

Order No. 001 are identified in Attachment J.1(a) Schedule of Deliverables of the 11th SOW. Further, as indicated in Sections G.22 and G.29, the Contracting Officer will use the Contractor Performance Assessment Reporting System (CPARS) criteria in performing evaluations: Quality, Schedule/Timeliness, Cost/Price Control, Business Relations, Management, and Small Business. Performance on the evaluation criteria defined in Attachment J-1(b) will be considered for assessment of the Quality sub-factor for the CPARS assessment.

If we choose, we may notify the QIN-QIO of the intention not to renew the QIN-QIO contract, and inform the QIN-QIO of the QIN-QIO's rights under the current statute. Any failure at one or more of the annual or 54th month evaluations for any Task may result in the QIN-QIO receiving an adverse performance evaluation. Further, failure may impact on the QIN-QIO's ability to continue similar work in or eligibility for future QIO Program awards.

We reserve the right at any point, prior to the notification of our intention not to continue the option for a Task and/or to renew the contract, to revise measures or adjust the expected minimum thresholds for satisfactory performance or remove criteria from a Task evaluation protocol for any reason, including, but not limited to, data gathered based on experience with the amount of improvement achieved during the contract cycle or in pilot projects currently in progress, information gathered through evaluation of the QIN-QIO performance overall, or any unforeseen circumstances. Further, in accordance with standard contract procedures, we reserve the right at any time to discontinue all or part of one or more tasks for one or more states or territories in the QIN area or any other part of this contract regardless of QIN-QIO performance on the Task.

#### *Rounding Rules*

The rounding of results to assess the minimum performance criteria indicated in Section J, Attachment J.1(b) uses the following rules.

#### 1. Interim Calculations

We will not round the interim results of calculations used to produce results. (For example, we will not round the results from steps used to calculate the criteria or result). For example, we will not first round baseline and re-measurement rates for the calculation of relative improvement.

#### 2. Percentages/Proportions/Rates

Use conventional rounding "round half up." For example, to round from the hundredth to the tenth digit, round using the tie-break rule of "half-up." 5.45 will become 5.5 whereas 5.44 will become 5.4. Apply conventional rounding to one digit beyond that used to specify the criteria (for example, for whole numbers, to the tenths place). For example, for a criterion expressed as 5 percent, 4.46 percent rounds to 4.5 percent and 4.44 percent rounds to 4.4 percent.

#### 3. Integers

For discrete numbers of units required for improvement, round to the more favorable (typically lower) integer with a minimum of one. We note that this method is applied selectively to special cases as indicated in Section J, Attachment J.1(b). This method is more than a rounding rule. We calculate a minimum performance target using the minimum performance criteria and the size of the re-measurement criteria. For example, for a minimum criteria of 95 percent and a re-measurement denominator of 10,  $10 \times 0.95 = 9.5$ , which is rounded down (the more favorable direction) to 9. For this example, if CMS specified use of the integer rounding rule for this measure, the minimum performance criteria of 95 percent would be met by achieving at least 9 cases given a re-measurement denominator count of size 10. If we do not specifically indicate that the integer rounding rule applied to this measure, the percentage rounding rule would be used.

### III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

### IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

### VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Dated: June 3, 2014.

**Marilyn Tavenner,**

*Administrator, Centers for Medicare & Medicaid Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Proposed Information Collection Activity; Comment Request

##### *Proposed Projects:*

*Title:* Annual Report/ACF 204 (State MOE)—1 collection.

*OMB No.:* 0970-0248.

*Description:* The Administration for Children and Families (ACF) is requesting a three-year extension of the ACF-204 (Annual MOE Report). The report is used to collect descriptive program characteristics information on the programs operated by States and Territories in association with their Temporary Assistance for Needy Families (TANF) programs. All State and Territory expenditures claimed toward States and Territories MOE requirements must be appropriate, i.e., meet all applicable MOE requirements. The Annual MOE Report provides the ability to learn about and to monitor the nature of State and Territory expenditures used to meet States and Territories MOE requirements, and it is an important source of information about the different ways that States and Territories are using their resources to help families attain and maintain self-sufficiency. In addition, the report is used to obtain State and Territory program characteristics for ACF's annual report to Congress, and the report serves as a useful resource to use in Congressional hearings about how TANF programs are evolving, in assessing State the Territory MOE expenditures, and in assessing the need for legislative changes.

*Respondents:* The 50 States of the United States, the District of Columbia, Guam, Puerto Rico, and the Virgin Islands.

## ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF-204 .....	54	1	118	6,372

*Estimated Total Annual Burden Hours: 6,372*

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-1076]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice

**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 proposed collection of information resulting from the guidance to manufacturers of veterinary and human drugs, including human biological drug products, on how to resolve disputes of scientific and technical issues relating to current good manufacturing practice (CGMP).

**DATES:** Submit either electronic or written comments on the collection of information by October 10, 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, 8455 Colesville Rd., COLE-14526, Silver

Spring, MD 20993-0002; [PRAStaff@fda.hhs.gov](mailto: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 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 of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice (OMB Control Number 0910-0563)—Extension

The guidance is intended to provide information to manufacturers of veterinary and human drugs, including human biological drug products, on how to resolve disputes of scientific and technical issues relating to CGMP. Disputes related to scientific and