

guideline is also available at <http://www.regulations.gov>.

To receive "Temporary Mandibular Condyle Reconstruction Plate Class II Special Controls Guideline," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1799 to identify the guidance you are requesting.

V. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

This final order refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910-0231; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910-0485.

VII. Clarifications to Special Controls Guidelines

The special controls guideline reflects changes the Agency is making to clarify its position on the binding nature of special controls. The changes include referring to the document as a "guideline," as that term is used in section 513(a) of the FD&C Act, which the Secretary has developed and disseminated to provide a reasonable assurance of safety and effectiveness for class II devices, and not a "guidance," as that term is used in 21 CFR 10.115. The guideline also clarifies that firms will need either to (1) comply with the particular mitigation measures set forth in the special controls guideline or (2) use alternative mitigation measures, but demonstrate to the Agency's satisfaction that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. Finally, the guideline uses mandatory language to emphasize

that firms must comply with special controls to legally market their class II devices. These revisions do not represent a change in FDA's position about the binding effect of special controls, but rather are intended to address any possible confusion or misunderstanding.

VIII. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) of the FD&C Act provided for FDA to issue regulations to reclassify devices. Although section 513(e) of the FD&C Act as amended requires FDA to issue final orders rather than regulations, FDASIA also provides for FDA to revoke previously issued regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, under section 513(e)(1)(A)(i) of the FD&C Act, as amended by FDASIA, in this final order, we are revoking the requirements in § 872.3960 related to the classification of TMCRPs as Class III devices and codifying the reclassification of TMCRPs into Class II.

List of Subjects in 21 CFR Part 872

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 872 is amended as follows:

PART 872—DENTAL DEVICES

■ 1. The authority citation for 21 CFR part 872 continues to read as follows:

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

■ 2. Section 872.3960 is amended by revising paragraph (c) to read as follows:

§ 872.3960 Mandibular condyle prosthesis.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 30, 1999, for any mandibular condyle prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before March 30, 1999, been found to be substantially equivalent to a mandibular condyle prosthesis that was in commercial distribution before May 28, 1976. Any other mandibular condyle prosthesis shall have an approved PMA or a declared completed

PDP in effect before being placed in commercial distribution.

■ 3. Section 872.4770 is added to subpart E to read as follows:

§ 872.4770 Temporary mandibular condyle reconstruction plate.

(a) *Identification.* A temporary mandibular condyle reconstruction plate is a device that is intended to stabilize mandibular bone and provide for temporary reconstruction of the mandibular condyle until permanent reconstruction is completed in patients who have undergone resective surgical procedures requiring removal of the mandibular condyle and mandibular bone. This device is not intended for treatment of temporomandibular joint disorders.

(b) *Classification.* Class II (special controls). The special controls for this device is FDA's guideline entitled "Temporary Mandibular Condyle Reconstruction Plate Class II Special Controls Guideline." See § 872.1(e) for the availability of this guidance document.

Dated: December 23, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-31217 Filed 12-27-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 985

[Docket No. FR-5729-N-01]

Partial Section Eight Management Assessment Program (SEMAP) Indicator Waiver; Family Self-Sufficiency (FSS) Program Demonstration

AGENCY: Office of Policy Development and Research and Office of Public and Indian Housing, HUD.

ACTION: Waiver.

SUMMARY: This document advises the public of a HUD regulation that has been temporarily waived in order to facilitate voluntary PHA participation in the FSS Program Demonstration. The FSS Program Demonstration is a study using a random assignment methodology to evaluate the effectiveness of the FSS program. Specifically, this document announces a temporary, partial waiver to the SEMAP rating criteria at 24 CFR 985.3(o) ("Family self-sufficiency (FSS) enrollment and escrow accounts"), for PHAs with a mandatory Housing Choice Voucher (HCV) FSS program who are

participating in the FSS Program Demonstration.

DATES: Effective December 30, 2013.

FOR FURTHER INFORMATION CONTACT: Regina Gray, Ph.D., Office of Policy Development and Research, Department of Housing and Urban Development, 451 7th Street SW., Room 8132, Washington, DC 20410; telephone number 202-402-2876 (this is not a toll-free number). Persons with hearing or speech impairments may access this number via TTY by calling the toll-free Federal Relay Service at 800-877-8339.

SUPPLEMENTARY INFORMATION:

I. Background

The Family Self-Sufficiency (FSS) Program Demonstration is a random assignment study conducted under contract by MDRC¹ and its subcontractors to evaluate the effectiveness of the FSS program, as part of the Transformation Initiative.² The FSS program has operated since 1992 and its objective is to enable participating low-income families to increase their earned income and reduce their dependency on welfare assistance and rental subsidies. FSS program coordinators create plans with participating families to achieve goals and connect them with services that will enhance their employment opportunities. As the family's earnings increase, money is credited to an escrow account on behalf of the family. This study, unlike the two previous studies of the FSS program, will use a random assignment model to determine whether FSS program features, rather than the characteristics of the participating families, cause participant incomes to increase.

PHAs participating in the FSS Program Demonstration may experience unintended consequences due to the requirements for participation and the methodology of the study. For example,

¹ MDRC is a nonprofit, nonpartisan education and social policy research organization dedicated to learning what works to improve programs that affect low-income individuals. See <http://www.mdrc.org/about/about-mdrc-overview-0>.

² In the Consolidated Appropriations Act of 2010, Public Law 111-117, Congress enacted the Transformation Initiative, which made up to one percent of program funds available for (1) research, evaluation, and program metrics; (2) program demonstrations; (3) technical assistance; and (4) information technology. The Transformation Initiative was renewed under the full-year continuing appropriations act for FY 2011, Public Law 111-242. The Consolidated and Further Continuing Appropriations Act of 2012, Public Law 112-55, renewed the Transformation Initiative again, but designated a specific amount of money to remain available until September 30, 2014. The continuing appropriations resolution for 2013, Public Law 112-175, did not impose any additional limitations on the Transformation Initiative.

PHAs are required to recruit and screen about twice as many families as they would usually enroll in the program in a year, to maintain stable enrollment in the FSS program when only half of the families are randomly assigned to a treatment group (enrollment in FSS) and the other half are assigned to a control group (non-enrollment). In fact, PHAs may voluntarily increase the number of FSS participants they have because of the program demand resulting from the enhanced recruitment methods they are using and their commitment to the evaluative process.

In addition to the requirement to screen more families for participation in the FSS program than in the past and the option to enroll more participants, PHAs participating in the FSS Program Demonstration will have less control over which participants are enrolled in their FSS programs due to the random assignment of families to either the treatment or control group. If families enrolled in the FSS program by random assignment (as a result of a PHA's participation in the FSS Program Demonstration) accrue escrow balances at lower rates than previous cohorts of families, PHAs participating in the FSS Program Demonstration may experience a decreased rating on the Section 8 Management Assessment Program (SEMAP) performance indicator that specifically measures for the percentage of families with escrow balances.

SEMAP, through a four-page questionnaire, provides one way for PHAs to certify their performance to HUD on fourteen indicators. Under current regulations at 24 CFR part 985, the SEMAP Certification form (HUD-52648) must be submitted annually by all PHAs administering Section 8 tenant-based assistance programs. (Information collection requirements have been approved by the Office of Management and Budget under control number 2577-0215). Upon receipt of the certification, HUD rates the PHA's performance under each SEMAP indicator in accordance with 24 CFR 985.3.

As discussed above, there is a possibility that participating in the FSS Program Demonstration may result in a PHA having a lower percentage of families with escrow account balances than they otherwise would have had in their FSS program. This is problematic because the indicator at 24 CFR 985.3(o),³ which corresponds to items 14a and 14b of the SEMAP Certification, awards a PHA a rating ranging from zero to ten points based on a combination of

³ Regulations at 24 CFR 985.3(o) are only applicable to PHAs with mandatory FSS programs.

two components: (1) The percentage of mandatory FSS slots filled; and (2) the percentage of FSS families that have escrow account balances. This, in turn, may negatively impact a PHA's overall performance rating, as described in 24 CFR 985.103. The possibility of this outcome may deter PHAs from volunteering to participate in this important study. In order to ensure that PHAs will not be affected negatively by participation in the FSS Program Demonstration, HUD is partially waiving 24 CFR 985.3(o), as discussed below.

II. Partial Waiver of 24 CFR 985.3(o)

This document announces a partial waiver to the rating criteria of the "Family self-sufficiency (FSS) enrollment and escrow accounts" SEMAP indicator item discussed at 24 CFR 985.3(o)(3)(i)-(vi) for PHAs with a mandatory HCV FSS program, who are participating in the FSS Program Demonstration, effective from December 30, 2013 through September 30, 2018. During only the second and third full reporting periods ending after the PHA's enrollment in the demonstration, PHAs meeting the aforementioned criteria may elect to have the SEMAP performance indicator for FSS enrollment and escrow accounts rated by omitting reference to the percent of FSS families with escrow balances (SEMAP indicator item 14b of form HUD-52648).⁴ Thus, the rating would be determined solely by the percentage of mandatory FSS slots that have been filled by the PHA, as reported in SEMAP indicator item 14a of form HUD-52648.⁵

In order to affirmatively elect to apply this waiver, a PHA participating in the FSS Program Demonstration must select "Check here if not applicable" under SEMAP indicator item 14b of form HUD-52648. PHAs participating in the demonstration that have a mandatory

⁴ For example, if a PHA enrolls in the FSS Program Demonstration in July 2013, and has a SEMAP reporting period of October 1 through September 30, the waiver would be applicable for October 1, 2014 through September 30, 2015 (the second full reporting period ending after the PHA's enrollment in the demonstration) and October 1, 2015 through September 30, 2016 (the third full reporting period ending after the PHA's enrollment in the demonstration). The waiver is not applicable to earlier reporting periods because the SEMAP score measures escrow among families with progress reports, and treatment group families generally will not have progress reports until the second full reporting period ending after the PHA's enrollment in the demonstration.

⁵ For example, if a PHA has filled 80 percent or more of its mandatory FSS slots, it will receive 10 points (24 CFR 985.3(o)(3)(i)), regardless of the percent of families with escrow account balances.

HCV FSS program⁶ must continue to report on item 14a and may *not* select “Check here if not applicable” under SEMAP indicator item 14a of form HUD-52648.

III. Authority To Grant Waivers

Under 24 CFR 5.110, HUD’s regulations in 24 CFR may be waived upon a determination of good cause, subject to statutory limitations. A partial waiver of 24 CFR 985.3(o) was determined necessary to eliminate penalties that may be associated with voluntary participation in the FSS Program Demonstration.

IV. Findings and Certifications

Paperwork Reduction Act

The information collection requirements applicable to this waiver have been submitted to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and assigned OMB Control Numbers 2528–0296 and 2577–0215. In accordance with the Paperwork Reduction Act, HUD may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless the collection displays a currently valid OMB control number.

Environmental Impact

This document does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this document is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Dated: December 19, 2013.

Sandra Henriquez,

Assistant Secretary for Public and Indian Housing.

[FR Doc. 2013–31044 Filed 12–27–13; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket Number USCG–2013–1030]

Drawbridge Operation Regulation; Upper Mississippi River, Rock Island, IL

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulations.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Rock Island Railroad and Highway Drawbridge across the Upper Mississippi River, mile 482.9, at Rock Island, Illinois. The deviation is necessary to allow the St. Patrick’s Day Road Race to cross the bridge. This deviation allows the bridge to be maintained in the closed-to-navigation position for two hours.

DATES: This deviation is effective from 10 a.m. to noon, March 15, 2014.

ADDRESSES: The docket for this deviation, [USCG–2013–1030] is available at <http://www.regulations.gov>.

Type the docket number in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation, West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Eric A. Washburn, Bridge Administrator, Western Rivers, Coast Guard; telephone 314–269–2378, email Eric.Washburn@uscg.mil. If you have questions on viewing the docket, contact Barbara Hairston, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The U.S. Army Rock Island Arsenal requested a temporary deviation for the Rock Island Railroad and Highway Drawbridge, across the Upper Mississippi River, mile 482.9, at Rock Island, Illinois to remain in the closed-to-navigation position for a two hour period from 10 a.m. to noon, March 15, 2014, while the St. Patrick’s Day Road Race is held between the cities of Davenport, IA and Rock Island, IL.

The Rock Island Railroad and Highway Drawbridge currently operates

in accordance with 33 CFR 117.5, which states the general requirement that drawbridges shall open promptly and fully for the passage of vessels when a request to open is given in accordance with the subpart.

There are no alternate routes for vessels transiting this section of the Upper Mississippi River.

The Rock Island Railroad and Highway Drawbridge, in the closed-to-navigation position, provides a vertical clearance of 23.8 feet above normal pool. Navigation on the waterway consists primarily of commercial tows and recreational watercraft. This temporary deviation has been coordinated with waterway users. No objections were received.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: December 18, 2013.

Eric A. Washburn,

Bridge Administrator, Western Rivers.

[FR Doc. 2013–31278 Filed 12–27–13; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2013–0934]

RIN 1625–AA87

Security Zone; On the Waters in Kailua Bay, Oahu, HI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone on the waters south of Kapoho Point and a nearby channel in Kailua Bay within the Honolulu Captain of the Port (COTP) Zone. This security zone is necessary to ensure the safety of the President of the United States.

DATES: This rule is effective without actual notice from December 30, 2013 through 10 p.m. (HST) on January 5, 2014. For the purposes of enforcement, actual notice will be used from 6 a.m. (HST) on December 20, 2013, through 10 p.m. (HST) on January 5, 2014.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG–2013–0934. To view documents mentioned in this preamble as being

⁶ Some PHAs are required, by statute, to carry out a FSS program; see 42 U.S.C. 1437u.