

type certificate to include another model incorporating the same novel or unusual design features, these special conditions would apply to that model as well.

### Conclusion

This action affects only certain novel or unusual design features of Boeing Model 747-8 airplanes. It is not a rule of general applicability.

### List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

### The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Boeing Model 747-8 airplanes.

1. The extendable escape slide must receive Technical Standard Order (TSO) C69c or latest TSO authorization published at the time of TSO application for the Door 1 Slide.

2. In addition to the requirements of § 25.810(a)(1)(iii) for usability in conditions of landing gear collapse, the deployed escape slide in the extended mode must demonstrate an evacuation rate of 45 persons per minute per lane at the sill height corresponding to activation of the extension.

3. In lieu of the requirements of § 25.810(a)(1)(iv), the escape slide with the extendable section activated must be capable of being deployed in 22-knot winds directed from the critical angle, with the airplane on all its landing gear, with the assistance of one person on the ground. Two deployment scenarios must be addressed as follows:

(a) Extendable section is activated during the inflation time of the basic slide and,

(b) Extendable section is activated after the basic slide is completely inflated.

4. Pitch sensor tolerances and accuracy must be taken into account when demonstrating compliance with § 25.1309(a) for the escape slide in both extended and unextended modes.

5.(a) There must be a "slide extension" warning such that the cabin crew is immediately made aware of the need to deploy the extendable section of the slide. The ability to provide such a warning must be available for ten minutes after the airplane is immobilized on the ground.

(b) There must be a positive means for the cabin crew to determine that the extendable portion of the slide has been fully erected.

6. Whenever passengers are carried on the main deck of the airplane, there must be a cabin crewmember stationed on each side of the airplane located near each Door 1 Exit. This special condition must be included in the airplane flight manual as a limitation.

Issued in Renton, Washington, on June 22, 2011.

**KC Yanamura,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2011-16507 Filed 6-30-11; 8:45 am]

**BILLING CODE 4910-13-P**

## SOCIAL SECURITY ADMINISTRATION

### 20 CFR Part 418

[Docket No. SSA-2009-0078]

RIN 0960-AH06

### Amendments to Regulations Regarding Major Life-Changing Events Affecting Income-Related Monthly Adjustment Amounts to Medicare Part B Premiums

**AGENCY:** Social Security Administration (SSA).

**ACTION:** Final rule.

**SUMMARY:** This final rule adopts, without change, the interim final rule with request for comments we published in the *Federal Register* on July 15, 2010 at 75 FR 41084. The interim final rule concerned what we consider major life-changing events for the Medicare Part B income-related monthly adjustment amount (IRMAA) and what evidence we require to support a claim of a major life-changing event. This final rule allows us to respond appropriately to circumstances brought about by the current economic climate and other unforeseen events, as described below.

**DATES:** The interim final rule with request for comments published on July 15, 2010 is confirmed as final effective July 1, 2011.

**FOR FURTHER INFORMATION CONTACT:** Craig Streett, Office of Income Security Programs, Social Security Administration, 2-R-24 Operations Building, 6401 Security Boulevard, Baltimore, MD 21235-6401, (410) 965-9793. For information on eligibility or filing for benefits, call our national toll-free number, 1-800-772-1213 or TTY 1-800-325-0778, or visit our Internet site, Social Security Online, at <http://www.socialsecurity.gov>.

## SUPPLEMENTARY INFORMATION:

### Background

The interim final rule concerned what we consider major life-changing events for the Medicare Part B IRMAA and what evidence we require to support a claim of a major life-changing event.

Medicare Part B is a voluntary medical insurance program that provides coverage for services such as physicians care, diagnostic services, and medical supplies. A beneficiary enrolled in Medicare Part B pays monthly premiums, deductibles, and co-insurance associated with covered services. The Centers for Medicare & Medicaid Services (CMS) promulgates rules and regulations about the Medicare program, including the standard monthly premium. We determine and deduct the amount of certain Medicare Part B premiums from beneficiaries' Social Security benefits and make rules and regulations necessary to carry out these functions.

The Federal Government subsidizes the cost of Medicare Part B medical coverage. However, beneficiaries with modified adjusted gross incomes (MAGI) above a specified threshold must pay a higher percentage of their cost than those with MAGIs below the threshold.<sup>1</sup> We refer to this subsidy reduction as an IRMAA. CMS determines and publishes the annual MAGI threshold and ranges. The Internal Revenue Service (IRS) provides us with MAGI information.

We use MAGI and Federal income tax filing status for the tax year two years before the effective year to determine whether a beneficiary must pay an IRMAA, and if so, how much.<sup>2</sup> If information is not yet available for the tax year two years before the effective year, we will use information from the tax year three years before the effective year until the later information becomes available. A beneficiary who experiences a major life-changing event may request that we use a more recent tax year to make a new IRMAA determination.

If a beneficiary provides evidence that the qualifying major life-changing event significantly reduced his or her MAGI, we will determine the IRMAA based on data from a more recent tax year.<sup>3</sup> We define a significant reduction in MAGI

<sup>1</sup> MAGI is defined in 42 U.S.C. 1395r(i)(4). The threshold amount is defined in 42 U.S.C. 1395r(i)(2).

<sup>2</sup> MAGI ranges are established in 42 U.S.C. 1395r(i)(3), (5). The MAGI dollar amounts listed in 1395r(i)(3) may increase annually based on changes in the Consumer Price Index under 42 U.S.C. 1395r(i)(5).

<sup>3</sup> 20 CFR 418.1201.

as any change that results in a reduction or elimination of IRMAA.<sup>4</sup> The Social Security Act provides that major life-changing events include marriage, divorce, death of spouse, or other events specified in our regulations.<sup>5</sup>

Prior to the publication of our interim final rule, our regulations identified only the following additional events as major life-changing events: (1) The termination of a marriage, (2) annulment of a marriage, (3) reduced hours or stoppage of work, (4) reductions in income due to certain losses of income-producing property, 5) a reduction in or loss of income due to a scheduled cessation of a pension, and 6) a reduction in or loss of income from an insured pension plan due to termination or reorganization of the plan.<sup>6</sup> Our regulations also provided that we did not consider events other than those described in 20 CFR 418.1205 to be major life-changing events. In addition, under those regulations, we did not consider events that affected expenses but not income, or that resulted in the loss of dividend income, to be major life-changing events.<sup>7</sup>

We have added a new paragraph (g) to 20 CFR 418.1205 to include the receipt of certain settlement payments from an employer or former employer in the list of major life-changing events. To qualify as a major life-changing event, a settlement payment received by a beneficiary or the spouse of a beneficiary must be the result of an employer's or former employer's closure, bankruptcy, or reorganization. This change allows a beneficiary to request that we base the IRMAA on the MAGI from a more recent tax year.

We also have revised 20 CFR 418.1205(e) to include the loss of investment property as a result of fraud or theft due to a criminal act by a third party.

We have also made several other changes to this section of our regulations. First, we have specifically provided in final section 418.1205(e) that the beneficiary's spouse may not direct the loss of income-producing property. Previously, our regulations stated that the loss could not be at the direction of the beneficiary. We amended our regulations to include both the beneficiary and spouse.

Second, we have revised section 418.1205(e) to clarify that the loss of income-producing property due to the ordinary risk of investment is not a major life-changing event. In some

cases, beneficiaries and adjudicators have misinterpreted our current regulations in this regard.

We have made a similar change to 20 CFR 418.1210(b) to clarify that we do not consider events that result in the loss of dividend income because of the ordinary risk of investment to be major life-changing events.

We have replaced "insured pension plan" with "employer's pension plan" in 20 CFR 418.1205(f). Previously, our regulations provided that "a reduction in or loss of income from an insured pension plan due to termination or reorganization of the pension plan or a scheduled cessation of pension" qualified as a major life-changing event.<sup>8</sup> This language change qualifies both insured and uninsured pension plans.

We also have revised sections 418.1205(e) and (f) and 418.1255(e) and (f) to remove the wording that required a reduction in or loss of income from these life-changing events. The change made the wording of the revised subsections consistent with that of the subsections explaining other life-changing events found in 20 CFR 418.1205 and 20 CFR 418.1255.

#### Required Evidence

We also revised 20 CFR 418.1255 to clarify the type of evidence we require when a beneficiary asks us to use a more recent tax year to calculate an IRMAA based on certain changes in circumstance. If a beneficiary or his or her spouse experiences a loss of income-producing property due to criminal fraud or theft by a third party, we require proof of the conviction, such as a court document, and evidence of loss. If a beneficiary or his or her spouse experiences a scheduled cessation, termination, or reorganization of an employer's pension plan, we require evidence documenting the change in or loss of the pension. If a beneficiary or his or her spouse receives a settlement from an employer or a former employer because of the employer's closure, bankruptcy, or reorganization, we require evidence documenting the settlement and the reason(s) for the settlement. These changes make it easier for beneficiaries to meet their burden of proving that they have experienced a major life-changing event.

#### Technical Revisions

We have revised paragraph (d) of 20 CFR 418.1230 and paragraphs (c)(2) and (3) of 20 CFR 418.1265 to reflect the addition of new paragraph 418.1205(g), which concerns the receipt of certain settlements as life-changing events, as discussed above.

#### Public Comments

On July 15, 2010, we published an interim final rule with request for comments in the **Federal Register** at 75 FR 41084 and provided a sixty-day comment period. We received one comment from a member of the public. We carefully considered the concerns expressed in this comment but did not make any changes to the final rule.

We have summarized the commenter's view and have responded to the significant issues raised by the commenter that are within the scope of the interim final rule.

*Comment:* The commenter believes that we are too selective in what we consider a major life-changing event, ignoring other possible circumstances where an individual might experience an event that would have a major impact on his or her financial situation. Specifically, the commenter discussed a scenario in which an individual's long-term retirement income includes dividends from shares of a company that is later sold, forcing the individual to redeem that stock and experience a one-time gain that he or she must rely on for retirement. The commenter believes that the primary purpose of the MAGI is to require individuals with consistently higher incomes to pay higher premiums for their Medicare coverage. The commenter suggested that we apply MAGI only when the threshold is reached consistently, for example, in two out of three successive years.

The commenter also expressed concern about our revision to 20 CFR 418.1210(b). The commenter believed that using the phrase "because of the ordinary risk of investment" to qualify the type of dividend income loss not considered a major life-changing event suggests that any dividend loss not due to ordinary risk of investment should, in turn, qualify as a major life-changing event.

*Response:* We believe that the commenter was writing about the IRMAA and mistakenly referred to MAGI. We respond accordingly.

We may grant a request to use a more recent taxable year only if the individual's MAGI for that year is significantly less than the income for the normally applicable year due to a major life changing event. The Act requires that we determine whether IRMAA applies to an individual on an annual basis. We base each annual determination on a beneficiary's income from the specific tax year identified in section 1839(i)(4)(B) of the Act, which is generally the tax year from two years prior. Thus, we are unable to make

<sup>4</sup> 20 CFR 418.1215.

<sup>5</sup> 42 U.S.C. 1395r(i)(4)(C)(ii)(II).

<sup>6</sup> 20 CFR 418.1205.

<sup>7</sup> 20 CFR 418.1210.

IRMAA determinations based on a beneficiary's income for two out of three successive years. However, because we make determinations annually, a beneficiary will not be subject to an IRMAA in consecutive years unless the MAGI amount used is above the threshold in consecutive years. A one-time increase in MAGI should affect a beneficiary's IRMAA for only one year.

Additionally, the changes made to 20 CFR 418.1210 in the interim final rule help address the scenario discussed by the commenter. In the scenario, an individual received a one-time gain in income due to a forced sale of stock, but experienced a loss of dividend income in subsequent years because of the loss of the stock. The changes we made to 20 CFR 418.1210 clarify that we do not consider events that result in the loss of dividend income to be major life-changing events if the reasons for such loss are due to the ordinary risk of investment. Conversely, a loss of income-producing financial securities, if the circumstances causing the loss are truly beyond a beneficiary's or his or her spouse's control and do not involve the ordinary risk of investment, may qualify as a major life-changing event in the form of a loss of income-producing property under 20 CFR 418.1205(e).

Accordingly, the interim final rule remains unchanged and we are adopting it as final.

### Regulatory Procedures

*Executive Order 12866 as Supplemented by Executive Order 13563*

We have consulted with the Office of Management and Budget (OMB) and determined that this final rule meets the criteria for a significant regulatory action under Executive Order 12866 as supplemented by Executive Order 13563. Thus, the final rule was reviewed by OMB.

### Regulatory Flexibility Act

We certify that these final rules will not have a significant economic impact on a substantial number of small entities, because they affect individuals only. Therefore, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act, as amended.

### Paperwork Reduction Act

OMB previously approved the new public reporting requirements posed by this rule under a separate Information Collection Request (OMB No. 0960-0735). We are therefore not seeking OMB approval for these requirements here under the Paperwork Reduction Act.

(Catalog of Federal Domestic Assistance Program Nos. 93.774 Medicare Supplementary Medical Insurance; 96.002 Social Security—Retirement Insurance.)

### List of Subjects in 20 CFR Part 418

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Reporting and recordkeeping requirements, Supplemental Security Income (SSI), Medicare subsidies.

**Michael J. Astrue,**

*Commissioner of Social Security.*

Accordingly, the interim rule amending 20 CFR chapter III, part 418, subpart B that was published at 75 FR 41084 on July 15, 2010, is adopted as a final rule without change.

[FR Doc. 2011-16526 Filed 6-30-11; 8:45 am]

**BILLING CODE 4191-02-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 520

[Docket No. FDA-2011-N-0003]

#### Oral Dosage Form New Animal Drugs; Amprolium

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an original abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group Ltd. The ANADA provides for the use of amprolium soluble powder as an aid in the treatment and prevention of coccidiosis in calves.

**DATES:** This rule is effective July 1, 2011.

**FOR FURTHER INFORMATION CONTACT:** John K. Harshman, Center for Veterinary Medicine (HFV-170), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8197, e-mail: [john.harshman@fda.hhs.gov](mailto:john.harshman@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200-464 for the use of AMPROMED (amprolium) for Calves, a water-soluble powder used as an aid in the treatment and prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*. Cross Vetpharm Group Ltd.'s AMPROMED for Calves is approved as a generic copy of Huvepharma AD's

CORID (amprolium) 20% Soluble Powder, approved under NADA 33-165. The ANADA is approved as of May 23, 2011, and the regulations in 21 CFR 520.100 are amended to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33 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.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

#### List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

#### PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

■ 2. In § 520.100, add paragraph (b)(4) to read as follows:

#### § 520.100 Amprolium.

\* \* \* \* \*

(b) \* \* \*

(4) No. 061623 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

\* \* \* \* \*

Dated: June 24, 2011.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 2011-16501 Filed 6-30-11; 8:45 am]

**BILLING CODE 4160-01-P**