FOR FURTHER INFORMATION CONTACT: Benjamin 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 Washington SPA 08-002 which was submitted on January 7, 2007, and disapproved on September 26, 2008. The SPA proposed to add a methodology to the State plan that would be used in the event that a contract with Regional Support Network to provide mental health services under a managed care delivery system to the State of Washington was not continued.

Federal regulations at 42 CFR 430.20 and 447.205, are issued under the authority of general statutory requirements concerning methods of administration at section 1902(a)(4)(A) of the Social Security Act (the Act) and specific requirements at section 1902(a)(30)(A) concerning methods and procedures relating to payments to providers. These regulations require that public notice of changes in statewide methods and standards for setting payment rates be published in either a State register or the newspaper of widest circulation in the State (if there is not a city with a population of at least 50,000). In addition, they specify that the notice must be published before the effective date of the State plan.

Washington did not provide public notice which complied with Federal regulations at 42 CFR 447.205. Although, beginning in December of 2007, the State held meetings with providers to inform them of what would be proposed via SPA 08-002, it did not provide the notice required by Federal regulations at 42 CFR 447.205 until February 20, 2008. As a result, the State was informed the effective date of this plan could be no earlier than February 21, 2008. However, Washington failed to make this required change.

Pursuant to Federal regulations at 42 CFR 430.10, which is authorized by section 1902(a)(4) of the Act and implements the general requirements of section 1902(a) of the Act for a State plan, a State plan must provide sufficient information to describe the nature and scope of the State program and to provide a basis for Federal financial participation. And, Federal regulations at 42 CFR 441.252(b), which

implement in part provider payment provisions under section 1902(a)(30)(A) of the Act, require that the State plan include a comprehensive description of the methods and standards used to set payment rates. The proposed SPA did not meet these requirements because the payment methodologies were not understandable and auditable. CMS requested further information about the factors Washington used to set its rates, and how the payment methodologies would be administered, but the State failed to provide sufficient responsive information to assure us that providers and auditors could determine whether correct payments had been made. Absent this information, CMS cannot determine that the requirements under section 1902(a) of the Act have been met.

Based on the above, and after consultation with the Secretary of the Department of Health and Human Services as required under Federal regulations at 42 CFR 430.15(c)(2), CMS disapproved Washington SPA 08-002.

The hearing will involve the following issues:

- Whether the proposed effective date for the SPA was consistent with the limitations authorized under the requirements of sections 1902(a)(4)(A) and 1902(a)(30)(A) of the Act relating to methods of administration generally and methods and procedures for payment rates specifically, and the implementing regulations at 42 CFR 430.20 and 42 CFR 447.205, which require advance public notice of changes in payment rates before a State plan amendment can become effective. The State's proposed effective date for the SPA was earlier than the date of the publication of the public notice that the State submitted in support of the SPA.
- Whether Washington provided adequate documentation to document the proposed payment rates and to demonstrate that the proposed rates were consistent with efficiency and economy as required by section 1902(a)(30)(A) of the Act. Specifically, the State proposed the use of actuarially developed rates that included a range of rates as opposed to a single dollar amount. The State indicated that the single dollar amount was developed from the above mentioned rate range, however, they were not able to provide either the dollar amount or the documentation regarding the construction of the single rate.

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

Ms. Robin Arnold-Williams,
Secretary, Department of Social and Health Services, P.O. Box 45010,
Olympia, WA 98504-5010.

Dear Ms. Arnold-Williams:

I am responding to your request for reconsideration of the decision to disapprove the Washington Medicaid State plan amendment (SPA) 08-002, which was submitted on January 7, 2008, and disapproved on September 26, 2008. The SPA proposed to add a methodology to the State plan that would be used in the event that a contract with Regional Support Network to provide mental health services under a managed care delivery system to the State of Washington was not continued.

The issues to be considered at the hearing are:

- Whether the proposed effective date for the SPA was consistent with the limitations imposed by applicable appropriations statutes on the availability of funding for SPAs, the requirements of sections 1902(a)(4)(A) and 1902(a)(30)(A) of the Social Security Act (the Act) relating to methods and procedures generally and for payment rates specifically, and the implementing regulations at 42 CFR 430.20 and 42 CFR 447.205—which require advance public notice of changes in payment rates. The State's proposed effective date for the SPA was earlier than the date of the publication of the public notice that the State submitted in support of the SPA.

- Whether Washington provided adequate documentation to document the proposed payment rates and demonstrate that the proposed rates were consistent with efficiency and economy as required by section 1902(a)(30)(A) of the Act. Specifically, the State proposed the use of actuarially developed rates that included a range of

rates as opposed to a single dollar amount. The State indicated that the single dollar amount was developed from the above mentioned rate range, however, they were not able to provide either the dollar amount or the documentation regarding the construction of the single rate.

I am scheduling a hearing on your request for reconsideration to be held on February 5, 2009, at the Centers for Medicare & Medicaid Services Seattle Regional Office, 2201 Sixth Avenue, MS/RX-43, Seattle, Washington 98121, in order to reconsider the decision to disapprove SPA 08-002. 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 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 presiding officer at (410) 786-3169. 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.

Sincerely,
Kerry Weems,
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: December 22, 2008.

Kerry Weems,
Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0650]

Agency Information Collection Activities; Proposed Collection; Comment Request; General Administrative Procedures; Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions

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 contained in existing FDA regulations regarding the general administrative procedures for a person to petition the Commissioner of Food and Drugs (the Commissioner) to issue, amend, or revoke a rule; to file a petition for an administrative reconsideration or an administrative stay of action; and to request an advisory opinion from the Commissioner.

DATES: Submit written or electronic comments on the collection of information by March 2, 2009.

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: Jonna Capezzuto, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794.

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 the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice