

State, local, or tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

## VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

## VII. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

### List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 888 is amended as follows:

### PART 888—ORTHOPEDIC DEVICES

1. The authority citation for 21 CFR part 888 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 888.3670 is added to subpart D to read as follows:

#### **§ 888.3670 Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis.**

(a) *Identification.* A shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis is a device intended to be implanted to replace a shoulder joint. The device limits movement in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral component made of alloys such as cobalt-chromium-molybdenum (Co-Cr-Mo) and titanium-aluminum-vanadium (Ti-6Al-4V) alloys, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, or a combination of an articulating ultra-high molecular weight

bearing surface fixed in a metal shell made of alloys such as Co-Cr-Mo and Ti-6Al-4V. The humeral component and glenoid backing have a porous coating made of, in the case of Co-Cr-Mo components, beads of the same alloy or commercially pure titanium powder, and in the case of Ti-6Al-4V components, beads or fibers of commercially pure titanium or Ti-6Al-4V alloy, or commercially pure titanium powder. The porous coating has a volume porosity between 30 and 70 percent, an average pore size between 100 and 1,000 microns, interconnecting porosity, and a porous coating thickness between 500 and 1,500 microns. This generic type of device is designed to achieve biological fixation to bone without the use of bone cement.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance: Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis."

Dated: February 4, 2001.

**Linda S. Kahan,**

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

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## DEPARTMENT OF STATE

### 22 CFR Part 41

[Public Notice 3568]

RIN 1400 AA-96

#### **Bureau of Consular Affairs; Visas: Reissuance of O and P Nonimmigrant Visas**

**AGENCY:** Bureau of Consular Affairs, Department of State.

**ACTION:** Final rule.

**SUMMARY:** This rule amends the Department's regulation which allows designated officers in the Directorate for Visa Services to reissue certain categories of nonimmigrant visas for aliens who are maintaining status and intend to depart the United States and reenter in that status after a temporary absence abroad. This regulation will add "O" and "P" visas to those categories that can be "revalidated" in the United States. The Department is also taking this opportunity to make an editorial amendment substituting "Deputy Assistant Secretary for Visa Services" for "Director of the Visa Office." Some years ago, as part of an internal administrative reorganization, the title "Director of the Visa Office" was

replaced by the title "Deputy Assistant Secretary for Visa Services." The powers, duties and responsibilities of the position have not changed; only the title. There is, thus, no substantive significance to this substitution.

**DATES:** This rule takes effect on February 28, 2001.

**FOR FURTHER INFORMATION CONTACT:** H. Edward Odom, Chief, Legislation and Regulations Division, Visa Services, Department of State, Washington, DC 20520-0106, (202) 663-1204.

#### **SUPPLEMENTARY INFORMATION:**

*What Is the Authority for Reissuing Visas?*

The Department of State regulation at 22 CFR 41.111(b) authorizes the Director of the Visa Office and such officers of the Department of State as he or she may designate for such purpose to reissue nonimmigrant visas for aliens in certain nonimmigrant visa classifications who meet the requirements set forth in that section. The purpose of this authority, in part, is to provide a service to the international business community.

*Why Is the Regulation Being Amended?*

Section 207(a)(3) of the Immigration Act of 1990, (Pub. L. 191-649) amended INA 101(a)(15) by adding two new classes of nonimmigrant temporary workers, "O", aliens of extraordinary ability in the sciences, arts, education, business and athletics, and "P", internationally recognized athletes, and certain artists and entertainers. Since that time, the Department has been reissuing "O" and "P" visas. This rule codifies this long-established practice that complements our existing authority.

#### **Final Rule**

*How Is the Department Amending Its Regulation?*

The Department is amending 22 CFR 41.111(b) by adding the "O" and "P" visas to those categories of visas that the Department currently reissues.

#### **Administrative Procedure Act**

The Department's implementation of this regulation as a final rule is based upon the "good cause" exceptions found at 5 U.S.C. 553(b)(B) and (d)(3). Since the Department is providing an administrative service by reissuing visas in the United States for the benefit of aliens who are currently maintaining status in a nonimmigrant category who wish to travel temporarily abroad by reissuing visas in the United States, the Department believes that solicitation of

public comments would serve no purpose.

#### Regulatory Flexibility Act

The Department of State, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and, by approving it, certifies that this rule will not have a significant economic impact on a substantial number of small entities.

#### Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

#### Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Act of 1996. 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 significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

#### Executive Order 12866

The Department of State does not consider this rule, to be a "significant regulatory action" under Executive Order 12866, section 3(f), Regulatory Planning and Review, and the Office of Management and Budget has waived its review process under section 6(a)(3)(A).

#### Executive Order 13132

This regulation will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

#### Paperwork Reduction Act

This rule does not impose any new reporting or record-keeping

requirements. The information collection requirement (Form OF-156) contained by reference in this rule was previously approved for use by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

#### List of Subjects in 22 CFR Part 41

Aliens, Nonimmigrants, Passports and visas.

Accordingly, the Department amends 22 CFR part 41 as follows:

#### PART 41—[AMENDED]

1. The authority citation for Part 41 is revised to read as follows:

**Authority:** 8 U.S.C. 1104; 22 U.S.C. 2651a.

2. Revise § 41.111(b) introductory text and (b)(2) to read as follows:

#### § 41.111 Authority to issue visa.

(b) *Issuance in the United States in certain cases.* The Deputy Assistant Secretary for Visa Services and such officers of the Department as the former may designate are authorized, in their discretion, to issue nonimmigrant visas, including diplomatic visas, to:

\* \* \* \* \*

(2) Other qualified aliens who:

(i) Are currently maintaining status in the E, H, I, L, O, or P nonimmigrant category;

(ii) Intend to reenter the United States in that status after a temporary absence abroad; and

(iii) Who also present evidence that:

(A) They were previously issued visas at a consular office abroad and admitted to the United States in the status which they are currently maintaining; and

(B) Their period of authorized admission in that status has not expired.

Dated: January 21, 2001.

**Mary A. Ryan,**

*Assistant Secretary for Consular Affairs,  
Department of State.*

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#### DEPARTMENT OF STATE

#### 22 CFR Part 126

#### General Policies and Provisions

#### CFR Correction

In Title 22 of the Code of Federal Regulations, parts 1 to 299, revised as of Apr. 1, 2000, in part 126, beginning on page 469, the second § 126.5 is removed.

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Office of the Secretary

#### 45 CFR Parts 160 and 164

RIN 0991-AB08

#### Standards for Privacy of Individually Identifiable Health Information

**AGENCY:** Office for Civil Rights, HHS.

**ACTION:** Final rule; request for comments.

**SUMMARY:** This action provides for the submission of comments on a technical amendment to the final rule adopting standards for privacy of individually identifiable health information published on December 28, 2000, in the **Federal Register** (65 FR 82462), to convert it to a final rule with request for comments. The purpose of this action is to permit public comment on the final rule for a limited period before the rule becomes effective.

**DATES:** 1. Comments will be considered if received as provided below, no later than 5 p.m. on March 30, 2001.

2. The effective date of the final rule with request for comments published December 28, 2000 (65 FR 82462) was corrected to be April 14, 2001. See 66 FR 12434 (February 26, 2001).

**ADDRESSES:** Comments will be considered only if provided through any of the following means:

1. Mail written comments (1 original and, if possible, a floppy disk) to the following address: U.S. Department of Health and Human Services, Attention: Privacy I, Room 801, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

2. Deliver written comments (1 original and, if possible, a floppy disk) to Room 801, 200 Independence Avenue, SW., Washington, DC 20201.

3. Submit electronic comments at the following website: <http://aspe.hhs.gov/admsimp/>.

#### FOR FURTHER INFORMATION CONTACT:

Kimberly Coleman, 1-866-OCR-PRIV (1-866-627-7748) or TTY 1-866-788-4989.

#### SUPPLEMENTARY INFORMATION:

#### Comment Procedures, Availability of Copies, and Electronic Access

*Comment procedures:* All comments should include the full name, address, and telephone number of the sender or a knowledgeable point of contact. Each specific comment should specify the section of the final rule to which the specific comment pertains. If possible, please send an electronic version of the