device'', the panel submits to the Commissioner its recommendation containing the information set forth in § 860.84(d). A panel recommendation is regarded as preliminary until the Commissioner has reviewed it, discussed it with the panel, if appropriate, and developed a proposed reclassification order. Preliminary panel recommendations are filed at Dockets Management Staff upon receipt and are available to the public and posted at *https://www.regulations.gov.*

* * * * *

(6) Within 90 days after the panel's recommendation is received (and no more than 210 days after the date the petition was filed), the Commissioner denies or approves the petition by order in the form of a letter to the petitioner. If the Commissioner approves the petition, the order will classify the device into class I or class II in accordance with the criteria set forth in § 860.3(c) and subject to the applicable requirements of § 860.10, relating to the classification of implants and life-supporting or life-sustaining devices, and § 860.15, relating to exemptions from certain requirements of the Federal Food, Drug, and Cosmetic Act.

* * * * *

(c) By administrative order published under section 513(f)(3) of the Federal Food, Drug, and Cosmetic Act, the Commissioner may, on the Commissioner's own initiative, change the classification from class III under section 513(f)(1) either to class II, if the Commissioner determines that special controls in addition to general controls are necessary and sufficient to provide reasonable assurance of the safety and effectiveness of the device and there is sufficient information to establish special controls to provide such assurance, or to class I if the Commissioner determines that general controls alone would provide reasonable assurance of the safety and effectiveness of the device. The procedures for the reclassification proceeding under this paragraph (c) are as follows:

(1) The Commissioner publishes a proposed reclassification order in the **Federal Register** seeking comment on the proposed reclassification.

(2) The Commissioner may consult with the appropriate classification panel with respect to the reclassification of the device. The panel will consider reclassification in accordance with the consultation procedures of § 860.125.

(3) Following consideration of comments to a public docket and any panel recommendations or comments, the Commissioner may change the classification of a device by final administrative order published in the **Federal Register**.

(d) An administrative order under this section changing the classification of a device from class III to class II may establish the special controls necessary to provide reasonable assurance of the safety and effectiveness of the device.

■ 17. Amend § 860.136 by:

■ a. Revising the section heading, paragraph (a), and paragraph (b) introductory text;

■ b. Removing paragraph (b)(3);

■ c. Redesignating paragraphs (b)(4) through (6) as paragraphs (b)(3) through (5), respectively;

■ d. Revising newly redesignated paragraph (b)(4); and

■ e. Adding paragraphs (c) and (d).

The revisions and additions read as follows:

§ 860.136 Procedures for transitional products under section 520(l) of the Federal Food, Drug, and Cosmetic Act.

(a) Section 520(*l*)(2) of the Federal Food, Drug, and Cosmetic Act applies to reclassification proceedings initiated by the Commissioner or in response to a request by a manufacturer or importer for reclassification of a device currently in class III by operation of section 520(*l*)(1). This section applies only to devices that the Food and Drug Administration regarded as ''new drugs'' before May 28, 1976.

(b) The procedures for effecting reclassification under section 520(*l*) of the Federal Food, Drug, and Cosmetic Act when initiated by a manufacturer or importer are as follows:

* * * * *

(4) Within 180 days after the petition is filed (where the Commissioner has determined it to be adequate for review), the Commissioner, by order in the form of a letter to the petitioner, either denies the petition or classifies the device into class I or class II in accordance with the criteria set forth in § 860.3(c).

* * * * *

(c) By administrative order, the Commissioner may, on the Commissioner's own initiative, change the classification from class III under section 520(*l*) of the Federal Food, Drug, and Cosmetic Act either to class II, if the Commissioner determines that special controls in addition to general controls are necessary and sufficient to provide reasonable assurance of the safety and effectiveness of the device and there is sufficient information to establish special controls to provide such assurance, or to class I if the Commissioner determines that general controls alone would provide reasonable assurance of the safety and effectiveness of the device. The procedures for the reclassification proceeding under this paragraph (c) are as follows:

(1) The Commissioner publishes a proposed reclassification order in the **Federal Register** seeking comment on the proposed reclassification.

(2) The Commissioner may consult with the appropriate classification panel with respect to the reclassification of the device. The panel will consider reclassification in accordance with the consultation procedures of § 860.125.

(3) Following consideration of comments to a public docket and any panel recommendations or comments, the Commissioner may change the classification of a device by final administrative order published in the **Federal Register**.

(d) An administrative order under this section changing the classification of a device from class III to class II may establish the special controls necessary to provide reasonable assurance of the safety and effectiveness of the device.

Dated: December 7, 2018.

Scott Gottlieb,

Commissioner of Food and Drugs.

[FR Doc. 2018–27015 Filed 12–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9842]

RIN 1545–BO63

Tax Return Preparer Due Diligence Penalty Under Section 6695(g); Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to final regulations (TD 9842) that were published in the **Federal Register** on Wednesday, November 7, 2018. The final regulations relate to the tax return preparer penalty.

DATES: This correction is effective December 17, 2018 and applicable November 7, 2018.

FOR FURTHER INFORMATION CONTACT: Marshall French at (202) 317–6845 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9842) that are the subject of this correction are

under section 6695(g) of the Internal Revenue Code.

Need for Correction

As published November 7, 2018 (83 FR 55632), the final regulations (TD 9842) contain an error that needs to be corrected.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendment:

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 * * *

§ 1.6695–2 [Amended]

■ **Par. 2.** Section 1.6695–2 is amended by redesignating the second occurrence of paragraph (b)(3)(ii)(D) as paragraph (b)(3)(ii)(E).

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2018–26969 Filed 12–14–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 36

RIN 2900–AQ42

Loan Guaranty: Revisions to VA-Guaranteed or Insured Cash-Out Home Refinance Loans

AGENCY: Department of Veterans Affairs.

ACTION: Interim final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its rules on VA-guaranteed or insured cash-out refinance loans. The Economic Growth, Regulatory Relief, and Consumer Protection Act requires VA to promulgate regulations governing cash-out refinance loans. This interim final rule defines the parameters of when VA will permit cash-out refinance loans, to include defining net tangible benefit, recoupment, and seasoning requirements.

DATES: *Effective Date:* This rule is effective February 15, 2019.

Comment date: Comments are due on or before February 15, 2019.

ADDRESSES: Written comments may be submitted by email through *http://www.regulations.gov;* by mail or hand-delivery to Director, Regulations Management (00REG), Department of Veterans Affairs, 810 Vermont Avenue NW, Room 1063B, Washington, DC 20420; or by fax to (202) 273–9026. (This is not a toll-free number.) Comments should indicate that they are submitted in response to ''RIN 2900–AQ42, Loan Guaranty: Revisions to VA-Guaranteed or Insured Cash-out Home Refinance Loans.'' Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m. Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Greg Nelms, Assistant Director for Loan Policy & Valuation, Loan Guaranty Service (26), Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 632–8978. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On May 24, 2018, the President signed into law the Economic Growth, Regulatory Relief, and Consumer Protection Act (the Act), Public Law 115–174, 132 Stat. 1296. Section 309 of the Act, codified at 38 U.S.C. 3709, provides new statutory criteria for determining when, in general, VA may guarantee a refinance loan. The Act also requires VA to promulgate regulations for cash-out refinance loans within 180 days after the date of the enactment of the Act, specifically for loans where the principal of the new loan to be VA-guaranteed or insured is larger than the payoff amount of the loan being refinanced. Public Law 115–174, 132 Stat. 1296.

VA's current regulation concerning cash-out refinance loans is found at 38 CFR 36.4306. VA is revising § 36.4306 in this rulemaking, and planning additional rulemakings to implement other provisions of the Act.

I. VA's Refinance Program and New Section 3709

A. Two Types of Cash-Out Refinance Loans Under Section 3709

Refinancing loans guaranteed or insured by VA have historically fallen into two broad categories: (i) Cash-out refinance loans (cash-outs) offered under 38 U.S.C. 3710(a)(5) and (a)(9) and (ii) interest rate reduction refinancing loans (IRRRLs) authorized under 38 U.S.C. 3710(a)(8) and (a)(11). VA has not, until the enactment of the Act, seen any reason to delineate in VA's cash-out refinance rule, 38 CFR 36.4306, between cash-out refinance loans where the principal amount of the new loan is either: (a) Higher than, or (b) less than or equal to, the payoff amount of the loan being refinanced. The Act, however, bifurcates cash-out refinance loans relative to payoff amounts of the loan being refinanced, effectively requiring VA to treat the cash-out refinance loans differently, notwithstanding the fact that they are both authorized under the same statutory authority.

Subsections (a), (b), and (c) of 38 U.S.C. 3709 set forth standards for fee recoupment, net tangible benefits, and loan seasoning, respectively, related to the refinancing of loans guaranteed or insured by VA. Subsections (a) through (c) all contain similar introductory text, providing that when a borrower refinances a loan initially made for a purpose under VA's enabling statute in 38 U.S.C. 3710, the new refinance loan must meet the respective requirements of subsections (a), (b), and (c).

Subsections (a) through (c) do not expressly distinguish among the statutory types of refinancing loans that VA can guarantee or insure. While subsections (a) through (c) of section 3709 do not refer specifically to IRRRLs or cash-out refinance loans, subsection (d), which is identified under the statutory heading of ''Cash-out refinances'', explicitly states that subsections (a) through (c) do not apply to refinancing loans where the amount of the new loan is larger than the payoff amount of the loan being refinanced. The explicit delineation provided in subsection (d), *i.e.,* the distinction between loan refinance amounts relative to loan payoff amounts, requires VA to consider cash-out refinances separately. Based on the way Congress structured section 3709, VA-guaranteed or insured refinance loans are now effectively grouped into three categories: (i) IRRRLs, (ii) cash-outs in which the amount of the principal for the new loan is equal to or less than the payoff amount on the refinanced loan (Type I Cash-Outs), and (iii) cash-outs in which the amount of the principal for the new loan is larger than the payoff amount of the refinanced loan (Type II Cash-Outs). (For ease of reference, VA is referring in this preamble to the types of refinancing loans as IRRRLs, Type I Cash-Outs, and Type II Cash-Outs, respectively. VA is not using these terms in the rule text.)