WEST VIRGINIA—1997 ANNUAL $PM_{2.5}$ NAAQS

[Primary and secondary]

Designated Area	Designation [a]		Classification	
	Date [1]	Type	Date [2]	Type
* * * *	*		*	*
Martinsburg, WV-Hagerstown, MD:				
Berkeley County	11/25/14	Attainment.		
* * * *	*		*	*

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.
[2] This date is July 2, 2014, unless otherwise noted.

* * * * *

[FR Doc. 2015–02851 Filed 2–12–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0530; FRL–9922–07]

Pyrimethanil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of pyrimethanil in or on pomegranate at 5.0 parts per million (ppm). Janssen PMP requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 13, 2015. Objections and requests for hearings must be received on or before April 14, 2015, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2014–0530, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2014–0530 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 14, 2015. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2014–0530, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 17, 2014 (79 FR 75107) (FRL–9918–90), EPA issued a document pursuant to

FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F8213) by Janssen PMP, Janssen Pharmaceutica NV, 1125 Trenton-Harbourton Rd Titusville, NJ 08560–0200. The petition requested that the 40 CFR 180.518 be amended by establishing a tolerance for residues of the fungicide pyrimethanil in or on pomegranate at 5.0 parts per million (ppm). That document referenced a summary of the petition prepared by Janssen PMP, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for pyrimethanil including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyrimethanil follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Pyrimethanil is of low acute lethality by the oral, dermal, and inhalation routes. It is a slight eye irritant, is not irritating to the skin, and it is not a dermal sensitizer. A single oral dose of 1,000 milligram/kilogram (mg/kg) produced a number of acute signs of neurotoxicity, including ataxia, dilated pupils, and decreases in motor activity, hind limb grip strength, and body temperature. However, there was no evidence of neurotoxicity with repeated dosing in a subchronic neurotoxicity study in rats. The major target organs of repeated oral exposure were the liver, kidney, and the thyroid. These effects were accompanied by decreased body weight. Reproductive toxicity was not observed, and developmental effects (*e.g.,* decreased fetal weight, retarded ossification, extra ribs) were observed only at maternally toxic doses. Special short-term exposure studies demonstrated increased liver uridine diphosphate glucuronosyl transferase (UDPGT) activity leading to decreases in thyroid hormones (T3, T4) and compensatory increases in thyroid-stimulating hormone (TSH) in adult rats.

Thyroid adenomas were seen in rats following long-term exposure, and it was concluded that they were mediated via disruption of the thyroid/pituitary axis. There were no concerns for mutagenicity. The EPA has classified pyrimethanil as ''Not Likely To Be Carcinogenic To Humans At Doses That Do Not Alter Rat Thyroid Hormone Homeostasis.'' This decision was based on the following:

1. There were treatment-related increases in thyroid follicular cell tumors in male and female Sprague-Dawley rats at doses which were considered adequate to assess carcinogenicity; however, rats are substantially more sensitive than humans are to the development of thyroid follicular cell tumors in response to thyroid hormone imbalance.

2. There were no treatment-related tumors seen in male or female CD–1 mice at doses which were considered adequate to assess carcinogenicity.

3. There is no mutagenicity concern and there is no evidence for thyroid carcinogenesis mediated through a mutagenic mode of action.

4. The non-neoplastic toxicological evidence (*i.e.,* thyroid growth, thyroid hormonal changes) indicated that pyrimethanil was inducing a disruption in the thyroid-pituitary hormonal status. The overall weight-of-evidence was considered sufficient to indicate that pyrimethanil induced thyroid follicular tumors through a non-linear, antithyroid mode of action.

For these reasons, EPA determined that quantification of carcinogenic risk is not required and that the no observed adverse effect level (NOAEL) (17 mg/kg/day) established for deriving the chronic reference dose (cPAD) would be protective of cancer effects. Due to the non-linear mode of action of pyrimethanil, exposure at the NOAEL is not expected to alter thyroid hormone homeostasis nor result in thyroid tumor formation.

Specific information on the studies received and the nature of the adverse effects caused by pyrimethanil as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rule published in the **Federal Register** of August 1, 2012 (77 FR 45499) (FRL–9354–7).

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for pyrimethanil used for human risk assessment is discussed in Unit III. B. of the final rule published in the **Federal Register** of August 1, 2012 (77 FR 45500) (FRL–9354–7).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pyrimethanil, EPA considered exposure under the petitioned-for tolerances as well as all existing pyrimethanil tolerances in 40 CFR 180.518. EPA assessed dietary exposures from pyrimethanil in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for pyrimethanil. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed default processing factors (as necessary), empirical processing factors for orange and apple juice, tolerance-level residues, and 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003–2008 NHNES/WWEIA. As to residue levels in food, EPA assumed default processing factors (as necessary), empirical processing factors for orange and apple juice, tolerance-level residues, and 100 PCT for all commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that pyrimethanil should be classified as ''Not Likely to be Carcinogenic to Humans at Doses That Do Not Alter Rat Thyroid Hormone Homeostasis''. Therefore a separate cancer exposure assessment was not performed.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for pyrimethanil. Tolerance-level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for pyrimethanil in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyrimethanil. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of pyrimethanil for acute exposures are estimated to be 86.5 parts per billion (ppb) for surface water and 4.8 ppb for ground water. For chronic exposures for non-cancer assessments, they are estimated to be 29.4 ppb for surface water and 4.8 ppb for ground water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For acute dietary risk assessment, the water concentration value of 86.5 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 29.4 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Pyrimethanil is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found pyrimethanil to share a common mechanism of toxicity with any other substances, and pyrimethanil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that pyrimethanil does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicology database for pyrimethanil includes rat and rabbit developmental toxicity studies and a 2-generation reproduction toxicity study in rats. As discussed in Unit III.A., there was no evidence of increased quantitative or qualitative susceptibility of fetuses or offspring following exposure to pyrimethanil in these studies.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for pyrimethanil is complete.

ii. Although there is evidence of neurotoxicity in the acute neurotoxicity study, concern is low since effects were only seen at the limit dose, effects are well-characterized with clearly established NOAEL/LOAEL values, and the selected endpoints are protective for the observed effects. The thyroid has been shown to be one of the target organs in adult animals for pyrimethanil-induced toxicity thus raising a potential concern for thyroid toxicity in the young. EPA, however concluded that there is no concern for thyroid toxicity in the young based on the following weight of evidence considerations: The effects seen on the thyroid and the liver database, while treatment-related, are not severe in nature; and in each of the studies that show an effect on thyroid hormone levels, as well as in all studies chosen for PODs selection, there is a wide dose spread (~10-fold difference between NOELs and LOAELs) which provides a measure of protection for any potential effects linked to decreased thyroid hormone levels in offspring.

iii. There is no evidence that pyrimethanil results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or

in young rats in the 2-generation reproduction study.

iv. The exposure databases are sufficient to determine the nature/magnitude of the residue in food and dietary analyses are unlikely to underestimate risk of exposure from pyrimethanil.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to pyrimethanil will occupy 38% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pyrimethanil from food and water will utilize 78% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for pyrimethanil.

3. *Short-term risk.* Short-term and intermediate-term aggregate exposure takes into account short-and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short- and intermediate-term adverse effect was identified; however, pyrimethanil is not registered for any use patterns that would result in short-and/or intermediate-term residential exposure. Short-and intermediate-term risk is assessed based on short-and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short-and intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-and intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-and intermediate-term risk for pyrimethanil.

4. *Aggregate cancer risk for U.S. population.* The Agency determined that the thyroid tumors seen in rat studies arise through a non-linear mode of action and the NOAEL (17 mg/kg/day) established for deriving the cRfD is not expected to alter thyroid hormone homeostasis nor result in thyroid tumor formation. Thus, the chronic risk assessment addresses any cancer risk. Based on the results of chronic risk assessment, EPA concludes that aggregate exposure to pyrimethanil will not cause a cancer risk.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to pyrimethanil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography (HPLC)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for pyrimethanil in or on pomegranate.

V. Conclusion

Therefore, a tolerance is established for residues of pyrimethanil, in or on pomegranate at 5.0 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as

described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 6, 2015.

Daniel J. Rosenblatt,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—AMENDED

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.518, alphabetically add the commodity ''Pomegranate'' to the table in paragraph (a)(1) to read as follows:

§ 180.518 Pyrimethanil; tolerance for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * *	
Pomegranate	5.0
* * * * *	

* * * * *

[FR Doc. 2015–02949 Filed 2–12–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 406, 407, and 408

[CMS–4176–NR]

Announcement of Ruling: Implementing United States v. Windsor for Purposes of Entitlement and Enrollment in Medicare Hospital Insurance and Supplementary Medical Insurance

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of CMS ruling.

SUMMARY: This document announces a CMS Ruling that states the CMS policies for implementing *United States* v. *Windsor* (''Windsor''), in which the Supreme Court held that section 3 of the Defense of Marriage Act (DOMA), enacted in 1996, is unconstitutional. Section 3 of DOMA defined ''marriage'' and ''spouse'' as excluding same-sex marriages and same-sex spouses, and effectively precluded the Federal government from recognizing same-sex marriages and spouses.

DATES: The CMS ruling announced in this document is applicable beginning February 9, 2015, with respect to appeals pending on, initiated, or reopened in accordance with applicable rules after February 9, 2015, for entitlement and enrollment determinations made on or after June 26, 2013. This ruling does not apply to appeals of entitlement and enrollment determinations made before June 26, 2013.

FOR FURTHER INFORMATION CONTACT: Patty Helphenstine (410) 786–0622.

SUPPLEMENTARY INFORMATION: In ''Windsor,'' (570 U.S. 12, 133 S. Ct. 2675 (2013), the Supreme Court held that section 3 of the Defense of Marriage Act (DOMA), enacted in 1996 (codified at 1 U.S.C. 7), is unconstitutional.

The CMS Administrator signed Ruling CMS–4176–R on February 9, 2015. This CMS Ruling, as well as other CMS Rulings are available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/index.html.* For the readers' convenience, the text of the CMS Ruling 4176–R is set forth in the Appendix to this notice of CMS ruling.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 9, 2015.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

APPENDIX

CMS Rulings

Department of Health and Human Services

Centers for Medicare & Medicaid Services

Ruling No.: CMS–4176–R

Date: February 9, 2015

Centers for Medicare & Medicaid Services (CMS) Rulings are decisions of the Administrator of CMS that serve as precedential final opinions, orders and statements of policy and interpretation. They provide clarification and interpretation of complex provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters. They are published under the authority of the Administrator.

CMS Rulings are binding on all CMS components, Part A and Part B Medicare Administrative Contractors (MACs), Qualified Independent Contractors (QICs), the Provider Reimbursement Review Board, the Medicare Geographic Classification Review Board, and on the Medicare Appeals Council and Administrative Law Judges (ALJs) who hear Medicare appeals. Rulings promote consistency in interpretation of policy and adjudication of disputes.

This Ruling states the CMS policies for implementing *United States* v. *Windsor,* 570 U.S. 12, 133 S. Ct. 2675 (2013) (''*Windsor*''), in which the Supreme Court held that section 3 of the Defense of Marriage Act (DOMA), enacted in 1996 (codified at 1 U.S.C. 7), is unconstitutional. Section 3 of DOMA defined ''marriage'' and ''spouse'' as excluding same-sex marriages and same-sex spouses, and effectively precluded the Federal government from recognizing same-sex marriages and spouses.

MEDICARE PROGRAM

Entitlement and Enrollment in Medicare Hospital Insurance (Part A) and Medicare Supplementary Medical Insurance (Part B)

CITATIONS: Sections 216(h), 226, 226A, 1818(c)–(d), 1837(i) and 1839 of the Social Security Act (42 U.S.C. Sections 416, 426, 426–1, 1395i–2, 1395p and 1395r); 42 CFR 406.5, 406.10, 406.13, 406.24, 406.32(c)–(d), 406.33, 406.34, 407.20, 407.22(a)(5), 407.25(c), 407.27(b), 408.22 and 408.24.