

OFFICE OF PERSONNEL MANAGEMENT

45 CFR Part 800

RIN: 3206-AM47

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

AGENCY: U.S. Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The U.S. Office of Personnel Management (OPM) is issuing a final regulation establishing the Multi-State Plan Program (MSPP) pursuant to 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. Through contracts with OPM, health insurance issuers will offer at least two multi-State plans (MSPs) on each of the Affordable Insurance Exchanges (Exchanges). One of the issuers must be non-profit. Under the law, an MSPP issuer may phase in the States in which it offers coverage over 4 years, but it must offer MSPs on Exchanges in all States and the District of Columbia by the fourth year in which the MSPP issuer participates in the MSPP. This rule aims to balance adhering to the statutory goals of MSPP while aligning its standards to those applying to qualified health plans to promote a level playing field across health plans.

DATES: Effective [INSERT 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER], except for § 800.503. OPM will publish a document announcing the effective date of § 800.503 in the Federal Register.

Note: Section 2719 of the Public Health Service Act and its implementing regulations apply to all non-grandfathered group health plans and health insurance issuers, including MSPP issuers, with respect to internal claims and appeals and external review. Because rulemaking implementing section 2719 has not yet been completed, the provisions of this regulation relating to external review (§ 800.503) will take effect on the effective date of those regulations.

FOR FURTHER INFORMATION CONTACT: Julia Elam by telephone at (202) 606-2128, by FAX at (202) 606-0033, 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 Health Insurance Marketplaces, or Exchanges, in each State, where individuals and small businesses can purchase qualified coverage. The Exchanges will provide competitive marketplaces for individuals and small employers to directly compare available private health insurance options on the basis of price, quality, and other factors. The Exchanges will 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 U.S. Office of Personnel Management is issuing this final regulation to implement section 1334 of the Affordable Care Act by establishing the Multi-State Plan Program, as described below.

Abbreviations:

FEHBA	Federal Employees Health Benefits Act (5 U.S.C. 8901 <i>et seq.</i>)
FEHBP	Federal Employees Health Benefits Program
HHS	U.S. Department of Health and Human Services
HMO	Health Maintenance Organization
I/T/Us	Indian Health Service, tribes and tribal organizations, and urban Indian organizations
MSP	Multi-State Plan
MSPP	Multi-State Plan Program
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

Pursuant to its responsibilities under the Affordable Care Act, the U.S. Department of Health and Human Services (HHS) issued regulations outlining standards to certify Exchanges and qualified health plans (QHPs) that will be offered on Exchanges. If a State does not elect to operate an Exchange or is not certified (or conditionally approved) to operate one, HHS will operate the Exchange in that State.

Section 1334 of the Affordable Care Act directs the U.S. Office of Personnel Management (OPM) to establish the Multi-State Plan Program (MSPP) to foster competition among plans competing in the individual and small group health insurance markets on the Exchanges. Specifically, section 1334 directs OPM to contract with private health insurance issuers (one of which must be non-profit) to offer at least two

multi-State plans (MSPs) on each of the Exchanges in each State. The law allows MSPP issuers to phase in coverage, but coverage must be offered on Exchanges in all States and the District of Columbia by the fourth year in which the MSPP issuer participates in the MSPP. The first open enrollment period for plans offered through Exchanges will begin on October 1, 2013, for coverage starting January 1, 2014.

The purpose of this regulation is to outline the process by which OPM will establish and administer the MSPP, as well as to establish standards and requirements for MSPs and MSPP issuers.

Summary of Comments

On December 5, 2012, OPM published proposed regulations (77 FR 72582) establishing the MSPP at part 800 of title 45, Code of Federal Regulations. The comment period for the proposed rule closed on January 4, 2013. OPM received about 350 comments from a wide variety of entities and individuals. A summary of the comments we received follows, along with our responses to the comments and changes we are making to the proposed regulations in light of the comments. In addition, we are making some minor technical and editorial changes to the proposed regulations to correct errors and improve clarity and readability.

Responses to Overarching Comments

Of the approximately 350 comments we received on the proposed rule, about 105 were unique comment letters. Many of the others were form letters, including letters requesting an extension of the comment period.

A broad range of stakeholders commented on the proposed regulation, including 14 States and the National Association of Insurance Commissioners (NAIC). We also

received comments from about a dozen health insurance issuers, group health plans, and their associations. Most of the remaining comments came from health care providers, pharmaceutical companies, business groups, labor unions, and consumer groups.

Length of the Comment Period

We received many comments about the 30-day comment period and whether we would extend it. Some commenters contended that the 30-day comment period did not provide sufficient time to provide feedback.

Our comment period is consistent with the Administrative Procedure Act and Executive Orders 12866 and 13563. OPM values the participation of a broad array of diverse stakeholders, and we have succeeded in obtaining that participation, as evidenced by the volume of comments as well as the diversity of viewpoints offered in response to our proposed regulation. Moreover, OPM has provided several other opportunities for public input on policies relating to the MSPP. On June 16, 2011, OPM issued a Request for Information (RFI) to solicit feedback from stakeholders about the program. On September 21, 2012, OPM issued a draft MSPP application and received public comments over a 30-day period. OPM has also held meetings and phone calls with numerous stakeholders to seek input and guidance, including from the NAIC, States, tribal governments, consumer advocates, health insurance issuers, labor organizations, provider associations, and trade groups.

Church Plans

One commenter urged OPM to consider entering into an MSPP contract with a church plan. The commenter explained that church plans are defined in various sections of the law, including section 414(e) of the Internal Revenue Code and section 3(33) of the

Employee Retirement Income Security Act (ERISA). A church plan does not, by itself, meet the definition of health insurance issuer in section 2791(b)(2) of the PHS Act; in addition, enrollment is limited to church employees and members of the clergy. The commenter interpreted section 1334 of the Affordable Care Act as allowing OPM to contract with church plans to offer coverage through the MSPP. First, the commenter stated that, while section 1334(a)(1) provides that the Director shall enter into contracts for MSPs with health insurance issuers, it does not expressly preclude OPM from entering into contracts with entities other than issuers. The commenter asserted that church plans should be considered eligible to contract for an MSP because OPM can treat a church plan as equivalent to an issuer under the Church Parity and Entanglement Protections Act, Pub. L. 106-244 (“Parity Act”). The commenter recommended that OPM could exercise its discretion to exempt church plans from a number of requirements for MSPs, including permitting a church plan MSP to limit enrollment to members of the clergy and church employees.

We disagree with the commenter’s interpretation of section 1334 and do not believe that a church plan meets the requirements necessary for OPM to offer such a plan under an MSPP contract. Section 1334(a)(1) explicitly requires OPM to enter into contracts for MSPs with “health insurance issuers,” and we do not agree that the statute authorizes OPM to enter into contracts with entities other than health insurance issuers. Because church plans, by themselves, do not meet the definition of health insurance issuers as described above, OPM does not have the authority to contract for them under § 1334.

Responses to Comments on the Regulations

Subpart A – General Provisions and Definitions

Basis and scope (§ 800.10)

OPM proposed this section to define the basis and scope of part 800, which establishes the primary authority for the establishment of the MSPP under the Affordable Care Act. Other relevant statutory provisions MSPP issuers and MSPs must comply with include all provisions of part A of title XXVII of the Public Health Service (PHS) Act. Section 800.10 also sets forth the scope of this regulation, which establishes standards for health insurance issuers wishing to contract with OPM to participate in the MSPP and for the appeals processes for both MSPP issuers and enrollees.

We received no comments on § 800.10 as proposed. Accordingly, we are adopting it as final, with no changes.

Definitions (§ 800.20)

In § 800.20, OPM proposed definitions for terms that are used throughout part 800. In general, the definitions contained in § 800.20 come from the following sources: title I of the Affordable Care Act and the final Exchange regulation at 45 CFR parts 155, 156, and 157; title XXVII of the PHS Act and the regulations at 45 CFR part 144; and the Federal Employees Health Benefits Act (FEHBA) at chapter 89 of title 5, United States Code, and the regulations governing the Federal Employees Health Benefits Program (FEHBP) at 5 CFR part 890 and 48 CFR 1609.70. Some new definitions were created for the purpose of implementing the MSPP. The application of the terms defined in this section is limited to this final rule.

OPM proposes definitions for several terms based on three HHS regulations. First, HHS published an Essential Health Benefits (EHB) final rule in the Federal

Register on February 25, 2013, to provide standards related to EHB, actuarial value (AV), and accreditation. Second, HHS published a final rule in the Federal Register on February 27, 2013, to provide standards related to fair health insurance premiums, guaranteed availability, guaranteed renewability, risk pools, and rate review (the health insurance market rules). Third, HHS published a final rule elsewhere in today's edition of the Federal Register, to provide notice of standards relating to benefit and payment parameters for 2014, including standards related to advance payments of the premium tax credit and cost-sharing reductions (the payment rule). OPM is using the definitions promulgated by HHS.

Comments: OPM received several comments recommending changes in the definitions in proposed § 800.20. A few commenters expressed concern with how OPM plans to operationalize the definition of “Indian.” Specifically, the commenters suggested that OPM adopt the definition at 42 CFR 447.50 and not use the definition at 45 CFR 155.300(a) as we proposed. OPM was also asked to correct the definition of “Indian Plan Variation,” which currently cross references 45 CFR 156.400, so that there is no confusion regarding eligibility of Indians for zero-cost-sharing and variable cost-sharing plan variations.

Response: While the terms “Indian” and “Indian Plan Variation” were introduced in the proposed rule, referencing 45 CFR 155.300(a) and 45 CFR 155.400, respectively, we are removing them from the final rule, as they are not used elsewhere in the rule.

Comments: A few commenters noted that OPM should not exclude policies and contracts from the “benefit plan material or information” definition. Two commenters said that we should not exclude policies and contracts from the definition, because

including them in the scope of the regulation could be helpful to limited-English-proficient (LEP) individuals in making effective decisions.

One commenter wanted us to clarify that a provider directory falls within the definition of “benefit plan material or information.”

Response: We are adopting the proposed definition of “benefit plan material or information.” The term, as defined, includes 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. As it does in the FEHBP, OPM will review and approve the policy or contract for health insurance coverage. Such approval is necessary for effective contract administration and oversight. We agree that a provider directory does fall within the scope of the definition.

Comment: One commenter suggested that introducing a second prong to the definition of “group of issuers” – to include “an affiliation of health insurance issuers and an entity who is not an issuer but who owns a nationally licensed service mark” – would expand the authority granted under section 1334 of the Affordable Care Act. The commenter recommended that we not expand the definition of “group of issuers” to include entities not identified in the Affordable Care Act as potential participants in the MSPP.

Response: Section 1334 does not define “group of issuers,” but only provides examples of affiliations of health insurance issuers that may be considered health insurance issuers. Thus, OPM, in the exercise of its discretion, and within the parameters set by section 1334, has established a definition that we believe affords flexibility in terms of the types of entities with which OPM may contract. In addition, this definition,

which attempts to encompass a diversity of contractual arrangements similarly available to OPM under the FEHBP, promotes the goals of section 1334(a) of the Affordable Care Act, which directs OPM to implement the MSPP in a manner similar to the manner in which we implement the contracting provisions with respect to carriers under the FEHBP. As we noted in the proposed rule, this definition of “group of issuers” is applicable only for the purposes of section 1334.

Comment: One commenter recommended that OPM revise the definition of “non-profit entity” to exclude the portion of the definition that states a non-profit entity may also be, for purposes of the MSPP, “a group of health insurance issuers licensed under State law a substantial portion of which are incorporated under State law as non-profit entities,” as this would further reduce competition in a State where a “for-profit” issuer may already have a significant market share.

Response: We are adopting the proposed definition of “non-profit entity.” This definition is consistent with the manner in which OPM implements the contracting provisions with respect to carriers under the FEHBP and builds on our significant experience in contracting with and overseeing carriers under that program.

Comment: Another commenter recommended amending the definitions of “multi-State plan (MSP)” and “Multi-State Plan Program issuer (MSPP issuer)” to clarify whether each MSP will be under separate contract with OPM or will contract through the MSPP issuer.

Response: OPM is revising the definition of “MSP” to clarify that an MSP is offered under contract with OPM via an MSPP issuer.

Comment: A commenter suggested that OPM broaden the definition of “State Insurance Commissioner” to acknowledge the potential for multiple regulatory roles in a State.

Response: We understand the commenter’s concern and acknowledge the possibility of multiple regulatory roles in some States, but we are retaining the proposed definition. This term is a standard term that is understood in the industry; therefore, we decline to amend the definition. Our definition of “State Insurance Commissioner” aligns with the definition used in many of the model acts issued by the National Association of Insurance Commissioners (NAIC) to ensure consistency with definitions widely used by State insurance regulatory entities.

Subpart B – Multi-State Plan Program Issuer Requirements

General requirements (§ 800.101)

Section 800.101 of the proposed rule sets forth standards to implement § 1334(b) of the Affordable Care Act. The general requirements include licensure, a contract with OPM, required levels of coverage, eligibility and enrollment, compliance with OPM direction and other legal requirements. In § 800.101(i), we also proposed that an MSPP issuer must comply with applicable non-discrimination statutes and ensure that their MSPs do not discriminate based on race, color, national origin, disability, age, sex, gender identity, or sexual orientation. We sought comment on any unique enrollment and eligibility issues that might affect MSPs. A broad spectrum of consumer and professional organizations commented on this provision.

Comments: Many commenters support OPM’s intent to include non-discrimination provisions, but recommended adding specific additional language to

strengthen these protections, including clarifying non-discrimination based on sex or gender identity.

Some commenters requested that OPM add specific non-discrimination language in § 800.101(d) that describes the MSP and MSPP issuer responsibilities for eligibility and enrollment. The specific suggestion was to notify MSPP issuers that benefit packages must be “substantially equal” to EHB benchmarks and not include any discriminatory benefit design elements as defined under 45 CFR 156.125.

Response: In response to comments, we are revising § 800.101(i) of this final rule to ensure consistency with the prohibition on discrimination with respect to EHB in 45 CFR 156.125 and the non-discrimination standards applicable to QHPs under 45 CFR 156.200(e). With regard to defining EHB benchmarks, we have determined that these comments are outside the scope of this rule. These standards are governed by HHS regulations.

Comments: Some commenters suggested that certain health care providers be included as protected categories for non-discrimination, and one commenter wanted MSPP issuers and MSPs to align their payment systems to comply with State and Federal non-discrimination provisions.

Response: The broad prohibition on discrimination in § 800.101(i) clearly bars discrimination against certain health care providers of the MSPP issuer. Similar comments were addressed in § 800.109, concerning health providers and network adequacy. We are concerned that specifying types of providers who are protected from discrimination would detract from the larger issue of broadly ensuring access to the full

range of covered services. Accordingly, no further change in proposed § 800.101(i) is needed to address this concern.

Comments: A few commenters recommended that OPM expressly clarify in § 800.101(i) that the Indian Health Service, tribes and tribal organizations, and urban Indian organizations (collectively, I/T/Us) are not violating the non-discrimination requirements if they limit their services, in whole or part, to American Indians/Alaska Natives.

Response: An MSPP issuer would not violate the non-discrimination requirements by contracting with health care providers who are authorized or directed by law to serve specific populations, such as Indian health providers. We note that an MSPP issuer must meet all standards related to network adequacy and essential community providers specified in § 800.109 and 45 CFR 156.235, respectively.

Comments: A few commenters stated that OPM should clarify that MSPs and MSPP issuers must comply with any consumer protections and regulatory procedures a State or Exchange has put in place.

Response: As explained in our proposed regulation, MSPs and MSPP issuers are generally required to comply with applicable State law. This would include the application of stronger protections in the Exchange provided by State law, as long as application of those provisions to the MSPP is consistent with the Affordable Care Act. We received no comments to indicate that the consumer protections applicable to the MSPP are any weaker than those required by any State or Exchange. On the contrary, OPM intends to protect consumers through its administration of the MSPP in a manner similar to the manner in which it has protected enrollees in the FEHBP for more than 50

years. In any event, if there are specific consumer protections and regulatory procedures that go above and beyond Federal standards, OPM encourages States to identify them so OPM can consider and address them through a memorandum of understanding (MOU) with the State and, if appropriate, in its contracts with issuers.

Comments: A few commenters asked how OPM will work with active purchasing Exchanges and recommended that OPM incorporate a “do no harm” objective in the preamble.

Response: We will retain our current language and decline to incorporate a “do no harm” provision, as such a provision would be vague and ambiguous. Instead, we will maintain our approach of applying standards that neither competitively advantage nor disadvantage MSPs and MSPP issuers.

Comment: One commenter stated that OPM should require MSPP issuers to meet standards for certification and licensing prior to signing a contract with OPM for MSPs in the State.

Response: Section 800.101 clearly provides that an MSPP issuer must be licensed as a health insurance issuer in each State where it offers health insurance coverage, and it is deemed certified by OPM when it signs a contract with OPM.

Compliance with Federal law (§ 800.102)

Proposed § 800.102 specifies the Federal laws with which MSPP issuers must comply as a condition of participation in the MSPP. Paragraph (a) refers to applicable provisions of title XXVII of the PHS Act, while paragraph (b) refers to applicable provisions of title I of the Affordable Care Act.

In this final rule, paragraphs (a) and (b) no longer refer to Appendix A and B, respectively, which in the proposed rule listed specific provisions of title XXVII of the PHS Act and title I of the Affordable Care Act. We are omitting these appendices because, although the statutes listed in those appendices do apply to MSPP issuers, they may not necessarily be a comprehensive list of all applicable statutes. Also, it is possible that the list of statutes in the appendices may change over time.

We are also omitting Appendix C in this final rule, because § 36B of the Internal Revenue Code does not set forth responsibilities of issuers.

Comments: Commenters suggested that OPM had erroneously neglected to include section 2716 of the PHS Act and section 1312 of the Affordable Care Act.

Response: MSPP issuers that choose to participate in the Small Business Health Options Program (SHOP) will operate under the same rules as issuers of health insurance coverage in the small group market generally. OPM agrees that section 1312 of the Affordable Care Act applies to MSPP issuers.

Comments: A few commenters noted that we listed section 2707 of the PHS Act in Appendix A to the proposed rule, which listed PHS Act provisions applicable to MSPs, and asked OPM to clarify that the PHS Act requirements were applicable solely to the off-Exchange markets and would not apply to MSPP issuers for products sold through an Exchange.

Response: While all the requirements applicable to QHP issuers contained in section 2707 are also contained in requirements applicable to QHPs, they also apply directly.

Authority to contract with issuers (§ 800.103)

As provided in section 1334(a)(1) of the Affordable Care Act, OPM proposed in § 800.103 that it may enter into an MSPP contract with a group of issuers affiliated either by common ownership and control or by the use of a nationally licensed service mark, or an affiliation of health insurance issuers and an entity that is not an issuer but that owns a nationally licensed service mark.

We received no substantive comments on this section. Accordingly, we are adopting proposed § 800.103 as final, with no changes.

Phased expansion (§ 800.104)

In § 800.104, we proposed phased expansion of the MSPP into States and that MSPP issuers may provide partial coverage within a State. We also proposed that MSPP issuers must be licensed in the State where they offer coverage and OPM may enter into a contract with an issuer that is not licensed in all States. We stated in the preamble of the proposed regulation that § 800.104 implements provisions of section 1334(e) of the Affordable Care Act regarding the phase-in of multi-State plans. OPM proposed in § 800.104(b) that MSPP issuers offering MSPs can offer coverage in part of a State, and do not have to offer coverage throughout the entire State. We also solicited comment on whether an MSPP issuer should be required to offer coverage statewide by the fourth year of participation in the MSPP, when coverage must be offered in each Exchange in all States and the District of Columbia.

Comments: Several commenters expressed support for phased expansion into States. Another commenter stated that a multi-year phase-in process will allow MSPs to build appropriate networks and partnerships to satisfy the requirements of the Affordable Care Act and satisfy the needs of the citizens of each State. One commenter stated that

MSPP issuers should be required to offer coverage on each Exchange in all States and the District of Columbia as soon as possible or in as many States as possible. Another commenter recommended an extension of the phase-in period to 6 years instead of a 4-year phase-in.

Response: We are retaining the standards that are outlined in section 1334(e) of the Affordable Care Act. However, we have removed from the regulatory text the number of States that an issuer must phase into because section 1334(e) refers to percentages and not specific numbers. We believe the phased expansion approach into States will encourage MSPP issuers to expand MSPs to provide more consumer choice throughout the country. It is our intention to ensure that MSPP issuers have appropriate networks to adequately serve MSP enrollees, and we will take these comments into consideration when we are evaluating potential MSPP issuers.

Comment: One commenter was concerned that MSPP issuers will subcontract to meet the phase-in requirements and that these will encourage “marriages of convenience.”

Response: Section 1334 permits OPM to contract with health insurance issuers and entities that come together in order to apply as an MSP issuer. We encourage any such new entities to give careful thought and planning to their strategies for phasing in coverage to the States and the District of Columbia, and we will ensure through our application review and contracting process that these entities are prepared to offer quality health insurance options in the States for which they are applying.

Comment: One commenter recommended that OPM should require licensure in all jurisdictions by the end of the phase-in.

Response: We have adequately addressed the licensure requirement in § 800.104(c). As stated in that section, OPM may enter into a contract with an MSPP issuer that 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 for the phase-in.

Comments: We received many comments on whether OPM should have a role in selecting the States in which MSPP issuers should or should not offer coverage during phased expansion. Several commenters recommended that OPM not specify which States an MSPP issuer must cover in the first year. Other commenters recommended that OPM should consider slow-tracking implementation of the MSPP in certain States and granting these States waivers from participation. Another commenter suggested that OPM limit MSPP issuers to offering MSPs in States that will have Federally-facilitated Exchanges or State Partnership Exchanges in 2014. One commenter suggested that OPM focus the phase-in on States where consumers lack viable coverage options.

Response: OPM declines to identify specific States that MSPP issuers should cover during phased expansion. We recognize the importance of providing consumers with more health insurance coverage options and, while we will not choose specific States where MSPP issuers must provide coverage during the phase-in, we will use our oversight and contract negotiation roles to provide consumers with the additional choice of two high-quality health insurance plans and promote competition on the Exchanges.

Comments: One commenter supported OPM's proposal that OPM may enter into contracts with issuers that cannot provide statewide coverage and stated that it will give

MSPP issuers time to develop the capacity to offer coverage throughout a service area, which will enhance competition in the MSPP. Several commenters appreciated that issuers failing to offer statewide coverage must propose a plan for becoming statewide, but expressed that without more specificity American Indians/Alaska Natives will not be able to access MSPs.

Response: We acknowledge the importance of access to health coverage and MSPs, especially in rural and underserved areas. However, we are providing in the final regulation that OPM may enter into a contract with an MSPP issuer that will provide partial coverage within a State. We recognize the challenges that issuers would face if there were a requirement to offer coverage statewide, and we were made aware of these challenges from issuers in the MSPP Request for Information as well as comments on the proposed rule. However, we are maintaining in the final rule our proposed requirement for MSPP issuers who are offering partial coverage in a State to supply a plan for offering coverage throughout the State. As we review MSPP issuer applications, we will pay special attention to service areas that are medically underserved, such as rural areas and American Indian/Alaska Native populations. We intend to encourage issuers to offer coverage statewide where they have capacity to do so, and will take these comments into consideration when negotiating MSPP contracts.

Comments: Several commenters wanted clarification of phased expansion in terms of MSPs being able to meet network adequacy standards. One commenter recommended that MSPP issuers not be permitted to offer MSPs in a State unless the plan is capable of offering coverage to all residents of a State, including meeting network adequacy standards throughout the State, to avoid selective coverage by issuers.

Response: While we appreciate the concern for network adequacy, we decline to set a standard of phased expansion and statewide coverage in terms of network adequacy. We believe that network adequacy is sufficiently addressed in § 800.109 to ensure that an MSP's services are available to all enrollees.

Comments: Many commenters were concerned by our proposal to allow partial coverage within a State. Some stated that MSPP issuers should be required to comply with all State requirements regarding geographic scope of coverage that apply to QHPs. One commenter recommended that MSPs follow specific State standards for statewideness. Some commenters stated that, without a requirement of statewideness, there is a possibility of red-lining by MSPP issuers or adverse selection resulting in MSPP issuers avoiding certain populations. Commenters were also concerned about market dislocation. One commenter stated that MSPP issuers would be able to avoid offering coverage in rural and other high-cost areas, which would give them a competitive advantage over both QHP issuers and issuers not offering on an Exchange. Lastly, one commenter stated that a core purpose of the MSPP is to benefit individuals who lack options, and allowing issuers to avoid certain difficult areas in a State contradicts this basic purpose. One commenter suggested that we include language indicating that we will consult with State regulators and the State Exchange in determining that MSP coverage does not exclude specific high-utilizing, high-cost, or medically-underserved populations.

Response: We are not prohibiting MSPP issuers from being statewide; on the contrary, we encourage them to do so from the start if they have the capacity. MSPP issuers should follow State laws regarding statewideness to the extent it is within their

capability to do so. In addition, we are finalizing this regulation with the requirement for an MSPP issuer to provide a plan for expanding coverage statewide. Furthermore, we intend to address an MSPP issuer's ability to expand coverage statewide as part of the MSPP application and contract negotiation processes. We acknowledge the commenters' concern for red-lining and other "cherry-picking" practices where an issuer might offer plans only in geographic areas that are expected to have lower risk. Therefore, we will evaluate MSPP issuers to ensure that the locations in which they propose to offer MSP coverage have been established without regard to racial, ethnic, language, 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. We agree that a core purpose of the MSPP is to provide additional choice of health insurance plans and promote competition on the Exchanges, and MSPP issuers should not be permitted to avoid areas in a State that are difficult to serve. We are aware of these concerns and are committed to MSPP issuers being neither competitively advantaged nor disadvantaged, compared to QHP issuers.

OPM proposed that, by the end of the phase-in period, MSPP issuers should be required to offer coverage on the SHOP in addition to the individual Exchange. We solicited comments on this approach to SHOP participation, including on whether participation in SHOP should be required from the outset or whether we should allow MSPP issuers to provide a plan that requires a period longer than the phase-in period to fully participate in the SHOP. We received comments on the phase-in to SHOPS from States, an issuer association, and professional organizations.

Comments: Several commenters supported our approach of allowing MSPP issuers the flexibility to phase-in to SHOPs. One commenter asked that OPM clarify whether the statement in the preamble that the “MSPP issuer may choose to participate in the SHOP” is a proposal to phase-in MSPP issuer coverage in the SHOP. Some commenters were concerned that MSPs will have a competitive advantage if they are not required to follow the same rules as the Federally-facilitated Exchange and State requirements for QHPs to offer coverage in both the individual and SHOP markets. One commenter noted that OPM’s approach presents a significant challenge, since it has merged markets. Some commenters would like OPM to require participation in the SHOP from the outset or require full participation in the SHOP at the fourth year of phase-in.

Response: We appreciate the support for our approach of allowing MSPP issuers the flexibility to phase-in coverage to the SHOPs, which was discussed in the preamble of the proposed rule, though not addressed in the regulatory text. Based on the policy for Federally-facilitated SHOP participation published in the HHS Payment Notice, we are finalizing our regulation to require MSPP issuers to comply with 45 CFR 156.200(g). In the HHS Payment Notice, HHS adopted a provision stating that a QHP issuer applicant will participate in a Federally-facilitated SHOP based on an issuer applicant’s current small group market share. The provision uses a threshold of 20 percent market share to determine whether a small group market issuer is subject to the tying provision for QHPs in the Federally-facilitated SHOPs. For the MSPP, we believe this standard for the Federally-facilitated SHOP can be met if a State-level MSPP issuer or any other issuer in

the same issuer group affiliated with an MSPP issuer provides coverage on the Federally-facilitated SHOP.

In this final rule, we adopt a policy for the MSPP that mirrors the standard set by HHS for the Federally-facilitated SHOP. We also adopt a policy for SHOP participation on State-based Exchanges that is consistent with our approach to State law under § 800.114 while retaining OPM discretion on timing of MSPP issuers to participate in the SHOP. For State-based SHOPS, we will permit an MSPP issuer flexibility to phase-in participation in the SHOP if the State has set a standard that requires QHPs to participate. We understand the burden of building capacity and network in order to offer in the SHOPS and want to balance the needs of small employers, MSPP issuers, and States. We believe section 1334(e) provides OPM discretion to allow an MSPP issuer to phase-in SHOP participation in States that require participation and this flexibility meets the needs of many stakeholders. Therefore, we are finalizing regulatory text in § 800.104(c) that requires MSPP issuers to comply with standards in 45 CFR 156.200(g) and with State standards for SHOP participation, subject to § 800.114, and gives OPM discretion to provide MSPP issuers flexibility during the initial years of the program to phase into the SHOP in a State-based Exchange. We also clarify that an MSPP issuer must offer coverage for both individuals and small groups in a State with a merged individual and small group market. We encourage MSPP issuers to expand coverage in States and SHOPS when they have adequate capacity to accept enrollees.

Benefits (§ 800.105)

In § 800.105, OPM proposed to implement section 1334(c)(1)(A) of the Affordable Care Act, which directs an MSP to offer a benefits package that is uniform in

each State and consists of the EHB described in section 1302 of the Affordable Care Act. OPM developed its benefits policy in coordination with HHS, which promulgated the EHB rule. Generally, under that rule, EHB would be defined by a benchmark plan selected by each State or, in the absence of a State benchmark designation, a default benchmark. However, the EHB rule also states at 45 CFR 156.105 that MSPs must meet benchmark standards set by OPM.

In § 800.105(a)(1), OPM proposed that an MSPP issuer must offer a uniform benefits package for each MSP and that the benefits for each MSP must be uniform within a State, but not necessarily uniform among States. In § 800.105(a)(2), OPM proposed that the benefits package referred to in § 800.105(a)(1) must comply with section 1302 of the Affordable Care Act, as well as any applicable standards set by OPM or HHS in regulations. Together, these provisions clarify that MSPP issuers must comply with applicable HHS requirements and that OPM may issue additional guidance regarding any issues unique to MSPs.

In § 800.105(b)(1), OPM proposed allowing MSPP issuers to offer a benefits package, in all States, that is substantially equal to either (1) each State's EHB-benchmark plan in each State in which it operates; or (2) any EHB-benchmark plan selected by OPM. The second option offers administrative efficiencies for MSPP issuers, who face a number of challenges in being able to offer MSPs on each Exchange in all States and the District of Columbia. We also noted in our proposed rule that MSPP issuers could potentially achieve a similar consistency in their benefits offerings by adhering to State EHB-benchmark plans and applying the EHB substitution rules at 45 CFR 156.115.

Comments: We received many comments on the proposed EHB-benchmark policy from a broad range of stakeholders. Many commenters argued that the proposed policy would lead to adverse selection or consumer confusion. Some commenters argued that the proposed policy would also constitute Federal preemption of State authority to regulate insurance. At least one commenter said that the proposed policy would lead to administrative complexities and inefficiencies. Finally, some commenters preferred to have only a national benchmark.

Some commenters noted that differences between an OPM-selected benchmark and State-selected benchmark are unlikely to be actuarially significant. Some commenters also noted that the proposed policy would encourage issuers to participate in the MSPP. Other commenters also noted that OPM-selected benchmarks would provide robust prescription drug coverage, obesity treatment services, medical nutrition therapy, pediatric services, and chiropractic care.

Response: We agree with commenters who noted that the differences between an OPM-selected benchmark and State-selected benchmark are unlikely to be actuarially significant. We are not aware of any compelling evidence that multiple benchmarks would lead to adverse selection or consumer confusion, nor did the commenters produce any evidence of adverse selection or consumer confusion. Accordingly, we are adopting as final the proposed provision to allow an MSPP issuer to offer a benefits package in all States that is substantially equal to either the EHB-benchmark plan in each State in which it proposes to offer an MSP or any EHB-benchmark plan selected by OPM.

Comments: Several commenters discussed the need for national MSPs for American Indians/Alaska Natives.

Response: We acknowledge that consistency among States would be helpful for I/T/Us that may consider purchasing plans for tribes that are in multiple States. Members of tribes would still need to access the Exchanges in their States to determine their eligibility and enrollment for products available through the Exchange, including an MSP. While the MSPP is not a national plan, reciprocity of coverage among MSPs in States is an issue we intend to take up in contract negotiations with MSPP issuers. We look forward to conferring with tribes on this approach and engaging them in how the MSPP may best meet their needs.

Comments: Several commenters asked us to eliminate or provide additional guidance regarding the “substantially equal” standard.

Response: Because HHS is defining the standard for the term “substantially equal,” we expect MSPP issuers to follow HHS guidance relating to this term.

OPM also proposed that even if an MSPP issuer chooses to use an EHB-benchmark plan selected by OPM in all States, the MSPP issuer must still use a State-selected benchmark in States that do not allow any substitution for services within the benchmark benefits. The reason for this is if an MSPP issuer were to use an OPM-selected benchmark in States that require all plans to offer the same set of benefits, then the MSP in that State would be different from all of the other plans offered on the market, which could potentially lead to market disruption, adverse selection, or consumer confusion could occur.

Comments: Many commenters supported the policy that OPM-selected benchmarks and substitutions not be allowed in States having standard benefit designs.

Response: We are adding a paragraph (b)(3) to § 800.105 to clarify that an MSPP issuer must comply with any State standards relating to substitution of benchmark benefits or standard benefit designs. Accordingly, in a State that does not allow substitution of benchmark benefits, or that has standard benefit designs, an MSPP issuer that has chosen to use an OPM-selected EHB-benchmark plan under paragraph (b)(2)(ii) must use the State's EHB-benchmark plan.

No matter which option an MSPP issuer chooses, it must apply that option uniformly in each State in which the MSPP issuer proposes to offer MSPs. This means that, except as discussed above, our approach will not permit an issuer to use a State benchmark plan in some States in which it operates and an OPM-chosen benchmark plan in others.

In § 800.105(c)(1), OPM proposed selecting, as EHB-benchmark plans, the three largest FEHBP plan options by enrollment that are open to Federal employees and annuitants, which were identified by HHS pursuant to section 1302(b) of the Affordable Care Act. On July 3, 2012, HHS identified the three largest FEHBP 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.¹ An MSPP issuer that selects one of these benchmarks must offer this benefits package in all States in which it operates an MSP.

Several commenters urged OPM to be judicious in evaluating all proposed benchmarks. Based on initial comparative research, it appears that the proposed OPM-selected EHB-benchmark plans are largely similar in scope of benefits covered to those

¹ Centers for Medicare and Medicaid Services, Essential Health Benefits: List of the Largest Three Small Group Products by State, available at <http://cciio.cms.gov/resources/files/largest-smgroup-products-7-2-2012.pdf>.PDF (July 3, 2012).

benchmark-eligible plans in the small group markets.² This research also indicates that the OPM-selected EHB-benchmark plans, like other benchmark-eligible plans, may lack coverage for pediatric oral services, pediatric vision services, and habilitative services and devices. Moreover, the EHB-benchmark may also lack State-required benefits. Accordingly, OPM proposed standards to supplement the OPM-selected EHB-benchmark plans in § 800.105(c)(2)-(c)(4).

In § 800.105(c)(2), we proposed 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 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.

We also solicited comments on the provision of pediatric oral services by MSPs in order to meet the requirements of section 1302(b)(1)(J) of the Affordable Care Act. Under one proposed approach, an MSP would include pediatric oral services in its benefit package. Finally, we solicited comments on how stand-alone dental plans offered on the Exchanges should affect this requirement, if at all.

² U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, ASPE Research Brief, Essential Health Benefits: Comparing Benefits in Small Group Products and State and Federal Employee Plans, available at <http://aspe.hhs.gov/health/reports/2011/MarketComparison/rb.pdf> (December 2011).

Comments: While some commenters favored offering stand-alone dental plans, others expressed concern that the expense of separate out-of-pocket maximums might discourage families from purchasing separate coverage for pediatric oral services. Some commenters proposed to require all MSPs to offer both a complete medical package and an identical plan without pediatric oral services in areas where stand-alone pediatric dental coverage is available.

Response: Given the range of possible benefit designs, we are not promulgating any further regulatory provisions regarding coverage of pediatric oral services. Instead, we will keep these comments in mind during MSPP contract negotiations, which would allow greater flexibility on benefit designs.

In § 800.105(c)(3), we proposed that an MSPP issuer must follow State definitions for habilitative services and devices where the State chooses to specifically define this category pursuant to 45 CFR 156.110(f). When a State chooses not to define this category and any OPM-selected EHB-benchmark plan lacks coverage of habilitative services and devices, OPM may determine what to include in this category.

Comments: All commenters supported OPM's intention to include habilitative services and devices in the MSPs. However, they disagreed on whether we should defer to State definitions or have OPM define a specific set of habilitative services and devices that each MSP must cover. Some asked that we require parity in scope, amount, and duration for habilitative and rehabilitative services. Other commenters supported our proposed approach for when a State chooses not to define the category of habilitation. When this happens, we will determine what habilitative services and devices must be included in an OPM-selected EHB-benchmark plan. One commenter suggested that we

refer to both habilitative “services and devices” in § 800.105(c)(3) as we do in § 800.105(c)(4).

Response: Based on the comments, we will direct MSPP issuers to follow State definitions of habilitative services and devices where they exist and, where they do not exist, OPM will consider these comments during MSPP contract negotiation. We are adopting proposed § 800.105(c)(3) as final, with the one technical correction mentioned above.

In § 800.105(c)(4), OPM proposed that, at least for years 2014 and 2015, OPM’s EHB-benchmark plans would also include, for each State, any State-required benefits enacted by December 31, 2011, that are included in a State’s EHB-benchmark plan or specific to the market in which the MSPP issuer offers coverage. Accordingly, these State-required benefits would be treated as part of the EHB. However, consistent with 45 CFR 155.170, OPM proposed that State-required benefits enacted after December 31, 2011, would be in addition to the EHB. Under section 1334(c)(4) of the Affordable Care Act, a State must assume the cost of such additional benefits over the EHB by making payments either to the enrollee or on behalf of the enrollee to the MSPP issuer, if applicable. An MSPP issuer must calculate and report the costs of additional State-required benefits pursuant to § 800.105(e). This standard is also consistent with 45 CFR 155.170.

Comments: Most commenters supported the inclusion of State-required benefits before December 31, 2011. However, one commenter opposed the inclusion of State-required benefits. Another commenter stated that the cutoff date for inclusion of State-

required benefits should be November 26, 2012, the date when the proposed EHB rule was published.

Response: We are making no changes to § 800.105(c)(4), because it is consistent with standards applicable to QHPs at 45 CFR 155.170.

Comments: Several commenters recommended that State payments for State-required benefits above the EHB benchmark be made only to issuers instead of allowing States the option of making payments to either issuers or enrollees.

Response: We are making no changes to proposed § 800.105(e), because it is consistent with section 1334(c)(4) of the Affordable Care Act, as well as standards applicable to QHPs at 45 CFR 155.170.

In § 800.105(d), OPM proposed that an MSPP issuer's benefits package, including its prescription drug list, must be submitted to and approved by OPM, which will determine whether a benefits package proposed by an MSPP issuer is substantially equal to an EHB-benchmark plan, in accordance with the requirements set forth by HHS in the proposed EHB rule. In determining whether an MSPP issuer's benefits package should be approved, OPM proposed to follow the HHS approach set forth at 45 CFR 156.115, 156.122, and 156.125. Section 156.115(b) of title 45, Code of Federal Regulations, allows issuers to make benefit substitutions within each EHB category and directs issuers to submit evidence of actuarial equivalence of substituted benefits to a State. We requested comments on whether MSPP issuers should submit evidence of actuarial equivalence of substituted benefits to OPM in addition to, or in lieu of, their submission to a State.

Comments: Many commenters recommended that, if MSPP issuers are allowed to make actuarially equivalent substitutions, evidence should be submitted to both States and OPM.

Response: We are adopting the proposed § 800.105(d), and we will work collaboratively with State regulatory officials during the MSPP application process to ensure they receive evidence of actuarial equivalence of substituted benefits.

In reviewing an MSPP issuer's proposed benefit design, OPM plans to review an MSPP issuer's benefits package for discriminatory benefit design, consistent 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 benefit design in MSPs.

In summary, we are adopting proposed § 800.105 as final, with the change described above relating to standardized benefit designs. We also are making minor technical corrections, including by inserting a reference to both habilitative "services and devices" in § 800.105(c)(3) to be consistent with § 800.105(c)(4).

Cost-sharing limits, premium tax credits, and cost-sharing reductions (§ 800.106)

In § 800.106(a), OPM proposed that, for each MSP it offers, an MSPP issuer must ensure that the cost-sharing provisions of the MSP comply with section 1302(c) of the Affordable Care Act as well as any applicable standards set by OPM or HHS in regulations. The HHS standards are set forth in 45 CFR 156.130. In § 800.106(b), OPM proposed that an MSPP issuer, for each MSP it offers, must ensure that an eligible individual receives advance payments of premium tax credits under section 36B of the Internal Revenue Code (the Code) and cost-sharing reductions under section 1402 of the

Affordable Care Act. This provision would establish MSPP issuer responsibilities under section 1334(c)(3)(A) of the Affordable Care Act, which specifies that an individual enrolled in an MSP is eligible for the premium tax credits and cost-sharing reductions in the same manner as an individual who is enrolled in a QHP. We clarify that under § 800.106(b), MSPP issuers must comply with the same standards as QHP issuers, including applicable provisions of sections 1402(a)(2) and 1412(c)(2)(B) of the Affordable Care Act and 45 CFR part 156, subpart E. OPM may issue additional guidance regarding any unique issues faced by MSPs.

We received comments on this section from a broad spectrum of consumer and professional organizations and a few individual States. In general, our intention is to require MSPP issuers to comply with Exchange rules to ensure that MSPs operate on a level playing field with other issuers operating in the Exchanges. To the extent any rules governing MSPs differ from those governing QHPs, OPM will design them to afford the MSPs and MSPP issuers neither a competitive advantage nor a disadvantage with respect to other plans offered on the Exchange.

Comments: Some commenters requested that OPM clarify its requirement that MSPPs must comply with State cost-sharing restrictions.

Response: It is our intention to require MSPP issuers to follow HHS rules regarding cost-sharing except when State laws impose stricter requirements for their Exchanges. In the event a State standardizes cost-sharing arrangements and these standards comply with HHS regulations, an MSPP issuer will also be required to comply with State standards for cost-sharing.

Comments: One group of commenters suggested that OPM require an MSP to cover out-of-network subspecialty care with the same cost-sharing arrangements as in-network.

Response: As acknowledged in our final application for the MSPP, we may, in some circumstances, also require MSPP issuers to provide in-network benefits for services from certain out-of-network providers; however, this would not be done through rulemaking. We will take these comments under consideration during our contract negotiation with MSPP issuers.

Concerns about the cost-sharing variation for American Indian/Alaska Native families who want to purchase child-only coverage are not within the scope of OPM's rulemaking authority. The Exchanges and HHS will facilitate all plan variations between MSPP issuers and potential enrollees just as they will do for families participating in the QHPs. However, where appropriate, OPM will coordinate closely with HHS on areas of special concern for American Indian/Alaska Native adults and children.

We are adopting proposed § 800.106(a) as final, with no changes, and we are making technical changes to § 800.106(b).

Levels of coverage (§ 800.107)

In §800.107, we proposed that an MSPP issuer, like a QHP issuer participating in Exchanges, must offer at least one plan at the silver level of coverage and one plan at the gold level of coverage in each Exchange in which the issuer is certified to offer an MSP pursuant to a contract with OPM. OPM will use its discretion about whether an MSPP issuer may offer products in addition to the required gold and silver products.

We also proposed that an MSPP issuer must offer a child-only plan 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. OPM proposed that MSPP issuers must comply with applicable HHS requirements to offer plan variations that will reduce or eliminate cost-sharing for eligible enrollees pursuant to section 1402 of the Affordable Care Act. Any MSP plan variations will be submitted to OPM for review and approval, and OPM will coordinate its approach to them with the final HHS notice of benefit and payment parameters for 2014. OPM will exercise this discretion to promote the best interests of enrollees and potential enrollees in the MSPP and to ensure adequate administrative oversight of each MSP and MSPP issuer.

A number of comments, although informative, relate to issues that do not fall within the scope of OPM's rulemaking. In general, our intention is to direct MSPP issuers to comply with State requirements related to the offering of levels of coverage, including but not limited to standardized benefit designs and tiers.

Comments: Some commenters recommended that OPM require or encourage MSPP issuers to offer coverage beyond gold and silver plans. The suggestions included requiring MSPP issuers to offer one or more of the following: at least one bronze plan; a plan in both the MSP and State Medicaid program; and catastrophic coverage.

Response: The Affordable Care Act requires each MSPP issuer to offer both a gold and silver plan. OPM will not require bronze coverage through this regulation, but has the discretion to approve other levels of coverage through contract negotiation with issuers. Therefore, where a State allows it, we will consider plans that offer catastrophic or bronze levels of coverage. We will also consider applicants to the MSPP that propose

to offer an MSP in the Exchange and simultaneously provide coverage through a State Medicaid program. We agree with commenters that this would reduce the potential for gaps as consumers transition between Medicaid and Exchange eligibility. However, we do not have authority to require MSPP issuers to participate in Medicaid.

No changes are needed in § 800.107 in light of the comments we received. Therefore, we are adopting proposed § 800.107 as final, with no changes.

Assessments and user fees (§ 800.108)

The proposed rule provides OPM discretion to collect an assessment or user fee from MSPP issuers as a condition of participating in the MSPP. The proposed rule also describes, generally, that any OPM-collected assessments and user fees would be to cover the administrative costs of performing the contracting and certification of MSPs and of operating the program, functions typically conducted through an Exchange for QHPs.

Comments: Some commenters asked OPM to confirm that MSPP issuers would pay any State-based Exchange user fees in addition to the MSPP-specific assessments or user fees. These commenters were concerned that any administrative fee above and beyond the Exchange fee charged to QHP issuers is duplicative and could lead to a competitive disadvantage for MSPP issuers. One commenter asked how the process for paying assessments and user fees to OPM would work.

Response: In this final rule, OPM is preserving its discretion to collect an MSPP assessment or user fee, and clarifies that it may begin collecting the fee in 2015; OPM does not intend to collect an assessment or user fee in 2014. The user fee could be used to fund OPM activities directly related to MSPP certification and administration. We

currently estimate that any future assessment or fee would be no more than 0.2 percent of premiums.

The MSPP user fee would not be a substitute for any user fee or assessment imposed by a State-based Exchange or Federally-facilitated Exchange. Rather, OPM intends for any MSPP user fee it collects to be offset against any State-based Exchange or Federally-facilitated Exchange user fee that the MSPP issuer must pay. This offset would preserve a level playing field for MSPP issuers. Under this approach, the MSPP issuers would pay the same total assessment or user fee to participate in an Exchange as all other QHPs participating in that Exchange. In addition, this process would allow the Exchanges to receive the bulk of the user fee from MSPP issuers to cover the Exchange costs, while also providing a marginal amount to fund the certification activities that OPM will perform in the place of an Exchange with respect to the MSPs.

OPM would issue further guidance in advance of collecting any user fees in 2015. For example, OPM would provide instructions on whether MSPP issuers should pay the MSPP portion of the user fee to OPM and pay separately the balance of the State-based or Federally-facilitated Exchange user fee to the State or HHS, as appropriate.

Comments: Several commenters wanted more detail about OPM's costs for certifying and administering the MSPP and to what use the assessment or user fee would be put. One commenter suggested eliminating the assessment or user fee since MSPP administration is a function of OPM.

Response: As stated in the proposed rule, the MSPP assessment or user fee would be used for OPM's MSPP functions for administration, including entering into contracts with, certifying, recertifying, decertifying, and overseeing MSPs and MSPP issuers for

that plan year. OPM will communicate such costs to MSPP issuers and Exchanges when available. The MSPP user fee is similar to a fee that OPM collects and uses to administer contracts for the FEHBP and will only be used to administer the MSPP as it performs plan management functions similar to State-based and Federally-facilitated Exchanges.

Network adequacy (§ 800.109)

OPM proposed, in § 800.109, a standard for network adequacy for the MSPP that mirrors the HHS standard set forth in 45 CFR 156.230 and is intended to ensure that an MSP's services are available to all enrollees. Consistent with the Exchange final rule's alignment with the NAIC Model Act, OPM proposed directing an MSPP issuer to (1) maintain a network that is sufficient in the number and types of providers to ensure that all services will be accessible without reasonable delay for enrollees; (2) offer a provider network that is consistent with network adequacy provisions set forth in section 2702(c) of the PHS Act; and (3) offer a provider network that includes essential community providers in compliance with 45 CFR 156.235. OPM intends for an MSPP issuer to make its provider directory available to the Exchange for online publication and to potential enrollees in hard copy, upon request. The proposed regulation stated that OPM would issue guidance containing the criteria and standards that OPM will use to determine the adequacy of a provider network. In addition, we solicited comment on State licensure and any issues for MSPs with respect to State-specific network adequacy requirements.

Comments: Some commenters recommended that network adequacy provisions include specific provider types, such as certified registered nurse anesthetists, tribal health care providers, chiropractic physicians, optometrists, and Christian Science

providers. Some commenters also stated that OPM should prohibit discrimination against specific provider types. A few commenters recommended that OPM require MSPP issuers to adopt a standard Indian Addendum for contracting with tribal health care providers.

Response: While the MSP network adequacy standard should provide access to a range of health care providers, specifying the inclusion of specified provider types, beyond what is required under the Affordable Care Act for QHPs (e.g., essential community providers), would detract from the larger issue of broadly ensuring affordable access to the full range of covered services. Accordingly, the final rule retains the language in proposed § 800.109(a) that requires MSPP issuers to maintain networks that include sufficient numbers and types of providers to ensure all services will be accessible without unreasonable delay. This includes providers representing medical, surgical, pediatric, mental health, and allied health disciplines to meet the anticipated health care needs of a diverse patient population. We acknowledge the importance of having standards in place to prevent discrimination against specific provider types, because a variety of providers is important for accessing services. However, we believe that the non-discrimination standards set forth in §§ 800.101 and 800.102 adequately prohibit discrimination against specific provider types. OPM will reinforce these protections through its contract negotiations with MSPP issuers.

With regard to the comments on the standard Indian Addendum, OPM recognizes that furnishing MSPP issuers with a standard Indian Addendum to a provider contract may make it easier for MSPP issuers to contract with Indian providers. We are aware that the Centers for Medicare and Medicaid Services (CMS) has partnered with the

Indian Health Service to develop a Draft Model Qualified Health Program Addendum for contracting between QHP issuers and tribal health care providers. However, CMS has not required that QHP issuers use the Addendum in the Exchange rule. We think it more appropriate to address this issue in our contract negotiations. We will continue to coordinate closely with CMS on the use of the standard Indian Addendum by MSPP issuers when contracting with Indian providers.

Comments: A few commenters recommended that OPM require MSPP issuers to contract with “any willing essential community provider.” Similarly, a few commenters suggested that OPM require MSPP issuers to comply with any State laws concerning “any willing provider” or “any willing pharmacy.”

Response: In proposed § 800.109(a)(3), OPM adopted an approach that mirrors that of HHS regarding inclusion of essential community providers for QHPs. OPM intends for MSPP issuers to contract with essential community providers. We do not intend to change this provision of the proposed regulation, but we wish to assure commenters that we consider §§ 800.109(a) and 800.114 to require MSPP issuers to comply with State “any willing provider” laws.

Comments: We received some comments related to standards for provider directories under proposed § 800.109(b). Overall, commenters supported the proposed standards, which mirrored the HHS standards in the Exchange final rule. However, one commenter suggested that OPM require MSPP issuers to maintain a dedicated email address that providers and consumers could use to submit inaccurate provider directory information for correction. In addition, another commenter requested that OPM streamline requirements for provider directories by allowing downloadable electronic

versions in place of hard copy and avoiding requiring regular updates of providers accepting new patients.

Response: The proposed § 800.109(c) mirrors the HHS approach to provider directories for QHPs. We will consider, during the MSPP contract negotiations, the comment on an MSPP issuer maintaining a dedicated email address for changes in provider directory information. With regard to the commenter who suggested that MSPP issuers not be required to provide a hard copy of the provider directory to potential enrollees upon request, this suggestion conflicts with HHS standards.

Comments: We received numerous comments related to establishing a uniform MSPP network adequacy standard. Many commenters did not support OPM developing a uniform standard for the MSPP. These commenters suggested that not applying the same standards to all QHPs and MSPs within a State would lead to adverse selection and market dislocation, and would not be in the best interests of consumers, though they did not submit any evidence to support these contentions. Specifically, two commenters identified States that had existing network adequacy standards for managed care products and recommended that an MSPP issuer comply with those standards. Conversely, many other commenters recommended that OPM establish a national, uniform standard for network adequacy for the MSPP. These commenters indicated that a uniform standard would be considered a critical component of the MSPP and is especially important in ensuring that MSPs provide reasonable and timely access to health care.

Response: OPM recognizes that many, though not all, States direct health insurance issuers to evaluate the adequacy of their provider networks on an ongoing basis and monitor network adequacy in their traditional role of regulating health insurance.

Based on comments received on the proposed rule, and informed by previous comments concerning the RFI and the draft application, we have adopted an approach under which the MSPP will establish a uniform standard for network adequacy using time and distance standards that are based on those published by CMS for Medicare Advantage plans (for providers and facilities) and Medicare Part D (for retail pharmacies), which we note meet the QHP network standards in 45 CFR 156.230. For 2014, we will assess MSPP issuers' compliance with these time and distance standards for a broad, diverse list of provider types and facility types, which we believe adequately reflects the ability of an MSPP issuer to assure that all services will be accessible without unreasonable delay for enrollees. More information is available in our final MSPP application that was published on January 18, 2013, on the Federal Business Opportunities website at www.FBO.gov under solicitation number OPM35-12-R-0006, Multi-State Plan Program.

In the first year of the MSPP, we will apply only the MSPP standard for MSPP issuer networks, and in future years may require an MSPP issuer to meet State network standards, if appropriate and in the best interest of MSP enrollees. Accordingly, we are adopting proposed § 800.109 as final, with no changes; however, we will continue to consider these comments during the MSPP contract negotiations.

Service area (§ 800.110)

In § 800.110, OPM proposed that MSPP issuers comply with the service areas defined by Exchanges, but this does not necessarily require that an MSP be offered in all defined service areas. We also proposed that for each State in which the MSPP issuer does not offer coverage in all service areas, the MSPP issuer's application for participation in the MSPP and the information it submits to support renewal of a contract

must include a plan for offering coverage throughout the State. We sought comment on whether MSPP issuers should be required to offer MSPs in all service areas by the fourth year of participation in the MSPP.

Comments: We received some support for our proposal on service areas from a commenter stating that our policy allows MSPP issuers time to develop the capacity to offer coverage throughout a service area and this will enhance competition. Several commenters were concerned about MSPP issuers' ability to cherry-pick the areas where they offer plans. Some commenters recommended that MSP service and rating areas be aligned to prevent issuers from cherry-picking. Another commenter recommended that MSPs be required to comply with the service area requirements applicable to all other issuers in a State. One commenter recommended that MSPs be required to cover geographic service areas in a particular State where they are licensed if their license is other than statewide, and the commenter also recommended that MSPs should follow the same rules as QHPs, concerning partial rating regions. Finally, several commenters were concerned that our proposed policy may not ensure access in a meaningful way or promote competition.

Response: Similar to our response to comments on § 800.104, we are not prohibiting MSPP issuers from offering coverage in all service areas; on the contrary, we encourage them to do so if they have the capacity. We are clarifying in the final rule that MSPs will be required to comply with the service area requirements applicable to all QHPs in a State. We are not making any additional requirements regarding partial rating regions or geographic service areas in States with certain licensure laws that determine service area. We acknowledge the commenters' concern that issuers may cherry-pick

certain service areas. However, we believe that requiring that MSPs be subject to the same service area requirements as QHPs will create a level playing field and prevent issuers from cherry-picking. In addition, we intend to pay special attention to whether service areas include rural areas and American Indian/Alaska Natives during MSPP contract negotiations. We will evaluate the service area of an MSP to ensure that it has been established without regard to racial, ethnic, language, health status-related factors specified under section 2705(a) of the PHS Act, or other factors that exclude specific high-utilizing, high-cost or medically-underserved populations.

Similar to our changes under § 800.104, we are removing the requirement in the proposed rule that, for each State in which the MSPP issuer does not offer coverage in all service areas, the MSPP issuer would submit a plan on expanding coverage throughout the State. For reasons described in our responses to comments on § 800.104 related to statewide coverage, we intend to encourage MSPP issuers to expand coverage and will assess their capacity to do so through the MSPP contract negotiations.

Accreditation requirement (§ 800.111)

In § 800.111, OPM proposed a requirement that MSPP issuers be or become accredited consistent with the HHS standards for QHP issuers. We also proposed that the MSPP issuer must authorize the accrediting entity to release to OPM and to Exchanges a copy of the MSPP issuer's most recent accreditation survey, along with any survey-related information that OPM or an Exchange may require. OPM also proposed that an 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 in accordance with 45 CFR 155.1045.

Comments: Several commenters recommended that OPM set a timeframe for accreditation that meets the accreditation timeframe set for QHP issuers either participating in Federally-facilitated Exchanges or in State-based Exchanges. Some commenters supported a unique timeline for MSPP issuer accreditation.

Response: OPM intends to follow the timeframe for accreditation in 45 CFR 155.1045 and similar provisions adopted by State-based Exchanges, though we are reserving the authority to set our own timeframe under narrow circumstances that take into account the unique nature of the MSPP. Due to the broad geographic coverage required for the MSPP, MSPP issuers may need additional time to collect data on local performance for accreditation. Similarly, a group of issuers coming together to contract as an MSPP issuer under a common service mark may need additional time to coordinate between accrediting entities or among component plans. Additional time may also be required if a component plan has previously been accredited by an entity other than the accrediting entities recognized by the Secretary. Therefore, in accordance with our authority under 45 CFR 155.1045, we are adopting our proposed approach in the final regulation, with no changes.

Comment: One commenter recommended that the MSPP issuer must have a schedule for a review of policies and procedures with a recognized accrediting agency during that initial year and have documentation that a readiness review for accreditation has been completed.

Response: OPM will consider this comment in creating contract language for MSPP issuers who are obtaining accreditation in accordance with § 800.111(c).

Comment: One commenter asked OPM to clarify how consumers will be educated about the differences between an accredited and unaccredited plan; another commenter requested that accreditation surveys be made public.

Response: Accreditation status of MSPP issuers (as well as all QHP issuers) will be made available to consumers through Exchange systems. No change in the regulation is needed.

Comment: One commenter suggested that to allow a group of independent insurance issuers to jointly offer an MSP, accreditation must be required at the State level rather than at a national level.

Response: MSPP issuers will be accredited on the basis of local performance in accordance with the requirements for QHP issuers specified in section 1311 of the Affordable Care Act and 45 CFR 156.275(a). No change is required in the proposed rule.

Reporting requirements (§ 800.112)

The proposed § 800.112(a) specified that OPM may collect such data and information as are permitted or required by the Affordable Care Act to be collected from an MSPP issuer. OPM has also proposed to collect such other data and information as it determines necessary for the oversight and administration of the MSPP.

OPM will use its FEHBP contract administration as a model for reporting requirements. Examples of reporting that is currently required for FEHBP carriers and that may be required for the MSPP include financial reports, premium payment information, enrollment reporting, and quality assurance information.³ OPM will determine the data and information that MSPP issuers report and the frequency and

³ OPM's Routine Reports and Submissions required for FEHB carriers is available at <http://www.opm.gov/carrier/reports/index.asp>.

process for submitting such reports to be published in future guidance. Reporting of certain types of information is critical for OPM to implement and administer the MSPP. To oversee MSPP contracts, OPM will need to collect certain information to ensure the integrity of the MSPP, to protect enrollees, to prevent fraud and abuse, to monitor quality and quality improvement, and for other purposes.

Comments: Commenters raised several issues with regard to MSPP reporting requirements. Many commenters noted that MSPP issuers should comply with applicable State and Exchange standards.

Response: We note that § 800.115(e) requires MSPP issuers to comply with all Federal and State quality improvement and reporting requirements.

Comments: Many commenters also urged that we coordinate with States on data collection to avoid duplicative efforts. Some also asked us to share data with the public. A couple of commenters stated that OPM should not use a centralized health claims data warehouse for the MSPP, but adopt a decentralized approach.

Response: We agree with commenters that our approach to data collection should be coordinated with States. OPM intends to enter into MOUs with States to streamline data collection and reduce duplicate reporting requirements. This rule does not address specifics of how OPM will collect data, and our method for data collection will be developed in future policy guidance, in consultation with HHS.

Comment: One commenter stated that the MSPP should adopt the pharmacy benefit manager (PBM) transparency standards that OPM has established for the FEHBP, while another commenter opposed such an approach.

Response: PBM transparency standards will be established through the MSPP contract, and we will consider these comments in developing contract language.

Comments: Several commenters urged us to adopt specific data collection requirements, such as annual reports on each health plan, including data on the number of enrollees receiving treatment for drug and alcohol abuse and MSPP issuer definitions of medical necessity and rider policies.

Response: Specific reporting requirements may change from year to year based on the needs of the program. Accordingly, such issues are more appropriately addressed through contract negotiations, rather than this regulation.

Comments: The preamble of the proposed rule also suggested that OPM may collect demographic data. Several commenters supported data collection on demographics. A couple of commenters noted that issuers may not currently collect demographic data and, in some States, demographic data collection could be prohibited by law. One commenter opposed all demographic data collection.

Response: Although we are not finalizing any specific demographic data collection in this rule, our authority to administer MSPP contracts includes collection of demographic data, if we decide to do so in the future. In that event, we will consult with any States that have laws prohibiting collection of demographic data.

Section 800.112(b) specifies quality and quality improvement standards. With respect to quality reporting, under the FEHBP, OPM requires all health plans to report their performance through Healthcare Effectiveness Data and Information Set (HEDIS) metrics and Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys, independent of the source of plan accreditation. This allows for comparison

among plans in a consistent manner. OPM expects to begin with a similar approach to performance measurement in MSPs to facilitate oversight. We expect our approach to evolve as HHS sets forth further guidance on quality reporting standards for QHPs.

Comments: Several commenters supported our proposed approach regarding quality and quality improvement standards. One commenter was concerned that requiring HEDIS reporting, which is proprietary to one accrediting entity, would be an undue burden to other accrediting entities. One commenter recommended that we immediately use the eValue8 quality reporting tool. Another commenter noted that we include measures applicable to children, including specific modules for children with special health care needs across the entire breadth of conditions and domains (preventive care, mental health, and chronic care).

Response: We are adopting in this final regulation our proposed approach to quality and quality improvement standards, because it reflects current FEHBP policies and Federal standards for QHPs. We anticipate that quality reporting standards will evolve over time, and we will consider these comments as the standards develop.

Benefit plan material or information (§ 800.113)

In proposed § 800.20, OPM defined the term “benefit plan material or information” to include 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. As it does in the FEHBP, OPM will review and approve the policy or contract for health insurance coverage. We view oversight of such contractual documents as uniquely within OPM’s responsibilities under section 1334(a)(4) to implement the MSPP in a manner similar to the manner in which we

implement the contracting provisions with respect to carriers under the FEHBP. OPM cannot manage MSPP contracts similarly to FEHBP contracts without the authority to review and revise these documents. See the discussion of § 800.20 for our responses to comments on the definition of “benefit plan material or information.”

Section 800.113(a) states that MSPP issuers must comply with Federal and State laws related to benefit plan material or information. An MSPP issuer must also comply with OPM guidance specifying OPM standards, process, and timeline for approval of benefit plan material or information.

Comments: We received many comments about the proposed policy on compliance with Federal and State law. Several commenters supported the requirement that MSPP issuers comply with both Federal and State laws relating to benefit plan material or information. Several commenters wanted OPM to clarify that State approval of a policy form is a precondition of OPM approval. One commenter wanted OPM to defer to States for approval of policy forms, except where a State’s action or inaction prevents an MSP from being offered on an exchange.

Response: While OPM intends to review and approve policy forms for health insurance coverage, OPM expects MSPP issuers to comply with related State law requirements for form review. Accordingly, an MSPP issuer’s requirement to comply with State law includes the requirement to comply with form review laws. However, State approval of a policy form is not a precondition of OPM approval. OPM expects that few disagreements will arise between OPM and a State regarding form review and, if they do, we will work with the State to successfully resolve the discrepancy in a manner that is acceptable to both OPM and the particular State.

Proposed § 800.113(b) states that all MSP enrollee notices must meet minimum access standards for individuals with limited English proficiency (LEP) and for individuals with disabilities as described in 45 CFR 155.205(c). As stated in the final Exchange rule, HHS intends to issue further guidance on minimum standards to address language access and coordinate HHS accessibility standards with insurance affordability programs, and across HHS programs, as appropriate. OPM expects MSPP issuers to comply with these minimum access standards once HHS publishes this guidance. OPM may also establish additional standards for MSPP applications and notices.

Comments: Several commenters wanted OPM to clarify that obligations to provide materials in different languages be calculated by State or service area, not nationwide. Two commenters wanted us to provide clearer guidance on our language access policies. They suggested that, to start with, OPM clarify that LEP guidance set forth by HHS' Office of Civil Rights, which is referenced in footnote 48 of the HHS proposed rule with respect to appeals, will also apply to other benefit material or information.

Response: Such guidance will be addressed through the contract negotiation process.

Section 800.113(c) states that an MSPP issuer is responsible for the accuracy of its benefit plan material or information. Section 800.113(d) states that benefit plan material or information must also be in plain language, be truthful, not be misleading, and have no material omissions.

QHPs must comply with the provisions of section 2715 of the PHS Act and its implementing regulations at 45 CFR 147.200 on Summary of Benefit and Coverage and

Uniform Glossary requirements. Under § 800.113(e), OPM also will require MSPs to comply with the statute and regulations. Additionally, OPM expects that MSPP issuers will meet any requirements that allow standardized benefit information to be displayed on HHS or Exchange web portals.

Section 800.113(f) states that OPM will review and approve certain benefit plan material or information as defined in § 800.20 of the proposed regulation. OPM may not necessarily review all benefit plan material or information. It may request from MSPP issuers those materials that it wishes to review and approve. OPM's review will focus on the MSPP issuer's compliance with the standards promulgated by OPM with respect to benefit plan material or information.

Comments: One commenter did not want OPM to review and approve benefit plan material or information. One commenter was concerned about the practical difficulties for both issuers and regulators with respect to the dual requirement that OPM review and approve policy forms and that issuers also comply with State requirements. One commenter wanted more clarity on the interplay between Federal and State review. One commenter stated that OPM review of communication materials, and its discussion with States, should be concluded no later than 90 days prior to the beginning of the annual enrollment period.

Response: OPM cannot entirely cede responsibility for the review of benefit plan material or information since such review is important to oversight. Nonetheless, in order to avoid unnecessary duplication and burden, OPM will work with States concerning the review of benefit plan material or information and may work with States

to define respective roles through MOUs. OPM will also aim for prompt review of benefit plan material or information.

Section 800.113(g) states that OPM will allow an MSPP issuer to state that OPM has certified a plan as an MSP and will oversee its administration. OPM is aware that many States have adopted laws or regulations prohibiting issuers from using advertisements that “may lead the public to believe that the advertised coverages are somehow provided by or endorsed by [a] governmental agenc[y].”⁴ However, because OPM will have certified an MSPP issuer and an MSP as meeting certain standards, potential issuers may wish to include this fact in materials they distribute to the public subject to review by OPM. OPM does not view this as a violation of State law anti-endorsement provisions because it is not misleading, but rather a recitation of the fact that the issuer is providing coverage pursuant to a contract with OPM.

Comment: One commenter did not want MSPP issuers to include a statement on certification by OPM.

Response: For the reasons set forth above, we are adopting the proposed policy regarding statement of certification.

Comments: Several commenters stated that it is critical that the information about the special protections for American Indians/Alaska Natives be clearly stated in all plan materials so that they are informed about the cost-sharing plan variations that may apply to them so they can enroll in the correct plan. The commenters also stated that American Indians/Alaska Natives should know whether a plan network includes their I/T/U provider.

⁴ These State law prohibitions derive from the NAIC’s Advertisements of Accident and Sickness Insurance Model Regulation § 13.C. (Apr. 1999).

Response: We acknowledge that certain American Indians/Alaska Natives should be made aware of special protections and whether a plan includes I/T/U providers. We encourage MSPP issuers to make this information available to MSPP plan participants. We will continue to work with CMS and the Indian Health Service to make sure American Indians/Alaska Natives are informed about the cost-sharing plan variations.

Because no changes are required based on the comments received, OPM is adopting proposed § 800.113 as final, with no changes.

Compliance with applicable State law (§ 800.114)

As proposed, § 800.114 would require MSPP issuers generally to comply with State law. Paragraph (a) of the proposed regulation restated the requirement set forth in section 1334(b)(2) of the Affordable Care Act, including the three categories of State laws with which MSPP issuers need not comply: (1) State laws that are inconsistent with section 1334; (2) State laws that prevent the application of a requirement of part A of title XXVII of the PHS Act; and (3) State laws that prevent the application of a requirement of title I of the Affordable Care Act. We have made a technical edit in paragraph (a) to make it more consistent with § 800.116.

In paragraph (b) of proposed § 800.114, we provided greater detail on the methods OPM would use to determine whether a State law fits into one of the above categories. Specifically, we proposed that OPM would use a list of four factors: (1) whether the law in question imposes a requirement that differs from those applicable to QHPs and QHP issuers on one or more Exchanges in the State; (2) whether the law creates responsibilities, administrative burdens, or costs that would significantly deter or impede the MSPP issuer from offering a viable product on one or more Exchanges; (3)

whether the law creates responsibilities, administrative burdens, or costs that significantly deter or impede OPM’s effective implementation of the MSPP; or (4) whether the law prevents an MSPP issuer from offering an MSP on one or more Exchanges in the State.

Comments: Many commenters found the factors listed in paragraph (b) to be too broad and vague. A few commenters noted that paragraph (b)(1) compares MSP requirements to QHP requirements, whereas (b)(2) appears to lack an analog against which to measure responsibilities, administrative burdens, or costs that apply to MSPs and MSPP issuers. A few commenters expressed specific concern about the use of the words “significantly deter or impede” in paragraphs (b)(2) and (b)(3). A few commenters requested that the word “unreasonable” be added to paragraph (b)(2) to modify “responsibilities, administrative burdens, or costs.” A few commenters generally opposed OPM’s authority to find that a State law is inconsistent with Federal law, and one commenter questioned OPM’s legal authority to preempt State law through a determination of inconsistency.

Response: At proposed § 800.114(a), we listed the justifications for nonapplicability of a State law to the MSPP, as set forth at section 1334(b)(2) of the Affordable Care Act, which provides that an MSPP issuer must be “subject to all requirements of State law not inconsistent with this section, 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 [PHS] Act, or a requirement of this title [I of the Affordable Care Act.]” In proposed paragraph (b), we listed factors that may inform OPM’s analysis under paragraph (a). Although these listed elements would be considered relevant to the analysis, OPM would only be authorized to excuse an MSPP issuer from compliance with

a State law that is inconsistent with section 1334 of the Affordable Care Act, prevents the application of a provision of part A of title XXVII of the PHS Act, or prevents the application of a requirement of title I of the Affordable Care Act.

In light of the concerns expressed concerning the regulatory factors identified in the proposed regulation, we have amended the regulatory text to remove the list of factors. By removing these factors from the regulation, we do not disavow them as relevant considerations in evaluating whether the statutory standard for preemption has been satisfied. Rather, we do not wish to give the impression that they are any more or less important than any other factors that may be relevant in a specific circumstance to a determination of whether a State law should be preempted.

Comment: One commenter recommended that OPM consider the seamlessness of a consumer's experience purchasing health insurance on an Exchange and the avoidance of consumer confusion in evaluating State laws under this section.

Response: We will consider all relevant information, including consumers' experiences in shopping on Exchanges, when determining whether a State law must be preempted under the statutory standards listed in paragraph (a). Each determination under this section will depend on specific facts and circumstances.

Comments: A few commenters recommended that OPM consult with States and Exchanges prior to making a determination of inconsistency under this section.

Response: We agree that OPM should work collaboratively with States, particularly in making determinations regarding State laws. OPM intends to continue to establish and cultivate working relationships with officials in State regulatory agencies and Exchanges. Such relationships may exist informally, or may eventually be reflected

in MOUs, as OPM intends to pursue MOUs with each State in which the MSPs are being offered. In either case, OPM would consult with States during the process of making a determination of inconsistency regarding a State law. We have changed paragraph (b) to state expressly our intention to engage in such consultation.

Comments: Some commenters expect that OPM’s ability to render a determination of inconsistency under this section will create competitive advantages for MSPs over QHPs. A few commenters stated that “double regulation,” by both OPM and each State, will competitively disadvantage MSPs.

Response: We are sensitive to concerns that the MSPP will create disruptions in different markets, and this regulation has been designed to comply with the statutory directives of the Affordable Care Act while minimizing any such disruptions. The proposed rule reflects a balanced approach under which an MSPP issuer will comply with all State laws except any with respect to which OPM has determined that such State law is contrary to Federal law. This approach will keep each MSP in relative balance with QHPs offered on the same Exchange. No evidence has been offered to support the commenters’ assertion that OPM’s reservation and potential exercise of this authority creates a competitive advantage for the MSPs or MSPP issuers.

Moreover, OPM’s proposed framework for MSPP compliance incorporates State law and sets standards and requirements similar to those used successfully under the FEHBP. We designed this regulatory framework to ensure that the program is capable of sufficient flexibility to facilitate its implementation. We intend to employ that flexibility to take any appropriate action to ensure that MSPs are neither unreasonably competitively advantaged nor disadvantaged.

Comments: Some commenters recommended that we require compliance not only with State law but also with QHP standards set by States and Exchange authorities. A few commenters recommended that OPM require MSPP issuers to enter into contracts with Exchanges that will actively or selectively contract with QHP issuers. One commenter requested clarification that MSPP issuers would be required to comply with technical requirements for QHPs, such as data submission formatting.

Response: As noted in the preamble to the proposed rule, we intend that MSPs and MSPP issuers be subject to all of the same standards and requirements as QHPs and QHP issuers, except where deviations are authorized by law. We look forward to working collaboratively with States to ensure that we are aware of all relevant standards, including those of a technical nature, to ensure that MSPs and MSPP issuers comply with such standards.

Requiring MSPP issuers to enter into a contract with Exchanges would circumvent section 1334(d) of the Affordable Care Act, which vests certification authority for MSPs in OPM rather than Exchanges by providing that MSPs offered under a contract with OPM are deemed to be certified by an Exchange. We consider active or selective contracting models employed by Exchanges to be operational processes rather than QHP standards, and we will not direct MSPP issuers to participate in such processes, consistent with statute.

Comment: One commenter requested clarification that OPM's determination of inconsistency under this section would only apply to MSPs and MSPP issuers in Exchanges in one State, as opposed to throughout all States.

Response: A determination of inconsistency under this section would be limited to the State in which the State law in question exists. OPM recognizes that some State laws are based on model acts, and that several States may employ the same or similar language in State laws. However, we also realize that the facts and circumstances that give rise to a determination of inconsistency may vary from one State to another. OPM will evaluate State laws carefully, and will refer to previous determinations as precedent when determining the applicability of a State law, but will not automatically apply a determination of inconsistency to more than one State law without consulting with the State regulatory agencies and Exchange(s), and thoroughly evaluating the unique facts and circumstances in each State.

Comment: One commenter requested clarification as to whether OPM would conduct independent research or rely on a complaint-driven process to select which State laws may be subject to a determination of inconsistency under this section.

Response: We intend to use all available information to assess the compatibility of State laws with the MSPP, including complaints from enrollees, communication with issuers, collaboration with States, and additional research.

Comment: One commenter recommended that OPM adopt a standard for noncompliance with State law where only a “compelling national goal” would justify a finding that a State law does not apply to MSPP issuers.

Response: The standards we have adopted are those set forth in the statute.

Comment: One commenter supported the proposed approach, but requested acknowledgement that OPM would assume responsibility for enforcement of State law with respect to MSPP issuers.

Response: Although we intend to communicate closely with States to ensure compliance with State and Federal laws, OPM is not authorized to assume responsibility for enforcement of State law. The same vehicles available to States to enforce their laws against QHPs would also be available to enforce them against MSPs. As noted above, we look forward to working collaboratively with States to ensure that consumers receive high-quality coverage.

Comment: One commenter supported our proposal, but requested clarification that OPM would decide whether a State law applies, as opposed to an issuer or another party.

Response: As reflected in the proposed regulatory text, we agree that OPM should decide whether a State law meets one of the three standards in paragraph (a). This responsibility flows from the statutory authority granted to OPM by section 1334 of the Affordable Care Act to implement and administer the MSPP.

Comments: A few commenters recommended that Federal Indian law be recognized separately from State law.

Response: The requirement for MSPP issuer compliance with State law set forth in § 800.114 is included in the final regulation to implement section 1334(b)(2) of the Affordable Care Act, which specifies that an MSPP issuer “is 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 27 of the PHS Act or title I of the Affordable Care Act. We acknowledge the unique concerns of I/T/Us, including concerns that involve the interaction of State

law and Federal Indian law, and we intend to address them, to the extent practicable, through contractual terms.

Level playing field (§ 800.115)

In § 800.115, we proposed that an MSPP issuer would comply with Federal and State laws involving guaranteed renewal, rating, preexisting conditions, non-discrimination, quality improvement and reporting, fraud and abuse, licensure, solvency and financial requirements, market conduct, prompt payment, appeals and grievances, privacy and confidentiality, and benefit plan material or information. This section addresses compliance directly involving these areas of law, which are expressly listed at section 1324 of the Affordable Care Act. Section 1324 states that, if an MSP is not subject to a Federal or State law that falls into one of the 13 categories listed, no private health insurance coverage would be subject to such law. We received comments from States, Exchanges, consumer groups, providers and provider groups, pharmaceutical companies, and professional associations.

Comments: A few commenters, while generally supporting OPM's proposed approach, expressed concern that our approaches to rate review, benefit plan material and information, and external review may trigger section 1324 (i.e., that they would cause private insurance plans to be exempt from laws listed in that section).

Response: As explained in the preamble to the proposed rule and in the responses to comments regarding §§ 800.201, 800.501-504, and 800.113, our approach to rate review, benefit plan material or information, and external review would not excuse private health insurance coverage from compliance under section 1324. First, laws

involving rate review do not fall within a category listed in section 1324 of the Affordable Care Act.

Second, our proposed rule explicitly requires MSPP issuers to comply with Federal and State laws related to benefit plan material or information. As set forth in § 800.20, and as discussed in responses to comments regarding that section and § 800.113, the definition of “benefit plan material and information” does not include a policy or contract for health insurance coverage.

Finally, as we indicated in the proposed rule, we believe that our approach to external review is required by section 1334 of the Affordable Care Act and does not trigger the level playing field provisions of section 1324 because our approach will comply with external review requirements.

Specifically, we believe our approach to external review is required by section 1334(a)(4), which directs OPM to implement the MSPP in a manner similar to the manner in which we implement the contracting provisions with respect to carriers under the FEHBP. External review is part of the contracting process. Through the external review process, matters of contract coverage are resolved.

As noted in the proposed rule, section 2719 of the PHS Act and its implementing regulations apply to all non-grandfathered group health plans and health insurance issuers, including MSPP issuers, with respect to internal claims and appeals and external review. We understand that the Departments of HHS, Labor, and the Treasury (the tri-Departments) intend to amend those regulations at 45 CFR 147.136 to clarify that the MSPP external review process is governed by section 2719(b)(2)(B). Under section 2719(b)(2), the external review requirements that must be met are established by the tri-

Departments, which have made the judgment that the external review process adopted in this rule satisfies the requirements under that section. Thus, the level playing field provisions of section 1324 of the Affordable Care Act would not be triggered because MSPs and MSPP issuers would comply with the external review requirements in section 2719(b) of the PHS Act, just as other health insurance issuers in the group and individual markets are required to do. As noted in the “Dates” section of this notice of final rulemaking, rulemaking by the tri-Departments interpreting section 2719 in this manner has not yet been completed. We are making the provisions of this regulation on external review effective on the date that such tri-Department regulations become effective.

In addition, our approach to external review does not afford the MSPs any competitive advantage. Although OPM – instead of the States – will administer the external review process for MSPs, that process provides for application of the standards and requirements with which other issuers must comply under section 2719(b)(2) of the PHS Act. Thus, MSPs will in fact be subject to, and comply with, the same law on external review as other issuers.

No commenter identified any State external review law that imposes higher standards than does the Federal external review law proposed for the MSPP. Based on our experience with the disputed claims process under the FEHBP, we believe that our external review process is comparable to any State external review process. We look forward to working collaboratively with States to ensure that our external review process is no less protective than the most protective State standards.

Comment: One commenter recommended the expansion of the scope of “licensure” under this section.

Response: We recognize that licensure laws in some States may impose varying requirements on health insurance issuers. Compliance with a broader range of State laws that may be conditions of licensure would be required under § 800.114 of this regulation, subject to the exceptions listed there. However, for purposes of analysis under this section, an MSPP issuer complies with laws “relating to” licensure by being licensed in each State in which the issuer offers an MSP.

Comment: One commenter requested clarification as to whether the inverse of section 1324 would also be required, i.e., whether the other private health insurance coverage in a State would be subject to a State law to which an MSP is subject.

Response: States typically regulate health insurance markets, and the MSPs will operate within those markets. As set forth in § 800.114, MSPs and MSPP issuers generally are subject to the same laws to which the rest of the health insurance market is subject.

Comments: A few commenters expressed concern that OPM would prompt a “race to the bottom” by circumventing, through the MSPP, consumer protections provided by State laws.

Response: The MSPP will promote uniformly high standards for MSPs to be made available to consumers. As noted in the proposed rule, we will deviate from State standards only when the standards are inconsistent with the implementation of OPM’s statutory directive to implement this program. Like plans offered through the FEHBP, MSPs will be high-quality products that are subject to the experienced oversight of OPM.

We are adopting proposed § 800.115 as final, with no changes.

Process for dispute resolution (§ 800.116)

In § 800.116, we proposed a process by which a State may request that OPM reconsider a determination under § 800.114 that a State law does not apply to MSPs or MSPP issuers. The proposed process calls for a State to demonstrate that the State law at issue is not inconsistent with section 1334 of the Affordable Care Act, does not prevent the application of a requirement of part A of title XXVII of the PHS Act, and does not prevent the application of a requirement of title I of the Affordable Care Act. This section goes on to set forth the procedural framework for the process, including the form of the request, permissible supporting information and documentation, the timeframe for resolution, and the nature of OPM's written decision as final agency action. Most of the comments we received regarding this section were from States and Exchanges, and a few additional comments were submitted by consumer groups, issuers, and professional organizations.

Comments: A few commenters recommended that this process be conducted by a third party outside of OPM. One commenter suggested that disputes over the applicability of State law be conducted through State administrative and judicial processes.

Response: OPM cannot cede authority to make these determinations to an outside entity, because Congress directed OPM to implement and administer the MSPP.

The process outlined in this section offers a formal route to seek resolution of a complaint without having to initiate costly, contentious litigation over the applicability of State laws under the MSPP. Thus, review under this section would be conducted by a different official within OPM than the official who made an initial determination under § 800.114. Similar review is conducted under certain circumstances in the FEHBP when a

dispute arises between OPM and a carrier. OPM's experience with such review has shown that it is an effective means of resolving disputes.

Comments: One commenter requested a shorter timeframe than the 60 days proposed in paragraph (c)(3). Another commenter recommended that OPM ensure the resolution of all potential disputes involving a State's law prior to an MSP being offered on an Exchange within that State.

Response: Sixty days is an appropriate period within which written decisions must be issued, but we intend to resolve each dispute under this section as quickly as possible after it arises.

We have attempted, through the provisions of this regulation, to anticipate potential Exchange approaches to substantive standards and requirements. However, we are aware that new State laws may be enacted or QHP standards established subsequent to the promulgation of this regulation. This process is necessitated in part by the evolving nature of health insurance regulation and QHP standards. In addition, we anticipate that any inconsistencies between State laws and section 1334 of the Affordable Care Act may not become apparent until after MSPP operations have begun. We intend to work collaboratively with States to mitigate or avoid any potential disruptions that may result from the ongoing nature of this process.

Comments: A few commenters recommended that a *de novo* review be conducted under this section, that State law applicability be presumed, or that OPM bear the "burden" of demonstrating that a determination of inconsistency is supported.

Response: This process is designed to create an avenue for a State to show that OPM's considered determination under § 800.114 was made in error, which would

present an opportunity to avoid potential litigation that could arise from such a determination. As such, the State is responsible for demonstrating consistency between Federal and State law.

Comments: A few commenters recommended that determinations regarding laws under both §§ 800.114 and 800.115 be subject to the process for dispute resolution under this section. Other commenters requested clarification as to whether the dispute resolution applied to all State laws or only to State laws that do not fit into the list of categories under section 1324(b) of the Affordable Care Act.

Response: We agree that a State should have an opportunity to request reconsideration of a determination of inconsistency regarding any State law and we are revising paragraph (a) accordingly.

Comment: One commenter recommended that the record for judicial review under paragraph (c)(4) include all relevant information, not only the record that was before OPM when a decision was rendered.

Response: The Administrative Procedure Act permits judicial review of final agency action, and limits such review to the record that was before the agency when it took the action being reviewed. This regulation neither restricts nor expands that limitation.

Comments: A few commenters recommended that parties other than States be permitted to seek dispute resolution under this section. One commenter recommended that MSPP issuers bear the burden of demonstrating that State laws should not apply to them.

Response: This process is designed to assist States in working with OPM to prevent and mitigate market disruptions. State health insurance laws are regulatory by nature; the most expert entities to address them are therefore the regulatory agency and/or Exchange charged with their implementation. Regulatory agencies and Exchanges are well-equipped to represent the interests of the issuers with which they work and the consumers they serve.

We are amending paragraph (a) of § 800.116 as indicated above, to reflect that a determination of inconsistency involving any State law may be the subject of the process outlined in this section. We are also making a technical correction in paragraph (b) and inserting a technical amendment in paragraph (c)(3) for greater clarity.

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

General requirements (§ 800.201)

Under § 800.201, OPM proposed a number of standards for setting rates in the MSPP. First, we proposed that OPM would negotiate premiums, as provided in section 1334(a)(4) of the Affordable Care Act, in a similar manner to the way we negotiate with FEHBP carriers each year.

Second, the proposed rule included a provision that required MSPP rates to remain in effect for the 12-month plan year.

Third, OPM proposed to issue rating guidance for the MSPP, similar to the way OPM communicates with FEHBP carriers.

Fourth, we proposed that MSPP issuers comply with standards in HHS guidance for calculating actuarial value (AV), specifically those standards proposed in 45 CFR 156.135.

Fifth, OPM proposed a process for rate setting and review that requires an MSPP issuer to follow State rating standards with respect to rating factors generally applicable in a State. With respect to rate review, OPM's proposal reflected that some States have a prior approval process for rates and the authority to reject rates. Therefore, we proposed to work closely with each State in approving a rate for the MSPs in that State and to consult with that State about patterns in its markets and about other rates that an MSPP issuer might be proposing in that State for non-MSPs. In doing so, MSPP issuers would be required to file rates with a State, but the final decision regarding rates for MSPs would rest with OPM, as required by the statute. As described in proposed § 800.201(e) and (f), with respect to rate review, OPM's rate process and analysis will be transparent to States in which the MSP is operating. MSPP issuers will be 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. OPM proposed that, for States with Effective Rate Review Programs under section 2794 of the PHS Act, the MSPP issuer would comply with the State standards. In addition, OPM proposed that in States where HHS is reviewing rates, HHS would accept the judgment of OPM for MSP rates. Furthermore, MSPP issuers must comply with the reporting and disclosure requirements for all rate justifications to HHS, States, and Exchanges, such as the requirements set forth in 42 CFR 156.210(c). In the event that a State withholds approval of an MSP rate for reasons that OPM determines, in its discretion, to be arbitrary, capricious, or an abuse of discretion, the Act authorizes the Director to make the final decision to approve rates for participation in the MSPP, notwithstanding the absence of State approval.

Finally, OPM proposed that MSPP issuers must comply with section 1312(c)(1) and (2) of the Affordable Care Act and implementing regulations, which provide that a health insurance issuer consider all enrollees in all non-grandfathered health plans in the individual market to be members of a single risk pool and all enrollees in non-grandfathered health plans in the small group market to be members of a single risk pool within a State. With proposed § 800.201(g), OPM clarified that an MSPP issuer must consider MSP enrollees to be members of the same risk pool as all other enrollees of the issuer in non-grandfathered health plans in the individual and small group markets, respectively. OPM received several comments on our general standards related to MSPP rate setting and review policies applicable to an MSPP issuer and related to compliance with sections 2701 and 2794 of the PHS Act.

Comments: Many commenters supported the general rate review approach set out for the MSPP, such as compliance with State rate review processes, single risk pool, calculation of AV, and State-based rating. Most of these commenters were concerned about OPM retaining discretion to negotiate premiums and having final approval of rates. A few commenters noted that there are administrative and judicial remedies available under State law for issuers who believe that rate approval has been withheld for reasons that are “arbitrary, capricious, or an abuse of discretion” and generally a State would be violating its own laws if it were to withhold for reasons that are “arbitrary, capricious, or an abuse of discretion.” The commenters also noted that this standard is broad and asked OPM to narrow its scope. One commenter suggested that if OPM were to bypass these remedies, MSPs would be given an unfair advantage over QHPs and would be violating State law. A few commenters recommended that OPM not reserve discretion in States

with Effective Rate Review Programs. One commenter believed OPM's authority to negotiate rates in section 1334 of the Affordable Care Act is constrained by sections 1324 and 1252.

Response: Based on support from some commenters on our proposed approach, we are adopting this section as final, with modifications. Section 1334(a)(4) of the Affordable Care Act explicitly authorizes the Director to make the final decision to approve rates for participation in the MSPP, notwithstanding the existence or absence of State approval. We are fully aware of the complexities of rate review in 2014 and subsequent years, and we intend to collaborate closely with HHS and States on MSP rates. We agree with comments that MSPP issuers should use the remedies available under State laws related to rate review decisions. OPM will require MSPP issuers to allow the rate review process in States, including administrative and judicial remedies, to proceed unless the timeline for administration of the MSPP is threatened. In order to give MSPP issuers adequate time to prepare for open enrollment periods, we maintain our discretion to issue final decisions on MSP rates. For this reason, we are revising § 800.201(f) to clarify that OPM would exercise its discretion only in the event that the State's action would impede the Federal objective by preventing OPM from operating the MSPP. In addition, we are removing from the final regulation the "arbitrary, capricious, or an abuse of discretion" language, based on the comments we received. We expect that the Director will rarely, if ever, have to exercise this authority to disapprove or approve MSP rates over the approval or non-approval of a State.

We disagree with the interpretation that sections 1324 and 1252 constrain OPM's authority to negotiate premiums. Were we to interpret these sections in the manner

suggested by the commenter, section 1334(a)(4) of the Affordable Care Act, which requires the Director to “negotiate[.]...with each multi-state plan...the premiums to be charged,” would be rendered inoperative. Section 1324(b)(2) refers to “rating.” OPM has defined “rating” for purposes of section 1324(b)(2) to require compliance with the rating factors permitted by the PHS Act as detailed in § 800.202. Rating factors refer to the factors issuers must use to develop their premiums. With regard to the MSPP, we do not consider “rating” to be the same as “rate review.” Rate review is a broader concept and is a necessary component of premium negotiation. As mentioned above, we intend to conduct our own process to review rates, and each State will have the opportunity to review the MSP rates under its own procedures. We intend to work cooperatively with the States, and have coordinated our policy with HHS.

In addition, the MSPP will comply with section 1252 of the Affordable Care Act. That section, entitled “Rating Reforms Must Apply Uniformly. . .” requires rating reforms adopted by a State pursuant to title I of the Affordable Care Act to apply uniformly within a market. Rating reforms, again, do not equate to “rate review” processes. Rather, consistent with OPM’s interpretation of “rating” for purposes of section 1324(b)(2), rating reforms refer to reforms that constrain the factors upon which issuers rely to develop their premiums. Section 1252 does not constrain the Director’s power to negotiate rates with MSP issuers under section 1334(a)(4).

Comment: In addition, the same commenter indicated its view that section 1252 constrains network adequacy rules.

Response: OPM does not agree with this comment, as section 1252 is limited in its scope to rating reforms.

Comment: This commenter further indicated that section 1301(a)(2) applies with “equal force” to MSPP issuers.

Response: While OPM acknowledges that QHP standards generally apply to the MSPP, section 1334(c) specifically reserves to the Director the discretion to determine whether QHP rules are satisfied in the context of the MSPP. Therefore, OPM does not agree that section 1301(a)(2) causes QHP rules to apply to MSPP “with equal force,” as they do not apply in the same manner with respect to enforcement.

Comment: One commenter asked OPM to clarify that the single risk pool standard proposed in the rule applies to MSPP issuers’ pools within a State and not across States.

Response: Our intent was for an MSPP issuer to consider all enrollees in an MSP to be in the same risk pool as all enrollees in all other non-grandfathered health plans in the individual market or small group market, respectively, in compliance with section 1312(c) of the Affordable Care Act as well as HHS regulations implementing that section. Consistent with HHS guidance, we affirm that MSPP issuers will pool risk within a State and not across States, but we do not believe a change in the regulatory text is needed.

Comments: Some commenters suggested that OPM establish rules and conditions that will facilitate tribal sponsorship, to allow tribes to perform premium aggregation for individuals to enroll in MSPs.

Response: We are exploring whether potential issuers have the capacity to perform premium aggregation and/or accept aggregated premiums. In the MSPP issuer

application, OPM will ask applicants to indicate whether they have this capacity and will take the applicants' responses into consideration when negotiating contracts.

Rating factors (§ 800.202)

The proposed § 800.202 required MSPP issuers to comply with section 2701 of the PHS Act, as amended by the Affordable Care Act. We proposed in § 800.202(a) that MSPP issuers must comply with requirements setting standards for fair health insurance premiums appearing in HHS regulations. In addition, we proposed that MSPP issuers must follow standards set for rating areas in a State established under any HHS or State regulations implementing section 2701 of the PHS Act. OPM received numerous comments related to rating standards and factors from States, consumer organizations, and issuers.

Comments: Many commenters supported the general approach we proposed that MSPP issuers must comply with Federal standards and more narrow State standards for rating factors. A few commenters asked OPM to clarify the requirement that MSPP issuers use the age curves established under Federal regulations implementing section 2701(a), including that an MSPP issuer must also use any age curve established by a State pursuant to 45 CFR 147.103(e).

Response: We clarify that our intent is for an MSPP issuer to use any age curve established by a State pursuant to 45 CFR 147.103(e). In the event that a State does not establish an age curve, the MSPP issuer would use the standard age curve established by HHS. We are amending proposed § 800.202(c)(2) to reference State-established age curves.

Comments: A few commenters requested that OPM have MSPP issuers comply with PHS Act section 2705 and its implementing regulations on incentives for nondiscriminatory wellness programs in group health plans pursuant to 45 CFR parts 146 and 147, 29 CFR part 2590, and 26 CFR part 54.

Response: We agree with the commenters and their suggestion. Accordingly, we have added a paragraph (f) to § 800.202 to require MSPP issuers offering group health plans to comply with section 2705 of the PHS Act and any implementing Federal or State regulations. We believe this appropriately resolves the concerns of commenters.

Comments: Some commenters urged OPM to clarify how MSPP issuers will define “family” as it applies to coverage and rating. Specifically, commenters recommended OPM coordinate with HHS to ensure that the coverage and rating requirements established by HHS under section 2701 clearly apply to MSPs, adopt broad definitions for minimum categories for family policies, and adopt four types of family coverage categories: individual; two adults; adult plus child(ren); and two-adult with child(ren) or other family composition.

Response: The proposed rule did not require specific standards around categories of family members, and intended to coordinate MSPP standards with HHS standards published at 45 CFR part 147. Therefore, the final rule does not specify the minimum categories of family members that must be rated in a family policy.

However, we encourage MSPs to provide the same benefits for all family compositions, including but not limited to same-sex domestic partners and their children. We note that individuals not eligible for family coverage will be able to purchase individual coverage on a guaranteed issue basis.

While we intend to administer the MSPP in a manner that supports a broad definition of family coverage categories, we are finalizing the proposed provision without a change. We must coordinate our approach in applying rating factors consistent with HHS guidance and State law, and as a result will implement the policy for extending coverage rules so that they apply to a broad definition of family coverage categories through the MSPP contract negotiation process.

Medical loss ratio (§ 800.203)

The proposed rule requires MSPP issuers to attain the medical loss ratio (MLR) in section 2718 of the PHS Act. The proposed rule also codifies section 1334(a)(4) of the Affordable Care Act, which gives OPM the explicit authority to negotiate premiums, profit margins, and an MLR by allowing OPM to set an MSP-specific MLR that is either in the interest of MSP enrollees or conforms to State MLR standards. Failure to attain the MLR could result in intermediate sanctions, which include, but are not limited to, suspension of marketing, decertification in one or more States, or termination of an MSPP issuer's contract.

Comments: Several commenters expressed support for OPM's approach. Commenters supported an MLR calculation that was State-based, rather than nationwide. Commenters also supported pooling MSP and non-MSP experience in MLR calculation.

Response: OPM is retaining in the final rule its approach to have MSPP issuers calculate MLR on a State-by-State basis as well as pool MSP and non-MSP experience within a State.

Comments: Several commenters expressed concern that OPM having authority to set an MSP-specific MLR different from the State or Federal standard could give MSPs an advantage over QHPs.

Response: OPM recognizes the concerns of States and other stakeholders regarding authority to set an MLR standard for the MSPP. However, section 1334(a)(4)(B) of the Affordable Care Act explicitly grants OPM legal authority to negotiate an MLR with each MSP. As a matter of policy, however, OPM does not foresee exercising the authority to set an MSP-specific MLR. If OPM were to consider implementing an MSP-specific MLR, it would only be under extraordinary and rare circumstances, and after consulting with the State.

Comment: A commenter was concerned that OPM may decertify an MSP mid-year for failing to meet the applicable MLR standard.

Response: While OPM has the authority to decertify an MSP at any time, we do not want to disrupt State insurance markets or harm consumers. Decertifying an MSP is one of many compliance actions OPM proposed in the rule. We want to clarify that OPM would only decertify an MSP mid-year under unusual circumstances, such as widespread and repeated failure to comply with the legal or MSPP contractual requirements. Before decertifying an MSP, we would consult with a State and/or HHS, as appropriate, to avoid market disruption and protect consumers. Our approach to compliance actions is discussed in more detail in relation to § 800.404.

Comment: One commenter requested that MSPP issuers pay a rebate in addition to other MLR sanctions.

Response: MSPP issuers, like all health insurance issuers regulated by HHS, are subject to the MLR rebate requirements under the Affordable Care Act, and OPM will not require additional rebates.

Comment: One commenter wants MSPP user fees to qualify for MLR inclusion.

Response: This final rule clarifies in § 800.108 that MSPP user fees will be part of the State-based Exchange or Federally-facilitated Exchange user fee. According to technical guidance document CCIIO 2012—002, released April 20, 2012, by HHS, Exchange user fees are subtracted from premiums in the MLR calculation, as are all other Federal and State regulatory and licensing fees. MSPP user fees, therefore, will not be included in the MLR calculation.

We are adopting § 800.203 of the proposed rule as final, with one technical correction in paragraph (b), relating to the sanctions for not attaining the required medical loss ratio.

Reinsurance, risk corridors, and risk adjustment (§ 800.204)

The proposed § 800.204 would require MSPP issuer participation in the transitional reinsurance program in the individual market, risk adjustment program, and temporary risk corridors program to ensure that all issuers have the same fiscal responsibilities and protections. OPM proposed that MSPP issuers be required to participate in the transitional reinsurance program for the individual market established pursuant to section 1341 of the Affordable Care Act, and comply with HHS standards set forth in 45 CFR part 153 and, if applicable, any State regulations implementing the program. OPM also proposed that an MSPP issuer must participate in the temporary risk corridors program established pursuant to section 1342 of the Affordable Care Act and

comply with 45 CFR part 153, as well as any additional HHS standards implementing the program. Finally, OPM proposed that an MSPP issuer must participate in the risk adjustment program established pursuant to section 1343 of the Affordable Care Act and comply with HHS standards set forth in 45 CFR part 153 and, if applicable, any State standards implementing the program.

Comments: The majority of the comments we received supported OPM's approach to requiring MSPP issuers to participate, like QHP issuers, in the transitional reinsurance program, risk adjustment program, and temporary risk corridors program. States, consumer organizations, and issuers supported the general approach OPM proposed that MSPP issuers must comply with Federal standards and State standards, if applicable, in the administration of the reinsurance program and risk adjustment program. One commenter suggested OPM has legal discretion to allow a church health plan offered through the MSPP to vary premiums to adjust for risk across its enrollees, using risk adjustment criteria related to Medicare Part D and Medicare Advantage plans.

Response: OPM appreciates the comments and is adopting the proposed regulation as final, with two technical corrections. First, in § 800.204(b), we are changing "any applicable Federal or State regulations under that section" to "any applicable Federal regulations under that section" because HHS will be operating the temporary risk corridors program. Second, we are correcting an editorial error in paragraph (c) of § 800.204 by changing "An MSPP issuer must comply with participate in the risk adjustment program established pursuant to section 1343 of the Affordable Care Act" to "An MSPP issuer must comply with section 1343 of the Affordable Care Act".

Finally, we do not agree with the commenter's analysis that OPM would have legal discretion to allow a church health plan offered through the MSPP to vary premiums to adjust for risk across its enrollees, using risk adjustment criteria related to Medicare Part D and Medicare Advantage plans. Therefore, we are not adopting this suggestion.

Subpart D – Application and Contracting Procedures

In subpart D of proposed 45 CFR part 800, OPM set forth proposed processes for accepting and evaluating applications to participate in the MSPP and for executing contracts to offer coverage under the MSPP. In general, these processes were designed based on OPM's experience in the operation of the FEHBP while reflecting the unique aspects of the MSPP, as directed in section 1334 of the Affordable Care Act. Subpart D includes sections relating to an application process, review of applications, MSPP contracting, term of the contract, contract renewal process, and nonrenewal. OPM received both general comments on this subpart and specific comments on several sections. We address first the general comments on the subpart, followed by comments on specific sections within the subpart. Any regulatory changes are noted within the discussion of each section.

Comment: One commenter requested additional information on the application and contracting procedures, including form, manner, and timeline for submission and review of applications, contracting, and renewal of contracts.

Response: OPM has released a final paper application setting forth the information that we will collect from health insurance issuers that apply to become MSPP issuers, available on the Federal Business Opportunities website at www.FBO.gov under

solicitation number OPM35-12-R-0006, Multi-State Plan Program. The final paper application was posted on January 18, 2013. The solicitation notes that OPM expects to begin receiving application material from issuers in February 2013, and instructs issuers to submit a notice of intent to apply to receive access to the MSPP Portal, through which issuers will submit the requested information to OPM electronically.

Due to the generally compressed deadlines for the first year of this program and the first years of operation of many Exchanges, timelines may vary from one year to the next. We therefore will not establish rigid timelines in this regulation, but will evaluate MSPP timelines and address them through guidance. Similarly, we intend to share additional information on initial execution and renewal of contracts through guidance.

Comments: A few commenters recommended that OPM incorporate States and Exchanges into the process of evaluating applicants and negotiating contracts with issuers. Specifically, commenters noted that some Exchanges will employ an “active purchaser” model, whereby QHP certification will depend on a contract between a QHP issuer and the Exchange, and recommended that OPM address this model in its application and contracting procedures. Other commenters voiced concern that the absence of State representation in application and contracting procedures, including evaluation of rate and benefit proposals, would result in inconsistent application of State insurance laws and regulations.

Response: OPM is directed by section 1334 of the Affordable Care Act to enter into contracts with health insurance issuers, and to do so in a manner similar to the manner in which contracting provisions under the FEHBP are implemented. The Affordable Care Act also provides for deemed certification of MSPs by virtue of an

MSPP contract. We acknowledge that States will retain responsibility for the enforcement of their insurance laws and regulations, and we will continue to develop relationships with States' Departments of Insurance and Exchange authorities to collaborate to ensure that MSPs may be offered on Exchanges without creating market disruptions.

Based on the phased expansion provisions of section 1334 of the Affordable Care Act and of § 800.104 of this regulation, we do not expect each MSPP issuer to offer an MSP on each Exchange in 2014. We will communicate with appropriate State officials on an ongoing basis regarding the MSPs that we expect to certify.

Application and contracting procedures (§ 800.301)

In § 800.301, we proposed that a health insurance issuer may submit an application to OPM to participate in the MSPP. We specified that such applications would meet guidelines to be released regarding the form and manner of applications, and the timeline for submission. OPM received a few comments specifically addressing this section.

Comment: One commenter noted the absence of specific timeframes in the proposed regulation and requested that such timeframes allow each State to perform its “traditional role” in regulating health insurance products.

Response: As discussed in greater depth regarding subpart C of this regulation, OPM intends to collaborate with appropriate State officials regarding the review and approval of rates and benefits. We intend to be as flexible as possible to ensure that each State has adequate opportunity to review MSP documentation as appropriate.

Comment: One commenter recommended that OPM ensure that issuers' proprietary information be protected from information requests, including under the Freedom of Information Act (FOIA).

Response: We acknowledge that certain information given to OPM by applicant issuers may be proprietary, and should therefore not be subject to public inspection. Applicants will be given an opportunity to mark submitted information as confidential, pursuant to instructions that will accompany the application in the MSPP Portal, subject to the limits of FOIA and its implementing regulations.

OPM does not believe that any of these comments require any changes in the regulatory text. Therefore, we are adopting proposed § 800.301 as final, with no changes.

Review of applications (§ 800.302)

Proposed § 800.302 provided that an issuer that has applied under § 800.301 may be accepted to enter into contract negotiations if OPM determines that the applicant meets the requirements of part 800; that OPM may request additional information from issuers in making such a determination; that OPM will inform the applicant in writing if OPM declines to enter into contract negotiations with the applicant; that OPM alone may determine whether an application is to be accepted or declined; and that a declined applicant may apply for a subsequent year. OPM received no specific comments on this section. Therefore, we are adopting proposed § 800.302 as final, with no changes.

MSPP contracting (§ 800.303)

In proposed § 800.303, OPM provided that, to become an MSPP issuer, an applicant must execute a contract with OPM; that OPM would establish a standard contract for the MSPP; 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 MSPP issuers would be certified to offer MSP coverage on Exchanges.

Comments: Several commenters recommended that I/T/Us be contractually allowed to participate in MSP networks as providers, and that MSPP issuers comply with Federal laws governing I/T/Us.

Response: OPM will address the specific terms of the MSPP standard contract through a development process following the publication of this final rule. We acknowledge the unique concerns of I/T/Us, and we intend to address them, to the extent practicable, through contractual terms.

Comment: One commenter recommended that OPM adopt for the MSPP the same transparency and pass-through pricing standards and requirements that exist under the FEHBP for PBMs.

Response: As noted above, OPM will address specific contract terms through a process following the publication of this rule. Such terms will include standards and requirements for PBMs.

Comments: A few commenters suggested that OPM's proposed contracting process would be duplicative of State regulatory or Exchange processes or would circumvent such processes. One commenter recommended that MSPP issuers be required to attest to compliance with all State laws as a condition of certification. Another commenter recommended that issuers be required to attest to understanding and compliance with a specific State law as a condition of contracting. One commenter

recommended that MSPP contracts incorporate consultation with State-based Exchanges to measure performance and compliance.

Response: In general, MSPP issuers will be expected to comply with State laws and regulations. Although we intend to monitor such compliance and to evaluate contract performance in part on such compliance, we decline to specifically list State laws with which issuers must comply. Specifically listing laws with which an issuer must comply may have the unintended result of implying that an issuer need not comply with unlisted laws and regulations, and OPM cannot list every relevant State law with which an MSPP issuer must comply.

We intend to promote information sharing between OPM and States, and OPM will measure MSP performance using standards similar to those measured under the FEHBP. Sharing information with States will help ensure that MSPs meet comparable standards to QHPs in the same markets and that issuers comply with State laws. By measuring contract quality assurance standards across MSPs, OPM will be able to ensure that MSPs are of comparably high quality across States. We will set forth the specific standards that MSPs will be expected to meet in the model MSPP contract.

We are adopting proposed § 800.303 as final, with the inclusion of a minor editorial correction.

Term of the contract (§ 800.304)

In § 800.304, we proposed that the term of an MSPP contract be for a period of at least 12 consecutive months, as set forth in the MSPP contract; that a plan year be a consecutive 12-month period during which an MSP provides coverage for health benefits; and that a plan year may be a calendar year or other 12-month period.

Comment: One commenter recommended that the term of the MSPP contract coincide with the calendar year so that MSP plan years and open enrollment periods would coincide with those of QHPs, which would preserve a level playing field.

Response: In § 800.20, we are adopting the definition of “plan year” established by HHS at 45 CFR 155.20. Section 800.101 states that MSPs will comply with the same standards for eligibility, enrollment, and termination of coverage as QHPs on the same Exchange. Open enrollment periods for MSPs, therefore, will coincide with those of QHPs.

Comment: One commenter recommended that OPM adopt an initial contract term of 3 to 5 years, rather than 1 year.

Response: We acknowledge that participation in the MSPP may require significant initial investment on the part of MSPP issuers, and that a longer contract term may assure issuers that such investment may require several years of participation in the program to become cost-effective. OPM has modeled the application and contracting procedures in subpart D after those used in the FEHBP, including the automatically renewable nature of contracts. We anticipate that all MSPP issuers will participate in the program for many contract terms. However, rates and benefits will be revised each year, and some terms of the MSPP contract may need to be updated from one term to the next. Therefore, the contract term will be 1 year.

We are adopting proposed § 800.304 as final, with no changes.

Contract renewal process (§ 800.305)

In proposed § 800.305, we set forth a process by which OPM and an MSPP issuer would renew an MSPP contract, including the issuer’s submission of information to OPM

and criteria for a determination by OPM of whether to renew the contract. This section also provides that if OPM and the issuer fail to agree to premiums and/or benefits with respect to an MSP on an Exchange, the contract may nevertheless be renewed with the same premiums and benefits in effect for the previous term. OPM received no comments directly addressing this section. Therefore, we are adopting proposed § 800.305 as final, with no changes.

Nonrenewal (§ 800.306)

In § 800.306, we proposed that either OPM or an issuer could decline to renew an MSPP contract at the end of a plan year by timely notifying the other party and MSP enrollees.

Comments: Some commenters recommended lengthening the period of notice to enrollees of nonrenewal from 90 days to 180 days.

Response: OPM proposed that issuers would be required to notify enrollees of nonrenewal of an MSPP contract no fewer than 90 days prior to the date on which coverage would end. The proposed 90-day period was taken from the same requirement in the FEHBP. Conversely, Exchanges may have notice periods as short as 30 days. As noted at § 800.306(c), the 90-day requirement would only take effect in the absence of an Exchange rule requiring a different notice period.

Comments: Some commenters recommended that OPM require issuers to assist MSP enrollees who will lose their coverage to find new coverage. One commenter recommended that OPM defer to a determination by the Centers for Medicare and Medicaid Services that a QHP issuer must continue to offer coverage outside of an Exchange.

Response: Enrollment of individuals in QHPs following nonrenewal of an MSPP contract falls outside of the responsibilities set forth at section 1334 of the Affordable Care Act. However, as noted throughout this regulation, we look forward to working collaboratively with States and Exchanges to best serve consumers, including by ensuring cooperation with efforts to assist enrollees who lose MSP coverage.

Comments: A few commenters recommended that OPM clarify the language of paragraph (c) to require issuers to comply with any State law requirements relating to nonrenewal of coverage and withdrawal from an Exchange market.

Response: Proposed § 800.306(c) states that an MSPP issuer must comply with “any requirements imposed by an Exchange with respect to the termination of a QHP . . .” Such requirements would include a State law requirement relating to nonrenewal of coverage or withdrawal from an Exchange market. Therefore, no change to § 800.306 is necessary.

Comment: One commenter noted that § 800.404(d), like § 800.306(c), addresses notice to enrollees who will lose coverage due to an MSP ceasing to be offered on an Exchange, and recommended using the same language in both sections.

Response: We agree that the language should be the same in both sections.

OPM is adopting proposed § 800.306 as final, with one change. Paragraph (c) will be revised as follows, to include a technical, clarifying edit: “The MSPP issuer’s written notice of nonrenewal must be made in accordance with its MSPP contract with OPM. The MSPP 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 was offered, including a requirement to provide advance written notice of

termination to enrollees. If an Exchange does not have requirements about advance written notice of termination to enrollees, the MSPP issuer must inform current MSP enrollees in writing of the nonrenewal of the MSP no later than 90 days prior to termination of coverage, unless OPM determines that good cause justifies less than 90 days' notice.” We will also revise § 800.404(d) to mirror this language.

Subpart E – Compliance

In subpart E of the proposed rule, OPM set forth standards and requirements with which MSPP issuers must comply and a non-exhaustive list of actions OPM may take to enforce provisions of an MSPP contract. Like subpart D, these standards, requirements, and compliance actions have been designed based on OPM’s experience in the operation of the FEHBP, while reflecting the unique aspects of the MSPP, as required by section 1334 of the Affordable Care Act. Subpart E addresses contract performance, contract quality assurance, fraud and abuse, compliance actions, and a process for reconsideration of compliance actions. OPM received both general comments on this subpart and specific comments on several sections. We address first the general comments on this subpart, followed by comments on specific sections within this subpart. Any regulatory changes are noted within the discussion of each individual section.

Commenters on this subpart included States and State Exchange authorities, plan/issuer associations, consumer advocacy organizations, and a public policy advocacy organization. Comments on this subpart generally supported the overall structure of contract compliance under the MSPP, and several offered specific suggestions for improvement. We received one comment regarding cost accounting systems that is outside the scope of this rulemaking.

Comments: Some commenters recommended adding specific requirements, such as network adequacy, to one of the sections of this subpart as a contract performance standard, a contract quality assurance standard, or a basis for a compliance action.

Response: OPM acknowledges the importance of requirements and consumer protections like network adequacy, and addressed network adequacy in § 800.109 of the proposed rule. We have set forth other provisions in this regulation that we intend to enforce through contractual measures and compliance actions; this subpart is structured to provide OPM the authority to do so in a manner similar to the administration of the FEHBP. In particular, § 800.404(a)(1) lists as a cause for OPM to impose a compliance action a failure by the MSPP issuer to meet the requirements of § 800.401(a), which includes any violation of section 1334 of the Affordable Care Act or these regulations. Therefore, a violation of network adequacy standards, or any other MSPP standard or requirement, would constitute cause for a compliance action.

Comments: A few commenters recommended that review of financial resources, records, novation and change of name agreements, and claims processing practices be left solely to States, and that OPM rely on States to communicate findings regarding these matters. One commenter noted States' experience in measurements of these kinds. Another commenter recommended establishing a notice and communication process between OPM and the States and Exchanges to ensure MSPP issuers comply with State laws as well as OPM's standards and requirements.

Response: We acknowledge States' expertise in measuring performance and compliance, and, as noted above in our responses to comments on subpart D, we look forward to working with States to ensure compliance and comparability within States as

well as across States. We also note that OPM has more than 50 years of experience administering the FEHBP, which includes measurement of numerous performance standards, contract quality assurance measures, and compliance actions. Section 1334 of the Affordable Care Act directs OPM to implement this program in a manner similar to the manner in which the contracting provisions of the FEHBP are implemented, which includes the compliance measures set forth in subpart E.

Contract performance (§ 800.401)

In proposed § 800.401, we set forth requirements for MSPP issuers, including that the issuer must comply with section 1334 of the Affordable Care Act and with the provisions of this regulation; that it must meet minimum threshold issuer standards; that it must demonstrate specified prudent business practices; that it must not engage in specified poor business practices; and that OPM may collect an assessment to a performance escrow account. OPM received several comments specifically addressing this section.

Comment: One commenter recommended that these regulations reflect OPM's commitment to the protection of enrollees' private and confidential information. Specifically, the commenter recommended that we require issuers to comply with Fair Information Practice Principles by listing failure to comply with such Principles as a poor business practice.

Response: We appreciate the need to protect private and confidential information in the MSPP. Personally identifiable information (PII) and protected health information (PHI) are protected by the Health Insurance Portability and Accountability Act (HIPAA) and the Privacy Act of 1974, as well as contractual provisions that will mirror those used

under the FEHBP. By ensuring compliance with these laws and provisions, OPM will adequately protect PII and PHI.

Comments: Several commenters recommended adding to the list of “poor business practices” failure to properly pay I/T/Us in compliance with 25 U.S.C. 1621e and the cost-sharing protections under section 1402 of the Affordable Care Act.

Response: The list of “poor business practices” does not include failures to comply with specific laws. This regulation, at § 800.102, addresses compliance with Federal and State laws. Section 800.404(a)(4) permits OPM to impose a compliance action for any violation of law or regulation. We will address compliance more specifically in the terms of MSPP contracts.

Comment: One commenter interpreted the list of “poor business practices” to include innovative payment arrangements or delivery models such as Accountable Care Organizations (ACOs) or Patient-Centered Medical Homes (PCMHs), and recommended that such models not be prohibited.

Response: The list of “poor business practices” does not address health care delivery models. The list includes “[e]ntering into contracts or employment agreements . . . 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 MSPP.” Limitation of communication about medically necessary services to enrollees is not an innovative payment arrangement or delivery model, and is not a feature of an ACO or PCMH.

Comments: A few commenters recommended against requiring issuers to contribute to a performance escrow account. One commenter requested clarification that

OPM's proposal to reserve authority to require MSPP issuers to contribute to a performance escrow account is limited to MSPP issuers, presumably as opposed to QHP issuers; that contributions would be based on premiums rather than a flat fee; that contributions be assessed at the beginning of the year; and that any refunds be remitted to consumers similarly to MLR rebates.

Response: We continue to explore establishing a performance escrow account to use in enforcement of MSPP contracts. OPM may develop more specific policies to begin using such an account no sooner than 2015. We will issue specific guidance on the operations of a performance escrow account well in advance of the date on which it takes effect.

We are adopting proposed § 800.401 as final, with no changes except for minor technical edits.

Contract quality assurance (§ 800.402)

In proposed § 800.402, we set forth general policies and procedures to ensure that MSPP contracts conform to quality standards and requirements, specifically with respect to the issuer's internal controls and performance standards to be set by OPM.

Comment: One commenter recommended that OPM require MSPP issuers to meet and comply with States' quality assurance standards and requirements. The commenter suggested that OPM ensure such compliance by requiring MSPP issuers to contract with each State, in addition to contracting with OPM, or by inserting regulatory text.

Response: As noted throughout our responses to comments, we appreciate the need for coordination with States to ensure that MSPs are comparable to a QHP offered

on the same Exchange. Requiring MSPP issuers to enter into a contract with Exchanges would circumvent section 1334(d) of the Affordable Care Act, which vests certification authority for MSPs in OPM rather than State Exchanges by providing that MSPs offered under a contract with OPM are deemed to be certified by an Exchange. We intend to hold MSPs to performance standards that are comparable to those set for QHPs by States and Exchanges. OPM will establish and enforce these standards through contractual negotiation and compliance.

We are adopting proposed § 800.402 as final, with no changes.

Fraud and abuse (§ 800.403)

In proposed § 800.403, we required MSPP issuers to maintain a program to assess and address vulnerabilities to fraud and abuse, to maintain a system to detect and eliminate fraud and abuse, and to provide certain information to OPM. One commenter specifically addressed this section, requesting further information on the required fraud detection system. We intend to set forth specific standards and requirements for systems to detect and eliminate fraud and abuse in the model MSPP contract. This does not require a change in the proposed rule; therefore, we are adopting § 800.403 of the proposed regulation as final, with no changes.

Compliance actions (§ 800.404)

In § 800.404 of the proposed rule, we set forth the bases for OPM to impose a compliance action; the compliance actions that OPM may impose; the notices that OPM will send to issuers upon imposition of a compliance action; and the notices that issuers must send to enrollees upon imposition of certain compliance actions.

Comment: One commenter noted that mid-year decertification of MSPs may disrupt markets and harm consumers and recommended that OPM clarify that such a compliance action would be used only when it is strictly necessary.

Response: We agree that mid-year decertification creates potential for disruption, and OPM would only terminate or decertify an MSP if, in the discretion of the Director, such action was necessary. However, compliance actions are discretionary, so the regulatory text need not be modified to reflect that those particular compliance actions would not be routinely imposed.

Comment: One commenter recommended using State performance evaluations in reviewing MSP performance and developing processes to communicate with States and Exchanges regarding compliance actions.

Response: As noted above, we look forward to working with States and Exchanges to ensure that MSPs meet appropriate standards within States and across States. Because some compliance actions directly affect Exchange markets, we agree that Exchanges should receive notice of such compliance actions. Specifically, regulatory text will be amended to provide that OPM will notify State and/or Exchange officials when we reduce the service area or areas of an MSP in the State, withdraw certification for an MSP in the State, decline to renew the MSPP contract under which an MSP is offered in the State, or terminate the MSPP contract under which an MSP is offered in the State.

Section 800.404 of the proposed rule is adopted as final, with two changes:

First, the following new paragraph will be added after paragraph (c)(2): “(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.”

Second, pursuant to a comment on subpart D of this regulation, we are inserting language in paragraph (d) of this section to add clarity and to conform to the wording of § 800.306(c), which sets forth a similar notice requirement. The revised paragraph (d) will read as follows: “If OPM terminates an MSPP issuer’s MSPP contract with OPM, or OPM withdraws the MSPP issuer’s certification to offer the MSP on an Exchange, the MSPP issuer 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 was offered, including a requirement to provide advance written notice of termination to enrollees. If an Exchange does not have requirements about advance written notice of termination to enrollees, the MSPP issuer must inform current MSP enrollees in writing of the nonrenewal of the MSP no later than 90 days prior to termination of coverage, unless OPM determines that good cause justifies less than 90 days’ notice.”

Reconsideration of compliance actions (§ 800.405)

In proposed § 800.405, we set forth the right of an MSPP issuer to request reconsideration of the imposition of certain compliance actions, the form and manner of such a request, and OPM’s notice to the issuer of a decision upon reconsideration. One commenter specifically addressed this section, recommending that OPM notify States of requests for reconsideration under this section. As noted above, we intend to communicate extensively with States and Exchanges to ensure that MSPs meet appropriate standards. No change is needed in the wording of proposed § 800.405; therefore, we are adopting it as final, with no changes.

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

In subpart F, we proposed a process by which MSP enrollees (and individuals acting on behalf of enrollees) could seek an internal appeal and external review of an adverse benefit determination. The proposed subpart included sections on general requirements, MSPP issuer internal claims and appeals processes, MSPP issuer internal claims and appeals timeframes and notice of determination, external review, and judicial review. The proposed regulation adopted the standards and timeframes established under section 2719 of the PHS Act, and will be administratively similar to the disputed claims process employed within the FEHBP. By adopting the standards and timeframes applicable to health insurance issuers under the PHS Act, we proposed to provide MSP enrollees with comparable processes to those that will apply to QHPs and other coverage. In particular, the MSPP external review process will include binding final decisions by independent review organizations (IRO) on enrollee disputes that involve medical judgment (including, but not limited to, those based on medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit). The preamble to our proposed rule noted that we intend to issue further guidance explaining the details of these processes.

As indicated in the proposed rule, OPM has considerable experience in resolving disputed claims pursuant to OPM's statutory authority under 5 U.S.C. 8902(j). Claims disputed by FEHBP enrollees, generally governed by 5 CFR 890.105, are first submitted to FEHBP carriers for an internal level of reconsideration, and FEHBP carriers are required to comply with the same timeframes that are contained in section 2719 of the PHS Act. OPM then externally reviews any FEHBP carrier reconsideration decisions

that enrollees submit for OPM's review – including decisions related to medical judgment, as well as decision related to interpretation of contract coverage. This process is central to OPM's contractual oversight of FEHBP carriers, allowing OPM to determine whether the health plan's daily operations are functioning appropriately and whether the plan's benefits are meeting enrollees' needs, which informs the following benefit negotiation cycle. OPM reviews claims efficiently; in 2012, 97 percent of all FEHB disputed claims reviewed by OPM were resolved by OPM within 60 days of being received.

Accordingly, in addition to engaging an independent review organization for final, binding decisions on MSPP claims disputes involving medical judgments, we have designed the external review process for the MSPP to accommodate final, binding decisions by OPM on claims disputes involving interpretation of contract coverage that does not involve medical judgments.

Commenters on this subpart included States, Exchanges, State associations, consumer groups, provider groups, pharmaceutical companies, and plan and issuer groups. Several comments were generally supportive of the proposed approach, whereas some commenters generally preferred specific compliance with each separate State process in each State. Some commenters expressed support for the adoption of the standards and timeframes applicable under section 2719 of the PHS Act. A few commenters recommended specific changes. Below, we address first the general comments on the approach proposed in this subpart, followed by the specific content of each section of the final regulation.

Comments: Some commenters suggested that consumers would be confused by OPM's approach, noting that MSPs in some States would seek an internal appeal or external review by following a different process than a QHP on the same Exchange. A few commenters recommended that notices to enrollees include contact information for Consumer Assistance Programs (CAPs) or Ombudsman offices available to assist consumers in filing appeals.

Response: We believe the proposed process adequately addresses the potential for confusion in several ways. First, MSP issuers must comply with the internal claims and appeals process under 45 CFR 147.136(b). Regarding external review, MSP enrollees would send any request for external review, whether of a determination based on medical judgment or otherwise, to OPM. Some processes may call for resolution of medical judgment determinations separately from, for example, determinations of whether a benefit is covered under a plan. OPM plans to ensure that this process will be explained clearly in plan documents and enrollee notices. Second, the process will be administratively operated based on the existing disputed claims process under the FEHBP. We have operated this process for more than 35 years across the country, alongside health coverage that has been subject to different appeals processes, (for example, separate processes applicable to ERISA plans, commercial insurance products, non-Federal governmental plans, or church plans). OPM has nevertheless guided consumers through the disputed claims process. Finally, we will ensure that notices to enrollees are accessible and meet the standards established under section 2719 of the PHS Act and its implementing regulations.

We agree that notices should include contact information for CAPs and Ombudsman offices. Proposed §§ 800.502 and 800.503 state that MSPP issuers must comply with 45 CFR 147.136(b), which includes the following provision at § 147.136(b)(2)(ii)(E)(4): issuers “must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.”

Comments: Some commenters objected to the proposed process in general, preferring instead that MSP enrollees be limited to the processes available in their State. A few of those commenters suggested that the proposed approach may trigger the “level playing field” provision at section 1324 of the Affordable Care Act, as discussed under § 800.115 of this regulation.

Response: As noted in the preamble to the proposed rule, our primary objectives in establishing the internal appeals and external review processes are to ensure that (1) enrollees have adequate access to review of adverse benefit determinations and (2) OPM collects the information necessary for the enforcement of MSPP contracts and implementation of the program. We consider both objectives integral to the implementation of the MSPP, and therefore required under section 1334 of the Affordable Care Act.

We have addressed the applicability of the “level playing field” provision in our responses to comments relating to § 800.115 of this regulation. As explained in that discussion, our approach to external appeals will not trigger the level playing field

provision because MSPP issuers will be subject to the same rules as other issuers:

Section 2719 of the PHS Act and its implementing regulations.

Comments: A few commenters recommended that OPM require MSPP issuers to comply with our proposed process unless a State's process is more protective, in which case the more protective State provisions would take effect for MSP enrollees.

Response: Our proposed process protects consumers by allowing us to ensure that all MSP enrollees are able to seek review of a broad range of determinations, and that requests for external review are resolved consistently across the States. Although States' appeals processes, in many cases, offer a different approach to consumer protection, we believe that our processes provide a comparable or greater degree of protection, which would apply uniformly across the States for MSP enrollees.

Comments: A few commenters noted that State regulatory agencies often use external review as a means of ascertaining information regarding compliance with laws and regulations, and recommended that we therefore decline to establish a process that would preclude States' collection of such information. Of those commenters, two suggested that States provide OPM with data and information to use for the MSPP, and one requested that OPM develop a process to share information with States and Exchanges to facilitate enforcement of State laws and standards.

Response: As noted above, OPM intends to use these processes to monitor and enforce MSPP contracts. We consider our ability to resolve disputes arising under MSPP contracts integral to our implementation of this program. However, we recognize that external review data and information may also be important to State regulatory agencies and Exchanges, and we intend to share information collected through this process, to the

extent that it is legally and operationally feasible, with States and Exchanges. We look forward to working in collaboration with States and Exchanges to ensure that the appropriate information is shared seamlessly.

General requirements (§ 800.501)

In this section, we set forth definitions, and provide that an MSP enrollee or a person acting on behalf of an MSP enrollee may seek review of an adverse determination under this program. We are adopting proposed § 800.501 as final, with no changes.

MSPP issuer internal claims and appeals processes (§ 800.502) and MSPP issuer internal claims and appeals timeframes and notice of determination (§ 800.503)

In § 800.502, we provided that an MSPP issuer must comply with internal claims and appeals processes applicable under 45 CFR 147.136(b). In § 800.503, we provide that an MSPP issuer must comply with notice requirements under 45 CFR 147.136(b) and (e) upon rendering a determination on a claim under § 800.502. We are not making any substantive changes in these sections; however, because they are so closely related, we have decided to combine §§ 800.502 and 800.503 into a single section numbered 800.502, with paragraph (a) of § 800.502 containing the content of proposed § 800.502, and paragraph (b) of § 800.502 containing the content of proposed § 800.503.

External review (§ 800.504)

In § 800.504, we proposed an external review process under which OPM would conduct external review of adverse benefit determinations under the MSPP, enrollees would receive notices pursuant to 45 CFR 147.136(e), and MSPP issuers would be required to pay a claim or provide a service pursuant to a final decision by OPM or an IRO. In the proposed rule, we referred to the State external review process under

standards in paragraph (c)(2) of the appeals regulation, 45 CFR 147.136(c)(2). The standards outlined in paragraph (c)(2), however, expressly apply only to a State external review process, and would be inconsistent with the national approach OPM was proposing. OPM's national approach more appropriately falls under 45 CFR 147.136(d). We therefore wish to clarify that we intended the State external review standards in paragraph (c)(2) to serve as a model for the consumer protections that OPM would incorporate into its proposed external review process. Accordingly, the change in citation from 45 CFR 147.136(c)(2) to 45 CFR 147.136(d) has been made.

Judicial review (§ 800.505)

In proposed § 800.505, we provided that OPM's written decision pursuant to completed external review of an adverse benefit determination would constitute final agency action under the Administrative Procedure Act, and that review of such a decision in the appropriate U.S. district court would be limited to the record that was before OPM when it made its decision. We are adopting proposed § 800.505 as final, with one change, and renumbering it as § 800.504. Although OPM will conduct external review under the MSPP, final decisions on adverse benefit determinations related to medical judgment will be made by IROs, in accordance with section 2719 of the PHS Act. Decisions made by IROs will be final, and OPM will not be responsible for their approval. Such decisions therefore cannot be considered final agency action. The regulation will provide that a decision by an IRO on external review of an adverse benefit determination related to medical judgment will not be considered final agency action.

Subpart G – Miscellaneous

Reservation of authority (§ 800.601)

We received no comment on this section of the proposed rule, which simply provides that OPM reserves the right to implement and supplement its regulations with written operational guidelines. Therefore, we are adopting this section as final, with no changes.

Consumer choice with respect to certain services (§ 800.602)

Section 800.602 of the proposed rule requires that at least one MSP on each Exchange not offer services described at section 1303(b)(1)(B)(i) of the Affordable Care Act. Further, MSPs in States that prohibit these services must comply with State law.

Comments: Several commenters expressed concern that OPM is proposing to preempt State law regarding coverage of services described in section 1303(b)(1)(B)(i) of the Affordable Care Act. Some commenters expressed a preference that at least one MSP in each Exchange be required to provide coverage for these services. In particular, there was concern that, since FEHBP plans do not generally cover services described at section 1303(b)(1)(B)(i), the FEHBP benchmark plan would exclude these services for an MSP. One commenter was concerned that requiring enrollees to make separate payments for these services would be burdensome.

Response: OPM is complying with section 1334(a)(6) of the Affordable Care Act, which directs that at least one of the MSPs in a State not offer services described in section 1303(b)(1)(B)(i). If an MSP is offered in a State that requires coverage of the services described in section 1303(b)(1)(B)(i), OPM will discuss options for compliance with State and Federal laws in contract negotiations with MSPP applicants. Although an FEHBP benchmark would not include services described in section 1303(b)(1)(B)(i), MSPP issuers can include services permitted by law as long as the EHB benefits are

substantially equal. OPM will require MSPs to comply with HHS rules about segregation of funds as described in 45 CFR part 156.

We are adopting as final proposed subpart G, with a technical correction to § 800.602, which included an incorrect reference to the Affordable Care Act provision describing the services in section 1303(b)(1)(B)(i).

Executive Orders 13563 and 12866; Regulatory Review

OPM has examined the impact of this 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 one 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.

The economic impact of this rule may exceed the \$100 million threshold for at least one year; we therefore assess costs and benefits as required by the Executive order.

This rule gives health insurance issuers the opportunity to contract with OPM to offer a product on the Affordable Insurance Exchanges, but does not require those issuers to outlay funds. In 2013, the Congressional Budget Office (CBO) and the Joint Committee on Taxation (JCT) estimated the effects of the Affordable Care Act on nationwide insurance enrollment and on the Federal budget.⁵ CBO and JCT estimated that from 2016 on, between 24 million and 27 million people will receive individually purchased coverage through the Exchanges, and another 3-4 million people will receive employment-based coverage through the Exchanges. In the preamble to the proposed rule, we noted that OPM lacks the information necessary to make assumptions about the potential enrollment penetration for MSPs on the Exchanges. We sought comments on the number of States where MSPs will participate and the influence of current market dynamics on enrollment in MSPs, but received none. As we have not yet begun contract negotiations or closed the application process, we do not have any more information on projected enrollment than we had at the time of the proposed rule. As such, this analysis will continue to largely reflect qualitative analysis, with quantitative analysis where possible.

⁵ Congressional Budget Office, *Effects of the Affordable Care Act on Health Insurance Coverage – February 2013 Baseline*, available at <http://www.cbo.gov/publication/43900> (February 5, 2013)..

One primary benefit of health insurance coverage would be an increase in longevity or health for newly-enrolled individuals. Improved access to health care services has been shown to lead to higher use of preventive services and health improvements, such as reduced hypertension, improved vision and better self-reported health status, as well as better clinical outcomes and lower mortality.^{6,7}

Additional benefits would be generated for newly-enrolled individuals in the form of improved financial security. There is evidence that bankruptcy filings, for instance, decrease in response to increases in Medicaid eligibility.⁸ Furthermore, a 2011 analysis by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) found that most of the uninsured were unable to afford a single hospitalization, because 90 percent of the uninsured reported having total financial assets below \$13,000.⁹ A related benefit would be generated by increased access to non-employment-based health insurance, which can give individuals greater flexibility to take positions that better match their skills or interests.

Expansion of health insurance coverage leads to many benefits, such as improved access to health care and improved financial security for the newly insured. However,

⁶ Brook, Robert H., John E. Ware, William H. Rogers, Emmett B. Keeler, Allyson Ross Davies, Cathy D. Sherbourne, George A. Goldberg, Kathleen N. Lohr, Patricia Camp and Joseph P. Newhouse. *The Effect of Coinsurance on the Health of Adults: Results from the RAND Health Insurance Experiment*. Santa Monica, CA: RAND Corporation, 1984. Finkelstein, A. et al. "The Oregon Health Insurance Experiment: Evidence from the First Year." *NBER Working Paper* No. 17190, July 2011. Doyle, J.J. "Health Insurance, Treatment and Outcomes: Using Auto Accidents and Health Shocks." National Bureau of Economic Research. *NBER Working Paper* No. 11099, February 2005.

⁷ See the regulatory impact analysis developed by HHS for the Exchange Establishment final rule, available at <http://cciio.cms.gov> under "Regulations and Guidance", for a comprehensive overview of the empirical evidence on the benefits of enhanced availability of quality, affordable health insurance, which to great extent applies to the MSPP program and this proposed rule as well.

⁸ Gross, T., Notowidigdo, M. "Health Insurance and the Consumer Bankruptcy Decision: Evidence from Medicaid Expansions." *Journal of Public Economics* 95(7-8): 2011.

⁹ Assistant Secretary for Planning and Evaluation *The Value of Health Insurance: Few of the Uninsured Have Adequate Resources to Pay Potential Hospital Bills*: 2011. Washington DC: US Department of Health and Human Services.

insurance coverage can lead to increased utilization of health services for individuals who become newly insured. While a portion of this increased utilization may be economically inefficient, studies that estimated the effects of Medicare found that the cost of this inefficiency is likely more than offset by the benefit of risk reduction.^{10 11}

Administrative costs of the rule would be generated both within OPM and by issuers deciding to offer MSPs. The costs that MSPP issuers may incur are the same as those of QHPs and, as stated in 45 CFR part 157, 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.

Finally, some of the most notable effects of Exchanges in general, and MSPs in particular, may not be net social costs or benefits, but would instead be transfers between members of society – in particular, decreases in uncompensated care.

OPM lacks data to quantify most of these benefits, costs and transfers. Perhaps most notably, OPM cannot isolate the effects of MSPs from forecasts of the overall effects of the Affordable Care Act coverage provisions. We requested comments on our cost-benefit analysis, but received no comments.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35; see 5 CFR part 1320) requires that 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

¹⁰ Finkelstein, A, McKnight R: “What Did Medicare Do? The Initial Impact of Medicare on Mortality and Out Of Pocket Medical Spending ” Journal of Public Economics 2008, 92:1644-1668.

¹¹ Finkelstein, A., “The Aggregate Effects of Health Insurance: Evidence from the Introduction of Medicare,” National Bureau of Economic Research. Working Paper No. 11619, Sept, 2005.

any collection of information unless it displays a current valid OMB control number. OPM will have several collections from MSPP issuers or applicants seeking to become MSPP issuers, but we have determined that they are exempt from the requirements of the Paperwork Reduction Act. For example, we seek to collect information in connection with the MSPP application process and reporting requirements under § 800.112. We are also requiring issuers to authorize accrediting entities to send documentation to OPM under § 800.111. We are setting up a process under § 800.116 for States to request that OPM reconsider a standard applicable to MSPs or MSPP issuers that does not comply with that State's laws for QHPs. Under § 800.503, MSPP issuers are directed to provide certain written notices, which are third-party disclosures under the Paperwork Reduction Act. These collections would generally be considered reporting requirements under the Paperwork Reduction Act. Moreover, based on responses to the RFI, subsequent conversations with both responding health insurance issuers and other health insurance issuers subsequent to the RFI, and other practical considerations, OPM expects fewer than ten responsible entities to respond to all of the collections noted above. For that reason alone, the collections are exempt from the Paperwork Reduction Act under 44 U.S.C. 3502(3)(A)(i). There may also be other reasons why these collections are exempt from these requirements. We sought comments on these assumptions but received none.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)¹² requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the final rule on small entities, unless the head of the agency can certify that the rule would not have a significant economic impact on a substantial number of small entities. The RFA generally defines a

¹² 5 U.S.C. 601 *et seq.*

“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 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.¹³

OPM does not think that small businesses with annual receipts less than \$7.0 million would likely have sufficient economies of scale to become MSPP issuers or be part of a group of MSPP issuers. Similarly, while the Director must enter into an MSPP 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 MSPP issuers or be part of a group of MSPP issuers.

OPM does not think that these regulations will 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 MSPP contract with at least one non-profit entity, OPM does not think that these regulations will have a

¹³ 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>).

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 these regulations will 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 these regulations will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA)¹⁴ requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or tribal government, in the aggregate, or by the private

¹⁴ Pub. L. 104-4.

sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold is approximately \$150 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.

These regulations do not place any Federal mandates on State, local, or tribal governments, or on the private sector. This final rule would establish the MSPP, a voluntary Federal program that provides health insurance issuers the opportunity to contract with OPM to offer MSPs 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.

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.

These regulations have federalism implications, because they have 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 or MSPP issuer. However, in OPM's view, the federalism implications of these regulations 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 or MSPP issuer.

We received one comment that OPM is not in compliance with Executive Order 13132, because we do not defer to more consumer-protective State standards. However, we respectfully disagree because, as noted throughout this rule, OPM defers to more consumer-protective State standards. Moreover, 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. OPM expects to act in a similar fashion in enforcing the Affordable Care Act requirements. Throughout the process of developing these final regulations, OPM has attempted to balance the States' interests in regulating health insurance issuers, and the statutory requirement to provide two MSPs in all Exchanges in the 50 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 these regulations, OPM certifies that it has complied with the requirements of Executive Order 13132 for the attached regulations in a meaningful and timely manner.

Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, *et seq.*), which specifies that before a rule can take effect, the Federal agency promulgating the rule must submit to each House of Congress and to the Comptroller General a report containing a copy of the rule along with other specified information. In accordance with this requirement, OPM has transmitted this rule to Congress and the Comptroller General for review.

List of Subjects in 5 CFR Part 800

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

U.S. Office of Personnel Management

John Berry,
Director

Accordingly, the U.S. Office of Personnel Management is adding part 800 to title 45, chapter VIII, 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.

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 MSPP 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 MSPP 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.

Authority: Sec. 1334 of Pub. L. 111-148, 124 Stat. 119; Pub. L. 111-152, 124 Stat. 1029.

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 plans 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 Multi-State Plan Program (MSPP) and standards for an enrollee in a multi-State plan (MSP) to appeal denials of payment or services by an MSPP 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 MSPs 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 FEHBP 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 who are affiliated either by common ownership and control or by common use of a nationally licensed service mark (as defined in this paragraph); 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 paragraph).

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 HMO 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 an HMO) 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 or MSP means a health plan that is offered under a contract between OPM and the MSPP issuer pursuant to section 1334 of the Affordable Care Act and that meets the requirements of this part.

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

Multi-State Plan Program issuer or MSPP 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.

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

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

Subpart B – Multi-State Plan Program Issuer Requirements

§ 800.101 General requirements.

An MSPP 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. MSPs and MSPP 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. Ensure that each of its MSPs 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. MSPs and MSPP 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 MSPP, an MSPP 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 MSPP, an MSPP 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 MSPs 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 MSPs, OPM will enter into a contract with at least one non-profit entity as defined in § 800.20 of this part.

(c) Group of issuers. Any contract to offer an MSP 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.

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

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

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

(3) With respect to the third such year, the health insurance issuer will offer the MSP in at least 85 percent of the States; and

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

(b) Partial coverage within a State. OPM may enter into a contract with an MSPP issuer even if the MSPP issuer's MSPs for a State cover fewer than all the service areas specified for that State pursuant to § 800.110. For each State in which the MSPP issuer offers partial coverage, the MSPP issuer must submit a plan for offering coverage throughout the State. OPM will monitor the MSPP issuer's progress in implementing the plan as part of its contract compliance activities under subpart E of this part.

(c) Participation in SHOPS. (1) An MSPP 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 MSPP 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 MSPP 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 MSPP 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) Benefits package. (1) An MSPP issuer must offer a uniform benefits package, including the essential health benefits (EHB) described in section 1302 of the Affordable Care Act, for each MSP within a State.

(2) The benefits package 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 or HHS.

(b) Benefits package options. (1) An MSPP issuer must offer a benefits package, in all States, 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 MSPP must select one of the two benefits package options described in paragraph (b)(1) of this section in its application.

(3) An 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 Program (FEHBP) 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) An MSPP issuer must follow State definitions where the State chooses to specifically define the habilitative services and devices category pursuant to 45 CFR 156.110(f). In the case of any State that chooses not to define this category, if any OPM-selected EHB-benchmark plan lacks coverage of habilitative services and devices, OPM may determine what habilitative service and devices are to be included in that EHB-benchmark plan.

(4) 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 MSPP issuer's benefits package, including its prescription drug list, must be submitted for approval by OPM, which will review a benefits package proposed by an MSPP 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 or 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 assume the cost of such additional benefits by making payments either to the enrollee or on behalf of the enrollee to the MSPP issuer.

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

(a) Cost-sharing limits. For each MSP it offers, an MSPP issuer must ensure that the cost-sharing provisions of the MSP comply 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 it offers, an MSPP 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 MSPP 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 MSPP issuer must offer at least one MSP at the silver level of coverage and at least one MSP at the gold level of coverage on each Exchange in which the issuer is certified to offer an MSP pursuant to a contract with OPM.

(b) Bronze or platinum metal levels of coverage permitted. Pursuant to a contract with OPM, an MSPP issuer may offer one or more MSPs 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 MSPP issuer must offer a child-only plan 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 MSPP 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 MSPP 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 2015, OPM may require an MSPP issuer to pay an assessment or user fee as a condition of participating in the MSPP.

(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 MSPs and MSPP 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 MSPP issuer for the year for the MSP

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 MSPP assessment or user fees. OPM may require an MSPP issuer to make payment of the MSPP assessment or user fee amount directly to OPM, and the MSPP issuer will deduct the MSPP assessment or user fee required under paragraph (a) of this section from the amount for any State-based Exchange or Federally-facilitated Exchange and the MSPP issuer would forward the remainder of the payment to the State or to HHS, as appropriate.

§ 800.109 Network adequacy.

(a) General requirement. An MSPP issuer must ensure that the provider network of each of its MSPs, 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 MSPP issuer must make its provider directory for an MSP 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 MSPP issuer must identify providers that are not accepting new patients.

(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 MSPP issuer must offer an MSP 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 MSPP issuer must obtain OPM's approval for its proposed service areas. Pursuant to § 800.104, OPM may enter into a contract with an MSPP issuer even if the MSPP issuer's MSPs for a State cover fewer than all the service areas specified for that State. MSPs will follow the same standards for service areas for QHPs pursuant to 45 CFR 155.1055. As part of its contract compliance activities under subpart E of this part, OPM will consult with State regulators and the State Exchange to monitor the MSPP issuer's progress expanding coverage statewide and will ensure that MSPs meet QHP requirements in 45 CFR 155.1055(b).

§ 800.111 Accreditation requirement.

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

(b) Release of survey. An MSPP issuer must authorize the accrediting entity that accredits the MSPP 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 MSPP 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 MSPP 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 MSPP. OPM will also specify the form, manner, processes, and frequency for the reporting of data and information. The Director may require that MSPP issuers submit claims payment and enrollment data to facilitate OPM's oversight and administration of the MSPP in a manner similar to the FEHBP.

(b) Quality and quality improvement standards. An MSPP 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 MSPP 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 MSPP 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 MSPP 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 MSPP 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 MSPP 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 MSPP 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 MSPP issuer may include a statement in its benefit plan material or information that:

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

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

§ 800.114 Compliance with applicable State law.

(a) Compliance with State law. An MSPP issuer must, with respect to each of its MSPs, generally comply with State law pursuant to section 1334(b)(2) of the Affordable Care Act. However, the MSPs and MSPP 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 MSPP 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 MSPP issuer must, with respect to each of its MSPs, meet the following requirements in order to ensure a level playing field:

(a) Guaranteed renewal. Guarantee that an enrollee can renew enrollment in an MSP 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;

(h) Solvency and financial requirements. Comply with the solvency standards set by each State in which it offers an MSP;

(i) Market conduct. Comply with the market conduct standards of each State in which it offers an MSP;

(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 162 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 or MSPP issuer of a State law, the State may request that OPM reconsider a determination that an MSP or MSPP 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 MSPP issuer, on a State by State basis, the premiums for each MSP offered by that issuer in that State. Such negotiations may include negotiations about the cost-sharing provisions of an MSP.

(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 MSPP. That guidance will follow State rating standards generally applicable in a State, to the greatest extent practicable.

(d) Calculation of actuarial value. An MSPP 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 MSPP issuer must participate in the rate review process established by OPM to negotiate rates for MSPs. 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 MSPs, an MSPP 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 MSPs' proposed rate increase. If a State withholds approval of an MSP and OPM determines, in its discretion, that the State's action would prevent OPM from operating the MSPP, OPM retains authority to make the final decision to approve rates for participation in the MSPP, notwithstanding the absence of State approval.

(g) Single risk pool. An MSPP issuer must consider all enrollees in an MSP 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, an MSPP 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 MSPP 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 MSPP issuer must use the ratio established by the State in which the MSP is offered, if it is less than 3:1.

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

(2) Age curves. An MSPP 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 must use the rating areas appropriate to the State in which the MSP is offered and established under HHS regulations implementing section 2701(a) of the PHS Act.

(e) Tobacco rating. An MSPP 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 MSPP issuer must comply with any applicable Federal or State laws and regulations implementing section 2702 of the PHS Act.

§ 800.203 Medical loss ratio.

(a) Required medical loss ratio. An MSPP 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 MSPP 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 in one or more States, or terminating an MSPP issuer's contract pursuant to § 800.404.

§ 800.204 Reinsurance, risk corridors, and risk adjustment.

(a) Transitional reinsurance program. An MSPP 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 MSPP 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 MSPP 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 section 6101(b)-(d) of title 41, United States Code, or any other statute requiring competitive bidding, OPM may consider annually applications from health insurance issuers, including groups of health insurance issuers as defined in § 800.20, to participate in the MSPP. If OPM determines that it is not beneficial for the MSPP to consider new applications for an upcoming year, OPM will issue a notice to that effect.

(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 MSPP.

(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 MSPP.

(c) Declination of application. If, after reviewing an application to participate in the MSPP, 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 MSPP is committed to OPM's discretion.

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

§ 800.303 MSPP contracting.

(a) Participation in MSPP. To become an MSPP 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 MSPP.

(c) Premiums. OPM and the applicant will negotiate the premiums for an MSPP 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.

(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 MSPP contract will contain a certification that specifies the Exchanges in which the MSPP issuer is authorized to offer an MSP, as well as the

specific benefit packages authorized to be offered on each Exchange and the premiums to be charged for each benefit package on each Exchange.

(2) An MSPP issuer may not offer an MSP on an Exchange unless its MSPP contract with OPM includes a certification authorizing the MSPP issuer to offer the MSP 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 MSPP 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 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 MSPP, an MSPP 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 MSPP issuer continues to meet the requirements of this part.

(b) OPM decision. Subject to paragraph (c) of this section, OPM will renew the MSPP contract of an MSPP 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 MSPP issuer if:

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

(2) The MSPP issuer has engaged in conduct described in § 800.404(a) of this part; or

(3) OPM determines that the MSPP 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 MSPP issuer has complied with paragraph (a) of this section and OPM and the MSPP issuer fail to agree on premiums and benefits for an MSP 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 on the Exchange or Exchanges for that plan year. In addition, if OPM and the MSPP issuer fail to agree on benefits and premiums for an MSP 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 MSPP contract will be renewed and the existing premiums and benefits for that MSP on that Exchange or Exchanges will remain in effect for the subsequent plan year.

§ 800.306 Nonrenewal.

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

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

(c) MSPP issuer responsibilities. The MSPP issuer's written notice of nonrenewal must be made in accordance with its MSPP contract with OPM. The MSPP 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 was offered, including a requirement to provide advance written notice of termination to enrollees. If an Exchange does not have requirements about advance written notice of termination to enrollees, the MSPP issuer must inform current MSP enrollees in writing of the nonrenewal of the MSP no later than 90 days prior to termination of coverage, unless OPM determines that good cause justifies less than 90 days' notice.

Subpart E – Compliance

§ 800.401 Contract performance.

(a) General. An MSPP issuer must perform an MSPP contract with OPM in accordance with the requirements of section 1334 of the Affordable Care Act and this part. The MSPP issuer must continue to meet such requirements while under an MSPP contract with OPM.

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

(1) It must have, in the judgment of OPM, the financial resources to carry out its obligations under the MSPP;

(2) It must keep such reasonable financial and statistical records, and furnish to OPM such reasonable financial and statistical reports with respect to the MSP or the MSPP, as may be requested by OPM;

(3) It must 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 at such reasonable times and places as may be designated by OPM or the U.S. Government Accountability Office;

(4) It must 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) It must perform the MSPP contract in accordance with prudent business practices, as described in paragraph (c) of this section; and

(6) It must not perform the MSPP contract in accordance with poor business practices, as described in paragraph (d) of this section.

(c) Prudent business practices. 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 MSPP 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 MSPP contract, which includes segregating and pricing MSP 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 MSPP 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 are accurately and fairly disclosed in all reports required by OPM.

(d) Poor business practices. 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 assure that the MSP 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 MSPP. 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 MSPP 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 MSPP contracts conform to the contract's quality requirements.

(b) Internal controls. OPM will periodically evaluate the contractor's system of internal controls under the quality assurance program required by the contract and will acknowledge in writing whether or not the system is consistent 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 MSPP contracts and will inform MSPP 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) MSPP issuers must comply with the performance standards issued under this section.

§ 800.403 Fraud and abuse.

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

(c) Submission of information. An MSPP 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 MSPP 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 MSPP issuer:

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

(2) An MSPP issuer's sustained failure to perform the MSPP 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.

(b) Compliance actions. (1) OPM may impose a compliance action against an MSPP issuer at any time during the contract term if it determines that the MSPP 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 MSPP issuer to offer the MSP on one or more Exchanges;

(vi) Nonrenewal of the MSPP contract; and

(vii) Withdrawal of approval or termination of the MSPP contract.

(c) Notice of compliance action. (1) OPM must notify an MSPP 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 paragraphs (b)(2)(v) through (b)(2)(vii) of this section, such notice must include a statement that the MSPP 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 OPM terminates an MSPP issuer's MSPP contract with OPM, or OPM withdraws the MSPP issuer's certification to offer the MSP on an Exchange, the MSPP issuer 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 was offered, including a requirement to provide advance written notice of termination to enrollees. If an Exchange does not have requirements about advance written notice of termination to enrollees, the MSPP issuer must inform current MSP enrollees in writing of the nonrenewal of the MSP no later than 90 days prior to termination of coverage, unless OPM determines that good cause justifies less than 90 days' notice.

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

§ 800.405 Reconsideration of compliance actions.

(a) Right to request reconsideration. An MSPP issuer may request that OPM reconsider a determination to impose one of the following compliance actions:

- (1) Withdrawal of the certification of the MSPP issuer to offer the MSP on one or more Exchanges;
- (2) Nonrenewal of the MSPP contract; or
- (3) Termination of the MSPP contract.

(b) Request for reconsideration and/or hearing. (1) An MSPP 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 MSPP issuer's receipt of the notice of compliance action. The MSPP issuer may request that OPM's reconsideration allow a representative of the MSPP issuer to appear personally before OPM.

(4) A request under this section must include a detailed statement of the reasons that the MSPP 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 MSPP issuer with a copy of any additional information it obtains and provide an opportunity for the MSPP 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 MSPP issuer, in writing, of OPM's final decision on the MSPP 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 MSPP issuer internal claims and appeals.

(a) Processes. MSPP 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 MSPP 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 MSPP issuer

denies a claim (or a portion of the claim), the enrollee may appeal the adverse benefit determination to the MSPP 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 MSPP 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 MSPP issuers on each Exchange in each State offers at least one MSP 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 may not offer abortion coverage in any State where such coverage of abortion services is prohibited by State law.

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