III. 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). 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/Drugs/Guidance
ComplianceRegulatoryInformation/
Guidances/default.htm; or http://www.fda.gov/BiologicsBloodVaccines/
GuidanceComplianceRegulatory
Information/Guidances/default.htm; or http://www.regulations.gov.

Dated: February 3, 2015.

Leslie Kux,

Associate Commissioner for Policy. [FR Doc. 2015–02561 Filed 2–9–15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF STATE

22 CFR Part 96

[Public Notice: 9023] RIN 1400-AD45

Adoptions: Regulatory Change To Clarify the Application of the Accreditation Requirement and Standards in Cases Covered by the Intercountry Adoption Universal Accreditation Act

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule amends the Department of State (Department) interim rule on the accreditation and approval of adoption service providers in intercountry adoptions, and adopts the interim rule as final. The revisions reflect the requirement of the Intercountry Adoption Universal Accreditation Act of 2012 (UAA) that the accreditation standards developed in accordance with the 1993 Hague Convention on Protection of Children and Co-operation in Respect of Intercountry Adoption (Convention) and the Intercountry Adoption Act of 2000 (IAA), which previously only applied in Convention adoption cases, apply also in non-Convention adoption cases. Nonconvention adoption cases are known as "orphan" cases, defined in the Immigration and Nationality Act (INA). This rule also revises the accreditation rule by referring to the Department of Homeland Security (DHS) Convention home study regulation and deleting obsolete references, such as any reference to temporary accreditation.

DATES: This document finalizes the interim final rule published on July 14, 2014 (79 FR 40629), and is effective

FOR FURTHER INFORMATION CONTACT: 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:**

February 10, 2015.

Why is the Department promulgating this rule?

This rule clarifies that under the Intercountry Adoption Universal Accreditation Act of 2012 (UAA), signed into law January 14, 2013, and effective July 14, 2014, the accreditation requirement and standards found in 22 CFR part 96 apply to any person (including non-profit agencies, for-profit agencies and individuals but excluding government agencies and tribal authorities), providing adoption services on behalf of prospective adoptive parents in an "orphan" intercountry adoption case described under section 101(b)(1)(F) of the Immigration and Nationality Act. Specifically, under Section 2 of the UAA "[t]he provisions of title II and section 404 of the Intercountry Adoption Act of 2000 (42 U.S.C. 14901 et seq.), and related implementing regulations, shall apply to any person offering or providing adoption services in connection with a child described in section 101(b)(1)(F) of the Immigration and Nationality Act (8 U.S.C. 1101(b)(1)(F)), to the sameextent as they apply to the offering or provision of adoption services in connection with a Convention adoption."

Title II of the Intercountry Adoption Act of 2000 (IAA) (Pub. L. 106–279) requires that any person providing adoption services in a Convention case be an accredited, approved, or an exempted adoption service provider, and section 404 imposes civil and criminal penalties for violations of the Act. On February 15, 2006 the Department of State published implementing regulations at 71 FR 8064, on the accreditation and approval of agencies and persons in accordance with the Convention and the IAA.

The UAA extends that rule from Convention cases to "orphan" cases.

This regulatory change includes a number of technical edits to facilitate interpretation of the regulatory requirements and clarify designated accrediting entities' authority under the UAA and the IAA.

The Department is amending the regulation to make 22 CFR part 96, as affected by the UAA, easier to read. This rule will aid the accrediting entity applying the standards and adoption service providers required to comply with the standards. In particular, this rule adds references to the UAA where the IAA is referenced; adds a sentence concerning the UAA effective date; redefines "Central Authority" to include competent authorities, thereby clarifying how the term applies in countries that are not party to the Convention; redefines adoption records to include non-Convention case records and changes Section 96.25(b) concerning accrediting entity access to non-Convention records in cases subject to the UAA; defines the terms INA, IAA, and intercountry adoption; refers to "accreditation and approval" instead of to "Convention accreditation and approval;" revises § 96.46(a)(4) to clarify that foreign supervised providers in non-Convention countries may not have a pattern of licensing suspensions relating to key Convention principles; and revises references to "Convention adoption," "cases subject to the Convention," "Convention case," "Convention country," and "Convention-related activity" to ensure that such references include non-Convention adoptions, activities, countries, and cases under the UAA.

Additionally, this rule corrects the references in 22 CFR 96.37(f)(2), and 96.47(a)(4) and (b), to refer to the correct Department of Homeland Security (DHS) definition of home study preparer and home study requirements. When the original rule was issued in 2006, DHS had not yet published its final rule concerning home studies in Convention cases. Thus, the 2006 State Department rule referred to the "orphan" home study requirements under 8 CFR 204.3(b) and (e), instead of the Convention home study requirements found in 8 CFR 204.301 and 311. This rule references the correct DHS regulation. The change clarifies that the home study must be prepared by an accredited agency, approved person, exempted provider, or a supervised provider. In addition, when the home study is not performed in the first instance by an accredited agency, then an accredited agency must review and approve it. The orphan and Convention home study requirements also differ concerning the required elements,

applicable definitions, and the duty to disclose. The Department notes that, since the publication of the interim final rule, DHS published interim specific guidance in the USCIS Adjudicator's Field Manual, Chapter 21.5(e)(2)(C), on how the Convention home study requirements apply in orphan cases. Finally, the rule amends 22 CFR part 96 to delete obsolete provisions, including any references to temporary accreditation, deleting subpart N in its entirety. Under the IAA, temporary accreditation was only possible for a one- or two-year period following the entry into force of the Convention. Because the Convention entered into force for the United States on April 1, 2008, more than two years ago, temporary accreditation is no longer possible. The rule also deletes the section on "special provisions for agencies and persons seeking to be accredited or approved as of the time the Convention enters into force for the United States" and a reference to that section. Further, the rule revises requirements concerning "notification of accreditation and approval decisions" and "length of accreditation or approval period," deleting provisions that applied only during the transitional period to the Convention entering into force and clarifying that for purposes of the notification requirement the phrase "accreditation or approval decisions" refers to whether an application is granted or denied.

Cases that are grandfathered under Section 2(c) of the UAA are not affected by this rule. See the *Department's adoption Web site* and the *DHS/USCIS Web site* for information on this grandfathering provision.

The interim final rule received no public comment about the changes in the accreditation regulations. The Department is making corrections to the interim final rule in the final rule. In § 96.14(a) the terms "Convention adoption case" and "Convention case" were both meant to be replaced by the term "intercountry adoption case," but the replacement only occurred for "Convention case" and a space disappeared between "adoption" and "case" resulting in an anomalous term "intercountry adoption case". The final rule corrects these errors.

Administrative Procedure Act

The Department published this rule as an interim final rule based on its determination for good cause that delaying the effect of this rule during the period of public comment would be impractical, unnecessary and contrary to public interest under Section 553 of the Administrative Procedure Act

(APA), 5 U.S.C. 553(b)(3)(B). The rule was published and went into effect on the date that the UAA went into effect, July 14, 2014, which aided the accrediting entity in its accreditation and oversight function and avoided confusion among adoption service providers and other members of the public about how the accreditation standards apply in "orphan" intercountry adoption cases. As noted above, the only change to the text of the interim final rule is a correction in § 96.14(a).

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 rule does not have a significant economic impact on a substantial number of small entities. The rule clarifies the requirements imposed by the UAA and IAA on adoption service providers providing services in "orphan" intercountry adoption cases described under section 101(b)(1)(F).

Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 109 Stat. 48, codified at 2 U.S.C. 1532) generally requires agencies to prepare a statement before proposing any rule that may result in an annual expenditure of \$100 million or more by State, local, or tribal governments, or by the private sector. This rule does not result in any such expenditure, nor will it significantly or uniquely affect small governments or the private sector.

Small Business Regulatory Enforcement Fairness Act of 1996

This 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). This rule will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign-based companies in domestic and import markets.

Executive Order 12866

The Department of State has reviewed this 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 within the scope of section 3(f)(1) of the Executive Order.

The rule does not add any new legal requirements to Part 96 but reflects the changes affected by the UAA to apply these accreditation standards in orphan cases. The UAA and this rule benefit prospective adoptive parents, children, and birth families involved in the intercountry adoption process by ensuring that adoption service providers providing services in orphan cases are subject to the same accreditation standards and ongoing oversight and monitoring that apply in Convention cases

Concerning the cost of the UAA, the Report from the Congressional Budget Office (CBO) on October 17, 2012, notes that the UAA imposes "a private sector mandate by requiring all providers of placement services for intercountry adoptions to be compliant with the accreditation standards of the Hague Convention." The report notes, further, that "[t]he initial fees for obtaining accreditation can range between \$10,000 and \$16,000 depending on the size and annual revenue of the entity seeking accreditation. Annual fees to maintain accreditation are less than \$1,000 on average, but are also subject to change based on the revenue of the entity. The cost of liability insurance for adoption agencies varies from state to state and can range between \$10,000 and \$50,000 per year." Overall, CBO concluded: "Based on information gathered from industry professionals, the Department of Health and Human Services, and an accreditation agency, the number of entities that would be affected is relatively small. Therefore, CBO estimates that the aggregate cost of the mandate to the private sector would fall below the annual threshold established in UMRA [Unfunded Mandates Reform Act] (\$146 million in 2012, adjusted annually for inflation)."

The Council on Accreditation (COA), the accrediting entity designated by the Department, reports that approximately forty new agencies applied for accreditation since the UAA became law in January of 2013. This number is much fewer than COA had anticipated.

Executive Orders 12372 and 13132: Federalism

This regulation 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 the rule have federalism implications warranting

the application of Executive Orders 12372 and No. 13132.

Executive Order 12988: Civil Justice Reform

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

Paperwork Reduction Act

This 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.

For the reasons stated in the preamble, the interim final rule amending 22 CFR part 96, which was published at 79 FR 40629 on July 14, 2014, is adopted as a final rule with the following changes:

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.

§ 96.14 [Amended]

■ 2. Amend § 96.14(a) by removing the terms "Convention adoption case" and "intercountry adoptioncase" and adding in place of each the term "intercountry adoption case".

Dated: January 27, 2015.

David T. Donahue,

Senior Advisor for Consular Affairs, U.S. Department of State.

[FR Doc. 2015–02248 Filed 2–9–15; 8:45 am]

BILLING CODE 4710-06-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9710]

RIN 1545-BK50

Foreign Tax Credit Splitting Events

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document contains final Income Tax Regulations with respect to a provision of the Internal Revenue Code (Code) that addresses situations in which foreign income taxes have been separated from the related income. These regulations are necessary to provide guidance on applying the statutory provision, which was enacted as part of legislation commonly referred to as the Education Jobs and Medicaid Assistance Act (EJMAA) on August 10, 2010. These regulations affect taxpayers claiming foreign tax credits or deducting foreign income taxes.

DATES: Effective date: These regulations are effective on February 10, 2015.

Applicability dates: For dates of applicability, see \S 1.704–1(b)(1)(ii)(b)(3), 1.909–1(e), 1.909–2(c), 1.909–3(c), 1.909–4(b), 1.909–5(c), and 1.909–6(h).

FOR FURTHER INFORMATION CONTACT:

Suzanne M. Walsh, (202) 317–6936 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

On February 14, 2012, a notice of proposed rulemaking by cross-reference to temporary regulations (REG–132736–11) under sections 909 and 704 of the Code and temporary regulations (TD 9577) (2012 temporary regulations) were published in the **Federal Register** at [77 FR 8184] and [77 FR 8127], respectively.

Section 1.909–6T of the 2012 temporary regulations set forth an exclusive list of splitter arrangements that applied to foreign income taxes paid or accrued by a section 902 corporation in a taxable year beginning on or before December 31, 2010, comprised of reverse hybrid structure splitter arrangements, foreign consolidated group splitter arrangements, group relief or other loss sharing regime splitter arrangements, and hybrid instrument splitter arrangements (pre-2011 splitter arrangements).

For foreign income taxes paid or accrued by any person in a taxable year

beginning on or after January 1, 2011, § 1.909–5T of the 2012 temporary regulations adopted the same list of splitter arrangements as § 1.909–6T, but added partnership inter-branch payment splitter arrangements to the list.

For foreign income taxes paid or accrued by any person in a taxable year beginning on or after January 1, 2012, § 1.909–2T adopted the list of splitter arrangements applicable to prior taxable years with certain changes. Because regulations under section 901 were modified for taxable years beginning after February 14, 2012, to address the application of the legal liability rule to combined income regimes, consolidated group splitter arrangements were removed from the list (although § 1.909-5T applied the consolidated group splitter arrangement rules to foreign income taxes paid or accrued by any person in a taxable year beginning on or after January 1, 2012, and on or before February 14, 2012). In addition, the definitions of hybrid instrument splitter arrangements and loss-sharing splitter arrangements were expanded.

Sections 1.909–3T and 1.909–6T provided interim mechanical rules for tracking taxes paid or accrued with respect to a splitter arrangement (split taxes) as well as the related income with respect to such taxes.

The 2012 temporary regulations also removed the special rule for interbranch payments previously set forth in $\S 1.704-1(b)(4)(viii)(d)(3)$.

A public hearing was not requested and none was held. However, the IRS and the Treasury Department received written comments in response to the notice of proposed rulemaking. After consideration of all the comments, the proposed regulations under section 909 are adopted as amended by this Treasury decision. The revisions are discussed in this preamble. This Treasury decision also adopts the proposed regulations under section 704 without amendment.

Explanation of Revisions and Summary of Comments

I. Splitter Arrangements—In General

This Treasury decision makes clarifying changes to certain of the definitions of splitter arrangements in § 1.909–2T. It also makes a clarifying change to the interim mechanical rules for tracking split taxes and related income. Apart from this clarifying change, this Treasury decision does not address mechanical issues, which are still under consideration and will be addressed in future guidance.