OFFICE OF HOUSING

U.S. DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
WASHINGTON, DC 20410-8000

JUN - 3 2014

MEMORANDUM FOR: All Primary Inspection Agencies and State Administrative Agencies

FROM: Pamela Beck Danner
Administrator
Office of Manufactured Housing Programs

SUBJECT: Final Rule - Correction of Reference Standard for Anti-Scald Valves

Attached is a final rule which amends 24 CFR §§ 3280.604(b)(2) and 3280.607 of the Federal Manufactured Home Construction and Safety Standards by incorporating the correct reference standard for anti-scald temperature limiting devices for bathtubs and whirlpool baths without showers, ASSE 1070-2004, Performance Requirements for Water Temperature Limiting Devices. In the December 9, 2013, final rule which becomes effective on June 9, 2014, HUD had previously incorrectly required bathtubs to meet requirements for anti-scald protection under ASSE 1016-2005, Performance Requirements for Automatic Compensating Valves for Individual Shower and Tub Shower Combinations. This amendment to the Standards corrects that oversight.

Because this correction and amendment does not become effective until July 3, 2014, HUD will allow the use of temperature limiting devices that conform to the ASSE 1070 -2004 standard for bathtubs and whirlpool baths upon the effective date of June 9, 2014, for the new requirements that were published on December 9, 2013.

We request that the PIAs distribute this memorandum to the manufacturers that they service. If you have any questions regarding this issue, please call or email your PIA or SAA contact at (202) 708-6423.

Attachment

List of Subjects in 21 CFR Part 878

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 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for 21 CFR part 878 continues to read as follows:

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

■ 2. Add § 878.4790 to subpart E to read as follows:

§ 878.4790 Powered surgical instrument for improvement in the appearance of cellulite.

(a) *Identification.* A powered surgical instrument for improvement in the appearance of cellulite is a prescription device that is used for the controlled release of subcutaneous tissue for improvement in the appearance of cellulite. The device consists of a cutting tool powered by a motor and a means for instrument guidance to control the areas of subcutaneous tissue cutting underneath the cellulite depressions or dimples.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Non-clinical testing must be performed to demonstrate that the device meets all design specifications and performance requirements, and to demonstrate durability and mechanical integrity of the device.

(2) In vivo evaluation of the device must demonstrate device performance, including the safety of the release methodology and blood loss at the treatment sites.

(3) All elements of the device that may contact the patient must be demonstrated to be biocompatible.

(4) Electrical safety and electromagnetic compatibility of the device must be demonstrated.

(5) The labeling must include a summary of in vivo evaluation data and all the device specific warnings, precautions, and/or contraindications.

(6) Sterility and shelf-life testing for the device must demonstrate the sterility of patient contacting components and the shelf life of these components.

Dated: May 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–12814 Filed 6–2–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 3280

[Docket No. FR–5787–F–01]

RIN 2502–AJ21

Manufactured Housing Constructions and Safety Standards: Correction of Reference Standard for Anti-Scald Valves

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Final rule.

SUMMARY: This final rule amends the Federal Manufactured Home Construction and Safety Standards by incorporating the correct reference standard for anti-scald devices designed for bathtubs and whirlpool tubs without showers, ASSE 1070–2004, Performance Requirements for Water Temperature Limiting Devices. Anti-scald valves mitigate the danger of serious burns and other hazards caused by bursts of hot water resulting from sudden changes in water pressure. In a final rule published on December 9, 2013, HUD incorporated ASSE 1016–2005, an anti-scalding device designed for showers and tub-shower combinations. HUD failed to incorporate, however, ASSE 1070–2004, which is designed for fixtures such as bathtubs and whirlpool tubs that do not have showers. To correct this and ensure the safety of occupants of manufactured homes with bathtubs and whirlpool tubs without showers, this final rule incorporates ASSE 1070–2004.

DATES: *Effective Date:* July 3, 2014. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of July 3, 2014.

FOR FURTHER INFORMATION CONTACT: Pamela Beck Danner, Administrator, Office of Manufactured Housing Programs, Room 9168, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410; telephone number 202–708–6423 (this is not a toll-number). Persons with hearing or speech impairments may access this number via TTY by calling the Federal Relay Service at 1–800–877–8389 (this is a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

The National Manufactured Housing Construction and Safety Standards Act of 1974 (42 U.S.C. 5401–5426) (the Act) authorizes HUD to establish and amend the Federal Manufactured Home Construction and Safety Standards codified in 24 CFR part 3280. The Act was amended in 2000 by the Manufactured Housing Improvement Act of 2000 (Pub. L. 106–569), by expanding its purposes and creating the Manufactured Housing Consensus Committee (MHCC).

As amended, the purposes of the Act (enumerated at 42 U.S.C. 5401) are: "(1) To protect the quality, durability, safety, and affordability of manufactured homes; (2) to facilitate the availability of affordable manufactured homes and to increase homeownership for all Americans; (3) to provide for the establishment of practical, uniform, and, to the extent possible, performance-based Federal construction standards for manufactured homes; (4) to encourage innovative and cost-effective construction techniques for manufactured homes; (5) to protect residents of manufactured homes with respect to personal injuries and the amount of insurance costs and property damages in manufactured housing consistent with the other purposes of this section; (6) to establish a balanced consensus process for the development, revision, and interpretation of Federal construction and safety standards for manufactured homes and related regulations for the enforcement of such standards; (7) to ensure uniform and effective enforcement of Federal construction and safety standards for manufactured homes; and (8) to ensure that the public interest in, and need for, affordable manufactured housing is duly considered in all determinations relating to the Federal standards and their enforcement."

II. This Final Rule

On December 9, 2013, at 78 FR 73966, HUD published a final rule that amended the Federal Manufactured Home Construction and Safety Standards at 24 CFR part 3280 by adopting certain recommendations made to HUD by the MHCC, as modified by HUD. Among other changes, HUD's December 9, 2013, final rule revised the Manufactured Home Construction and Safety Standards by updating the incorporated reference standards that establish the standards for the various components of a manufactured home. Most of HUD's changes codified existing building practices or conformed HUD standards to HUD interpretive bulletins or existing building codes.

One update codified by HUD's December 9, 2013, final rule was to require that shower, bath, and tub-shower combination valves be either balanced pressure, thermostatic, or a combination of mixing valves that conforms to the requirements of ASSE

1016–2005, Performance Requirements for Automatic Compensation Valves for Individual Showers and Tub/Shower Combinations. HUD codified this requirement in §§ 3280.4(o)(8), 3280.604(b), and 3280.607(b)(3)(v). HUD stated that these valves must have handle position stops that are adjustable in accordance with the valve manufacturer's instructions, to a maximum setting of 120 °F to prevent scalding and burn injuries to occupants from very hot water. This change was based on public safety and intended to reduce the number of injuries and deaths resulting from tap water scald burns. As HUD states in its final rule, the Centers for Disease Control and other organizations report that a majority of scald burn victims are young children whose injuries may have been prevented by the use of an anti-scald valve. Requiring the use of anti-scald valves is also consistent with International Residential Code (IRC) requirements for one- and two-family dwellings.

Since publishing the December 9, 2013, final rule, HUD has determined that ASSE 1016–2005, is an anti-scalding device designed for showers and tub-shower combinations. It is not the correct standard for an anti-scalding device designed for bathtub and whirlpool tubs without showers. Rather, the correct reference standard for anti-scald devices designed for bathtubs and whirlpool tubs without showers is ASSE 1070–2004, Performance Requirements for Water Temperature Limiting Devices, approved February 2004. There are some significant differences between ASSE 1016–2005 and ASSE 1070–2004. Most important, ASSE 1070–2004 has more stringent controls for minimum test flows than does ASSE 1016–2005. ASSE 1016–2005 valves are tested for temperature control at a minimum flow of 2.5 gallons/minute, the standard showerhead rating. ASSE 1070–2004 valves are tested to a minimum flow of 0.5 gallons/minute. This difference is important because accurate controls of water flows for bathtubs and whirlpool tubs at low flows are critical to user safety. The IRC identifies ASSE 1070–2004 as the correct standard for anti-scald devices designed for bathtubs and whirlpool tubs without showers.

Codifying ASSE 1070–2004 is a technical correction. In its July 13, 2010 (75 FR 39871), proposed rule, HUD proposed to require "that shower, bath, and tub-shower combination valves" be either balanced pressure, thermostatic, or a combination of mixing valves that conform to ASSE 1016–1996. In response to public comments, HUD stated that it would add new reference standards "for shower, bath, and tub-shower combination valves." The December 9, 2013, final rule, however, incorporated the correct standard for only showers and tub-shower combinations. This rule corrects this oversight by adding ASSE 1070–2004 as the correct standard for bathtubs and whirlpool baths without showers.

To make this correction, this final rule revises § 3280.607(b)(3)(v) by clarifying that shower and tub shower combination valves must conform to the requirements of ASSE 1016–2005. Valves designed for bathtubs and whirlpool bathtubs without showers must conform to the requirements of ASSE 1070–2004. This final rule also makes conforming changes to §§ 3280.4 and 3280.604(b)(2).

III. Incorporation by Reference

The incorporation by reference of ASSE 1070–2004 is approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the standard may be obtained from the organization that developed the standard. As described in § 3280.4, this standard is also available for inspection at HUD's Office of Manufactured Housing Programs and at the National Archives and Records Administration. This final rule incorporates a standard developed by the following organization:

ASSE—American Society of Sanitary Engineering, 901 Canterbury Road, Suite A, Westlake, Ohio 44145; telephone number 440–835–3040; fax number 440–835–3488; Web site, *http://www.asse-plumbing.org.*

IV. Justification for Final Rulemaking

HUD generally publishes a rule for public comment before issuing a rule for effect, in accordance with its own regulations on rulemaking at 24 CFR part 10. Part 10 provides for exceptions to the general rule if the agency finds good cause to omit advance notice and public participation. The good cause requirement is satisfied when prior public procedure is "impracticable, unnecessary, or contrary to the public interest" (24 CFR 10.1). For the following reasons, HUD finds that good cause exists to publish this rule for effect without first soliciting public comment.

This final rule amends the Federal Manufactured Home Construction and Safety Standards by incorporating the correct reference standard for anti-scald devices designed for bathtubs and whirlpool baths without showers, ASSE 1070–2004. Anti-scald valves mitigate the danger of serious burns and other hazards caused by bursts of hot water resulting from sudden changes in water pressure. In both its July 13, 2010, proposed rule and its December 9, 2013, final rule, HUD stated its intent to require anti-scald valves for all showers, baths, and tub-shower combinations. Public comments received in response to HUD's proposed rule supported HUD's proposed requirement and recognized that the installation of anti-scald valves is safety driven and would prevent, mitigate, or reduce the number of injuries to individuals living in manufactured homes. One commenter, citing the study conducted by Safe Kids [1] referenced in HUD's proposed rule, stated that requiring anti-scald valves in all showers, baths and tub-shower combinations was a low-cost measure that would prevent an estimated 100 kids from death by scalding hot water and an estimated 3000 people from being hospitalized and treated for scalding hot water. HUD responded to these comments by stating that it would add new reference standards "for shower, bath, and tub-shower combination valves." HUD's final rule, however, incorporated a reference standard for shower and tub-shower combinations, but failed to incorporate a standard for bathtubs and whirlpool baths that do not have showers. To correct this and ensure the safety of occupants of manufactured homes with bathtubs and whirlpool baths without showers, this final rule incorporates ASSE 1070–2004.

Therefore, HUD determined that it is unnecessary to publish this rule for public comment prior to publishing the rule for effect.

V. Findings and Certifications

Regulatory Review—Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if the regulation is necessary, to select the regulatory approach that maximizes net benefits. As discussed above in this preamble, HUD's December 9, 2013, final rule did not incorporate the correct standard for anti-scald valves designed for fixtures such as bathtubs and whirlpool tubs that do not have showers. This final rule corrects this oversight. As a result, this rule was determined to not be a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review and, therefore, was not reviewed by the

[1] National SAFE KIDS Campaign (NSKC). Burn Injury Fact Sheet. Washington (DC): NSKC, 2004.

Office of Management and Budget (OMB).

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 605(b)) generally requires an agency to conduct regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Since notice and comment rulemaking is not necessary for this final rule, the provisions of the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612) do not apply.

Executive Order 13132, Federalism

Executive Order 13132 (entitled "Federalism") prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on state and local governments and is not required by statute, or the rule preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. This final rule will not have federalism implications and would not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive order.

Environmental Review

A Finding of No Significant Impact with respect to the environment was made at the proposed rule stage (75 FR 39871) in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)). The Finding of No Significant Impact is applicable to this final rule and is available for public inspection between the hours of 8 a.m. and 5 p.m., weekdays, in the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. Due to security measures at the HUD Headquarters building, please schedule an appointment to review the finding by calling the Regulations Division at 202–402–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number through TTY by calling the Federal Information Relay Service at 800–877–8339 (this is a toll-free number).

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments, and the private sector. This final rule does not impose any Federal mandates on any state, local, or tribal government, or the private sector, within the meaning of UMRA.

List of Subjects in 24 CFR Part 3280

Housing standards, Incorporation by reference, Manufactured homes.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance number for Manufactured Housing Construction and Safety Standards is 14.171.

Accordingly, for the reasons stated in the preamble, HUD is amending 24 CFR part 3280 as follows:

PART 3280—MANUFACTURED HOME CONSTRUCTION AND SAFETY STANDARDS

■ 1. The authority citation for part 3280 continues to read as follows:

Authority: 42 U.S.C. 3535(d), 5403, and 5424.

■ 2. Amend § 3280.4 by adding paragraph (o)(15) to read as follows:

§ 3280.4 Incorporation by reference.

* * * * *

(o) * * *

(15) ASSE 1070–2004, Performance Requirements for Water Temperature Limiting Devices, IBR approved for §§ 3280.604(b) and 3280.607(b).

* * * * *

■ 3. Amend § 3280.604(b)(2) by adding under the undesignated heading "Plumbing Fixtures," a reference standard for "Performance Requirements for Water Temperature Limiting Devices" at the end of the list, to read as follows:

§ 3280.604 Materials.

* * * * *

(b) * * *

(2) * * *

Plumbing Fixtures

* * * * *

Performance Requirements for Water Temperature Limiting Devices, approved February 2004, ASSE 1070–2004 (incorporated by reference, see § 3280.4).

* * * * *

■ 4. In § 3280.607, revise paragraph (b)(3)(v) to read as follows:

§ 3280.607 Plumbing fixtures.

* * * * *

(b) * * *

(3) * * *

(v) Shower and tub-shower combination valves must be balanced pressure, thermostatic, or combination mixing valves that conform to the requirements of ASSE 1016–2005, Performance Requirements for Automatic Compensating Valves for Individual Shower and Tub/Shower Combinations (incorporated by reference, see § 3280.4). Such valves must be equipped with handle position stops that are adjustable in accordance with the valve manufacturer's instructions and to a maximum setting of 120 °F. Hot water supplied to bathtubs and whirlpool bathtubs are to be limited to a temperature of not greater than 120 °F by a water temperature limiting device that conforms to the requirements of ASSE 1070–2004, Performance Requirements for Water Temperature Limiting Devices (incorporated by reference, see § 3280.4).

* * * * *

Dated: May 28, 2014.

Carol Galante,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2014–12731 Filed 6–2–14; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9666]

RIN 1545–BL79

Alternative Simplified Credit Election

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations relating to the election of the alternative simplified credit. The final and temporary regulations will affect certain taxpayers claiming the credit. The text of these temporary regulations also serves as the text of the proposed regulations (REG–133495–13) published in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective on June 3, 2014.

Applicability Date: For dates of applicability, see § 1.41–9T(d).

FOR FURTHER INFORMATION CONTACT: David Selig (202) 317–4137 (not a toll-free number).