

use under § 1271.45(c) even when the applicable donor eligibility requirements under subpart C of this part are not met. Nothing in this paragraph creates an exception for deficiencies that occurred in making the donor eligibility determination for either the oocyte donor or the semen donor as required under § 1271.45(b), or for deficiencies in performing donor screening or testing, as required under §§ 1271.75, 1271.80, and 1271.85.

(c) *Required labeling.* As applicable, you must prominently label an HCT/P described in paragraphs (a) and (b) of this section as follows:

* * * * *

(2) “NOT EVALUATED FOR INFECTIOUS SUBSTANCES,” unless you have performed all otherwise applicable screening and testing under §§ 1271.75, 1271.80, and 1271.85. This paragraph does not apply to reproductive cells or tissue labeled in accordance with paragraph (c)(6) of this section.

* * * * *

(6) “Advise recipient that screening and testing of the donor(s) were not performed at the time of recovery or cryopreservation of the reproductive cells or tissue, but have been performed subsequently,” for paragraphs (a)(3) or (a)(4) of this section.

§ 1271.370

■ 3. Amend § 1271.370(b)(4) by removing “§ 1271.90(b)” and by adding in its place “§ 1271.90(c)”.

Dated: June 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-14721 Filed 6-21-16; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9772]

RIN 1545-BN15

Modification of Treatment of Certain Health Organizations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide guidance to Blue Cross and Blue Shield organizations, and certain other organizations, on computing and applying the medical loss ratio and the

consequences for not meeting the medical loss ratio threshold. The final regulations reflect the enactment of a technical correction to section 833(c)(5) of the Internal Revenue Code by the Consolidated and Further Continuing Appropriations Act of 2015. The final regulations affect Blue Cross and Blue Shield organizations, and certain other organizations involved in providing health insurance.

DATES: *Effective Date:* These regulations are effective on June 22, 2016.

Applicability Date: For the date of applicability, see § 1.833-1(e).

FOR FURTHER INFORMATION CONTACT: Rebecca L. Baxter, at (202) 317-6995 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This Treasury decision contains final regulations that amend 26 CFR part 1 under section 833 of the Internal Revenue Code (the Code). Section 833(a) provides that Blue Cross and Blue Shield organizations, and certain other organizations involved in providing health insurance as described in section 833(c), are entitled to: (1) Treatment as stock insurance companies for purposes of sections 831 through 835 (related to taxation of non-life insurance companies generally); (2) a special deduction determined under section 833(b); and (3) computation of unearned premium reserves under section 832(b)(4) based on 100 percent, and not 80 percent, of unearned premiums for purposes of determining “insurance company taxable income” under section 832.

Section 833(c)(5) was added to the Code by section 9016 of the Patient Protection and Affordable Care Act (Pub. L. 111-148, 124 Stat. 119) (the Affordable Care Act), effective for taxable years beginning after December 31, 2009. Section 833(c)(5), as enacted by the Affordable Care Act, provided that section 833 did not apply to any organization unless the organization’s medical loss ratio (MLR) for the taxable year was at least 85 percent. For purposes of section 833, an organization’s MLR was its percentage of total premium revenue expended on reimbursement for clinical services provided to enrollees under its policies during such taxable year (as reported under section 2718 of the Public Health Service Act (42 U.S.C. 300gg-18)).

Section 2718 of the Public Health Service Act (PHSA) was added by section 1001 and amended by section 10101 of the Affordable Care Act. Section 2718 of the PHSA is administered by the Department of

Health and Human Services. Section 2718(a) of the PHSA requires a health insurance issuer to submit a report for each plan year to the Secretary of the Department of Health and Human Services concerning the percentage of total premium revenue, after accounting for collections or receipts for risk adjustment and risk corridors and payments of reinsurance, that the issuer expends: (1) On reimbursement for clinical services provided to enrollees under such coverage; (2) for activities that improve health care quality; and (3) on all other non-claims costs, excluding federal and state taxes and licensing or regulatory fees.

Section 2718(b) of the PHSA requires that a health insurance issuer offering group or individual health insurance coverage, with respect to each plan year, provide an annual rebate to each enrollee under such coverage, on a pro rata basis, if the ratio of the amount of the premium revenue the issuer expends on costs for reimbursement for clinical services provided to enrollees under such coverage and for activities that improve health care quality to the total amount of premium revenue (excluding federal and state taxes and licensing or regulatory fees and after accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance under sections 1341, 1342, and 1343 of the Affordable Care Act (42 U.S.C. 18061, 18062, and 18063)) for the plan year is less than a prescribed percentage. Section 2718(b)(1)(B)(ii) of the PHSA provides that beginning on January 1, 2014, the medical loss ratio computed under section 2718(b) of the PHSA shall be based on expenses and premium revenues for each of the previous three years of the plan.

The Department of Health and Human Services published in the **Federal Register** (75 FR 74864) an interim final rule under section 2718 of the PHSA on December 1, 2010, an interim final rule and final rule on December 7, 2011 (76 FR 76596 and 76574), and a final rule on May 16, 2012 (77 FR 28790). These rules implementing section 2718 of the PHSA are codified at 45 CFR part 158 (HHS Regulations).

On December 6, 2010, the Treasury Department and the IRS published Notice 2010-79 (2010-49 I.R.B. 809), which provided interim guidance and transitional relief to organizations under section 833(c)(5). The interim guidance applied to an organization’s first taxable year beginning after December 31, 2009.

The interim guidance provided that for purposes of determining whether an organization’s percentage of total premium revenue expended on reimbursement for clinical services

provided to enrollees was at least 85 percent (and thus satisfied the requirement of section 833(c)(5)), organizations were required to use the definition of “reimbursement for clinical services provided to enrollees” set forth in the HHS Regulations. In addition, the interim guidance provided that for purposes of determining whether the 85-percent requirement of section 833(c)(5) was satisfied, the IRS would not challenge the inclusion of amounts expended for “activities that improve health care quality” as described in the HHS Regulations.

Notice 2010–79 also stated that the consequences for an organization with an MLR of less than 85 percent (an insufficient MLR) were as follows: (1) The organization would not be taxable as a stock insurance company by reason of section 833(a)(1) (but may have been taxable as an insurance company if it otherwise met the requirements of section 831(c)); (2) the organization would not be allowed the special deduction set forth in section 833(b); and (3) the organization would only take into account 80 percent, rather than 100 percent, of its unearned premiums for purposes of computing premiums earned on insurance contracts under section 832(b)(4). However, Notice 2010–79 provided that solely for the first taxable year beginning after December 31, 2009, the IRS would not treat an organization as losing its status as a stock insurance company by reason of section 833(c)(5) provided the following conditions were met: (1) The organization was described in section 833(c) in the immediately preceding taxable year; (2) the organization would have been taxed as a stock insurance company for the current taxable year but for the enactment of section 833(c)(5); and (3) the organization would have met the requirements of section 831(c) to be taxed as an insurance company for the current taxable year but for its activities in the administration, adjustment, or settlement of claims under cost-plus or administrative services-only contracts.

On July 5, 2011, the Treasury Department and the IRS published Notice 2011–51 (2011–27 I.R.B. 36) extending the interim guidance and transitional relief provided in Notice 2010–79 to an organization’s first taxable year beginning after December 31, 2010. On June 11, 2012, the Treasury Department and the IRS published Notice 2012–37 (2012–24 I.R.B. 1014) extending the interim guidance and transitional relief provided in Notice 2010–79 and Notice 2011–51 through an organization’s first taxable year beginning after December 31, 2012.

On May 13, 2013, the Treasury Department and the IRS published in the **Federal Register** (78 FR 27873) a notice of proposed rulemaking (REG–126633–12) addressing the computation of an organization’s MLR for purposes of section 833(c)(5) and the consequences of non-application of section 833 if an organization had an insufficient MLR. The proposed regulations provided that the numerator of an organization’s MLR is the total premium revenue expended on “reimbursement for clinical services provided to enrollees” under its policies for the taxable year, but does not include amounts expended for “activities that improve health care quality.” In addition, the Treasury Department and the IRS concluded that, for administrative convenience and to be consistent with the MLR calculation under section 2718(b)(1)(B)(ii) of the PHSa, it was appropriate to compute the MLR for a taxable year under section 833(c)(5) using the same three-year period used under section 2718(b) of the PHSa. Therefore, the proposed regulations provided that amounts used for purposes of section 833(c)(5) for each taxable year should be determined based upon amounts reported under section 2718 of the PHSa for that taxable year and the two preceding taxable years, subject to the same adjustments that apply for purposes of the PHSa. The proposed regulations also provided that if an organization has an insufficient MLR, then section 833(a) does not apply to that organization.

On January 7, 2014, the Treasury Department and the IRS published in the **Federal Register** (79 FR 755) final regulations (TD 9651) adopting the provisions of the proposed regulations with certain modifications. These modifications included transition rules to phase in the same three-year period used under section 2718(b) of the PHSa to compute the MLR for a taxable year. Accordingly, the final regulations provide that for the first taxable year beginning after December 31, 2013, an organization’s MLR is computed on a one-year basis. For the first taxable year beginning after December 31, 2014, an organization’s MLR is computed on a two-year basis. Finally, for the first taxable year beginning after December 31, 2015, and for all succeeding taxable years, the final regulations provide that an organization’s MLR is determined based on amounts reported under section 2718 of the PHSa for that taxable year and the two preceding taxable years, subject to the same adjustments that apply for purposes of section 2718 of the PHSa. The final

regulations apply to taxable years beginning after December 31, 2013.

Congress subsequently passed the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113–235, 128 Stat. 2130) (the Appropriations Act), which was signed into law by the President on December 16, 2014. Section 102 of Division N of the Appropriations Act made a technical correction to section 833(c)(5) (the Technical Correction). The Technical Correction provides that in calculating its MLR numerator, an organization includes both the cost of reimbursement for clinical services and amounts expended for activities that improve health care quality. In addition, the Technical Correction provides that the consequences for not meeting the MLR threshold are only that section 833(a)(2) and (3) do not apply. Therefore, an organization with an insufficient MLR is treated as if it were a stock insurance company under section 833(a)(1). The Technical Correction applies to taxable years beginning after December 31, 2009.

Explanation of Provisions

These final regulations restate § 1.833–1 of the Income Tax Regulations (26 CFR part 1) and incorporate the Technical Correction. As explained in this preamble, the Technical Correction, in effect, retroactively amended the rules in the existing final regulations to determine the MLR and the consequences of an insufficient MLR. In order to avoid any confusion caused by the effect of the Technical Correction on the existing final regulations, the Treasury Department and the IRS are publishing the existing final regulations, as revised by the Technical Correction, in their entirety in this Treasury decision.

1. Determining the MLR

Section 1.833–1 of the Income Tax Regulations generally provides that an organization’s MLR with respect to a taxable year is the ratio, expressed as a percentage, of the organization’s MLR numerator to its MLR denominator. Prior to the Technical Correction, the existing final regulations only included in the MLR numerator an organization’s total premium revenue expended on reimbursement for clinical services provided to enrollees. Consistent with the Technical Correction, § 1.833–1(c)(1)(i) of these final regulations describes an organization’s MLR numerator as the total premium revenue the organization expended on reimbursement for clinical services and activities that improve health care quality provided to enrollees under its

policies for the taxable year. For purposes of section 833(c)(5), these final regulations define the term “activities that improve health care quality” to have the same meaning as the term has in section 2718 of the PHSA and the regulations issued under that section (see 45 CFR 158.150). In addition, consistent with the Technical Correction, the transition rules for computation of the MLR in § 1.833–1(c)(2)(i) and (ii) of these final regulations include the premium revenue expended on activities that improve health care quality.

2. Consequences of an Insufficient MLR

Consistent with the Technical Correction, these final regulations provide that the consequences for an organization described in section 833(c) that has an MLR of less than 85 percent are the following: (1) The organization is not allowed the special deduction set forth in section 833(b); and (2) it must take into account 80 percent, rather than 100 percent, of its unearned premiums under section 832(b)(4). Unlike under the rule in the existing final regulations, an organization that has an MLR of less than 85 percent does not lose its eligibility to be treated as a stock insurance company under section 833(a)(1).

Effective/Applicability Date

These final regulations apply to taxable years beginning after December 31, 2016. However, taxpayers may rely on these final regulations for taxable years beginning after December 31, 2009.

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirement of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply.

The Treasury Department and the IRS have determined that section 553(b) of the APA does not apply to these regulations, including because good cause exists under section 553(b)(B) of the APA. Section 553(b)(B) provides that an agency is not required to publish a notice of proposed rulemaking in the **Federal Register** when the agency, for good cause, finds that notice and public comment thereon are impracticable,

unnecessary, or contrary to the public interest. The Treasury Department and the IRS have determined that notice and public comment are unnecessary inasmuch as these revisions (1) merely incorporate the Technical Correction by adding or removing language in the existing final regulations and make nonsubstantive conforming changes to reflect the Technical Correction and (2) provide taxpayers with immediate guidance. For the same reason, a delayed effective date is not required pursuant to section 553(d)(3) of the APA. Pursuant to section 7805(f)(3) of the Code, these final regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comments on its impact on small businesses, and no comments were received.

Drafting Information

The principal author of these regulations is Rebecca L. Baxter, Office of Associate Chief Counsel (Financial Institutions & Products). However, other personnel from the Treasury Department and the IRS participated in their development.

Availability of IRS Documents

The IRS notices and Treasury decisions cited in this preamble are made available by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is 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 1.833–1 is revised to read as follows:

§ 1.833–1 Medical loss ratio under section 833(c)(5).

(a) *In general.* Section 833(a)(2) and (3) do not apply to an organization unless the organization’s medical loss ratio (MLR) for a taxable year is at least 85 percent. Paragraph (b) of this section provides definitions that apply for purposes of section 833(c)(5) and this section. Paragraph (c) of this section provides rules for computing an organization’s MLR under section 833(c)(5). Paragraph (d) of this section

addresses the treatment under section 833 of an organization that has an MLR of less than 85 percent. Paragraph (e) of this section provides the effective/applicability date.

(b) *Definitions.* The following definitions apply for purposes of section 833(c)(5) and this section.

(1) *Activities that improve health care quality.* The term *activities that improve health care quality* has the same meaning as that term has in section 300gg–18 of title 42, United States Code and the regulations issued under that section (see 45 CFR 158.150).

(2) *Reimbursement for clinical services.* The term *reimbursement for clinical services* has the same meaning as that term has in section 300gg–18 of title 42, United States Code and the regulations issued under that section (see 45 CFR 158.140).

(3) *Total premium revenue.* The term *total premium revenue* means the total amount of premium revenue (excluding federal and state taxes and licensing or regulatory fees and after accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance under sections 1341, 1342, and 1343 of the Patient Protection and Affordable Care Act, Public Law 111–148 (124 Stat. 119 (2010)) (42 U.S.C. 18061, 18062, and 18063)) as those terms are used for purposes of section 300gg 18(b) of title 42, United States Code and the regulations issued under that section (see 45 CFR part 158).

(c) *Computation of MLR under section 833(c)(5)*—(1) *In general.* Starting with the first taxable year beginning after December 31, 2015, and for all succeeding taxable years, an organization’s MLR with respect to a taxable year is the ratio, expressed as a percentage, of the MLR numerator, as described in paragraph (c)(1)(i) of this section, to the MLR denominator, as described in paragraph (c)(1)(ii) of this section.

(i) *MLR numerator.* The numerator of an organization’s MLR is the total premium revenue expended on reimbursement for clinical services and activities that improve health care quality provided to enrollees under its policies for the taxable year, computed using a three-year period in the same manner as those expenses are computed for the plan year for purposes of section 300gg–18(b) of title 42, United States Code and regulations issued under that section (see 45 CFR part 158).

(ii) *MLR denominator.* The denominator of an organization’s MLR is the organization’s total premium revenue for the taxable year, computed using a three-year period in the same manner as the total premium revenue is

computed for the plan year for purposes of section 300gg–18(b) of title 42, United States Code and regulations issued under that section (see 45 CFR part 158).

(2) *Transition rules.* The transition rules in paragraphs (c)(2)(i) and (ii) of this section apply solely for the first taxable year beginning after December 31, 2013, and the first taxable year beginning after December 31, 2014.

(i) *First taxable year beginning after December 31, 2013.* For the first taxable year beginning after December 31, 2013, the numerator of an organization's MLR is the total premium revenue expended on reimbursement for clinical services and activities that improve health care quality provided to enrollees under its policies for the first taxable year beginning after December 31, 2013, and the denominator of an organization's MLR is the organization's total premium revenue for the first taxable year beginning after December 31, 2013.

(ii) *First taxable year beginning after December 31, 2014.* For the first taxable year beginning after December 31, 2014, the numerator of an organization's MLR is the sum of the total premium revenue expended on reimbursement for clinical services and activities that improve health care quality provided to enrollees under its policies for the first taxable year beginning after December 31, 2013, and for the first taxable year beginning after December 31, 2014, and the denominator of an organization's MLR is the sum of the organization's total premium revenue for the first taxable year beginning after December 31, 2013, and for the first taxable year beginning after December 31, 2014.

(d) *Failure to qualify under section 833(c)(5)—(1) In general.* If, for any taxable year, an organization's MLR is less than 85 percent, then beginning in that taxable year and for each subsequent taxable year for which the organization's MLR remains less than 85 percent, paragraphs (d)(1)(i) and (ii) of this section apply.

(i) *Special deduction.* The organization is not allowed the special deduction set forth in section 833(b).

(ii) *Premiums earned.* The organization must take into account 80 percent, rather than 100 percent, of its unearned premiums under section 832(b)(4) as it applies to other non-life insurance companies.

(2) *No material change.* An organization's loss of eligibility for the treatment provided by sections 833(a)(2) and (3) solely by reason of section 833(c)(5) will not be treated as a material change in the operations of such organization or in its structure for purposes of section 833(c)(2)(C).

(e) *Effective/applicability date.* This section applies to taxable years beginning after December 31, 2016. However, taxpayers may rely on this section for taxable years beginning after December 31, 2009.

John Dalrymple,
Deputy Commissioner for Services and Enforcement.

Approved: May 18, 2016.

Mark J. Mazur,
Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2016–14784 Filed 6–21–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2016–0460]

RIN 1625–AA00

Safety Zone; Detroit River Days Air Show, Detroit River, Detroit, MI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of the Detroit River in the vicinity of Detroit, MI. This zone is intended to restrict and control movement of vessels in a portion of the Detroit River. This zone is necessary to protect spectators and vessels from potential hazards associated with the Detroit River Days Air Show.

DATES: This temporary final rule is effective from 12:30 p.m. on June 24, 2016 until 6:30 p.m. on June 26, 2016.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2016–0460 and are available online by going to 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 rulemaking. They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground floor, Room W12–140, 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 final rule, call or email Petty Officer Todd Manow, Prevention Department, Sector Detroit, Coast Guard; telephone

313–568–9508, email Todd.M.Manow@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
E.O. Executive Order
FR Federal Register
NAD 83 North American Datum of 1983
NPRM Notice of Proposed Rulemaking
U.S.C. United States Code

II. Background Information and Regulatory History

On February 10, 2016, the Tuskegee Airmen National Historical Museum submitted an application for a marine event for an aerial display spanning three days in conjunction with the Detroit River Days Festival on June 24, 25, and 26, 2016. A safety zone is required by the Federal Aviation Administration to separate aircraft from persons and property on the ground or water's surface for all air shows. For the purposes of this event, the Coast Guard is establishing a safety zone around the proposed flight path and a standoff zone between the flight path and the shore, matching the safety zone created for this same event in 2015 [USCG–2015–0491].

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231, 33 CFR 1.05–1 and 160.5; and Department of Homeland Security Delegation No. 0170.1. Having reviewed the application for a marine event submitted by the sponsor on February 10, 2016, the Captain of the Port Detroit (COTP) has determined that an aircraft aerial display proximate to a gathering of watercraft poses a significant risk to public safety and property. Such hazards include potential aircraft malfunctions, loud noise levels, and waterway distractions. Therefore, the COTP is establishing a safety zone around the event location to help minimize risks to safety of life and property during this event.

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking with