

10. Seiff, S. R., J. H. Sullivan, L. N. Freeman, and J. Ahn, "Pretarsal Fixation of Gold Weights in Facial Nerve Palsy," *Ophthalmic Plastic and Reconstructive Surgery*, vol. 5, no. 2, pp. 104–109, 1989.
11. Kartush, J. M., C. J. Linstrom, P. M. McCann, and M. D. Graham, "Early Gold Weight Eyelid Implantation for Facial Paralysis," *Otolaryngology—Head and Neck Surgery*, vol. 103, no. 6, pp. 1016–1023, December 1990.
12. Townsend, D. J., "Eyelid Reanimation for the Treatment of Paralytic Lagophthalmos: Historical Perspectives and Current Applications of the Gold Weight Implant," *Ophthalmic Plastic and Reconstructive Surgery*, vol. 8, no. 3, pp. 196–201, 1992.
13. Silver, A. L., R. W. Lindsay, M. L. Cheney, and T. A. Hadlock, "Thin-Profile Platinum Eyelid Weighting: A Superior Option in the Paralyzed Eye," *Plastic and Reconstructive Surgery*, vol. 123, no. 6, pp. 1697–1703, June 2009.
14. Schrom, T., A. Loch, M. Hölzl, and H. Scherer, Abstract: "Evaluation of a New Lid Implant for Rehabilitation of the Paralyzed Eye," *Laryngorhinotologie*, vol. 85, no. 1, pp. 38–42, January 2006.
15. Zwick, O. M. and S. R. Seiff, "Supportive Care of Facial Nerve Palsy with Temporary External Eyelid Weights," *Optometry*, vol. 77, no. 7, pp. 340–342, July 2006.
16. Williams, Z. R. and J. V. Aquavella, "Management of Exposure Keratopathy Associated with Severe Craniofacial Trauma," *Journal of Cataract and Refractive Surgery*, vol. 33, no. 9, pp. 1647–1650, September 2007.
17. Gautam, P., R. K. Adhikari, and B. R. Sharma, "A Profile of Eye-Lid Conditions Requiring Reconstruction Among the Patients Attending an Oculoplasty Clinic in Mid-Western Region of Nepal," *Nepalese Journal of Ophthalmology*, vol. 3, no. 5, pp. 49–51, January 2011.
18. Heier, J. S., R. W. Enzenauer, S. F. Wintermeyer, M. Delaney, and F. P. LaPiana, "Ocular Injuries and Diseases at a Combat Support Hospital in Support of Operations Desert Shield and Desert Storm," *Archives of Ophthalmology*, vol. 111, no. 6, pp. 795–798, June 1993.
19. Mader, T. H., J. V. Aragones, A. C. Chandler, J. A. Hazlehurst, J. Heier, J. D. Kingham, and E. Stein, "Ocular and Ocular Adnexal Injuries Treated by United States Military Ophthalmologists During Operations Desert Shield and Desert Storm," *Ophthalmology*, vol. 100, no. 10, pp. 1462–1467, October 1993.
20. Morley, M. G., J. K. Nguyen, J. S. Heier, B. J. Shingleton, J. F. Pasternak, and K. S. Bower, "Blast Eye Injuries: A Review for First Responders," *Disaster Medicine and Public Health Preparedness*, vol. 4, no. 2, pp. 154–160, June 2010.
21. Blozan, C. F. and S. A. Tucker, "Premarket Notifications: The First 24,000," *Medical Device & Diagnostic Industry*, pp. 59–69, January 1986.
22. U.S. Department of Commerce, Bureau of Economic Analysis, National Income and Product Accounts Table 1.1.9 Implicit

Price Deflators for Gross Domestic Product, <http://www.bea.gov/iTable/iTable.cfm?ReqID=9&step=1>, accessed January 17, 2013; National Income and Product Accounts Table 1.1.4 Price Indexes for Gross Domestic Product, <http://www.bea.gov/iTable/iTable.cfm?ReqID=9&step=1>, accessed January 17, 2013.

23. Geiger, D. R., "FY 2003 and 2004 Unit Costs for the Process of Medical Device Review," September 2005, <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109216.pdf>.

List of Subjects in 21 CFR Part 886

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 886 be amended as follows:

PART 886—OPHTHALMIC DEVICES

- 1. The authority citation for 21 CFR part 886 continues to read as follows:

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

- 2. Section 886.5700 is added to subpart F to read as follows:

§ 886.5700 Eyelid weight.

(a) *Identification.* An eyelid weight is a prescription device made of gold, tantalum, platinum, iridium, or surgical grade stainless steel that is rectangular in shape and contoured to the shape of the eye. The device is intended for the gravity assisted treatment of lagophthalmos (incomplete eyelid closure).

(1) The external eyelid weight is adhered to the outer skin of the upper eyelid.

(2) The implantable eyelid weight is implanted into the upper eyelid.

(b) *Classification.* (1) Class II (special controls) for the external eyelid weight. The external eyelid weight is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9. The special controls for the external eyelid weight are:

- (i) Testing demonstrating the biocompatibility of the device;
- (ii) Nonclinical testing evaluating the compatibility of the device in a magnetic resonance (MR) environment;
- (iii) Labeling to include all information required for the safe and effective use of the device as outlined in § 801.109(c) of this chapter, including specific instructions regarding the proper placement, sizing, and removal of the device; and

(2) Class II (special controls) for the implantable eyelid weight. The special controls for the implantable eyelid weight are:

- (i) Testing demonstrating the biocompatibility of the device;
- (ii) Testing demonstrating the sterility and shelf life of the device;
- (iii) Nonclinical testing evaluating the compatibility of the device in an MR environment.
- (iv) Patient labeling to convey information regarding the safety and compatibility of the device in an MR environment, the conditions under which a patient with the device can be safely scanned, and a mechanism for a healthcare provider to obtain detailed information about MR safety and compatibility if needed.

Dated: February 1, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–02862 Filed 2–7–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 571

[BOP–1090–P]

RIN 1120–AA85

Designation of Offenses

AGENCY: Federal Bureau of Prisons, Department of Justice.

ACTION: Proposed rule.

SUMMARY: The Bureau of Prisons (Bureau) proposes to remove rules which designate various offenses as sexual offenses for purposes of U.S. Code because that provision, which necessitated regulations, has been repealed in relevant part.

DATES: Comments are due by April 9, 2013.

FOR FURTHER INFORMATION CONTACT: Sarah Qureshi, Office of General Counsel, Bureau of Prisons, phone (202) 307–2105.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at www.regulations.gov. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your

name, address, etc.) as part of your comment, but do not want it to be posted online, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also locate all the personal identifying information you do not want posted online in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment but do not want it to be posted online, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment contains so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on www.regulations.gov.

Personal identifying information identified and located as set forth above will be placed in the agency's public docket file, but not posted online. Confidential business information identified and located as set forth above will not be placed in the public docket file. If you wish to inspect the agency's public docket file in person by appointment, please see the "For Additional Information" paragraph.

Proposed Rule

The Bureau proposes to remove rules which designate various offenses as sexual offenses for purposes of 18 U.S.C. 4042(c) because that provision, which necessitated regulations, has been repealed in relevant part. The Bureau published an interim rule on this subject on December 16, 1998 (63 FR 69386) (1998 interim rule). When this proposed rule is finalized, it will result in the retraction/deletion of the 1998 interim rule.

Previously, section 4042(c) of Title 18, United States Code, effective November 26, 1998, provided for notification of sex offender release and certain related functions to facilitate effective sex offender registration and tracking. Notifications were required to be made for persons convicted of the federal offenses noted in subsection (c)(4)(A) through (D). Subsection (c)(4)(E) authorized the Attorney General to designate other offenses as sexual offenses for purposes of subsection (c). The Attorney General delegated this authority to the Director of the Bureau of Prisons. (See 63 FR 69386, December 16, 1998.)

The 1998 interim rule designated additional offenses which are to be considered sexual offenses for purposes of 18 U.S.C. 4042(c). These additional designations, listed in current § 571.72, include state sexual offenses, District of Columbia Code sexual offenses, and certain Uniform Code of Military Justice offenses.

The current regulations, therefore, were specifically promulgated in accordance with language in § 4042(c)(4)(E) providing that offenses in addition to those specifically enumerated at 4042(c)(4)(A)–(D) may be "designated by the Attorney General as a sexual offense for the purposes of this subsection."

However, 18 U.S.C. 4042(c)(4) was repealed by the Sex Offender Registration and Notification Act (SORNA), which is Title I of the Adam Walsh Child Protection and Safety Act of 2006 (Pub. L. 109–248). Because the revised 18 U.S.C. 4042(c) requires release notice for persons required to register under SORNA, the Bureau no longer needs to separately designate sexual offenses in addition to those set forth by the statute. The offenses previously listed in the regulation are generally incorporated in SORNA's comprehensive list of covered offenses, thereby rendering the Bureau's current regulations in subpart H of 28 CFR part 571 unnecessary. We therefore now propose to remove and reserve 28 CFR part 571, subpart H.

Executive Order 12866

This regulation has been drafted and reviewed in accordance with Executive Order 12866, "Regulatory Planning and Review", section 1(b), Principles of Regulation. The Director, Bureau of Prisons has determined that this rule is not a "significant regulatory action" under Executive Order 12866, section 3(f), and accordingly this rule has not been reviewed by the Office of Management and Budget.

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 distribution of power and responsibilities among the various levels of government. Under Executive Order 13132, this rule does not have sufficient federalism implications for which we would prepare a Federalism Assessment.

Regulatory Flexibility Act

The Director of the Bureau of Prisons, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), reviewed this regulation.

By approving it, the Director certifies that it will not have a significant economic impact upon a substantial number of small entities because: this rule is about the correctional management of offenders committed to the custody of the Attorney General or the Director of the Bureau of Prisons, and its economic impact is limited to the Bureau's appropriated funds.

Unfunded Mandates Reform Act of 1995

This rule will not cause State, local and tribal governments, or the private sector, to spend \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. We do not need to take action under 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 § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 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.

List of Subjects in 28 CFR Part 571

Prisoners.

Charles E. Samuels, Jr.,
Director, Bureau of Prisons.

Under rulemaking authority vested in the Attorney General in 5 U.S.C. 301; 28 U.S.C. 509, 510 and delegated to the Director, Bureau of Prisons in 28 CFR § 0.96, we propose to amend 28 CFR part 571 as set forth below.

SUBCHAPTER D—COMMUNITY PROGRAMS AND RELEASE

PART 571—RELEASE FROM CUSTODY

■ 1. The authority citation for Part 571 continues to read as follows:

Authority: 5 U.S.C. 301; 18 U.S.C. 3565, 3568–3569 (Repealed in part as to offenses committed on or after November 1, 1987), 3582, 3621, 3622, 3624, 4001, 4042, 4081, 4082 (Repealed in part as to offenses committed on or after November 1, 1987), 4161–4166 and 4201–4218 (Repealed as to offenses committed on or after November 1, 1987), 5006–5024 (Repealed October 12, 1984 as to offenses committed after that date), 5031–5042; 28 U.S.C. 509, 510; U.S. Const., Art. II, Sec. 2; 28 CFR 0.95–0.99, 1.1–1.10.

Subpart H [Removed and Reserved]

■ 2. Subpart H, Designation of Offenses for Purposes of 18 U.S.C. 4042(c) is removed and reserved.

[FR Doc. 2013-02765 Filed 2-7-13; 8:45 am]

BILLING CODE 4410-05-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[EPA-R03-OAR-2013-0013; FRL-9777-6]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Removal of the Mount Saint Mary's College 1979 Consent Order

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the State of Maryland Department of the Environment (MDE) for the purpose of removing Mount Saint Mary's College 1979 Consent Order from the Maryland SIP. In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because EPA views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rulemaking action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this rulemaking action should do so at this time.

DATES: Comments must be received in writing by March 11, 2013.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA-R03-OAR-2013-0013 by one of the following methods:

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

B. *Email*: mastro.donna@epa.gov.

C. *Mail*: EPA-R03-OAR-2013-0013, Donna Mastro, Acting Associate Director, Air Protection Division, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery*: At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-R03-OAR-2013-0013. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov*, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland 21230.

FOR FURTHER INFORMATION CONTACT:

Maria Pino, Air Protection Division, Project officer, (215) 814-2181, or by email at pino.maria@epa.gov.

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action, with the same title, that is located in the "Rules and Regulations" section of this **Federal Register** publication.

Dated: January 25, 2013.

W.C. Early,

Acting Regional Administrator, Region III.

[FR Doc. 2013-02814 Filed 2-7-13; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket: CDC-2012-0010]

42 CFR Part 73

Influenza Viruses Containing the Hemagglutinin From the Goose/Guangdong/1/96 Lineage

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for information; reopening of comment period.

SUMMARY: With this notice, the Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) announces the re-opening of a public comment period for a request for information and comment published on October 17, 2012. The request for information sought information and comments from the public regarding whether highly pathogenic avian influenza (HPAI) H5N1 viruses that contain a hemagglutinin (HA) from the Goose/Guangdong/1/96 lineage, and their potential to pose a severe threat to public health and safety. The comment period closed on December 17, 2012. We are reopening the comment period to allow interested persons additional time to prepare and submit comments.

DATES: Written or electronic comments must be received on or before March 11, 2013.

ADDRESSES: You may submit comments, identified by Docket Number CDC-2012-0010, by any of the following methods

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail*: Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE., Mailstop A-46,