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OFFICE OF PERSONNEL MANAGEMENT

45 CFR Part 800

RIN 3206-AN12

**Patient Protection and Affordable Care Act; Establishment of the Multi-State Plan
Program for the Affordable Insurance Exchanges**

AGENCY: Office of Personnel Management.

ACTION: Proposed rule.

SUMMARY: The U.S. Office of Personnel Management (OPM) is issuing a proposed rule to implement modifications to the Multi-State Plan (MSP) Program based on the experience of the Program to date. OPM established the MSP Program pursuant to section 1334 of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, referred to collectively as the Affordable Care Act. This proposed rule clarifies the approach used to enforce the applicable requirements of the Affordable Care Act with respect to health insurance issuers that contract with OPM to offer MSP options. This proposed rule amends MSP standards related to coverage area, benefits, and certain contracting provisions under section 1334 of the Affordable Care Act. This document also makes non-substantive technical changes.

DATES: Comments are due on or before [INSERT DATE 30 DAYS AFTER PUBLICATION.]

ADDRESSES: You may submit comments, identified by Regulation Identifier Number (RIN) 3206-AN12 using any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Mail, Hand Delivery or Courier: National Healthcare Operations, Healthcare and Insurance, U.S. Office of Personnel Management, 1900 E Street, NW, Room 3468, Washington, DC 20415.

FOR FURTHER INFORMATION CONTACT: Cameron Stokes by telephone at (202) 606-2128, by FAX at (202) 606-4430, or by email at mspp@opm.gov.

SUPPLEMENTARY INFORMATION: The Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111– 152), together known as the Affordable Care Act, provides for the establishment of Affordable Insurance Exchanges, or “Exchanges” (also called Health Insurance Marketplaces, or “Marketplaces”), where individuals and small businesses can purchase qualified coverage. The Exchanges provide competitive marketplaces for individuals and small employers to compare available private health insurance options based on price, quality, and other factors. The Exchanges enhance competition in the health insurance market, improve choice of affordable health insurance, and give individuals and small businesses purchasing power comparable to that of large businesses. The Multi-

State Plan (MSP) Program was created pursuant to section 1334 of the Affordable Care Act to increase competition by offering high-quality health insurance coverage sold in multiple States on the Exchanges. The U.S. Office of Personnel Management (OPM) is proposing this regulation to modify the standards set forth for the MSP Program under 45 CFR Part 800 that was published as final rule on March 11, 2013 (78 FR 15560). This proposed rule will clarify OPM's intent in administering the Program as well as make regulatory changes in order to expand issuer participation and offerings in the Program to meet the goal of increasing competition.

Abbreviations:

EHB	Essential Health Benefits
FEHBA	Federal Employees Health Benefits Act
FEHB Program	Federal Employees Health Benefits Program
HHS	U.S. Department of Health and Human Services
MSP	Multi-State Plan
NAIC	National Association of Insurance Commissioners
OPM	U.S. Office of Personnel Management
PHS Act	Public Health Service Act
QHP	Qualified Health Plan
SHOP	Small Business Health Options Program

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 - I. Background

Section 1334 of the Affordable Care Act created the Multi-State Plan (MSP) Program to foster competition in the individual and small group health insurance markets on the Exchanges (also called Health Insurance Exchanges or Marketplaces) based on price, quality, and benefit delivery. The Affordable Care Act directs the U.S. Office of Personnel Management (OPM) to contract with private health insurance issuers to offer at least two MSP options on each of the Exchanges in the States and the District of Columbia.^{1,2} The law allows MSP issuers to phase in coverage.³

In the 2014 plan year, OPM contracted with one group of issuers to offer more than 150 MSP options in 31 States, including the District of Columbia. Approximately 371,000 individuals have enrolled in an MSP option to date. OPM added a second group of issuers for plan year 2015 and the MSP Program will expand into five additional States for a total of 36 States. The Program will offer more than 200 MSP options on the Exchanges during the 2015 plan year to further competition and expand choices available to individuals, families, and small businesses.

A. Affordable Insurance Exchanges

The Affordable Care Act established the Exchanges where individuals and small businesses can purchase qualified coverage. The Exchanges provide competitive marketplaces for individuals and small businesses to compare health insurance coverage based

¹ Multi-State Plan option or MSP option means a discrete pairing of a package of benefits with particular cost sharing (which does not include premium rates or premium rate quotes) that is offered under a contract with OPM.

² Note that the U.S. Department of Health & Human Services (HHS) determined that State-specific requirements in the ACA do not apply to U.S. territories, and thus territories are not required to establish Exchanges. See Letter to Commissioner Gregory R. Francis, Division of Banking & Insurance, St. Croix, Virgin Islands, from Marilyn Tavenner, Administrator, Centers for Medicare and Medicaid Services, July 16, 2014.

³ Multi-State Plan issuer or MSP issuer means a health insurance issuer or group of issuers that has a contract with OPM to offer MSP options pursuant to section 1334 of the Affordable Care Act.

on price, quality, and other factors. The goals of the Exchanges are to enhance competition in the health insurance market, improve choice of affordable health insurance, and provide individuals and small businesses purchasing power comparable to that of large businesses.

The purpose of this proposed rule is to modify the MSP Program final rule published March 11, 2013.⁴ Proposed changes to the regulation include clarifications to the process by which OPM administers the MSP Program, pursuant to section 1334 of the Affordable Care Act, and revisions to select sections of the regulation that establish standards and requirements applicable to MSP options and MSP issuers.

B. Objectives of the Multi-State Plan Program

MSP options were among several private health insurance coverage options offered on the Exchanges beginning in 2014. MSP options differ from QHPs in that MSP options are certified by OPM to be offered on an Exchange through the MSP Program application process and signing of a contract with OPM. In administering the MSP Program, OPM focuses on several important objectives:

- To ensure a choice of at least two options for high-quality health insurance coverage on each Exchange;
- To promote competition on the Exchanges to the benefit of all consumers;
- To provide strong, effective contractual oversight of the issuers that offer

MSP options; and

⁴ Patient Protection and Affordable Care Act; Establishment of the Multi-State Plan Program for the Affordable Insurance Exchanges, 78 FR 15560 (Mar. 11, 2013).

- To work cooperatively with States and HHS to ensure a level playing field between QHP issuers and MSP issuers.

Pursuant to section 1334 of the Affordable Care Act, the Director of OPM sets standards for the MSP Program. Under section 1334(b)(2), MSP issuers generally are also required to comply with requirements of State law not inconsistent with requirements in section 1334. OPM accordingly aligns standards for the MSP Program with the standards set for QHPs and QHP issuers by States, HHS, and the Exchanges. In certain unique and specific circumstances, MSP Program standards differ from QHP requirements. OPM will continue to ensure that to the extent that any of the rules governing MSP options and MSP issuers differ from those governing QHPs and QHP issuers, the standards afford the MSP options and MSP issuers neither a competitive advantage nor disadvantage with respect to other plans offered on the Exchange. OPM will continue to administer the MSP Program in a manner that is sensitive to the significant State and Federal interests affected by the MSP Program and informed by input from a broad array of stakeholders. Accordingly, OPM appreciates the ongoing coordination and cooperation with States and HHS in the administration of the MSP Program.

C. Review of OPM's Role in Contracting under the Federal Employees Health Benefits Program

Enacted in 1959, the Federal Employees Health Benefits Act (FEHBA) established health benefits for Federal employees, annuitants, and their dependents. More than eight million employees, annuitants, and their family members have coverage under the Federal Employees Health Benefits (FEHB) Program. Enrollees can choose fee-for-

service plans with preferred providers, local Health Maintenance Organizations, consumer-driven health plans, or high-deductible health plans in the FEHB Program. Among these options are six nationwide plans, each of which offers coverage in all 50 States and the District of Columbia.

For the 2014 and 2015 plan years, OPM negotiated with issuers to participate in the MSP Program. The process was guided by our experience in the FEHB Program, although it differed in certain respects from the FEHB Program process to account for the differences between the large group market, where OPM solely operated prior to the MSP Program, and the individual and small group markets served by the Exchanges.

D. Overview of the MSP Program's Statutory Requirements

Section 1334(a)(1) of the Affordable Care Act requires OPM to “enter into contracts with health insurance issuers, (which may include a group of health insurance issuers affiliated either by common ownership and control or by the common use of a nationally licensed service mark)... to offer at least 2 multi-State qualified health plans through each Exchange in each State.”⁵ The Director has the authority to implement and administer the MSP Program “in a manner similar to the manner in which the Director implements the contracting provisions with respect to carriers under the Federal Employees Health Benefit Program.”⁶ Further, OPM may enter into these contracts without regard to

⁵ Affordable Care Act section 1334(a)(1).

⁶ Affordable Care Act section 1334(a)(4).

competitive bidding laws.⁷ Each MSP Program contract must be for a term of at least one year, but can be automatically renewable in the absence of a notice of termination from either the MSP issuer or OPM.⁸

The statute grants to OPM the authority to certify MSP options.⁹ Any MSP options offered under a contract negotiated with OPM are “deemed to be certified by an Exchange for purposes of section 1311(d)(4)(A)” of the Affordable Care Act and would not need to apply separately for certification on each Exchange,¹⁰ as outlined at 45 CFR 155.1010(b)(1). The Director is authorized to withdraw approval of an MSP Program contract after notice and opportunity for a hearing.¹¹ The Director also has the authority to negotiate with each MSP issuer “(A) a medical loss ratio; (B) a profit margin; (C) the premiums to be charged; and (D) such other terms and conditions of coverage as are in the interests of enrollees in such plans.”¹²

MSP issuers are required to be licensed in each State in which they offer an MSP option¹³ and be “subject to all requirements of State law not inconsistent with this section [1334], including the standards and requirements that a State imposes that do not prevent the application of a requirement of part A of title XXVII of the Public Health Service Act

⁷ Affordable Care Act section 1334(a)(1).

⁸ Affordable Care Act section 1334(a)(2).

⁹ Affordable Care Act section 1334(d).

¹⁰ *Id.*

¹¹ Affordable Care Act section 1334(a)(7).

¹² Affordable Care Act section 1334(a)(4).

¹³ Affordable Care Act section 1334(b)(2).

(PHS Act) or a requirement of this title [I of the Affordable Care Act].”¹⁴ The Affordable Care Act directs that MSP issuers must comply with the minimum standards for FEHB Program carriers under section 8902(e) of title 5 of the United States Code to the extent that the standards do not conflict with provisions of title I of the Affordable Care Act.¹⁵ Congress also authorized OPM to establish additional standards for MSP options that OPM, in consultation with HHS, deems “appropriate.”¹⁶

E. Stakeholder Interaction

To assess the level of interest in the MSP Program, and to ascertain feedback from stakeholders about the program, OPM issued a Request for Information June 16, 2011.¹⁷ OPM received 19 responses representing the views of 39 groups and organizations. Responses came from health insurance issuers (including issuers of dental and vision insurance), employer organizations, labor organizations, consumer groups, patient organizations, and provider associations. On December 5, 2012, OPM published a notice of proposed rulemaking (77 FR 72582) establishing the MSP Program at part 800 of title 45, Code of Federal Regulations. OPM received about 350 comments from a wide variety of entities and individuals. Since publishing the final rule, OPM conducted presentations and met with numerous stakeholders to seek feedback on the implementation of the MSP Program. Stakeholder groups included representatives from the National Association of Insurance Commissioners (NAIC), States, tribal entities, consumer advocacy groups, health insurance issuers, provider associations, and trade groups. OPM also convened

¹⁴ Affordable Care Act section 1334(b)(2).

¹⁵ Affordable Care Act section 1334(b)(3).

¹⁶ Affordable Care Act section 1334(b)(4).

¹⁷ The Request for Information is available at https://www.fbo.gov/index?s=opportunity&mode=form&id=677e422dd3f2bc983cb985eb73995b63&tab=core&_cview=1.

groups of individuals – representing the general public as well as consumer advocates – to solicit input on branding and marketing of the MSP Program.

OPM is also in the process of establishing an MSP Program Advisory Board, the purpose of which will be to “provide recommendations on the activities” of the MSP Program.¹⁸ A “significant percentage of the members” of the MSP Program Advisory Board will be enrollees in an MSP option or representatives of such enrollees.¹⁹ Members of the MSP Program Advisory Board will exchange information, ideas, and recommendations regarding OPM’s administration of the MSP Program. OPM values the participation of diverse stakeholders and encourages them to submit comments on this proposed rule.

II. Proposed Regulatory Approach

A. Overview of Regulatory Approach

OPM’s approach to the development of this proposed regulation seeks to:

- Support a program that will attract additional issuers and thus, offer a greater selection of MSP options on each Exchange in every State and the District of Columbia.
- Balance State and Federal regulatory interests in a manner that will enable MSP issuers to offer viable plans on the Exchanges.

¹⁸ Affordable Care Act section 1334(h).

¹⁹ *Id.*

- Ensure a level playing field such that neither MSP options nor plans offered by non-MSP issuers are advantaged or disadvantaged on the Exchanges.

OPM seeks comment on whether these proposed changes to this regulation satisfy our goals. We are republishing the unchanged sections of the regulation to provide context for the proposed changes as well as to include non-substantive technical corrections.

B. Governing Law

The Affordable Care Act generally requires that the MSP Program be governed by all State and Federal laws that apply to QHPs. The Act, however, grants discretion to the Director to administer the MSP Program in a manner that fulfills OPM's statutory responsibility to ensure that there are at least two issuers offering MSP options on each Exchange in every State and the District of Columbia. OPM recognizes that potential MSP issuers seek administrative simplicity and some uniformity of standards in the MSP Program. Accordingly, in unusual circumstances, it may be necessary for the Director to adopt standards or requirements for the MSP Program that differ from standards and requirements applicable to QHPs under either State or Federal law. This proposed regulation, however, reflects the Director's continued intention for the MSP options and MSP issuers to generally adhere to all State and Federal laws applicable to QHPs and QHP issuers, except to the extent any such laws are inconsistent with section 1334. We propose to continue to implement these regulations in OPM guidance and OPM's contracts with MSP issuers.

III. Provisions of the Proposed Regulation

A. Subpart A—General Provisions and Definitions

Definitions (§ 800.20)

We seek comments on a definition for “group of issuers” that was defined in the final rule. We are specifically interested in whether this definition allows for alternative structures, such as decentralized health insurance issuers or organizations, to join together as potential applicants to offer MSP options. Under the definition in the MSP Program final rule, a “group of issuers,” for purposes of the MSP Program, may include:

(1) a group of health insurance issuers who are affiliated either by common ownership and control or by common use of a nationally licensed service mark (as defined in § 800.20); or (2) an affiliation of health insurance issuers and an entity that is not an issuer but owns a nationally licensed service mark.²⁰ We are making an editorial correction to this definition under (1) to state that “health insurance issuers that are affiliated.”

We propose to add the definition for “Multi-State Plan option,” which may also be referred to as “MSP option.” We propose the definition of “MSP option” as a discrete pairing of a package of benefits with particular cost sharing (which does not include premium rates or premium rate quotes) that is offered pursuant to a contract with OPM pursuant to section 1334 of the Affordable Care Act and meets the requirements of 45 CFR Part 800. We also propose to remove the definition of “Multi-State Plan.” The term

²⁰ 78 FR 15588.

“Multi-State Plan option” is more precise and avoids the confusion of the varying definitions of the word “plan” in the context of health insurance. In the past two years, OPM refined how to use the term “Multi-State Plan.” It is our intention to not apply the term “Multi-State Plan” as a general concept, but instead as a specific descriptor used under this Program. OPM registered the term “Multi-State Plan” as a mark with the U.S. Patent and Trademark Office,²¹ and we intend to enforce its exclusive use under this Program.

We also propose to add a definition for State-level issuer. This definition is consistent with the statutory concept of contracting with a group of issuers, and our experience reviewing MSP applications and negotiating contracts with MSP issuers. We propose to define a State-level issuer as a health insurance issuer designated by the MSP issuer to offer an MSP option or MSP options. The State-level issuer may offer health insurance coverage through one or more MSP options in all or part of one or more States.

OPM invites comments on the proposed changes to the definitions under 45 CFR 800.20.

B. Subpart B—Multi-State Plan Issuer Requirements

Phased Expansion: Coverage in all States; Coverage State-wide; and SHOP (§ 800.104)

²¹ U.S. Reg. No. 4599136.

Section 1334(e) of the Affordable Care Act provides for OPM to phase expansion of an issuer's participation in the MSP Program. In the final rule, OPM largely codified the statutory language for the phase-in standards and set standards for coverage within a State, participation in the Small Business Health Insurance Options Program (SHOP), and licensure. Since the publication of the final rule, OPM gained valuable insight and feedback from MSP issuers and potential MSP issuer applicants.

Coverage in all States.

Under § 800.104(a) of the final rule, OPM established a standard that it may enter into a contract with a health insurance issuer to offer MSP options if the health insurance issuer agrees to a phased expansion of coverage in States. We request comment on how we may expand participation in the Program to meet the goal of increasing competition while balancing consumers' needs for coverage across an entire State. OPM conducted outreach to potential MSP issuers and is engaged in ongoing discussions with current MSP issuers to address expansion of access to MSP options for consumers throughout the country. These issuers have expressed significant concern about the challenges of rapidly expanding access to MSP coverage both within and across State lines.

The text of section 1334 is clear in its intent that the primary purpose of the MSP Program is to promote competition on Exchanges by contracting with issuers to offer coverage in each State. Section 1334 contemplates interest from private health insurance issuers in participating in the Program; however, there is no requirement for health insurance issuers to participate in the Program. The statute sets forth standards to guide the exercise of this contracting authority, noting that section 1334(b)(1) contemplates offering coverage in every State and the District of Columbia, and outlining a framework

within which participation in the MSP Program is a feasible and attractive business activity. Such standards include the provisions under subsections (b) and (e) on offering coverage in every State. OPM intends to ensure that MSP coverage is available as expansively and as soon as practicable, but recognizes the operational challenges issuers may face.

OPM has discretion over how we may implement and expand the MSP Program. We request comment on timeframes and other appropriate parameters within which an MSP issuer could reasonably expand participation in the Program. For example, a MSP issuer may be expected to expand to a certain number of states within a specified timeframe. In addition, we request comment on how OPM may encourage MSP issuers to expedite their participation on the Exchanges in which there is limited competition. At this time, we do not propose any changes to the regulatory text.

State-wide coverage.

The final rule established a standard for MSP coverage in a State under § 800.104(b) that permits OPM to enter into a contract with an issuer that offers coverage in part of a State, but not necessarily the entire State. Most, but not all, of the MSP options available to consumers in plan years 2014 and 2015 provide coverage statewide.

In some circumstances, issuers in particular States have not consistently been able to offer statewide MSP coverage. Based on discussions with potential MSP issuers, we believe some of the challenges to providing statewide coverage in all States will continue to impede expansion or participation in the Program. One of these challenges is the licensing agreements for use of a nationally licensed service mark among the group of issuers participating in the MSP Program.²² Section 1334 requires that a group of issuers

²² 45 CFR 800.20. (2013).

offering MSP coverage must be affiliated in one of a few specific ways, including common use of a nationally licensed service mark. Antitrust and other laws that limit the permissible scope of interaction among issuers may make it difficult for a group of issuers under the MSP Program to coordinate nationally. OPM is sensitive to these constraints and recognizes that they may hinder development and implementation of issuers' plans to offer statewide MSP coverage.

OPM is committed to a goal of statewide coverage in the MSP Program, and intends to continue working with MSP issuers and potential MSP issuers to develop productive and ambitious approaches to achieving statewide coverage. In clarifying the status of the Program and how we are implementing the standards set under § 800.104, we propose to delete the standard for an MSP issuer to submit a plan to become statewide. In lieu of requiring a plan, OPM intends to negotiate with MSP issuers to determine their MSP coverage area. In the MSP Program contract negotiation process, we will consider the MSP issuers' capacity to provide statewide coverage. OPM will take into account many factors when assessing an MSP issuer's capacity for offering statewide coverage (e.g., other business commitments, financials, Exchange QHP standards, and OPM's dialogue with State regulators). In addition, OPM will assess consumers' needs for coverage, including ensuring that MSP issuers' proposed service areas have been established without regard to racial, ethnic, language, or health status-related factors listed in section 2705(a) of the PHS Act, or other factors that exclude specific high-utilizing, high-cost, or medically underserved populations.

SHOP Coverage.

The final rule established flexibility in SHOP participation for MSP issuers in § 800.104(c) by establishing a policy for participation consistent with standards set for QHP issuers. Specifically, we adopted standards that require MSP issuers to generally comply with standards in 45 CFR 156.200(g) and with State standards for SHOP participation if the State has set a standard that requires QHP issuers to participate. This policy provided OPM discretion to provide MSP issuers flexibility during the initial years of the Program to phase into the SHOP in a State-based Exchange. OPM provided that an MSP issuer may meet the requirements of 45 CFR 156.200(g)(3) if a State-level issuer or any other issuer in the same issuer group affiliated with an MSP issuer provides coverage on the Federally-facilitated SHOP. We discussed this policy in-depth in the final rule.²³

Section 1334 requires OPM to contract for coverage to be offered on each Exchange in each State, offering individual or small group coverage.

Based on our current experience implementing the Program, a number of challenges prevent issuer participation in the MSP Program, including timing and resources. Very few MSP issuers have offered MSP SHOP options in these initial years of the Program. We solicit comment on when MSP issuers should be required to participate on the SHOPS.

Benefits (§ 800.105)

The final rule adopted requirements in § 800.105(a) that an MSP issuer must offer a uniform package of benefits for each MSP option within a State and that the package of

²³ 78 FR 15565.

benefits must comply with section 1302 of the Affordable Care Act, as well as standards set by OPM and any applicable standards set by HHS.

In § 800.105(b), OPM finalized a rule that allowed MSP issuers to offer a package of benefits in all States that is substantially equal to either (1) each State's Essential Health Benefits (EHB)-benchmark plan in each State in which it operates; or (2) any EHB-benchmark plan selected by OPM. In response to comments received on the proposed rule, OPM clarified that the option chosen must be applied uniformly in each State in which the MSP issuer proposes to offer MSP options.

OPM continues to conduct outreach to potential MSP issuers and encourages ongoing discussions with current MSP issuers in hopes of expanding the Program. OPM interprets the discretion afforded to the Director under section 1334(a) of the Affordable Care Act, such that he or she may administer the Program in a way to attract issuers to the Program and grow the Program to meet the goal of increasing competition. By applying the Director's discretion to offer flexibility in the selection of the package of benefits, OPM hopes to reduce the number of obstacles and increase competition and consumer choice while maintaining benefit standards and protections

After completing two application cycles for the MSP Program and administering the Program since January 2014, OPM is proposing to adjust the approach to the selection of the package of benefits to allow for more flexibility to attract issuers to the MSP Program with the expectation of expanding competition on the Exchanges. OPM is requesting public comment on this approach. This flexibility would allow an MSP issuer to make benchmark selections on a State-by-State basis. The issuer would also be able to

offer two or more MSP options in each State, for example, one using the State-selected benchmark and one using the OPM-selected benchmark. OPM believes that allowing this flexibility will enable coalition building across issuers in different States, so that they can work together toward MSP options that meets the MSP Program standards. For example, an MSP issuer or potential issuer that chooses to offer an OPM-selected benchmark plan in one State may want to partner with another MSP issuer or potential issuer that would choose to offer a State EHB-benchmark plan in another State. We seek comments on whether this would have the desired effect of encouraging participation without causing consumer confusion or segmenting of risk.

In § 800.105(c)(1), OPM finalized the selection of EHB-benchmark plans. OPM selected the three largest FEHB Program plan options by enrollment that are open to Federal employees and annuitants. These FEHB Program benchmark plans were identified by HHS pursuant to section 1302(b) of the Affordable Care Act. On July 3, 2012, HHS identified the three largest FEHB Program plan options, as of March 31, 2012, as Blue Cross Blue Shield (BCBS) Standard Option; BCBS Basic Option; and Government Employees Health Association (GEHA) Standard Option.²⁴ OPM will continue to offer flexibility to MSP issuers to select among these benchmark options based on their business strategies and perceived needs of MSP enrollees.

In § 800.105(c)(2), OPM finalized the requirement that any OPM-selected EHB-benchmark plan lacking coverage of pediatric oral services or pediatric vision services must be supplemented by the addition of the entire category of benefits from the largest

²⁴ Centers for Medicare and Medicaid Services, Essential Health Benefits: List of the Largest Three Small Group Products by State, available at <http://ccio.cms.gov/resources/files/largest-smgroup-products-7-2-2012.pdf>.PDF (July 3, 2012).

Federal Employee Dental and Vision Insurance Program (FEDVIP) dental or vision plan option, respectively, pursuant to 45 CFR 156.110(b) and section 1302(b) of the Affordable Care Act. On July 3, 2012, HHS identified the largest FEDVIP dental and vision plan options, as of March 31, 2012, to be, respectively, MetLife Federal Dental Plan High Option and FEP BlueVision High Option.²⁵

OPM is proposing to add a clarification in the new § 800.105(c)(3). Based on outreach with potential MSP issuers and ongoing discussions with current MSP issuers, there is confusion about the prescription drug formulary standards of OPM-selected benchmarks. As is done in the FEHB Program, OPM will work with MSP issuers to negotiate a formulary that best manages the needs of MSP enrollees while focusing on managing costs and ensuring access. In addition, OPM will ensure that MSP issuers comply with any HHS standards related to drug formularies for QHPs and are not discriminatory in the formulary's design. OPM sees large variations in the formulary structures in the FEHB Program, and there are ongoing changes in the use of managed formularies. OPM also seeks comment on the feasibility of substituting an OPM-selected benchmark plan formulary with the formulary from the respective State's EHB-benchmark plan. This approach would promote consistency in benefits to enhance portability while maintaining a level playing field. By working with MSP issuers to build flexibility in the management of formularies, OPM believes the formulary will be seen as an opportunity to build a plan around the needs of enrollees while clarifying formulary requirements with the OPM-selected benchmarks.

²⁵ *Id.*

In the final rule at § 800.105(c)(3), proposed to be republished as § 800.105(c)(4), OPM finalized the use of State definitions for habilitative services where the State chooses to specifically define this category pursuant to 45 CFR 156.110(f). In this section of the final rule, OPM also reserved the authority to determine what to include in this category for the OPM-selected benchmarks where the State has not defined it and no definition exists in the OPM-selected benchmark. OPM is proposing to change this section to apply a Federal definition of habilitative services, should HHS choose to define the term.

We propose to renumber § 800.105(c)(4) to § 800.105(c)(5). We are not proposing changes to this standard.

In § 800.105(d), OPM finalized the rule that an MSP issuer's package of benefits, including its formulary, must be submitted to and approved by OPM, which will determine whether a package of benefits proposed by an MSP issuer is substantially equal to an EHB-benchmark plan. OPM also plans to review an MSP issuer's package of benefits for discriminatory benefit design, consistently with section 1302(b)(4) of the Affordable Care Act and 45 CFR 156.110(d), 156.110(e), and 156.125, and will work closely with States and HHS to identify and investigate any potentially discriminatory or otherwise noncompliant benefit design in MSP options.

In § 800.105(e), OPM finalized the rule that the cost of benefits required by the State in addition to those in the benchmark package would be assumed by the State. This policy was consistent with section 1334(c)(2) of the Affordable Care Act. OPM now pro-

poses to change “assume” to “defray” to make the language align with the language in the statute.

Assessments and User Fees (§ 800.108)

OPM has authority to collect MSP Program user fees, and continues to preserve its discretion to collect an MSP Program user fee. We wish to clarify that OPM may begin collecting the fee as early as plan year 2015. The user fee may be used to fund OPM activities directly related to MSP Program certification, administration, and operational costs. We currently estimate that any assessment or fee would be no more than 0.2 percent of premiums. In the Federally-facilitated Exchange, OPM is coordinating with HHS regarding the collection of user fees, so that issuers would not be affected operationally. We are revising the regulatory text to allow for flexibility in the process for collecting MSP Program assessments or user fees. We solicit comments on the process for collecting user fees in the State-based Exchanges. We also seek comments on the use of these fees.

Network Adequacy (§ 800.109)

We are proposing to add that an MSP issuer must also comply with any additional standards related to provider directories set by HHS for QHP issuers.

Accreditation (§ 800.111)

We revised the reference to the specific section in the Code of Federal Regulations to 45 CFR 156.275(a)(1) to be more precise.

Level playing field (§ 800.115)

We revised the regulatory text to clarify that all the areas listed under section 1324 of the Affordable Care Act are subject to §800.114. In addition, we are making a technical correction to § 800.114(l) to change a reference to 45 CFR part 162 to 45 CFR part 164.

C. Subpart D – Application and Contracting Procedures

Application Process (§ 800.301)

In § 800.301, OPM provided that health insurance issuers may submit applications to OPM for participation in the MSP Program. If OPM decided not to consider new applications for the upcoming year, it would issue a notice indicating so. This section also specified that applications would meet the form, manner, and timeframes prescribed by OPM.

The edit to § 800.301(a) is a technical correction that more accurately describes that OPM determines annually whether new issuer applications should be considered to participate in the MSP Program. This correction is meant to distinguish new applications from renewal applications. OPM's discretion over whether to consider issuer applications pertains to new issuers that want to apply to participate in the MSP Program for the first time. Issuers that already participate in the MSP Program, and would like to continue participating, may submit a renewal application to OPM on an annual basis. OPM will determine annually whether a renewal application is required.

MSP Contracting (§ 800.303)

In § 800.303, OPM provided that an applicant must execute a contract with OPM to become an MSP issuer; that OPM would establish a standard contract for the MSP Program; that OPM and an applicant would negotiate premiums for each plan year; that OPM would review for approval an applicant's benefit packages; that OPM may negotiate additional contractual terms and conditions; and that MSP issuers would be certified to offer MSP coverage on Exchanges.

The edit to § 800.303(f) is a technical correction to clarify that the MSP Program contract specifies that OPM certifies the MSP options that are authorized to provide coverage. We also propose a technical correction to § 800.303(f)(2) consistent with the edit to (f)(1) to provide that MSP options must be certified in order to be offered on an Exchange. These edits more accurately describe the information that is reflected in the MSP Program contract with respect to OPM's certification process.

Nonrenewal (§ 800.306)

The proposed language for § 800.306(a) serves to clarify two different nonrenewal concepts. The term "nonrenewal" as described in the current rule more accurately describes nonrenewal of an MSP Program contract because it pertains to the MSP issuer. Therefore, we propose the term "nonrenewal of contract" to clarify this concept. Addi-

tionally, there are instances where a State-level issuer may choose not to renew its participation in the MSP Program contract, even though the MSP issuer (of which the State-level issuer is a part) will continue to contract with OPM. The current regulatory language does not contemplate this latter concept. Therefore, we propose the term “nonrenewal of participation” to describe such concept. By distinguishing the two types of nonrenewal, the rule will better align with the terms described in the MSP Program contract, which already distinguishes these concepts. Despite this distinction, the notice requirements and MSP issuer responsibilities as provided in subsections (b) and (c) respectively, are still applicable. In subsection § 300.306(c), with respect to providing notice of termination to enrollees, we propose to reference § 800.404(d) instead of duplicating the explanation of the requirements in this section. This will ensure consistency across the MSP Program.

D. Subpart E—Compliance

Contract Performance (§ 800.401)

In addition to other MSP contract performance requirements, § 800.401 paragraphs (b)(5)-(6), (c), and (d) require an MSP issuer to perform its obligations under an MSP Program contract using prudent business practices that emphasize ethical standards and compliance with OPM directives and other applicable laws, regulations, and MSP contract provisions. The section prohibits fraud, waste, abuse, and deceptive business

practices. It also requires an MSP issuer to adjudicate claims promptly and maintain a system that accurately accounts for costs occurring under the MSP Program. Although this section lists numerous prudent and poor business practices, we did not intend them to be exhaustive. In addition, because industry standards and State markets are evolving constantly, we address business practice standards in each MSP Program contract. Therefore, we are clarifying that OPM will consider an MSP issuer's specific circumstances and facts in using its discretion to determine if an MSP issuer has fulfilled its obligations pursuant to this section. We seek comment on these issues.

Contract Quality Assurance (§ 800.402)

OPM proposes corrections to § 800.402 paragraphs (b) and (c). In paragraph (b), OPM proposes to clarify that it “may,” instead of “will,” periodically evaluate a contractor's system of internal controls. OPM also clarifies in paragraph (b) that it will only acknowledge in writing when the contractor's system of internal controls is inconsistent with the MSP Program contract requirements. In paragraph (c), OPM will correct a drafting error and clarify that MSP issuers must comply with the performance standards issued “pursuant” to this section.

Compliance Actions (§ 800.404)

OPM proposes to make technical edits to § 800.404 paragraphs (a), (b), (c) and (d). In paragraph (a)(4), we clarify that OPM may initiate a compliance action for viola-

tions of law or regulation as OPM may determine, “including pursuant to its authority under §§ 800.102 and 800.114.” This revision more accurately reflects OPM’s approach to enforcement and compliance.

In paragraph (b), we clarify that OPM may withdraw certification of the MSP option or options for noncompliance with applicable law or the MSP contract. Consistent with new paragraph 800.306(a)(2), we add “nonrenewal of participation” as a compliance action. Accordingly, we renumber the two subsequent compliance actions. We also revised “Nonrenewal of the MSPP contract” to “Nonrenewal of contract” to be consistent with the term as defined in new paragraph 800.306(a)(1). We revise paragraph (c)(2) to include nonrenewal of participation as a compliance action for which OPM must notify the MSP issuer of its right to reconsideration.

Paragraph (d) requires an MSP issuer to comply with State and Exchange requirements regarding termination of a plan when an MSP Program contract is terminated or when OPM withdraws certification. Absent State or Exchange requirements, the MSP issuer must provide enrollees 90 days’ notice. If a State or Exchange has a requirement to provide enrollees notice of more than 90 days, then the MSP issuer must comply with that standard. We clarify that these requirements are triggered in the event that one of the following occurs: the MSP Program contract is terminated, OPM withdraws certification of an MSP option, or if a State-level issuer’s participation is not renewed.

Reconsideration of compliance actions (§ 800.405)

OPM proposes technical edits and corrections to section 800.405. Section 800.405 describes the compliance actions for which the MSP issuer may request reconsideration. We correct paragraph (a)(1) to reflect that an MSP issuer may request reconsideration upon withdrawal of certification of the MSP option or options offered on an Exchange. Consistent with the approach 800.404(b), we revise (a)(2) to allow an MSP issuer to request reconsideration of the nonrenewal of participation of a State-level issuer. We renumber the subsequent paragraphs accordingly.

E. Subpart G—Miscellaneous

Consumer choice with respect to certain services (§ 800.602)

Section 1334(a)(6) of the Affordable Care Act requires OPM to contract with at least one MSP issuer that excludes coverage of abortion services, except in the case of rape or incest, or when the life of the woman would be endangered. In the MSP Program final rule, we codified the statutory language and provided sub-regulatory guidance to MSP issuer applicants on how to meet this requirement in their benefit proposals.

For the 2014 and 2015 plan years, OPM operationalized this policy by requiring each MSP issuer to offer at least one silver MSP option and one gold MSP option that excludes these services in each State in which it was under contract. MSP issuers also had discretion to cover these services if the issuer offered additional MSP options on the Exchange.

Consumers, State regulators, and other stakeholders expressed to OPM the desire to have greater transparency with regard to MSP options that exclude non-accepted abor-

tion services.²⁶ Section 2715 of the PHS Act requires group health plans and health insurance issuers of group or individual health insurance coverage to provide “a summary of benefits and coverage explanation that accurately describes the benefits and coverage under the applicable plan or coverage to applicants, enrollees, and policyholders or certificate holders.”²⁷ MSP issuers are required to notify consumers who purchase an MSP option that covers non-excepted abortion services of such coverage as part of the SBC at time of enrollment.²⁸

We are proposing to add a new paragraph (c) to § 800.602 that would require an MSP issuer to provide disclosure of coverage or exclusion of this benefit before a consumer enrolls in an MSP option. In addition, OPM will reserve the authority to review and approve these MSP notices and materials. OPM requests comments on the form and manner for the disclosure. Note that the question of how this coverage should be disclosed is not unique to MSP options; the Departments of Health and Human Services, Labor, and Treasury intend to issue guidance on the Summary of Benefits and Coverage in the future.

Disclosure of information (§ 800.603)

In order to effectively implement and operationalize the MSP Program, there may be circumstances in which OPM would share information with State entities, including State Departments of Insurance and Exchanges. The sharing of information is intended to keep such entities informed and to reflect OPM’s approach to compliance. The addition of this new section clarifies that OPM may use its discretion and authority to disclose in-

²⁶ These are services for which Federal funding is prohibited.

²⁷ PHS Act section 2715 (a) (2012).

²⁸ 45 CFR 156.280(f).

formation to such State entities. In all cases, OPM will adhere to any applicable privacy and security standards for the disclosure of such information.

Technical changes to 45 CFR Part 800

In addition to the changes proposed for the specific sections of the regulation, we also propose technical corrections to streamline the use of “MSP” throughout the rules. The changes are not substantive to our policy. These changes apply to all sections and include the following:

- “MSPP” will be replaced with “MSP Program;”
- “MSPP issuer” will be replaced with “MSP issuer;”
- “MSP” will be replaced with “MSP option” when referring to the plan that makes up the specific package of benefits and associated cost-sharing; and
- “MSPP contract” will be replaced with “MSP Program contract.”

IV. Regulatory Impact Analysis

OPM has examined the impact of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993) and Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects (\$100 million or more in

any 1 year adjusted for inflation). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule that may:

- (1) Have an annual effect on the economy of \$100 million or more in any one year or adversely affect in a material way a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal government or communities;
- (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- (3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or
- (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in Executive Order 12866.

OPM will continue to generally operate the MSP Program as it previously had in plan year 2014. The regulatory changes in this proposed rule are for purposes of policy clarification and any proposed changes will have minimal impact on the administration of the Program. Administrative costs of the rule are generated both within OPM and by issuers offering MSP options. The costs that MSP issuers may incur are the same as those of QHPs and, as stated in 45 CFR Part 156, will include: accreditation, network adequacy standards, and quality improvement strategy reporting. The costs associated with MSP certification offset the costs that issuers would face were they to be certified by the State, or HHS on behalf of the State, to offer QHPs through the Exchange. For the 2014 plan year, there are approximately 371,000 enrolled in MSP options and with an estimated av-

erage monthly premium of \$350, premiums collected by MSP issuers for consumers enrolled in MSP options is approximately \$1.4 billion this year. While the overall regulation and Program have a significant economic impact, this proposed rule provides for no substantial changes to the Program and will not be economically significant.

The economic impact of this rule is not expected exceed the \$100 million threshold; we therefore do not assess costs and benefits as required by the Executive Order.

V. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35; see 5 CFR part 1320) requires that the U.S. Office of Management and Budget (OMB) approve all collections of information by a Federal agency from the public before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number. OPM is not proposing any additional collections from MSP issuers or applicants seeking to become MSP issuers in this proposed rule. OPM continues to expect fewer than ten responsible entities to respond to all of the collections noted above. For that reason alone, the existing collections are exempt from the Paperwork Reduction Act under 44 U.S.C. 3502(3)(A)(i).

VI. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)²⁹ requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule would not have a significant

²⁹ 5 U.S.C. 601 *et seq.*

economic impact on a substantial number of small entities. The RFA generally defines a “small entity” as -- (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a not-for-profit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity.”

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a proposed rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, small non-profit organizations, and small government jurisdictions. Small businesses are those with sizes below thresholds established by the SBA. With respect to health insurers, the SBA size standard is \$7.0 million in annual receipts.³⁰

OPM does not think that small businesses with annual receipts less than \$7.0 million would likely have sufficient economies of scale to become MSP issuers or be part of a group of MSP issuers. Similarly, while the Director must enter into an MSP Program contract with at least one non-profit entity, OPM does not think that small non-profit organizations would likely have sufficient economies of scale to become MSP issuers or be part of a group of MSP issuers.

OPM does not think that this proposed rule would have a significant economic impact on a substantial number of small businesses with annual receipts less than \$7.0 million, because there are only a few health insurance issuers that could be considered small businesses. Moreover, while the Director must enter into an MSP contract with at

³⁰ According to the SBA size standards, entities with average annual receipts of \$7 million or less would be considered small entities for North American Industry Classification System (NAICS) Code 524114 (Direct Health and Medical Insurance Carriers) (for more information, see “Table of Size Standards Matched To North American Industry Classification System Codes,” effective March 26, 2012, U.S. Small Business Administration, available at <http://www.sba.gov>).

least one non-profit entity, OPM does not think that this proposed rule would have a significant economic impact on a substantial number of small non-profit organizations, because few health insurance issuers are small non-profit organizations.

OPM incorporates by reference previous analysis by HHS, which provides some insight into the number of health insurance issuers that could be small entities. Particularly, as discussed by HHS in the Medical Loss Ratio interim final rule (75 FR 74918), few, if any, issuers are small enough to fall below the size thresholds for small business established by the SBA. In that rule, HHS used a data set created from 2009 NAIC Health and Life Blank annual financial statement data to develop an updated estimate of the number of small entities that offer comprehensive major medical coverage in the individual and group markets. For purposes of that analysis, HHS used total Accident and Health earned premiums as a proxy for annual receipts. HHS estimated that there are 28 small entities with less than \$7 million in accident and health earned premiums offering individual or group comprehensive major medical coverage. OPM concurs with this HHS analysis, and, thus, does not think that this proposed rule would have a significant economic impact on a substantial number of small entities.

Based on the foregoing, OPM is not preparing an analysis for the RFA because OPM has determined, and the Director certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities.

VII. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA)³¹ requires that agencies assess anticipated costs and benefits and take certain other actions before

³¹ Pub. L. 104-4.

issuing a proposed rule (and subsequent final rule) that includes any Federal mandate that may result in expenditures in any one year by a State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately \$141 million. UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of costs, mainly those “Federal mandate” costs resulting from: (1) imposing enforceable duties on State, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs.

This proposed rule does not place any Federal mandates on State, local, or Tribal governments, or on the private sector. This proposed rule would modify the MSP Program, a voluntary federal program that provides health insurance issuers the opportunity to contact with OPM to offer MSP options on the Exchanges. Section 3 of UMRA excludes from the definition of “Federal mandate” duties that arise from participation in a voluntary Federal program. Accordingly, no analysis under UMRA is required.

VIII. Federalism

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have “substantial direct effects” on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies

promulgating regulations that have these federalism implications must consult with State and local officials, and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

This proposed regulation has federalism implications, because it has direct effects on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among various levels of government. In particular, under § 800.114, OPM may deem a State law to be inconsistent with section 1334 of the Affordable Care Act, and, thus, inapplicable to an MSP option or MSP issuer. However, in OPM's view, the federalism implications of this proposed regulation are substantially mitigated because, OPM expects that the vast majority of States have laws that are consistent with section 1334 of the Affordable Care Act. Furthermore, § 800.116 sets forth a process for dispute resolution if a State seeks to challenge OPM's determination that a State law is inapplicable to an MSP option or MSP issuer.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the States, OPM has engaged in efforts to consult with and work cooperatively with affected State and local officials, including attending meetings of the NAIC and consulting with State insurance officials on an individual basis. It is expected OPM will continue act in a similar fashion in enforcing the Affordable Care Act requirements. Throughout the process of administering the MSP Program and developing this proposed regulation, OPM has attempted to balance the States' interests in regulating health insur-

ance issuers, and the statutory requirement to provide two MSP options in all Exchanges in the every States and the District of Columbia. By doing so, it is OPM's view that it has complied with the requirements of Executive Order 13132.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signature affixed to this proposed regulation, OPM certifies that it has complied with the requirements of Executive Order 13132 for the attached regulation in a meaningful and timely manner.

List of Subjects in 45 CFR Part 800

Administrative practice and procedure, Health facilities, Health insurance, Health professions, Reporting and recordkeeping requirements.

Office of Personnel Management.

Katherine Archuleta,

Director.

Accordingly, the U.S. Office of Personnel Management is proposing to revise part 800 to title 45, Code of Federal Regulations, as follows:

PART 800 – MULTI-STATE PLAN PROGRAM

Subpart A – General Provisions and Definitions

Sec.

800.10 Basis and scope.

800.20 Definitions.

Subpart B – Multi-State Plan Program Issuer Requirements

800.101 General requirements.

800.102 Compliance with Federal law.

800.103 Authority to contract with issuers.

800.104 Phased expansion, etc.

800.105 Benefits.

800.106 Cost-sharing limits, advance payments of premium tax credits, and cost-sharing reductions.

800.107 Levels of coverage.

800.108 Assessments and user fees.

800.109 Network adequacy.

800.110 Service area.

800.111 Accreditation requirement.

800.112 Reporting requirements.

800.113 Benefit plan material or information.

800.114 Compliance with applicable State law.

800.115 Level playing field.

800.116 Process for dispute resolution.

Subpart C – Premiums, Rating Factors, Medical Loss Ratios, and Risk Adjustment

800.201 General requirements.

800.202 Rating factors.

800.203 Medical loss ratio.

800.204 Reinsurance, risk corridors, and risk adjustment.

Subpart D – Application and Contracting Procedures

800.301 Application process.

800.302 Review of applications.

800.303 MSP Program contracting.

800.304 Term of the contract.

800.305 Contract renewal process.

800.306 Nonrenewal.

Subpart E – Compliance

800.401 Contract performance.

800.402 Contract quality assurance.

800.403 Fraud and abuse.

800.404 Compliance actions.

800.405 Reconsideration of compliance actions.

Subpart F – Appeals by Enrollees of Denials of Claims for Payment or Service

800.501 General requirements.

800.502 MSP issuer internal claims and appeals.

800.503 External review.

800.504 Judicial review.

Subpart G – Miscellaneous

800.601 Reservation of authority.

800.602 Consumer choice with respect to certain services.

800.603 Disclosure of information.

Authority: Sec. 1334 of Pub. L. 111-148, 124 Stat. 119; Pub. L. 111-152, 124 Stat. 1029 (42 U.S.C. 18054).

Subpart A – General Provisions and Definitions

§ 800.10 Basis and scope.

(a) Basis. This part is based on the following sections of title I of the Affordable Care Act:

1001. Amendments to the Public Health Service Act.

1302. Essential Health Benefits Requirements.

1311. Affordable Choices of Health Benefit Plans.

1324. Level Playing Field.

1334. Multi-State Plans.

1341. Transitional Reinsurance Program for Individual Market in Each State.

1342. Establishment of Risk Corridors for Plans in Individual and Small

Group Markets.

1343. Risk Adjustment.

(b) Scope. This part establishes standards for health insurance issuers to contract with the United States Office of Personnel Management (OPM) to offer Multi-State Plan (MSP) options to provide health insurance coverage on Exchanges for each State. It also establishes standards for appeal of a decision by OPM affecting the issuer's participation in the MSP Program and standards for an enrollee in an MSP option to appeal denials of payment or services by an MSP issuer.

§ 800.20 Definitions.

For purposes of this part:

Actuarial value (AV) has the meaning given that term in 45 CFR 156.20.

Affordable Care Act means the Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152).

Applicant means an issuer or group of issuers that has submitted an application to OPM to be considered for participation in the Multi-State Plan Program.

Benefit plan material or information means explanations or descriptions, whether printed or electronic, that describe a health insurance issuer's products. The term does not include a policy or contract for health insurance coverage.

Cost sharing has the meaning given that term in 45 CFR 155.20.

Director means the Director of the United States Office of Personnel Management.

EHB-benchmark plan has the meaning given that term in 45 CFR 156.20.

Exchange means a governmental agency or non-profit entity that meets the applicable requirements of 45 CFR part 155 and makes qualified health plans (QHPs) and MSP options available to qualified individuals and qualified employers. Unless otherwise identified, this term refers to State Exchanges, regional Exchanges, subsidiary Exchanges, and a Federally-facilitated Exchange.

Federal Employees Health Benefits Program or FEHB Program means the health benefits program administered by the United States Office of Personnel Management pursuant to chapter 89 of title 5, United States Code.

Group of issuers means:

(1) A group of health insurance issuers that are affiliated either by common ownership and control or by common use of a nationally licensed service mark (as defined in this section); or

(2) An affiliation of health insurance issuers and an entity that is not an issuer but that owns a nationally licensed service mark (as defined in this section).

Health insurance coverage means benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or health maintenance organization contract offered by a health insurance issuer. Health insurance coverage includes group health insurance coverage, individual health insurance coverage, and short-term, limited duration insurance.

Health insurance issuer or issuer means an insurance company, insurance service, or insurance organization (including a health maintenance organization) that is required

to be licensed to engage in the business of insurance in a State and that is subject to State law that regulates insurance (within the meaning of section 514(b)(2) of the Employee Retirement Income Security Act (ERISA)). This term does not include a group health plan as defined in 45 CFR 146.145(a).

HHS means the United States Department of Health and Human Services.

Level of coverage means one of four standardized actuarial values of plan coverage as defined by section 1302(d)(1) of the Affordable Care Act.

Licensure means the authorization obtained from the appropriate State official or regulatory authority to offer health insurance coverage in the State.

Multi-State Plan Program issuer or MSP issuer means a health insurance issuer or group of issuers (as defined in this section) that has a contract with OPM to offer health plans pursuant to section 1334 of the Affordable Care Act and meets the requirements of this part.

Multi-State Plan option or MSP option means a discrete pairing of a package of benefits with particular cost sharing (which does not include premium rates or premium rate quotes) that is offered pursuant to a contract with OPM pursuant to section 1334 of the Affordable Care Act and meets the requirements of 45 CFR part 800.

Multi-State Plan Program or MSP Program means the program administered by OPM pursuant to section 1334 of the Affordable Care Act.

Nationally licensed service mark means a word, name, symbol, or device, or any combination thereof, that an issuer or group of issuers uses consistently nationwide to identify itself.

Non-profit entity means:

(1) An organization that is incorporated under State law as a non-profit entity and licensed under State law as a health insurance issuer; or

(2) A group of health insurance issuers licensed under State law, a substantial portion of which are incorporated under State law as non-profit entities.

OPM means the United States Office of Personnel Management.

Percentage of total allowed cost of benefits has the meaning given that term in 45 CFR 156.20.

Plan year means a consecutive 12-month period during which a health plan provides coverage for health benefits. A plan year may be a calendar year or otherwise.

Prompt payment means a requirement imposed on a health insurance issuer to pay a provider or enrollee for a claimed benefit or service within a defined time period, including the penalty or consequence imposed on the issuer for failure to meet the requirement.

Qualified Health Plan or QHP means a health plan that has in effect a certification that it meets the standards described in subpart C of 45 CFR part 156 issued or recognized by each Exchange through which such plan is offered pursuant to the process described in subpart K of 45 CFR part 155.

Rating means the process, including rating factors, numbers, formulas, methodologies, and actuarial assumptions, used to set premiums for a health plan.

Secretary means the Secretary of the Department of Health and Human Services.

SHOP means a Small Business Health Options Program operated by an Exchange through which a qualified employer can provide its employees and their dependents with access to one or more qualified health plans (QHPs).

Silver plan variation has the meaning given that term in 45 CFR 156.400.

Small employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least one but not more than 100 employees on business days during the preceding calendar year and who employs at least one employee on the first day of the plan year. In the case of plan years beginning before January 1, 2016, a State may elect to define small employer by substituting “50 employees” for “100 employees.”

Standard plan has the meaning given that term in 45 CFR 156.400.

State Insurance Commissioner means the commissioner or other chief insurance regulatory official of a State.

State means each of the 50 States or the District of Columbia.

State-level issuer means a health insurance issuer designated by the Multi-State Plan (MSP) issuer to offer an MSP option or MSP options. The State-level issuer may offer health insurance coverage through an MSP option in all or part of one or more States.

Subpart B – Multi-State Plan Program Issuer Requirements

§ 800.101 General requirements.

An MSP issuer must:

(a) Licensed. Be licensed as a health insurance issuer in each State where it offers health insurance coverage;

(b) Contract with OPM. Have a contract with OPM pursuant to this part;

(c) Required levels of coverage. Offer levels of coverage as required by §

800.107;

(d) Eligibility and enrollment. MSP options and MSP issuers must meet the same requirements for eligibility, enrollment, and termination of coverage as those that apply to QHPs and QHP issuers pursuant to 45 CFR part 155, subparts D, E, and H, and 45 CFR 156.250, 156.260, 156.265, 156.270, and 156.285;

(e) Applicable to each MSP issuer. Ensure that each of its MSP options meets the requirements of this part;

(f) Compliance. Comply with all standards set forth in this part;

(g) OPM direction and other legal requirements. Timely comply with OPM instructions and directions and with other applicable law; and

(h) Other requirements. Meet such other requirements as determined appropriate by OPM, in consultation with HHS, pursuant to section 1334(b)(4) of the Affordable Care Act.

(i) Non-discrimination. MSP options and MSP issuers must comply with applicable Federal and State non-discrimination laws, including the standards set forth in 45 CFR 156.125 and 156.200(e).

§ 800.102 Compliance with Federal law.

(a) Public Health Service Act. As a condition of participation in the MSP Program, an MSP issuer must comply with applicable provisions of part A of title XXVII of the PHS Act. Compliance shall be determined by the Director.

(b) Affordable Care Act. As a condition of participation in the MSP Program, an MSP issuer must comply with applicable provisions of title I of the Affordable Care Act. Compliance shall be determined by the Director.

§ 800.103 Authority to contract with issuers.

(a) General. OPM may enter into contracts with health insurance issuers to offer at least two MSP options on Exchanges and SHOPs in each State, without regard to any statutes that would otherwise require competitive bidding.

(b) Non-profit entity. In entering into contracts with health insurance issuers to offer MSP options, OPM will enter into a contract with at least one non-profit entity as defined in § 800.20.

(c) Group of issuers. Any contract to offer MSP options may be with a group of issuers as defined in § 800.20.

(d) Individual and group coverage. The contracts will provide for individual health insurance coverage and for group health insurance coverage for small employers.

§ 800.104 Phased expansion, etc.

(a) Phase-in. OPM may enter into a contract with a health insurance issuer to offer MSP options if the health insurance issuer agrees that:

(1) With respect to the first year for which the health insurance issuer offers MSP options, the health insurance issuer will offer MSP options in at least 60 percent of the States;

(2) With respect to the second such year, the health insurance issuer will offer the MSP options in at least 70 percent of the States;

(3) With respect to the third such year, the health insurance issuer will of-

fer the MSP options in at least 85 percent of the States; and

(4) With respect to each subsequent year, the health insurance issuer will offer the MSP options in all States.

(b) Partial coverage within a State. (1) OPM may enter into a contract with an MSP issuer even if the MSP issuer's MSP options for a State cover fewer than all the service areas specified for that State pursuant to § 800.110.

(2) If an issuer offers both an MSP option and QHP on the same Exchange, an MSP issuer must offer MSP coverage in a service area or areas that is equal to the greater of:

(i) The QHP service area defined by the issuer or,

(ii) The service area specified for that State pursuant to § 800.110 covered by the issuer's QHP.

(c) Participation in SHOPS. (1) An MSP issuer's participation in the Federally-facilitated SHOP must be consistent with the requirements for QHP issuers specified in 45 CFR 156.200(g).

(2) An MSP issuer must comply with State standards governing participation in State-based SHOPS, consistent with § 800.114. For these State-based SHOP standards, OPM retains discretion to allow an MSP issuer to phase-in SHOP participation in States pursuant to section 1334(e) of the Affordable Care Act.

(d) Licensed where offered. OPM may enter into a contract with an MSP

issuer who is not licensed in every State, provided that the issuer is licensed in every State where it offers MSP coverage through any Exchanges in that State and demonstrates to OPM that it is making a good faith effort to become licensed in every State consistent with the timeframe in paragraph (a) of this section.

§ 800.105 Benefits.

(a) Package of benefits. (1) An MSP issuer must offer a package of benefits that includes the essential health benefits (EHB) described in section 1302 of the Affordable Care Act for each MSP option within a State.

(2) The package of benefits referred to in paragraph (a)(1) of this section must comply with section 1302 of the Affordable Care Act, as well as any applicable standards set by OPM and any applicable standards set by HHS.

(b) Package of benefits options. (1) An MSP issuer must offer at least one uniform package of benefits in each State that is substantially equal to:

(i) The EHB-benchmark plan in each State in which it operates; or

(ii) Any EHB-benchmark plan selected by OPM under paragraph (c) of this section.

(2) An issuer applying to participate in the MSP Program may select either or both of the package of benefits options described in paragraph (b)(1) of this section in its application. In each State, the issuer may choose one EHB-benchmark for each product it offers.

(3) An MSP issuer must comply with any State standards relating to substitution of benchmark benefits or standard benefit designs.

(c) OPM selection of benchmark plans. (1) The OPM-selected EHB-benchmark plans are the three largest Federal Employees Health Benefits (FEHB) Program plan options, as identified by HHS pursuant to section 1302(b) of the Affordable Care Act, and as supplemented pursuant to paragraphs (c)(2) through (c)(4) of this section.

(2) Any EHB-benchmark plan selected by OPM under paragraph (c)(1) of this section lacking coverage of pediatric oral services or pediatric vision services must be supplemented by the addition of the entire category of benefits from the largest Federal Employee Dental and Vision Insurance Program (FEDVIP) dental or vision plan options, respectively, pursuant to 45 CFR 156.110(b) and section 1302(b) of the Affordable Care Act.

(3) In all States where an MSP issuer uses the OPM-selected EHB-benchmark plan, the MSP issuer may manage formularies around the needs of anticipated or actual users, subject to approval by OPM.

(4) An MSP issuer must follow State definitions where the State specifically defines the habilitative services category pursuant to 45 CFR 156.110(f) or any Federal definitions where HHS specifically defines habilitative services. In the case of any State that does not define this category and absent a clearly applicable Federal definition, if any OPM-selected EHB-benchmark plan lacks coverage of habilitative services and devices, OPM may determine what habilitative services are to be included in that EHB-benchmark plan.

(5) Any EHB-benchmark plan selected by OPM under paragraph (c)(1) of this section must include, for each State, any State-required benefits enacted before December

31, 2011, that are included in the State's EHB-benchmark plan as described in paragraph (b)(1)(i) of this section, or specific to the market in which the plan is offered.

(d) OPM approval. An MSP issuer's package of benefits, including its formulary, must be submitted for approval by OPM, which will review a package of benefits proposed by an MSP issuer and determine if it is substantially equal to an EHB-benchmark plan described in paragraph (b)(1) of this section, pursuant to standards set forth by OPM and any applicable standards set forth by HHS, including 45 CFR 156.115, 156.122, and 156.125.

(e) State payments for additional State-required benefits. If a State requires that benefits in addition to the benchmark package be offered to MSP enrollees in that State, then pursuant to section 1334(c)(2) of the Affordable Care Act, the State must defray the cost of such additional benefits by making payments either to the enrollee or to the MSP issuer on behalf of the enrollee.

§ 800.106 Cost-sharing limits, advance payments of premium tax credits, and cost-sharing reductions.

(a) Cost-sharing limits. For each MSP option it offers, an MSP issuer must ensure that the cost-sharing provisions of the MSP option complies with section 1302(c) of the Affordable Care Act, as well as any applicable standards set by OPM or HHS.

(b) Advance payments of premium tax credits and cost-sharing reductions. For each MSP option it offers, an MSP issuer must ensure that an eligible individual receives the benefit of advance payments of premium tax credits under section 36B of the Internal Revenue Code and the cost-sharing reductions under section 1402 of the Affordable Care

Act. An MSP issuer must also comply with any applicable standards set by OPM or HHS.

§ 800.107 Levels of coverage.

(a) Silver and gold levels of coverage required. An MSP issuer must offer at least one MSP option at the silver level of coverage and at least one MSP option at the gold level of coverage on each Exchange in which the issuer is certified to offer an MSP option pursuant to a contract with OPM.

(b) Bronze or platinum metal levels of coverage permitted. Pursuant to a contract with OPM, an MSP issuer may offer one or more MSP options at the bronze level of coverage or the platinum level of coverage, or both, on any Exchange or SHOP in any State.

(c) Child-only plans. For each level of coverage, the MSP issuer must offer a child-only MSP options at the same level of coverage as any health insurance coverage offered to individuals who, as of the beginning of the plan year, have not attained the age of 21.

(d) Plan variations for the reduction or elimination of cost-sharing. An MSP issuer must comply with section 1402 of the Affordable Care Act, as well as any applicable standards set by OPM or HHS.

(e) OPM approval. An MSP issuer must submit the levels of coverage plans and plan variations to OPM for review and approval by OPM.

§ 800.108 Assessments and user fees.

(a) Discretion to charge assessment and user fees. Beginning in plan year

2015, OPM may require an MSP issuer to pay an assessment or user fee as a condition of participating in the MSP Program.

(b) Determination of amount. The amount of the assessment or user fee charged by OPM for a plan year is the amount determined necessary by OPM to meet the costs of OPM's functions under the Affordable Care Act for a plan year, including but not limited to such functions as entering into contracts with, certifying, recertifying, decertifying, and overseeing MSP options and MSP issuers for that plan year. The amount of the assessment or user fee charged by OPM will be offset against the assessment or user fee amount required by any State-based Exchange or Federally-facilitated Exchange such that the total of all assessments and user fees paid by the MSP issuer for the year for the MSP option shall be no greater than nor less than the amount of the assessment or user fee paid by QHP issuers in that State-based Exchange or Federally-facilitated Exchange for that year.

(c) Process for collecting MSP assessment or user fees. OPM may require an MSP issuer to make payment of the MSP Program assessment or user fee amount directly to OPM, or may establish other mechanisms for the collection process.

§ 800.109 Network adequacy.

(a) General requirement. An MSP issuer must ensure that the provider network of each of its MSP options, as available to all enrollees, meets the following standards:

(1) Maintains a network that is sufficient in number and types of providers to assure that all services will be accessible without unreasonable delay;

(2) Is consistent with the network adequacy provisions of section 2702(c) of the Public Health Service Act; and

(3) Includes essential community providers in compliance with 45 CFR 156.235.

(b) Provider directory. An MSP issuer must make its provider directory for an MSP option available to the Exchange for publication online pursuant to guidance from the Exchange and to potential enrollees in hard copy, upon request. In the provider directory, an MSP issuer must identify providers that are not accepting new patients. An MSP issuer must also comply with any additional standards related to provider directories set by HHS for QHP issuers.

(c) OPM guidance. OPM will issue guidance containing the criteria and standards that it will use to determine the adequacy of a provider network.

§ 800.110 Service area.

An MSP issuer must offer an MSP option within one or more service areas in a State defined by each Exchange pursuant to 45 CFR 155.1055. If an Exchange permits issuers to define their service areas, an MSP issuer must obtain OPM's approval for its proposed service areas. Pursuant to § 800.104, OPM may enter into a contract with an MSP issuer even if the MSP issuer's MSP options for a State cover fewer than all the service areas specified for that State. MSP options will follow the same standards for service areas for QHPs pursuant to 45 CFR 155.1055.

§ 800.111 Accreditation requirement.

(a) General requirement. An MSP issuer must be or become accredited consistently with the requirements for QHP issuers specified in section 1311 of the Affordable Care Act and 45 CFR 156.275(a)(1).

(b) Release of survey. An MSP issuer must authorize the accrediting entity that accredits the MSP issuer to release to OPM and to the Exchange a copy of its most recent accreditation survey, together with any survey-related information that OPM or an Exchange may require, such as corrective action plans and summaries of findings.

(c) Timeframe for accreditation. An MSP issuer that is not accredited as of the date that it enters into a contract with OPM must become accredited within the timeframe established by OPM as authorized by 45 CFR 155.1045.

§ 800.112 Reporting requirements.

(a) OPM specification of reporting requirements. OPM will specify the data and information that must be reported by an MSP issuer, including data permitted or required by the Affordable Care Act and such other data as OPM may determine necessary for the oversight and administration of the MSP Program. OPM will also specify the form, manner, processes, and frequency for the reporting of data and information. The Director may require that MSP issuers submit claims payment and enrollment data to facilitate OPM's oversight and administration of the MSP Program in a manner similar to the FEHB Program.

(b) Quality and quality improvement standards. An MSP issuer must comply with any standards required by OPM for reporting quality and quality improvement activities, including but not limited to implementation of a quality improvement strategy,

disclosure of quality measures to enrollees and prospective enrollees, reporting of pediatric quality measures, and implementation of rating and enrollee satisfaction surveys, which will be similar to standards under section 1311(c)(1)(E), (H), and (I), (c)(3), and (c)(4) of the Affordable Care Act.

§ 800.113 Benefit plan material or information.

(a) Compliance with Federal and State law. An MSP issuer must comply with Federal and State laws relating to benefit plan material or information, including the provisions of this section and guidance issued by OPM specifying its standards, process, and timeline for approval of benefit plan material or information.

(b) General standards for MSP applications and notices. An MSP issuer must provide all applications and notices to enrollees in accordance with the standards described in 45 CFR 155.205(c). OPM may establish additional standards to meet the needs of MSP enrollees.

(c) Accuracy. An MSP issuer is responsible for the accuracy of its benefit plan material or information.

(d) Truthful, not misleading, no material omissions, and plain language. All benefit plan material or information must be:

(1) Truthful, not misleading, and without material omissions; and

(2) Written in plain language, as defined in section 1311(e)(3)(B) of the Affordable Care Act.

(e) Uniform explanation of coverage documents and standardized definitions. An MSP issuer must comply with the provisions of section 2715 of the PHS Act and regulations issued to implement that section.

(f) OPM review and approval of benefit plan material or information. OPM may request an MSP issuer to submit to OPM benefit plan material or information, as defined in § 800.20. OPM reserves the right to review and approve benefit plan material or information to ensure that an MSP issuer complies with Federal and State laws, and the standards prescribed by OPM with respect to benefit plan material or information.

(g) Statement on certification by OPM. An MSP issuer may include a statement in its benefit plan material or information that:

(1) OPM has certified the MSP option as eligible to be offered on the Exchange; and

(2) OPM monitors the MSP option for compliance with all applicable law.

§ 800.114 Compliance with applicable State law.

(a) Compliance with State law. An MSP issuer must, with respect to each of its MSP options, generally comply with State law pursuant to section 1334(b)(2) of the Affordable Care Act. However, the MSP options and MSP issuers are not subject to State laws that:

(1) Are inconsistent with section 1334 of the Affordable Care Act or this part;

(2) Prevent the application of a requirement of part A of title XXVII of the PHS Act; or

(3) Prevent the application of a requirement of title I of the Affordable Care Act.

(b) Determination of inconsistency. After consultation with the State and

HHS, OPM reserves the right to determine, in its judgment, as effectuated through an MSP Program contract, these regulations, or OPM guidance, whether the standards set forth in paragraph (a) of this section are satisfied with respect to particular State laws.

§ 800.115 Level playing field.

An MSP issuer must, with respect to each of its MSP options, meet the following requirements in order to ensure a level playing field, subject to § 800.114:

(a) Guaranteed renewal. Guarantee that an enrollee can renew enrollment in an MSP option in compliance with sections 2703 and 2742 of the PHS Act;

(b) Rating. In proposing premiums for OPM approval, use only the rating factors permitted under section 2701 of the PHS Act and State law;

(c) Preexisting conditions. Not impose any preexisting condition exclusion and comply with section 2704 of the PHS Act;

(d) Non-discrimination. Comply with section 2705 of the PHS Act;

(e) Quality improvement and reporting. Comply with all Federal and State quality improvement and reporting requirements. Quality improvement and reporting means quality improvement as defined in section 1311(h) of the Affordable Care Act and quality improvement plans or strategies required under State law, and quality reporting as defined in section 2717 of the PHS Act and section 1311(g) of the Affordable Care Act. Quality improvement also includes activities such as, but not limited to, implementation of a quality improvement strategy, disclosure of quality measures to enrollees and prospective enrollees, and reporting of pediatric quality measures, which will be similar to standards under section 1311(c)(1)(E), (H), and (I) of the Affordable Care Act;

- (f) Fraud and abuse. Comply with all Federal and State fraud and abuse laws;
- (g) Licensure. Be licensed in every State in which it offers an MSP option;
- (h) Solvency and financial requirements. Comply with the solvency standards set by each State in which it offers an MSP option;
- (i) Market conduct. Comply with the market conduct standards of each State in which it offers an MSP option;
- (j) Prompt payment. Comply with applicable State law in negotiating the terms of payment in contracts with its providers and in making payments to claimants and providers;
- (k) Appeals and grievances. Comply with Federal standards under section 2719 of the PHS Act for appeals and grievances relating to adverse benefit determinations, as described in subpart F of this part;
- (l) Privacy and confidentiality. Comply with all Federal and State privacy and security laws and requirements, including any standards required by OPM in guidance or contract, which will be similar to the standards contained in 45 CFR part 164 and applicable State law; and
- (m) Benefit plan material or information. Comply with Federal and State law, including § 800.113.

§ 800.116 Process for dispute resolution.

- (a) Determinations about applicability of State law under section 1334(b)(2) of the Affordable Care Act. In the event of a dispute about the applicability to

an MSP option or MSP issuer of a State law, the State may request that OPM reconsider a determination that an MSP option or MSP issuer is not subject to such State law.

(b) Required demonstration. A State making a request under paragraph (a) of this section must demonstrate that the State law at issue:

(1) Is not inconsistent with section 1334 of the Affordable Care Act or this part;

(2) Does not prevent the application of a requirement of part A of title XXVII of the PHS Act; and

(3) Does not prevent the application of a requirement of title I of the Affordable Care Act.

(c) Request for review. The request must be in writing and include contact information, including the name, telephone number, email address, and mailing address of the person or persons whom OPM may contact regarding the request for review. The request must be in such form, contain such information, and be submitted in such manner and within such timeframe as OPM may prescribe.

(1) The requester may submit to OPM any relevant information to support its request.

(2) OPM may obtain additional information relevant to the request from any source as it may, in its judgment, deem necessary. OPM will provide the requester with a copy of any additional information it obtains and provide an opportunity for the requester to respond (including by submission of additional information or explanation).

(3) OPM will issue a written decision within 60 calendar days after receiving the written request, or after the due date for a response under paragraph (c)(2) of this

section, whichever is later, unless a different timeframe is agreed upon.

(4) OPM's written decision will constitute final agency action that is subject to review under the Administrative Procedure Act in the appropriate U.S. district court. Such review is limited to the record that was before OPM when OPM made its decision.

Subpart C – Premiums, Rating Factors, Medical Loss Ratios, and Risk Adjustment

§ 800.201 General requirements.

(a) Premium negotiation. OPM will negotiate annually with an MSP issuer, on a State by State basis, the premiums for each MSP option offered by that issuer in that State. Such negotiations may include negotiations about the cost-sharing provisions of an MSP option.

(b) Duration. Premiums will remain in effect for the plan year.

(c) Guidance on rate development. OPM will issue guidance addressing methods for the development of premiums for the MSP Program. That guidance will follow State rating standards generally applicable in a State, to the greatest extent practicable.

(d) Calculation of actuarial value. An MSP issuer must calculate actuarial value in the same manner as QHP issuers under section 1302(d) of the Affordable Care Act, as well as any applicable standards set by OPM or HHS.

(e) OPM rate review process. An MSP issuer must participate in the rate review process established by OPM to negotiate rates for MSP options. The rate review

process established by OPM will be similar to the process established by HHS pursuant to section 2794 of the PHS Act and disclosure and review standards established under 45 CFR part 154.

(f) State effective rate review. With respect to its MSP options, an MSP issuer is subject to a State's rate review process, including a State's Effective Rate Review Program established by HHS pursuant to section 2794 of the PHS Act and 45 CFR part 154. In the event HHS is reviewing rates for a State pursuant to section 2794 of the PHS Act, HHS will defer to OPM's judgment regarding the MSP options' proposed rate increase. If a State withholds approval of an MSP option and OPM determines, in its discretion, that the State's action would prevent OPM from administering the MSP Program, OPM retains authority to make the final decision to approve rates for participation in the MSP Program, notwithstanding the absence of State approval.

(g) Single risk pool. An MSP issuer must consider all enrollees in an MSP option to be in the same risk pool as all enrollees in all other health plans in the individual market or the small group market, respectively, in compliance with section 1312(c) of the Affordable Care Act, 45 CFR 156.80, and any applicable Federal or State laws and regulations implementing that section.

§ 800.202 Rating factors.

(a) Permissible rating factors. In proposing premiums for each MSP option, an MSP issuer must use only the rating factors permitted under section 2701 of the PHS Act.

(b) Application of variations based on age or tobacco use. Rating variations permitted under section 2701 of the PHS Act must be applied by an MSP issuer based on the portion of the premium attributable to each family member covered under the coverage in accordance with any applicable Federal or State laws and regulations implementing section 2701(a) of the PHS Act.

(c) Age rating. For age rating, an MSP issuer must use the ratio established by the State in which the MSP option is offered, if it is less than 3:1.

(1) Age bands. An MSP issuer must use the uniform age bands established under HHS regulations implementing section 2701(a) of the PHS Act.

(2) Age curves. An MSP issuer must use the age curves established under HHS regulations implementing section 2701(a) of the PHS Act, or age curves established by a State pursuant to HHS regulations.

(d) Rating areas. An MSP issuer must use the rating areas appropriate to the State in which the MSP option is offered and established under HHS regulations implementing section 2701(a) of the PHS Act.

(e) Tobacco rating. An MSP issuer must apply tobacco use as a rating factor in accordance with any applicable Federal or State laws and regulations implementing section 2701(a) of the PHS Act.

(f) Wellness programs. An MSP issuer must comply with any applicable Federal or State laws and regulations implementing section 2705 of the PHS Act.

§ 800.203 Medical loss ratio.

(a) Required medical loss ratio. An MSP issuer must attain:

(1) The medical loss ratio (MLR) required under section 2718 of the PHS

Act and regulations promulgated by HHS; and

(2) Any MSP-specific MLR that OPM may set in the best interests of MSP enrollees or that is necessary to be consistent with a State's requirements with respect to MLR.

(b) Consequences of not attaining required medical loss ratio. If an MSP issuer fails to attain an MLR set forth in paragraph (a) of this section, OPM may take any appropriate action, including but not limited to intermediate sanctions, such as suspension of marketing, decertifying an MSP option in one or more States, or terminating an MSP issuer's contract pursuant to § 800.404.

§ 800.204 Reinsurance, risk corridors, and risk adjustment.

(a) Transitional reinsurance program. An MSP issuer must comply with section 1341 of the Affordable Care Act, 45 CFR part 153, and any applicable Federal or State regulations under section 1341 that set forth requirements to implement the transitional reinsurance program for the individual market.

(b) Temporary risk corridors program. An MSP issuer must comply with section 1342 of the Affordable Care Act, 45 CFR part 153, and any applicable Federal regulations under section 1342 that set forth requirements to implement the risk corridor program.

(c) Risk adjustment program. An MSP issuer must comply with section 1343 of the Affordable Care Act, 45 CFR part 153, and any applicable Federal or State regulations under section 1343 that set forth requirements to implement the risk adjustment program.

Subpart D – Application and Contracting Procedures

§ 800.301 Application process.

(a) Acceptance of applications. Without regard to 41 U.S.C. 6101(b)–(d), or any other statute requiring competitive bidding, OPM may consider annual applications from health insurance issuers, including groups of health insurance issuers as defined in § 800.20, to participate in the MSP Program. If OPM determines that it is not beneficial for the MSP Program to consider new issuer applications for an upcoming year, OPM will issue a notice to that effect. Each existing MSP issuer may complete a renewal application annually.

(b) Form and manner of applications. An applicant must submit to OPM, in the form and manner and in accordance with the timeline specified by OPM, the information requested by OPM for determining whether an applicant meets the requirements of this part.

§ 800.302 Review of applications.

(a) Determinations. OPM will determine if an applicant meets the requirements of this part. If OPM determines that an applicant meets the requirements of this part, OPM may accept the applicant to enter into contract negotiations with OPM to participate in the MSP Program.

(b) Requests for additional information. OPM may request additional information from an applicant before making a decision about whether to enter into contract negotiations with that applicant to participate in the MSP Program.

(c) Declination of application. If, after reviewing an application to participate in the MSP Program, OPM declines to enter into contract negotiations with the applicant, OPM will inform the applicant in writing of the reasons for that decision.

(d) Discretion. The decision whether to enter into contract negotiations with a health insurance issuer who has applied to participate in the MSP Program is committed to OPM's discretion.

(e) Impact on future applications. OPM's declination of an application to participate in the MSP Program will not preclude the applicant from submitting an application for a subsequent year to participate in the MSP Program.

§ 800.303 MSP Program contracting.

(a) Participation in MSP Program. To become an MSP issuer, the applicant and the Director or the Director's designee must sign a contract that meets the requirements of this part.

(b) Standard contract. OPM will establish a standard contract for the MSP Program.

(c) Premiums. OPM and the applicant will negotiate the premiums for an MSP option for each plan year in accordance with the provisions of subpart C of this part.

(d) Benefit packages. OPM must approve the applicant's benefit packages for an MSP option.

(e) Additional terms and conditions. OPM may elect to negotiate with an applicant such additional terms, conditions, and requirements that:

- (1) Are in the interests of MSP enrollees; or
- (2) OPM determines to be appropriate.

(f) Certification to offer health insurance coverage.

(1) For each plan year, an MSP Program contract will specify MSP options that OPM has certified, the specific package of benefits authorized to be offered on each Exchange, and the premiums to be charged for each package of benefits on each Exchange.

(2) An MSP issuer may not offer an MSP option on an Exchange unless its MSP Program contract with OPM includes a certification authorizing the MSP issuer to offer the MSP option on that Exchange in accordance with paragraph (f)(1) of this section.

§ 800.304 Term of the contract.

(a) Term of a contract. The term of the contract will be specified in the MSP Program contract and must be for a period of at least the 12 consecutive months defined as the plan year.

(b) Plan year. The plan year is a consecutive 12-month period during which an MSP option provides coverage for health benefits. A plan year may be a calendar year or otherwise.

§ 800.305 Contract renewal process.

(a) Renewal. To continue participating in the MSP Program, an MSP issuer must provide to OPM, in the form and manner and in accordance with the timeline prescribed by OPM, the information requested by OPM for determining whether the MSP issuer continues to meet the requirements of this part.

(b) OPM decision. Subject to paragraph (c) of this section, OPM will re-

new the MSP Program contract of an MSP issuer who timely submits the information described in paragraph (a).

(c) OPM discretion not to renew. OPM may decline to renew the contract of an MSP issuer if:

(1) OPM and the MSP issuer fail to agree on premiums and benefits for an MSP option for the subsequent plan year;

(2) The MSP issuer has engaged in conduct described in § 800.404(a); or

(3) OPM determines that the MSP issuer will be unable to comply with a material provision of section 1334 of the Affordable Care Act or this part.

(d) Failure to agree on premiums and benefits. Except as otherwise provided in this part, if an MSP issuer has complied with paragraph (a) of this section and OPM and the MSP issuer fail to agree on premiums and benefits for an MSP option on one or more Exchanges for the subsequent plan year by the date required by OPM, either party may provide notice of nonrenewal pursuant to § 800.306, or OPM may in its discretion withdraw the certification of that MSP option on the Exchange or Exchanges for that plan year. In addition, if OPM and the MSP issuer fail to agree on benefits and premiums for an MSP option on one or more Exchanges by the date set by OPM and in the event of no action (no notice of nonrenewal or renewal) by either party, the MSP Program contract will be renewed and the existing premiums and benefits for that MSP option on that Exchange or Exchanges will remain in effect for the subsequent plan year.

§ 800.306 Nonrenewal.

(a) Nonrenewal. Nonrenewal may pertain to the MSP issuer or the State-level issuer. The circumstances under which nonrenewal may occur are:

(1) Nonrenewal of contract. As used in this subpart and subpart E of this part, “nonrenewal of contract” means a decision by either OPM or an MSP issuer not to renew an MSP Program contract.

(2) Nonrenewal of participation. As used in this subpart and subpart E of this part, “nonrenewal of participation” means a decision by OPM, an MSP issuer, or a State-level issuer not to renew a State-level issuer’s participation in a MSP Program contract.

(b) Notice required. Either OPM or an MSP issuer may decline to renew an MSP Program contract by providing a written notice of nonrenewal to the other party.

(c) MSP issuer responsibilities. The MSP issuer’s written notice of nonrenewal must be made in accordance with its MSP Program contract with OPM. The MSP issuer also must comply with any requirements regarding the termination of a plan that are applicable to a QHP offered on an Exchange on which the MSP option was offered, including a requirement to provide advance written notice of termination to enrollees. MSP issuers shall provide written notice to enrollees in accordance with § 800.404(d).

Subpart E – Compliance

§ 800.401 Contract performance.

(a) General. An MSP issuer must perform an MSP Program contract with OPM in accordance with the requirements of section 1334 of the Affordable Care Act

and this part. The MSP issuer must continue to meet such requirements while under an MSP Program contract with OPM.

(b) Specific requirements for issuers. In addition to the requirements described in paragraph (a) of this section, each MSP issuer must:

(1) Have, in the judgment of OPM, the financial resources to carry out its obligations under the MSP Program;

(2) Keep such reasonable financial and statistical records, and furnish to OPM such reasonable financial and statistical reports with respect to the MSP option or the MSP issuer, as may be requested by OPM;

(3) Permit representatives of OPM (including the OPM Office of Inspector General), the U.S. Government Accountability Office, and any other applicable Federal Government auditing entities to audit and examine its records and accounts that pertain, directly or indirectly, to the MSP option at such reasonable times and places as may be designated by OPM or the U.S. Government Accountability Office;

(4) Timely submit to OPM a properly completed and signed novation or change-of-name agreement in accordance with subpart 42.12 of 48 CFR part 42;

(5) Perform the MSP Program contract in accordance with prudent business practices, as described in paragraph (c) of this section; and

(6) Not perform the MSP Program contract in accordance with poor business practices, as described in paragraph (d) of this section.

(c) Prudent business practices. OPM will consider an MSP issuer's specific circumstances and facts in using its discretion to determine compliance with paragraph

(b)(5) of this section. For purposes of paragraph (b)(5) of this section, prudent business practices include, but are not limited to, the following:

- (1) Timely compliance with OPM instructions and directives;
- (2) Legal and ethical business and health care practices;
- (3) Compliance with the terms of the MSP Program contract, regulations, and statutes;
- (4) Timely and accurate adjudication of claims or rendering of medical services;
- (5) Operating a system for accounting for costs incurred under the MSP Program contract, which includes segregating and pricing MSP option medical utilization and allocating indirect and administrative costs in a reasonable and equitable manner;
- (6) Maintaining accurate accounting reports of costs incurred in the administration of the MSP Program contract;
- (7) Applying performance standards for assuring contract quality as outlined at § 800.402; and
- (8) Establishing and maintaining a system of internal controls that provides reasonable assurance that:
 - (i) The provision and payments of benefits and other expenses comply with legal, regulatory, and contractual guidelines;
 - (ii) MSP funds, property, and other assets are safeguarded against waste, loss, unauthorized use, or misappropriation; and
 - (iii) Data is accurately and fairly disclosed in all reports required by OPM.

(d) Poor business practices. OPM will consider an MSP issuer's specific circumstances and facts in using its discretion to determine compliance with paragraph (b)(6) of this section. For purposes of paragraph (b)(6) of this section, poor business practices include, but are not limited to, the following:

(1) Using fraudulent or unethical business or health care practices or otherwise displaying a lack of business integrity or honesty;

(2) Repeatedly or knowingly providing false or misleading information in the rate setting process;

(3) Failing to comply with OPM instructions and directives;

(4) Having an accounting system that is incapable of separately accounting for costs incurred under the contract and/or that lacks the internal controls necessary to fulfill the terms of the contract;

(5) Failing to ensure that the MSP issuer properly pays or denies claims, or, if applicable, provides medical services that are inconsistent with standards of good medical practice; and

(6) Entering into contracts or employment agreements with providers, provider groups, or health care workers that include provisions or financial incentives that directly or indirectly create an inducement to limit or restrict communication about medically necessary services to any individual covered under the MSP Program. Financial incentives are defined as bonuses, withholds, commissions, profit sharing or other similar adjustments to basic compensation (e.g., service fee, capitation, salary) which have the effect of limiting or reducing communication about appropriate medically necessary services.

(e) Performance escrow account. OPM may require MSP issuers to pay an assessment into an escrow account to ensure contract compliance and benefit MSP enrollees.

§ 800.402 Contract quality assurance.

(a) General. This section prescribes general policies and procedures to ensure that services acquired under MSP Program contracts conform to the contract's quality requirements.

(b) Internal controls. OPM may periodically evaluate the contractor's system of internal controls under the quality assurance program required by the contract and will acknowledge in writing if the system is inconsistent with the requirements set forth in the contract. OPM's reviews do not diminish the contractor's obligation to implement and maintain an effective and efficient system to apply the internal controls.

(c) Performance standards. (1) OPM will issue specific performance standards for MSP Program contracts and will inform MSP issuers of the applicable performance standards prior to negotiations for the contract year. OPM may benchmark its standards against standards generally accepted in the insurance industry. OPM may authorize nationally recognized standards to be used to fulfill this requirement.

(2) MSP issuers must comply with the performance standards issued pursuant to this section.

§ 800.403 Fraud and abuse.

(a) Program required. An MSP issuer must conduct a program to assess its

vulnerability to fraud and abuse as well as to address such vulnerabilities.

(b) Fraud detection system. An MSP issuer must operate a system designed to detect and eliminate fraud and abuse by employees and subcontractors of the MSP issuer, by providers furnishing goods or services to MSP enrollees, and by MSP enrollees.

(c) Submission of information. An MSP issuer must provide to OPM such information or assistance as may be necessary for the agency to carry out the duties and responsibilities, including those of the Office of Inspector General as specified in sections 4 and 6 of the Inspector General Act of 1978 (5 U.S.C. App.). An MSP issuer must provide any requested information in the form, manner, and timeline prescribed by OPM.

§ 800.404 Compliance actions.

(a) Causes for OPM compliance actions. The following constitute cause for OPM to impose a compliance action described in paragraph (b) of this section against an MSP issuer:

(1) Failure by the MSP issuer to meet the requirements set forth in § 800.401(a) and (b);

(2) An MSP issuer's sustained failure to perform the MSP Program contract in accordance with prudent business practices, as described in § 800.401(c);

(3) A pattern of poor conduct or evidence of poor business practices such as those described in § 800.401(d); or

(4) Such other violations of law or regulation as OPM may determine, in-

cluding pursuant to its authority under §§ 800.102 and 800.114.

(b) Compliance actions. (1) OPM may impose a compliance action against an MSP issuer at any time during the contract term if it determines that the MSP issuer is not in compliance with applicable law, this part, or the terms of its contract with OPM.

(2) Compliance actions may include, but are not limited to:

(i) Establishment and implementation of a corrective action plan;

(ii) Imposition of intermediate sanctions, such as suspensions of marketing;

(iii) Performance incentives;

(iv) Reduction of service area or areas;

(v) Withdrawal of the certification of the MSP option or options offered on one or more Exchanges;

(vi) Nonrenewal of participation

(vii) Nonrenewal of contract; and

(viii) Withdrawal of approval or termination of the MSP Program contract.

(c) Notice of compliance action. (1) OPM must notify an MSP issuer in writing of a compliance action under this section. Such notice must indicate the specific compliance action undertaken and the reason for the compliance action.

(2) For compliance actions listed in § 800.404(b)(2)(v) through (b)(2)(viii), such notice must include a statement that the MSP issuer is entitled to request a reconsideration of OPM's determination to impose a compliance action pursuant to § 800.405.

(3) Upon imposition of a compliance action listed in paragraphs (b)(2)(iv) through (b)(2)(vii) of this section, OPM must notify the State Insurance Commissioner(s) and Exchange officials in the State or States in which the compliance action is effective.

(d) Notice to enrollees. If the contract is terminated, if OPM withdraws certification of an MSP option, or if a State-level issuer's participation in the MSP Program contract is not renewed, as described in §§ 800.306 and 800.404(b)(2) or any situation in which an MSP option is no longer available to enrollees, the MSP issuer must comply with any State or Exchange requirements regarding discontinuing a particular type of coverage that are applicable to a QHP offered on the Exchange on which the MSP option was offered including a requirement to provide advance written notice before the coverage will be discontinued. If a State or Exchange does not have requirements about advance notice to enrollees, the MSP issuer must inform current MSP enrollees in writing of the discontinuance of the MSP option no later than 90 days prior to discontinuing the MSP option, unless OPM determines that there is good cause for less than 90 days' notice.

(e) Definition. As used in this subpart, "termination" means a decision by OPM to cancel an MSP Program contract prior to the end of its contract term. The term includes OPM's withdrawal of approval of an MSP Program contract.

§ 800.405 Reconsideration of compliance actions.

(a) Right to request reconsideration. An MSP issuer may request that OPM

reconsider a determination to impose one of the following compliance actions:

(1) Withdrawal of the certification of the MSP option or options offered on one or more Exchanges;

(2) Nonrenewal of participation

(3) Nonrenewal of contract; or

(4) Termination of the MSP Program contract.

(b) Request for reconsideration and/or hearing. (1) An MSP issuer with a right to request reconsideration specified in paragraph (a) of this section may request a hearing in which OPM will reconsider its determination to impose a compliance action.

(2) A request under this section must be in writing and contain contact information, including the name, telephone number, email address, and mailing address of the person or persons whom OPM may contact regarding a request for a hearing with respect to the reconsideration. The request must be in such form, contain such information, and be submitted in such manner as OPM may prescribe.

(3) The request must be received by OPM within 15 calendar days after the date of the MSP issuer's receipt of the notice of compliance action. The MSP issuer may request that OPM's reconsideration allow a representative of the MSP issuer to appear personally before OPM.

(4) A request under this section must include a detailed statement of the reasons that the MSP issuer disagrees with OPM's imposition of the compliance action, and may include any additional information that will assist OPM in rendering a final decision under this section.

(5) OPM may obtain additional information relevant to the request from any source as it may, in its judgment, deem necessary. OPM will provide the MSP issuer with a copy of any additional information it obtains and provide an opportunity for the MSP issuer to respond (including by submitting additional information or explanation).

(6) OPM's reconsideration and hearing, if requested, may be conducted by the Director or a representative designated by the Director who did not participate in the initial decision that is the subject of the request for review.

(c) Notice of final decision. OPM will notify the MSP issuer, in writing, of OPM's final decision on the MSP issuer's request for reconsideration and the specific reasons for that final decision. OPM's written decision will constitute final agency action that is subject to review under the Administrative Procedure Act in the appropriate U.S. district court. Such review is limited to the record that was before OPM when it made its decision.

Subpart F – Appeals by Enrollees of Denials of Claims for Payment or Service

§ 800.501 General requirements.

(a) Definitions. For purposes of this subpart:

(1) Adverse benefit determination has the meaning given that term in 45 CFR 147.136(a)(2)(i).

(2) Claim means a request for:

(i) Payment of a health-related bill; or

(ii) Provision of a health-related service or supply.

(b) Applicability. This subpart applies to enrollees and to other individuals or entities who are acting on behalf of an enrollee and who have the enrollee's specific written consent to pursue a remedy of an adverse benefit determination.

§ 800.502 MSP issuer internal claims and appeals.

(a) Processes. MSP issuers must comply with the internal claims and appeals processes applicable to group health plans and health insurance issuers under 45 CFR 147.136(b).

(b) Timeframes and notice of determination. An MSP issuer must provide written notice to an enrollee of its determination on a claim brought under paragraph (a) of this section according to the timeframes and notification rules under 45 CFR 147.136(b) and (e), including the timeframes for urgent claims. If the MSP issuer denies a claim (or a portion of the claim), the enrollee may appeal the adverse benefit determination to the MSP issuer in accordance with 45 CFR 147.136(b).

§ 800.503 External review.

(a) External review by OPM. OPM will conduct external review of adverse benefit determinations using a process similar to OPM review of disputed claims under 5 CFR 890.105(e), subject to the standards and timeframes set forth in 45 CFR 147.136(d).

(b) Notice. Notices to MSP enrollees regarding external review under paragraph (a) of this section must comply with 45 CFR 147.136(e), and are subject to review and approval by OPM.

(c) Issuer obligation. An MSP issuer must pay a claim or provide a health-

related service or supply pursuant to OPM's final decision or the final decision of an independent review organization without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

§ 800.504 Judicial review.

(a) OPM's written decision under the external review process established under § 800.503(a) will constitute final agency action that is subject to review under the Administrative Procedure Act in the appropriate U.S. district court. A decision made by an independent review organization under the process established under § 800.503(a) is not within OPM's discretion and therefore is not final agency action.

(b) Judicial review under paragraph (a) of this section is limited to the record that was before OPM when OPM made its decision.

Subpart G – Miscellaneous

§ 800.601 Reservation of authority.

OPM reserves the right to implement and supplement these regulations with written operational guidelines.

§ 800.602 Consumer choice with respect to certain services.

(a) Assured availability of varied coverage. Consistent with § 800.104,

OPM will ensure that at least one of the MSP issuers on each Exchange in each State offers at least one MSP option that does not provide coverage of services described in section 1303(b)(1)(B)(i) of the Affordable Care Act.

(b) State opt-out. An MSP issuer may not offer abortion coverage in any State where such coverage of abortion services is prohibited by State law.

(c) Notice to enrollees — (1) Notice of exclusion. The MSP issuer must provide notice to consumers prior to enrollment when non-excepted abortion services are not a covered benefit in a State where such coverage of such abortion services is permitted by State law, in the form, manner, and timeline prescribed by OPM.

(2) Notice of coverage. If an MSP issuer chooses to offer an MSP option that covers non-excepted abortion services, in addition to an MSP option that does not provide coverage for these services, the MSP issuer must provide notice to consumers prior to enrollment that non-excepted abortion services are a covered benefit, in a manner consistent with 45 CFR 147.200(a)(3), to meet the requirements of 45 CFR 156.280(f). OPM may provide guidance on the form, manner, and timeline for this notice.

(3) OPM review and approval of notices. OPM may require an MSP issuer to submit to OPM such notices. OPM reserves the right to review and approve these consumer notices to ensure that an MSP issuer complies with Federal and State laws, and the standards prescribed by OPM with respect to § 800.602.

§ 800.603 Disclosure of information

(a) Disclosure to certain entities. OPM may provide information relating to the activities of MSP issuers or State-level issuers to a State Insurance Commissioner or Director of a State-based Exchange.

(b) Conditions of when to disclose. OPM shall only make a disclosure described in this section to the extent that such disclosure is:

(1) Necessary or appropriate to permit OPM's Director, a State Insurance Commissioner, or Director of a State-based Exchange to administer and enforce laws applicable to an MSP issuer or State-level issuer over which it has jurisdiction, or

(2) Otherwise in the best interests of enrollees or potential enrollees in MSP options.

(c) Confidentiality of information. OPM will take appropriate steps to cause the recipient of this information to preserve the information as confidential.

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