regulation establishes the following reporting requirements:

- The Preliminary Justification: This data collection is required of all health insurance issuers for all rate increases that exceed the "subject to review"' reporting threshold as defined in the rule. This information will be posted on an HHS Web site.
- Rate Review Final Determination: This data collection requires States with effective rate review programs and CMS to report their review findings and unreasonable rate increase determinations on all rate increases that are subject to review. This information will be posted on an HHS Web site.
- The Final Justification for An Unreasonable Rate Increase: This data collection is required of health insurance issuers that elect to implement a rate increase that is determined to be unreasonable based on State or CMS review. This information will be posted on the Health Insurance Issuer's Web site and on a CMS Web site.

2. Preliminary Justification

The Preliminary Justification consists of three parts, Part I: Rate Increase Summary, Part II: Written Explanation of the Rate Increase, and Part III: Rate Filing Documentation. Issuers must complete Parts I and II for all rate increases that exceed the reporting threshold as defined in the rule. As described in the preamble of the rule, this information would be collected to provide consumers with basic information on all rate increases that are subject to review under the rate review program.

Under the rule, "subject to review" rate increases would be reviewed by either States or CMS, depending on whether a State has an effective rate review program. Issuers would only be required to submit Part III of the Preliminary Justification when CMS is conducting the review of a rate increase that is "subject to review." Accordingly, Part III requires health insurance issuers to provide detailed rate data that would be used for the purposes of conducting thorough actuarial reviews and for making determinations about whether rate increases are unreasonable. This Notice contains the following information about the Preliminary Justification:

- Preliminary Justification Issuer Instructions: Health insurance issuer instructions for completing all three parts of the Preliminary Justification.
- Part I Worksheet: A standardized Excel worksheet that must be used to complete Part I of the Preliminary Justification.
- Sample Internet display of the Rate Review Consumer Disclosure: Information provided in the Preliminary Justification would be posted on an HHS Web site. This sample display shows how the information contained in the Part I Worksheet would be displayed to consumers.

3. Rate Review Final Determination

Under the rule, States and CMS would have to provide a Rate Review Final Determination at the close of their review of all "subject to review" rate increases. The Rate Review Final Determination must provide the State's or CMS' determination on whether a rate increase is 'unreasonable'. Section 154.301(a)(3) of the rule provides a list of actuarial review elements that must be taken into account as part of the rate review process. The Final Determination must provide a brief statement explaining how the review of elements set forth in § 154.301(a)(3) caused the State or CMS to arrive at its determination that the rate is unreasonable.

The Rate Review Final Determination will be entered into a data entry text box in the Rate Review Data Collection System. CMS is estimating that this statement would be approximately a paragraph in length. There is no specific form or set of instructions associated with this reporting requirement, apart from the reporting requirements provided in the rule. The information provided in the Rate Review Final Determination will be posted as part of the rate review consumer disclosure information on an HHS Web site.

4. Final Justification for An Unreasonable Rate Increase

The rule states that if a health insurance issuer implements a rate increase determined by CMS or a State to be unreasonable, the health insurance issuer must provide a Final Justification for an Unreasonable Rate Increase. In the Final Justification, issuers would have to provide a short statement about why they are electing to implement an unreasonable rate increase. This statement would be entered into a data entry text box in the Rate Review Data Collection System and would not need to be more than a paragraph or two in length. There is no form or instructions associated with this statement apart from the requirements provided in the regulation.

The Final Justification Statement will be posted on an HHS Web site in the same location as the Preliminary Justification and Rate Review Final Determination. Additionally, health insurance issuers implementing rate increases that were determined to be unreasonable, must post all of this information—the Preliminary Justification, the Rate Review Final Determination, and the Final Justification Statement on their Web sites for a period of 3 years. *Form Number:* CMS–10379; (OCN: 0938–NEW) *Frequency:* Annually; *Affected Public:* Private Sector and States; *Number of Respondents:* 452; *Number of Responses:* 3,571; *Total Annual Hours:* 11,902. (For policy questions regarding this collection, contact Sally McCarty at (301) 492–4489 or *RateReview@hhs.gov.* For all other issues call 410–786–1326.)

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *June 27, 2011.*

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, E-mail: *OIRA_submission@omb.eop.gov.*

Dated: May 26, 2011.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2011–13458 Filed 5–27–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: State Developmental Disabilities Council 5-Year State Plan.

OMB No.: 0980–0162.

Description: A Plan developed by the State Council on Developmental Disabilities is required by federal statute. Each State Council on Developmental Disabilities must develop the plan, provide for approval by the State Governor, and finally submit the plan on a five-year basis. On an annual basis, the Council must review the plan and make any amendments. The State Plan will be used (1) By the Council as a planning document; (2) by the citizenry of the State as a mechanism for commenting on the plans of the Council; and (3) by the Department as a stewardship tool, for ensuring compliance with the Developmental Disabilities Assistance and Bill of Rights Act, as one basis for providing technical assistance (*e.g.,*

during site visits), and as a support for management decision making.

Respondents: 55 State Developmental Disabilities Councils.

Annual Burden Estimates

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Developmental Disabilities Council 5-Year State Plan	55	1	367	20,185

Estimated Total Annual Burden Hours: 20,185

Additional Information

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. *E-mail address: 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, *Fax:* 202–395–7285. *E-mail: oira_submission@omb.eop.gov, Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–13416 Filed 5–31–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0305]

Draft Guidance for Industry and FDA Staff: Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions." This draft guidance document is intended for manufacturers and distributors of research use only (RUO) and investigational use only (IUO) in vitro diagnostic (IVD) products and any other entities who label IVD products.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by August 30, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Commercially Distributed in Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993 or Office of Communication, Outreach and Development (HFM–40), 1401 Rockville Pike, suite 200N, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to CDRH at 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov.* Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Tonya Wilbon, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 66, rm. 5663, Silver Spring, MD 20993–0002, 301–796–6224.

FOR QUESTIONS RELATING TO DEVICES REGULATED BY CBER, CONTACT: Stephen Ripley (HFM–17), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

RUO and IUO IVD products are distinctive in that they are devices that may themselves be used in research or investigations on human samples that may eventually lead to their clearance or approval for clinical diagnostic use, and they also may be marketed for and used in the research and investigation of other FDA-regulated products. Thus, the manufacturer of an IUO IVD product is not necessarily the sponsor of a clinical investigation that uses such an IVD product in a study. The manufacturer of such an IUO IVD product may legally distribute the product commercially without FDA premarket review, as long as the marketing is only for investigational use.

The marketing of unapproved and uncleared IVD products for purposes other than research or investigation (for example, for clinical diagnostic use) has led in some cases to diagnostic use of laboratory tests with unproven performance characteristics and manufacturing controls that are inadequate to ensure consistent manufacturing of the finished product. Use of such tests for clinical diagnostic purposes may mislead healthcare providers and cause serious adverse health consequences to patients who are not aware that they are being diagnosed with research or investigational products. FDA is therefore issuing this guidance to remind manufacturers of the requirements applicable to RUO and IUO IVDs.

This guidance will clarify the regulatory requirements applicable to IVD products intended for research use only or investigational use only and will provide the responses of CDRH and CBER to some frequently asked questions about how products should and should not be marketed.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance