- Hepatitis B Virus Among Persons Undergoing Blood Glucose Monitoring in Long-Term-Care Facilities—Mississippi, North Carolina, and Los Angeles County, California, 2003–2004", MMWR Morbidity and Mortality Weekly Report, 2005; 54(09):220–223. (Available at: http://www.cdc.gov/mmwr/preview/ mmwrhtml/mm5409a2.htm.)
- 28. Thompson, N.D. and J.F. Perz,
 "Eliminating the Blood: Ongoing
 Outbreaks of Hepatitis B Virus Infection
 and the Need for Innovative Glucose
 Monitoring Technologies", Journal of
 Diabetes Science and Technology, 2009;
 3(2):283–288.
- 29. Thompson, N.D., V. Barry, K. Alelis, et al., "Evaluation of the Potential for Bloodborne Pathogen Transmission Associated With Diabetes Care Practices in Nursing Homes and Assisted Living Facilities, Pinellas County", Journal of the American Geriatrics Society, 2010; 58:914–918.
- Patel, A.S., M.B. White-Comstock, D. Woolard, et al., "Infection Control Practices in Assisted Living Facilities: A Response to Hepatitis B Virus Infection Outbreaks", Infection Control and Hospital Epidemiology, 2009; 30:209–214.
- 31. Centers for Disease Control and Prevention (CDC), "Multiple Outbreaks of Hepatitis B Virus Infection Related to Assisted Monitoring of Blood Glucose Among Residents of Assisted Living Facilities—Virginia, 2009–2011", MMWR Morbidity and Mortality Weekly Report, 2012; 61(19):339–343. (Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6119a3.htm?s_cid=mm6119a3_w.)
- 32. Centers for Disease Control and Prevention (CDC), "Notes From the Field: Deaths From Acute Hepatitis B Virus Infection Associated With Assisted Blood Glucose Monitoring in an Assisted-Living Facility—North Carolina, August—October, 2010," MMWR Morbidity and Mortality Weekly Report, 2011; 60(6):182. (Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6006a5.htm?s_cid=mm6006a5 w.)
- Schaefer, M.K., M. Jhung, M. Dahl, et al., "Infection Control Assessment of Ambulatory Surgical Centers", Journal of the American Medical Association, 2010; 303(22):2273–2279.
- 34. Thompson, N.D. and M.K. Schaefer, "'Never Events': Hepatitis B Outbreaks and Patient Notifications Resulting From Unsafe Practices During Assisted Monitoring of Blood Glucose, 2009—2010", Journal of Diabetes Science and Technology, 2011; 5(6):1396–1402.
- 35. Centers for Disease Control and Prevention (CDC), "CDC Clinical Reminder: Use of Fingerstick Devices on More Than One Person Poses Risk for Transmitting Bloodborne Pathogens", available at http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html.
- Centers for Medical Services (CMS), "Survey and Certification Memorandum" (August 27, 2010)

- available at http://www.cms.gov/survey certificationgeninfo/downloads/ SCLetter10_28.pdf.
- 37. Centers for Disease Control and Prevention (CDC), "Notes From the Field: Transmission of HBV Among Assisted-Living-Facility Residents— Virginia, 2012", MMWR Morbidity and Mortality Weekly Report, 2013; 62(19):389. (Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6219a4.htm?s cid=mm6219a4 w.)
- 38. Desenclos, J.C., M. Bourdiol-Razes, B. Rolin, et al., "Hepatitis C in a Ward for Cystic Fibrosis and Diabetic Patients: Possible Transmission by Spring-Loaded Finger-Stick Devices for Self-Monitoring of Capillary Blood Glucose", Infection Control and Hospital Epidemiology, 2001; 22(11):701–707.
- 39. De Schrijver, K., I. Maes, P. Van Damme, et al., "An Outbreak of Nosocomial Hepatitis B Virus Infection in a Nursing Home for the Elderly in Antwerp (Belgium)", *Acta Clinica Belgica*, 2005; 60(2):63–69.
- 40. Gotz, H.M., M. Schutten, G.J. Borsboom, et al., "A Cluster of Hepatitis B Infections Associated With Incorrect Use of a Capillary Blood Sampling Device in a Nursing Home in the Netherlands, 2007", Euro Surveillance, 2008; 13(7– 9):1–5.

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, it is proposed that 21 CFR part 878, as proposed to be amended elsewhere in this issue of the **Federal Register**, be further 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 paragraph (d)(3) to § 878.4850, under subpart E, to read as follows:

§878.4850 Blood Lancets.

(3) 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 [A DATE WILL BE ADDED 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL ORDER CALLING FOR PMAs IN THE FEDERAL REGISTER OR 30 MONTHS AFTER DATE OF PUBLICATION OF A FUTURE FINAL ORDER RECLASSIFYING INTO CLASS III, WHICHEVER IS LATER] for any multiple use blood lancet for

multiple patient use described in paragraph (d)(1) of this section that was in commercial distribution before May 28, 1976, or that has, on or before [A DATE WILL BE ADDED 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL ORDER CALLING FOR PMAs IN THE **FEDERAL REGISTER** OR 30 MONTHS AFTER DATE OF PUBLICATION OF A FUTURE FINAL ORDER RECLASSSIFYING INTO CLASS III, WHICHEVER IS LATER], been found to be substantially equivalent to a multiple use blood lancet for multiple patient use described in paragraph (d)(1) of this section that was in commercial distribution before May 28, 1976. Any other multiple use blood lancet for multiple patient use shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Dated: February 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.
[FR Doc. 2016–04579 Filed 3–2–16; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG-123867-14]

RIN 1545-BM28

Utility Allowances Submetering

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: This document contains proposed regulations that amend the utility allowance regulations concerning the low-income housing credit. The proposed regulations relate to the circumstances in which utility costs paid by a tenant based on actual consumption in a submetered rentrestricted unit are treated as paid by the tenant directly to the utility company. The proposed regulations extend those rules to situations in which a building owner sells to tenants energy that is produced from a renewable source and that is not delivered by a local utility company. The proposed regulations affect owners of low-income housing projects that claim the credit, the tenants in those low-income housing projects, and the State and local housing credit agencies that administer the

credit. In the Rules and Regulations section of this issue of the Federal **Register**, the IRS is issuing temporary regulations concerning utility allowance regulations when the utility is generated from renewable sources and is not delivered by the local utility company. The text of those regulations also serves as the text of these proposed regulations. This document also contains a notice of a public hearing on these proposed regulations.

DATES: Comments and requests for a public hearing must be received by May

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG-123867-14), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG-123867-14), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, or sent electronically, via the Federal eRulemaking Portal at http://www.regulations.gov/ (IRS REG-123867-14).

FOR FURTHER INFORMATION CONTACT:

Concerning the proposed regulations, James Rider at (202) 317-4137; concerning submissions of comments and requests for a public hearing, Oluwafunmilayo Taylor at (202) 317-6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** amend 26 CFR part 1. The temporary regulations provide a special rule for a renewable-source utility arrangement in which the building owner does not pay a local utility company for the utility consumed by the tenant. The text of those regulations also serves as the text of these regulations. The preamble to the temporary regulations explains the temporary regulations and these proposed regulations.

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this regulation, and because the regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C.

chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking has been submitted to the Chief Counsel for Advocacy of the Small **Business Administration for comment** on its impact on small business.

Comments and Requests for Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS as prescribed in this preamble under the 'ADDRESSES'' heading. The IRS and the Treasury Department request comments on all aspects of the proposed regulations. All comments that are submitted by the public will be available for public inspection and copying at www.regulations.gov or upon request. A public hearing will be scheduled if requested in writing by any person that timely submits comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the Federal Register.

Drafting Information

The principal author of these regulations is David Selig, Office of the Associate Chief Counsel (Passthroughs and Special Industries), IRS. However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.42–10(e)(1)(i)(B) and (C), and (e)(1)(iv)(B) are revised to read as follows:

§ 1.42-10 Utility allowances.

(e) * * * (1) * * * (i) * * *

(B) [The text of the proposed amendments to § 1.42-10(e)(1)(i)(B) is the same as the text of § 1.42-10T(e)(1)(i)(B) published elsewhere in this issue of the Federal Register].

(C) [The text of the proposed amendments to § 1.42–10(e)(1)(i)(C) is the same as the text of § 1.42-10T(e)(1)(i)(C) published elsewhere in this issue of the Federal Register].

* (iv) * * *

(B) The text of the proposed amendments to § 1.42-10(e)(1)(iv)(B) is the same as the text of § 1.42-10T(e)(1)(iv)(B) published elsewhere in this issue of the Federal Register].

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2016-04618 Filed 3-2-16; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2016-0115]

RIN 1625-AA00

Safety Zone; Xterra Swim, Myrtle Beach, SC Intracoastal Waterway; Myrtle Beach, SC

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to issue a temporary safety zone on the waters of the Intracoastal Waterway in Myrtle Beach, South Carolina. The Xterra Swim is scheduled to take place on Sunday, April 24, 2016. The temporary safety zone is necessary for the safety of the swimmers, participant vessels, spectators, and the general public during the event. The temporary safety zone will restrict vessel traffic in a portion of the Intracoastal Waterway, preventing non-participant vessels from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Charleston or a designated representative.

DATES: Comments and related material must be received by the Coast Guard on or before April 4, 2016.

ADDRESSES: You may submit comments identified by docket number USCG-2016-0115 using the Federal eRulemaking Portal at http:// www.regulations.gov. See the "Public Participation and Request for Comments" portion of the SUPPLEMENTARY INFORMATION section for

further instructions on submitting comments.