The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. As we stated in the RIA for the February 2, 2011 final rule with comment period (76 FR 5952) and the regulatory impact statement of the March 23, 2011 notice (76 FR 16423), we do not believe that the application fee will have a significant impact on small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this notice would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. This notice does not mandate such expenditures by States and local governments.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this notice does not impose substantial direct costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

The costs associated with this notice involve the increase in the application fee that certain providers and suppliers must pay in CY 2012. In the RIA for the February 2, 2011 final rule with comment period (76 FR 5955 through 5958), we estimated the total amount of application fees for CYs 2011 through 2015. For 2012, and based on a $515 application fee, we projected in Tables 11 and 12 (76 FR 5955 and 5956) a total cost in fees of $71,803,875 for Medicare institutional providers (or 139,425 providers × $515). In the February 2, 2011 final rule with comment period (76 FR 5957 and 5958), we estimated the total cost in CY 2012 for Medicaid providers to be $12,944,010 (or 25,134 providers × $515), as indicated in Tables 13 and 14.

We are retaining the figure of 25,134 Medicaid providers for purposes of this notice. However, we are changing the Medicare provider estimate based on our plan to revalidate all Medicare providers and suppliers– even if the revalidation is considered ''off-cycle'' per 42 CFR 424.515(e).

1. Medicare

For purposes of this notice only, we estimate that approximately 840,000 Medicare providers and suppliers will be subject to revalidation in CY 2012. Of this total, we believe that roughly 80 percent will be exempt from the application fee requirement because the provider or supplier: (1) Is of a type (for example, a physician) that is exempt from the requirement, or (2) qualifies for a hardship exception under 42 CFR 424.514(c). This leaves 168,000 revalidating providers and suppliers that will have to pay the fee.

In the February 2, 2011 final rule with comment period (76 FR 5955), we estimated that 31,200 newly-enrolling institutional providers would be subject to the application fee in CY 2012. We stand by this projection for purposes of this notice. Using a figure of 199,200 providers and suppliers (168,000 + 31,200), we estimate an increase in the cost of the Medicare application fee requirement in CY 2012 of $1,593,600 (or 199,200 × $8.00).

2. Medicaid and CHIP

In the February 2, 2011 final rule with comment period (76 FR 5957 and 5958), we estimated that 25,134 (8,438 newly enrolling + 16,696 re-enrolling) Medicaid and CHIP providers would be subject to an application fee in CY 2012. This results in an increase in the cost of the Medicaid and CHIP application fee requirement in CY 2012 of $201,072 (or 25,134 × $8.00).

3. Total

Based on the foregoing, we estimate the total increase in the cost of the application fee requirement for Medicare, Medicaid, and CHIP providers and suppliers in CY 2012 to be $1,794,672.

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

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 30, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–28424 Filed 11–1–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Descriptive Study of Tribal Temporary Assistance for Needy Families (TANF) Programs.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF) is proposing an information collection activity as part of the Descriptive Study of Tribal TANF Programs. The proposed information collection consists of semi-structured interviews and focus groups with key Tribal TANF respondents on questions of Tribal TANF administration, policies, service delivery, and program context. Through this information collection, ACF seeks to gain an in-depth, systematic understanding of program implementation, operations, outputs and outcomes in selected sites, and identify promising practices and other areas for further study.

Respondents: Tribal TANF administrators, staff and participants, and staff of related programs.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Discussion Guide for Use with Tribal TANF administrators	13	1	2	26
Discussion Guide for Use with Tribal TANF staff	12	1	1	12
Discussion Guide for Focus Groups with Tribal TANF clients	20	1	2	40
Discussion Guide for Use with staff of related programs	20	1	1	20
All Instruments	65			98

Estimated Total Annual Burden Hours: 98.

In compliance with the requirements of Section 3506(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: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@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.

Dated: October 26, 2011.

Steven M. Hanmer,

Reports Clearance, Officer.

[FR Doc. 2011–28273 Filed 11–1–11; 8:45 am]

BILLING CODE 4184–09–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

President's Committee for People With Intellectual Disabilities Meeting, Via Conference Call, Cancellation

AGENCY: President's Committee for People with Intellectual Disabilities (PCPID).

ACTION: Notice of PCPID Conference Call Cancellation.

DATES: The conference call was scheduled for October 28, 2011, 1 p.m. to 2:30 p.m.

FOR FURTHER INFORMATION CONTACT: Laverdia Taylor Roach, Senior Advisor, President's Committee for People with Intellectual Disabilities, The Aerospace Center, Second Floor West, 370 L'Enfant Promenade SW., Washington, DC 20447. Telephone: (202) 619–0634. Fax: (202) 205–9519. Email: *LRoach@acf.hhs.gov.*

Further meetings will be announced through a separate **Federal Register** notice.

Dated: October 26, 2011.

Jamie Kendall,

Deputy Commissioner, Administration on Developmental Disabilities.

[FR Doc. 2011–28292 Filed 11–1–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1999–D–2955]

Revised Guidance for Industry on Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients (Revision), VICH GL18(R); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry (#100) entitled ''Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients (Revision)'' VICH GL18(R). This revised guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The guidance is intended to recommend acceptable amounts of residual solvents in new animal drugs (referred to as pharmaceuticals or veterinary medicinal products in this guidance) for the safety of the target animal as well as for the safety of human consumers of products derived from treated food producing animals. It is intended to assist in developing new animal drug applications (referred to as marketing applications in this guidance) submitted to the European Union, Japan, and the United States.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mai Huynh, Center for Veterinary Medicine (HFV–142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, (240) 276–8273, *mai.huynh@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: