

of public hearing will inform FDA's decision about whether and how to adjust the current enforcement policies for drug products labeled as homeopathic to reflect changes in the homeopathic product marketplace over the last approximately 25 years.

FDA is extending the comment period for an additional 60 days, until August 21, 2015. The Agency believes that an additional 60-day extension of the comment period for the notice of public hearing will allow adequate time for interested persons to submit comments without significantly delaying Agency decision making on these important issues.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). You should annotate and organize your comments to identify the specific questions or topic to which they refer. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: June 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF STATE

22 CFR Part 96

[Public Notice 9165]

RIN 1400-AD82

Intercountry Adoptions: Regulatory Change To Prevent Accreditation and Approval Renewal Requests From Coming Due at the Same Time

AGENCY: Department of State.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the Department of State (Department) regulation on the accreditation and approval of adoption service providers in intercountry adoptions. Most agencies and persons currently accredited received that accreditation at approximately the same time, which has resulted in a surge of concurrent renewal applications for consideration by the Council on

Accreditation (COA), the designated accrediting entity. Permitting some agencies or persons to qualify for an extension by one year of the accreditation or approval period will result in a more even distribution of applications for renewal in a given year. By distributing renewals, and the resources needed to process them, COA will be further enabled to effectively and consistently carry out its other functions.

DATES: Comments are due by July 10, 2015.

ADDRESSES: • *Internet:* You may view this proposed rule and submit your comments by visiting the Regulations.gov Web site at www.regulations.gov, and searching for docket number DOS-2014-0015.

• *Mail or Delivery:* You may send your paper, disk, or CD-ROM submissions to the following address: Comments on Proposed Rule 22 CFR part 96, Office of Legal Affairs, Overseas Citizen Services, U.S. Department of State, CA/OCS/L, SA-17, Floor 10, Washington, DC 20522-1710.

• All comments should include the commenter's name and the organization the commenter represents (if applicable). If the Department is unable to read your comment for any reason, the Department might not be able to consider your comment. Please be advised that all comments will be considered public comments and might be viewed by other commenters; therefore, do not include any information you would not wish to be made public. After the conclusion of the comment period, the Department will publish a final rule (in which it will address relevant comments) as expeditiously as possible.

FOR FURTHER INFORMATION CONTACT:

Carine Rosalia, Office of Legal Affairs, Overseas Citizen Services, U.S. Department of State, CA/OCS/L, SA-17, Floor 10, Washington, DC 20522-1710; (202) 485-6079.

SUPPLEMENTARY INFORMATION:

Why is the Department promulgating this rulemaking?

This proposed rule amends procedural aspects of the Intercountry Adoption Accreditation Regulations concerning the length of accreditation or approval found in 22 CFR part 96. Subpart G governs decisions on applications for accreditation and approval. Section 96.60 provides for accreditation or approval for a period of four years. Section 96.60 does not currently provide the opportunity to stagger the renewal applications, which

results in many renewal applications coming due at the same time.

This proposed rule will aid the accrediting entity in managing its workload. In particular, the amendments to this section will allow for a one-year extension of previously-granted accreditation or approval, not to exceed five years total, based on criteria included in the rule, and summarized here.

There will be criteria for selecting which agencies or persons are eligible for the one-year extension. As a threshold matter, only agencies and persons that have no pending adoption-related complaint investigations or adverse actions will be eligible for an extension under this procedure. Also, those entities that have undergone a change in corporate or internal structure (such as a merger or a leadership change in chief executive or chief financial officer) since their initial accreditation/approval or last renewal will not qualify for an extension under this procedure. If the agency or person meets the threshold criteria, in order to ensure that the extension achieves its purpose of staggering renewals thereafter, the Secretary, in his discretion may consider additional factors including, but not limited to, the agency's or person's volume of intercountry adoption cases in the year preceding the application for renewal or extension, the agency's or person's U.S. state licensure record, and the number of extensions available.

Since the President signed into law the Universal Accreditation Act of 2012, approximately 40 new agencies received accreditation, all in the same year. The resulting surge in the number of agencies requiring review in certain years argued strongly for establishing a mechanism that would allow COA to better manage the distribution of renewals. The procedure outlined in this rulemaking will allow a more even distribution of the number of renewals an accrediting entity must review in a given year.

The Department invites comment on the procedures described above.

Administrative Procedure Act

The Department is publishing this notice of proposed rulemaking with a 30-day period for public comments.

Regulatory Flexibility Act/Executive Order 13272: Small Business

Consistent with section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Department certifies that this proposed rule does not have a significant economic impact on a substantial number of small entities. For

the small business entities affected by the amendments, the cost is neutral because it does not change the cost per year of accreditation or renewal, but in only potentially the year in which renewal takes place.

Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995, (codified at 2 U.S.C. 1532) does not apply to this rulemaking.

Small Business Regulatory Enforcement Fairness Act of 1996

This proposed rule is not a major rule as defined by 5 U.S.C. 804, for purposes of congressional review of agency rulemaking under the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121).

Executive Order 12866

The Department of State has reviewed this proposed rule to ensure its consistency with the regulatory philosophy and principles set forth in Executive Order 12866 and has determined that the benefits of this final regulation justify its costs. The Department does not consider this rulemaking to be an economically significant action under the Executive Order. The proposed rule will not add any new legal requirements to Part 96; it merely adds administrative flexibility to the work of the Department-designated accrediting entity.

Executive Orders 12372 and 13132: Federalism

This proposed rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. Nor will it have federalism implications warranting the application of Executive Orders 12372 and No. 13132.

Executive Order 12988: Civil Justice Reform

The Department has reviewed the proposed rule in light of Executive Order No. 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13563: Improving Regulation and Regulatory Review

The Department has considered this proposed rule in light of Executive Order 13563, dated January 18, 2011, and affirms that it is consistent with the guidance therein.

Paperwork Reduction Act

This proposed rule does not impose information collection requirements subject to the provisions of the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Part 96

Adoption, Child welfare, Children, Immigration, Foreign persons, Accreditation, Approval.

For the reasons stated in the preamble, the Department of State proposes to amend 22 CFR part 96 as follows:

PART 96—INTERCOUNTRY ADOPTION ACCREDITATION OF AGENCIES AND APPROVAL OF PERSONS

- 1. The authority citation for part 96 continues to read as follows:

Authority: The Convention on Protection of Children and Co-operation in Respect of Intercountry Adoption (done at the Hague, May 29, 1993), S. Treaty Doc. 105-51 (1998), 1870 U.N.T.S. 167 (Reg. No. 31922 (1993)); The Intercountry Adoption Act of 2000, 42 U.S.C. 14901-14954; The Intercountry Adoption Universal Accreditation Act of 2012, Pub. L. 112-276, 42 U.S.C. 14925.

- 2. Revise § 96.60 to read as follows:

§ 96.60 Length of accreditation or approval period.

(a) The accrediting entity will accredit or approve an agency or person for a period of four years, except as provided in § 96.60(b). The accreditation or approval period will commence on the date that the agency or person is granted accreditation or approval.

(b) In order to stagger the renewal requests from agencies and persons applying for accreditation or approval and to prevent the renewal requests from coming due at the same time, the accrediting entity may extend the period of accreditation it has previously granted for no more than one year and such that the total period of accreditation does not exceed five years, as long as the agency or person remains in substantial compliance with the applicable standards in subpart F of this part. The only agencies and persons that may qualify for an extension are:

- (1) Those that have no pending Complaint Registry investigations or adverse actions (see § 96.70); and
- (2) Those that have not undergone a change in corporate or internal structure (such as a merger or change in chief executive or financial officer) during their current accreditation or approval period. For agencies and persons that meet these two criteria, the Secretary, in his or her discretion, may consider additional factors in deciding upon an

extension including, but not limited to, the agency's or person's volume of intercountry adoption cases in the year preceding the application for renewal or extension, the agency's or person's state licensure record, and the number of extensions available.

Dated: June 2, 2015.

Michele T. Bond,

Acting Assistant Secretary for Consular Affairs, U.S. Department of State.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R10-OAR-2015-0330; FRL-9928-95-Region 10]

Approval and Promulgation of Implementation Plans; Washington: Interstate Transport of Fine Particulate Matter

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Clean Air Act (CAA) requires each State Implementation Plan (SIP) to contain adequate provisions prohibiting air emissions that will have certain adverse air quality effects in other states. On May 11, 2015, the State of Washington submitted a SIP revision to the Environmental Protection Agency (EPA) to address these interstate transport requirements with respect to the 2006 24-hour fine particulate matter (PM_{2.5}) National Ambient Air Quality Standards (NAAQS). The EPA is proposing to find that Washington has adequately addressed certain CAA interstate transport requirements for the 2006 24-hour PM_{2.5} NAAQS.

DATES: Written comments must be received on or before July 10, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R10-OAR-2015-0330, by any of the following methods:

- www.regulations.gov: Follow the on-line instructions for submitting comments.

- **Email:** R10-Public_Comments@epa.gov.

- **Mail:** Jeff Hunt, EPA Region 10, Office of Air, Waste and Toxics (AWT-150), 1200 Sixth Avenue, Suite 900, Seattle, WA 98101.

- **Hand Delivery/Courier:** EPA Region 10 9th Floor Mailroom, 1200 Sixth Avenue, Suite 900, Seattle WA, 98101. Attention: Jeff Hunt, Office of Air, Waste and Toxics, AWT-150. Such deliveries