

Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/BusinessOpportunityRulePRA> by following the instructions on the web-based form. When 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 “Business Opportunity Rule Paperwork Comment, FTC File No. P114408” on your comment and on the envelope, and mail it to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610, Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible FTC Web site at <https://www.ftc.gov/>, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else’s Social Security number; date of birth; driver’s license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any “trade secret or any commercial or financial information which . . . is privileged or confidential”—as provided by 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)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled “Confidential,” and must comply with FTC Rule 4.9(c). 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). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC Web site—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC Web site, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

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 November 27, 2017. For information on the Commission’s privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

**David C. Shonka,**

*Acting General Counsel.*

[FR Doc. 2017–20846 Filed 9–27–17; 8:45 am]

**BILLING CODE 6750–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

[OMB No.: 0970—NEW]

#### Submission for OMB Review; Comment Request; Child Care and Development Fund Quality Progress Report

*Description:* Lead Agencies are required to spend a certain percent of their Child Care and Development Fund (CCDF) awards on activities to improve the quality of child care. Lead Agencies are also required to invest in at least one of 10 allowable quality activities included in the Child Care and Development Block Grant (CCDBG) Act of 2014. In order to ensure that States and Territories are meeting these requirements, the CCDBG Act and the CCDF final rule require Lead Agencies to submit an annual report, identified as the Quality Progress Report in the CCDF final rule. The report must describe how quality funds were expended, including what types of activities were funded and

measures used to evaluate progress in improving the quality of child care programs and services. The QPR replaces the Quality Performance Report that was previously an appendix to the CCDF Plan. The QPR increased transparency on quality spending and will continue to gather detailed information on how States and Territories are spending their quality funds, as well as more specific data points to reflect the requirements in the CCDBG Act and the CCDF final rule.

In the QPR, Lead Agencies are asked about the State’s or Territory’s progress in meeting its goals as reported in the CCDF Plan, and provide available data on the results of those activities. Specifically, this report will: (1) Ensure accountability for the use of CCDF quality funds, including a set-aside for quality infant and toddler care that begins in FY 2017; (2) track progress toward meeting State- and Territory-set indicators and benchmarks for improvement of child care quality per what they described in their CCDF Plans; (3) summarize how the Lead Agency is building a progression of professional development for child care providers as envisioned in the CCDBG Act of 2014 and CCDF final rule; and (4) inform federal technical assistance efforts and decisions regarding strategic use of quality funds.

The Office of Child Care (OCC) has given thoughtful consideration to the comments received during the 60-day Public Comment Period and has revised the QPR to better align with the new program requirements made under the CCDBG Act of 2014 and the final rule. The revised document also contains additional guidance and clarification where appropriate in order to improve the quality of information that is being collected. *Note:* A correction was also made to the burden hours. This 30-day Public Comment Period provides an opportunity for the public to submit comments to the Office of Management and Budget (OMB).

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L’Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*Respondents:* State and Territory CCDF Lead Agencies (56).

## ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
CCDF QPR .....	56	1	60.0	3,360

*Estimated Total Annual Burden Hours:* 3,360 hours.

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. All requests should be identified by the title of the information collection. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-0007]

#### Fee for Using a Rare Pediatric Disease Priority Review Voucher in Fiscal Year 2018

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the fee rate for using a rare pediatric disease priority review voucher for fiscal year (FY) 2018. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to determine and collect rare pediatric disease priority review user

fees for certain applications for review of human drug or biological products when those applications use a rare pediatric disease priority review voucher. These vouchers are awarded to the sponsors of rare pediatric disease product applications that meet all of the requirements of this program and that are submitted 90 days or more after July 9, 2012, upon FDA approval of such applications. The amount of the fee for using a rare pediatric disease priority review voucher is determined each FY, based on the difference between the average cost incurred by FDA in the review of a human drug application subject to priority review in the previous FY and the average cost incurred in the review of an application that is not subject to priority review in the previous FY. This notice establishes the rare pediatric disease priority review fee rate for FY 2018 and outlines the payment procedures for such fees.

**FOR FURTHER INFORMATION CONTACT:** Robert J. Marcarelli, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE-14202F, Silver Spring, MD 20993-0002, 301-796-7223.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Section 908 of FDASIA (Pub. L. 112-144) added section 529 to the FD&C Act (21 U.S.C. 360ff). In section 529 of the FD&C Act, Congress encouraged development of new human drugs and biological products for prevention and treatment of certain rare pediatric diseases by offering additional incentives for obtaining FDA approval of such products. Under section 529 of the FD&C Act, the sponsor of an eligible human drug application submitted 90 days or more after July 9, 2012, for a rare pediatric disease (as defined in section 529(a)(3)) shall receive a priority review voucher upon approval of the rare pediatric disease product application. The recipient of a rare pediatric disease priority review voucher may either use the voucher for a future human drug application submitted to FDA under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), or transfer (including by sale) the voucher to another party. The

voucher may be transferred (including by sale) repeatedly until it ultimately is used for a human drug application submitted to FDA under section 505(b)(1) of the FD&C Act or section 351(a) of the Public Health Service Act. A priority review is a review conducted with a Prescription Drug User Fee Act (PDUFA) goal date of 6 months after the receipt or filing date, depending on the type of application. Information regarding PDUFA goals is available at <http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm511438.pdf>.

The applicant that uses a rare pediatric disease priority review voucher is entitled to a priority review of its eligible human drug application, but must pay FDA a rare pediatric disease priority review user fee in addition to any user fee required by PDUFA for the application. Information regarding the rare pediatric disease priority review voucher program is available at: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm375479.htm>.

This notice establishes the rare pediatric disease priority review fee rate for FY 2018 at \$2,830,579 and outlines FDA's procedures for payment of rare pediatric disease priority review user fees. This rate is effective on October 1, 2017, and will remain in effect through September 30, 2018.

##### **II. Rare Pediatric Priority Review User Fee for FY 2018**

Under section 529(c)(2) of the FD&C Act, the amount of the rare pediatric disease priority review user fee is determined each fiscal year based on the difference between the average cost incurred by FDA in the review of a human drug application subject to priority review in the previous fiscal year, and the average cost incurred by FDA in the review of a human drug application that is not subject to priority review in the previous fiscal year.

A priority review is a review conducted with a PDUFA goal date of 6 months after the receipt or filing date, depending on the type of application. Under the PDUFA goals letter, FDA has committed to reviewing and acting on 90 percent of the applications granted