OFFICE OF PERSONNEL MANAGEMENT

45 CFR Part 800

RIN 3206–AN12

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

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The U.S. Office of Personnel Management (OPM) is issuing a final rule implementing modifications to the Multi-State Plan (MSP) Program based on the experience of the Program to date. OPM established the MSP Program pursuant to the Affordable Care Act. This rule clarifies the approach used to enforce the applicable standards of the Affordable Care Act with respect to health insurance issuers that contract with OPM to offer MSP options; amends MSP standards related to coverage area, benefits, and certain contracting provisions under section 1334 of the Affordable Care Act; and makes non-substantive technical changes.

DATES: Effective March 26, 2015.

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

SUPPLEMENTARY INFORMATION: The Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), together known as the Affordable Care Act, provides for the establishment of Affordable Insurance Exchanges, or ''Exchanges'' (also called Health Insurance Marketplaces, or ''Marketplaces''), where individuals and small businesses can purchase qualified coverage. The Exchanges provide competitive marketplaces for individuals and small employers to compare available private health insurance options based on price, quality, and other factors. The Exchanges enhance competition in the health insurance market, improve choice of affordable health insurance, and give individuals and small businesses purchasing power comparable to that of large businesses. The Multi-State Plan (MSP) Program was created pursuant to section 1334 of the Affordable Care Act to increase competition by offering high-quality health insurance coverage sold in multiple States on the Exchanges. The U.S. Office of Personnel Management (OPM) is issuing this final rule to modify the standards set forth for the MSP Program under 45 CFR Part 800 that was published as a final rule on March 11, 2013 (78 FR 15560). This rule clarifies OPM's intent in administering the Program, as well as makes regulatory changes in order to expand issuer participation and offerings in the Program to meet the goal of increasing competition.

Abbreviations

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

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

In the 2014 plan year, OPM contracted with one group of issuers to offer more than 150 MSP options in 31 States, including the District of Columbia. Approximately 371,000 individuals enrolled in an MSP option in 2014. For plan year 2015, OPM entered into contract with a second group of issuers, and MSP coverage expanded to 36 States. The Program currently offers more than 200 MSP options through the Exchanges to further competition and expand choices available to individuals, families, and small businesses.

This rule builds on the MSP Program final rule published March 11, 2013.[3] Changes to the regulations include clarifications to the process by which OPM administers the MSP Program, pursuant to section 1334 of the Affordable Care Act, and revisions to the standards and requirements applicable to MSP options and MSP issuers.

Summary of Comments

OPM published a proposed rule on November 24, 2014 (79 FR 69802), to modify standards related to the implementation of the MSP Program at part 800 of title 45, Code of Federal Regulations. The comment period for the proposed rule closed December 24, 2014. OPM received 43 comments from a broad range of stakeholders, including States, health insurance issuers, health care provider associations, pharmaceutical companies, and consumer groups.

While most of the comments were related to the proposed modifications addressed in the rule, a small number of the comments were on areas of the regulations for which we did not propose changes or request comment.

A summary of the comments we received follows, along with our responses and changes 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. Comments submitted on sections of the regulations that we did not propose to change are outside the scope of this rulemaking and are not addressed here.

Length of the Comment Period

Comments: Some commenters contended that the 30-day comment period did not provide sufficient time to provide feedback.

Response: OPM values the participation of a broad array of diverse stakeholders. In addition to the proposed rule, we continue to seek input and guidance from numerous stakeholders, including the National Association of Insurance Commissioners (NAIC), States, tribal governments, consumer advocates, health insurance issuers, labor organizations, health care provider associations, and trade groups.

Responses to Comments on the Proposed Regulations

Subpart A—General Provisions and Definitions

Definitions (§ 800.20)

We sought comments on two proposed definitions for the MSP Program. Specifically, we proposed to add the definition for ''Multi-State Plan

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

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

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

option,'' which may also be referred to as ''MSP option.'' We also proposed to remove the definition of ''Multi-State Plan'' because the term ''Multi-State Plan option'' is more precise and avoids the confusion of the varying definitions of the word ''plan'' in the context of health insurance. We also proposed to add a definition for ''State-level issuer'' as a health insurance issuer designated by the MSP issuer to offer an MSP option or MSP options. OPM invited comments on the proposed changes to the definitions under 45 CFR 800.20 as well as any comments on the current definition for ''group of issuers.'' OPM received no comments on the definition of ''State-level issuer,'' and we will adopt the definition as proposed.

Comments: OPM received comments that were generally supportive of adding the proposed definition of ''MSP option.'' One of these commenters asked that we replace ''package of benefits'' with the term ''product'' as it is defined in 45 CFR 144.103. We did not receive comments on removing the definition ''Multi-State Plan.''

Response: OPM will finalize the definition of ''MSP option'' as proposed and will remove ''Multi-State Plan.'' The definition of ''MSP option'' will ensure consistency within the MSP Program and avoid confusion with definitions from programs outside of OPM.

Comments: Commenters responded to our call for feedback on the definition of ''Group of Issuers'' in § 800.20. The commenters were generally opposed to expanding ''Group of Issuers'' to include alternative structures and requested further clarification from OPM. Some commenters were supportive of interpreting the definition of ''Group of Issuers'' to attract additional issuers to the MSP Program.

Response: OPM did not propose any changes to the ''group of issuers'' definition, and we appreciate the comments received. It was OPM's intention in the proposed rule to clarify that a group of issuers may come together in the MSP Program either by common control and ownership or by using a nationally licensed service mark. OPM recognizes there are a number of ways to organize using a nationally licensed service mark, and looks forward to working with current and potential MSP issuers who decide to come together under either one of these two options in the MSP Program.

Subpart B—Multi-State Plan Issuer Requirements

Phased Expansion, etc. (§ 800.104)

Section 1334(e) of the Affordable Care Act provides for OPM to allow issuers to phase in their participation in the MSP Program. Under § 800.104(a), OPM requested comment on how we may expand participation in the Program to meet the goal of increasing competition while balancing consumers' needs. Specifically, we asked for comment on the timeframes and other appropriate parameters within which an MSP issuer could reasonably expand participation in the Program. We did not propose any changes to the regulatory text for § 800.104(a). In clarifying the status of the Program and how we are implementing the standards set under § 800.104, we proposed to delete the standard for an MSP issuer to submit a plan to become statewide in § 800.104(b), and add a requirement that the MSP issuer service area for MSP coverage shall be greater than or equal to any service area proposed by the issuer for QHP coverage. Under § 800.104(c), we solicited comment on when MSP issuers should be required to participate on a Small Business Health Options Program (SHOP). Based on the comments received, the changes to § 800.104(b) will be accepted as proposed.

Comments: Some commenters commended OPM for clarifying § 800.104(a) of the rule and promoting increased flexibility on standards for coverage areas and geographic requirements, as it will attract issuers to the Program and promote competition. Other commenters urged OPM to encourage new and existing MSP issuers to offer plans that are national in scope and coverage.

Response: Through our continued engagement with current and potential MSP issuers, OPM has heard significant concerns about the challenges of rapidly expanding MSP coverage both within and across State lines. OPM agrees that increased flexibility around the schedule to expand to each Exchange in every State will help the MSP Program meet its goal of increasing competition while balancing consumers' needs for coverage. OPM intends to ensure that MSP coverage is available as expansively and as soon as practicable. We work closely with current and potential MSP issuers to address any operational challenges they may face in order to expand MSP coverage nationally or establish reciprocity.

Comments: Some commenters expressed that any potential MSP issuers should be held to the same standards as an MSP issuer who participated in the Program during the first year of operations. These commenters requested OPM set minimum threshold standards for participation, such as timeframes for expanding coverage and minimum standards for coverage areas.

Response: Since the first year of operations for the MSP Program, OPM consistently has applied the same standards to all current and potential MSP issuers, and we will continue to do so going forward. We are not making any changes to the text at this time.

Comment: Commenters disagreed with OPM's interpretation of 1334(b) and (e) stating that neither of the MSP issuers currently under contract with OPM meets the statutory requirements to participate in the Program.

Response: We respectfully disagree with the commenter. Section 1334 sets forth standards to guide the exercise of OPM's contracting authority, noting that section 1334(b)(1) contemplates offering coverage in every State and the District of Columbia, and outlines a framework within which participation in the MSP Program is a feasible and attractive business activity. Such standards include the provisions under subsections (b) and (e) on offering coverage in every State.

Comments: Many commenters supported OPM's proposal to delete the standard for an MSP issuer to submit a plan to become statewide and instead negotiate directly with MSP issuers to expand coverage based on business factors and consumers' needs. Commenters suggested that requiring a specific plan to become statewide may discourage participation in the Program, and flexibility on meeting geographic coverage standards would encourage competition. These commenters also commended OPM on efforts to evaluate MSP issuers' proposed service areas to ensure they are established without discrimination. Other commenters opposed the proposal and sought additional standards.

Response: OPM is committed to statewide coverage, but is sensitive to requirements that may discourage participation in the Program or does not serve the goal of promoting competition on the Exchanges. OPM will assess consumers' needs for coverage, including ensuring that MSP issuers' proposed service areas have been established without regard to racial, ethnic, language, or health status-related factors listed in section 2705(a) of the PHS Act, or other factors that exclude specific high-utilizing, high-cost, or medically underserved populations.

Comments: Commenters opposed the proposed change to the regulatory text to delete a plan for reaching statewide MSP coverage, stating that OPM should establish minimum thresholds for expected MSP coverage areas within a State. The commenter suggested OPM set a standard to require coverage as broadly as the area in which the issuer is licensed to sell coverage in a State, equal to any coverage offered as a Qualified Health Plan (QHP), or alternatively, a percent of population or geographic area. Similarly, other commenters recommended OPM require coverage of 75% of the State's counties or other geographic area.

Response: OPM is committed to a goal of statewide coverage in the MSP Program, and intends to continue working with current and potential MSP issuers to develop productive and ambitious approaches to achieving statewide coverage. OPM believes that our standard for an MSP issuer who offers both MSP options and QHPs to provide an MSP service area that is equal to or greater than the issuer's QHP service area is adequate and reasonable to ensure broad MSP coverage. We appreciate the specific examples of other minimum MSP standards for coverage areas. At this time, we will finalize § 800.104(b) as proposed maintaining the standard of an MSP coverage area to be equal to or greater than the coverage area proposed by the same issuer for their QHP service area.

Some commenters recommended OPM continue to implement SHOP participation standards consistent with standards set by U.S. Department of Health and Human Services (HHS) for a Federally-facilitated SHOP or, where applicable, standards set by State-based Exchanges for SHOP participation requirements that apply to QHP issuers. Other comments suggested that the MSP Program is not mature enough to require MSP issuers to participate in a SHOP at this time.

Response: In light of these comments, OPM intends to continue its flexibility in SHOP participation for MSP issuers in § 800.104(c). MSP issuers must meet the same standards for SHOP participation set for QHP issuers, including the requirements of 45 CFR 156.200(g) and any standards for issuers participating on a State-based SHOP. An MSP issuer may meet the requirements of 45 CFR 156.200(g)(3) if a State-level issuer or any other issuer in the same issuer group affiliated with an MSP issuer provides coverage on a Federally-facilitated SHOP. We discussed this policy in-depth in the March 2013 final rule.[4]

Benefits (§ 800.105)

In § 800.105(b), OPM proposed a change that would allow an MSP issuer to make essential health benefits (EHB)-benchmark selections on a State-by-State basis. The issuer would also be able to offer two or more MSP options in each State. For example, one option could use the State-selected EHB-benchmark, and one could use the OPM-selected EHB-benchmark. OPM proposed this change to allow for more flexibility to attract issuers to the MSP Program with the expectation of expanding competition on the Exchanges. This flexibility could facilitate coalition building across issuers in different States, so that issuers can work together toward MSP options that meet the MSP Program standards.

In § 800.105(c)(3), OPM proposed to clarify the policy on formularies with an OPM-selected EHB-benchmark plan. Under the proposed rule, OPM would allow the MSP issuer to manage formularies around the needs of actual or anticipated enrollees. As part of this proposal, OPM pointed to the current practice in the Federal Employees Health Benefits (FEHB) Program of negotiating formularies and also considered the option of substituting the formulary from the State-selected EHB-benchmark plan. OPM noted that, even with this change, OPM would still ensure compliance with any HHS standards related to drug formularies for QHPs and assurance that the formularies are not discriminatory. OPM also noted that this would allow MSP issuers to propose plans built around the needs of enrollees, subject to approval by OPM.

In the renumbered § 800.105(c)(4), OPM proposed a change to apply a Federal definition of habilitative services and devices, should HHS choose to define the term. In response to comments, in this final rule OPM will revert back to the term we used in our final rule published March 2013, ''habilitative services and devices,'' to ensure consistency with the recently published HHS Notice of Benefit and Payment Parameters for 2016.[5]

In § 800.105(d), OPM did not propose any change to the regulation. However, the preamble noted that OPM also plans to review an MSP issuer's package of benefits for discriminatory benefit design and intends to work closely with States and HHS to identify and investigate any potentially discriminatory or otherwise noncompliant benefit designs in MSP options.

In § 800.105(e), OPM proposed to change ''assume'' to ''defray'' to align with the language in section 1334(c)(2) of the Affordable Care Act.

Comments: We received comments on the proposed changes to § 800.105(b), which describes the EHB-benchmark policy, from a broad range of stakeholders. Some comments opposing the change cited consumer confusion while others raised concerns about an unlevel playing field between MSP issuers and QHP issuers or administrative efficiency. In contrast, other commenters supported the proposed changes, and highlighted the opportunity to increase competition in the MSP Program as well as additional choices for consumers. Commenters also highlighted that the change would allow issuers the flexibility needed to fulfill the goals of the Affordable Care Act.

Response: While we understand the concerns about adverse selection and consumer confusion, we have not seen nor are we aware of any compelling evidence that multiple EHB-benchmarks would cause these issues.

With the opportunity to use substitutions as well as expand benefits beyond the EHB-benchmark or EHB categories, there is already variation among plans available to consumers.

Additionally, under the framework that applied in the first two years of the Program, we were already reviewing MSP options using each State's EHB-benchmark. Even if the OPM-selected EHB-benchmark plan was not used in every State, there may be some administrative efficiency gained in the overlap.

We note that these changes only allow an MSP issuer to propose these types of packages. OPM still retains the authority to approve the package of benefits in § 800.105(d). OPM will scrutinize all proposals for evidence of discriminatory benefit designs and other issues of noncompliance. Keeping potential issues in mind, we are finalizing the changes as proposed in order to increase opportunities for competition in the MSP Program and create the potential for more choices for consumers.

Comments: We also received comments that focused on the need to maintain benefit standards and protections under any approach. These comments highlighted potential issues or vulnerabilities in need of consumer protection and identified key strategies for addressing them.

Response: We appreciate the feedback provided by these stakeholders and will

[4] March 11, 2013 **Federal Register** (78 FR 15560, 15565).

[5] 45 CFR 156.115(a)(5).

take this information under consideration as it relates to our review process. We are not making any further changes to § 800.105(b), but may use the comments to inform MSP Program operations or in drafting Program guidance in the future.

Comments: We received comments on the proposed changes to § 800.105(c)(3) to the formulary requirements with an OPM-selected EHB-benchmark plan from a variety of stakeholders. Commenters were generally supportive, interpreting the changes as OPM prioritizing the review of formularies proposed by MSP issuers.

Other commenters raised concerns about consumer confusion and potential misalignment of medical and drug benefits

Response: We appreciate the broad support from commenters on our proposal as well as their acknowledgement that OPM is prioritizing formulary review. While we understand concerns about the changes to the formulary requirements, including negotiating a formulary or using the formulary from the State-selected EHB-benchmark plan, we do not have any compelling evidence that this would cause consumer confusion or gaps in coverage between medical and drug benefits. OPM intends to use any tools, including the USP category and class count framework, created by HHS to analyze the formulary and inform our negotiations or evaluation of the formulary from the State-selected EHB-benchmark plan. Additionally, we intend to use our discretion in approval of a package of benefits and during any negotiations to identify and remedy gaps between medical and drug benefits. We appreciate the concerns that were raised, but believe we can use the review process to mitigate them, offering more flexibility and consumer choice.

Comments: Commenters asked to ensure that proposed formularies meet the requirements of section 2713 of the PHS Act and are compliant with other applicable standards. Other commenters that was supportive of the change asked for a similar change to be applied to State-selected EHB-benchmark plans.

Response: OPM has already identified in § 800.102 the requirement to comply with part A of title XXVII of the PHS Act and has also identified in § 800.105(d) that OPM approval of a proposed package of benefits, including the formulary, will include a review against standards set by HHS and OPM. For example, this would include the USP category and class count framework and the use of a pharmacy and therapeutics committee for formulary development as it applies to QHP issuers. Based on the comments we received and our analysis, we are finalizing § 800.105(c)(3) with no changes.

Comments: We received comments on the proposed changes to apply a Federal definition of habilitative services from a variety of stakeholders. Some commenters supported the change. Others recommended OPM modify and expand the definition proposed by HHS and requested OPM address habilitative devices or make provisions for specific types of services or devices. Commenters also asked for illustrative lists of habilitative services. Finally, the comments requested that the Federal definition be treated as a Federal floor.

Response: OPM is deferring to HHS on the substance and role of the Federal definition. In keeping with the HHS Notice of Benefit and Payment Parameters for 2016, we are now using the term ''habilitative services and devices'' in order to remain consistent and address the concerns raised by several commenters. We defer to HHS in determining the standards applicable under its definition of habilitative services and devices. It is not OPM's intention to allow the MSP issuer to choose between State and Federal definitions if both exist for a given State. In the finalized version of § 800.105(c)(4), OPM is taking the opportunity to add clarity to the paragraph in explaining when a State definition of habilitative services and devices applies and when a Federal definition applies. In the final § 800.105(c)(4), the Federal definition is set as the floor, consistent with the HHS Notice of Benefit and Payment Parameters for 2016. The State retains the flexibility to apply standards or a definition that does not conflict with the Federal definition. Finally, we continue to reserve authority for OPM to define habilitative services and devices for an OPM-selected EHB-benchmark plan absent a State or Federal definition.

Comments: We received comments on the issue of non-discrimination and OPM's review of MSP options as it relates to § 800.105(d). Commenters generally supported the proposal and asked for OPM to identify examples of discriminatory benefit designs, and one asked OPM to set specific standards for review in the regulation.

Response: OPM identified the requirement to comply with Federal law in § 800.102 and also identified related HHS standards against which MSP issuers and MSP options will be evaluated in § 800.105(d). At this time, we believe we have the authority necessary to apply and modify standards for non-discrimination, updating and adapting our review as we continue to learn about discriminatory benefit designs. In practice, we will align our review for non-discriminatory benefit designs with HHS.

We did not receive any comments on the proposed change to § 800.105(e). Therefore, we are adopting the proposed § 800.105(e) as final.

In § 800.105(c)(1), we are removing the reference to (c)(4) and replacing it with a reference to (c)(5) in § 800.105(c)(1) to correct an internal cross reference.

Assessments and User Fees (§ 800.108)

OPM has authority to collect MSP Program user fees, and continues to preserve its discretion to collect an MSP Program user fee. In the proposed rule, we clarified that OPM may begin collecting the fee as early as plan year 2015. OPM intends to use the MSP assessment or user fee to fund OPM's functions for administration of the Program, including but not limited to entering into contracts with, certifying, recertifying, decertifying, overseeing MSP options and MSP issuers for that plan year, and audits and investigations performed by OPM's Office of Inspector General related to the MSP Program. In the Federally-facilitated Exchanges, OPM is coordinating with HHS regarding the collection of user fees, so that issuers would not be affected operationally. We proposed to revise the regulatory text to allow for flexibility in the process for collecting MSP Program assessments or user fees. We also solicited comments on the process for collecting user fees in the State-based Exchanges and the general use of any fees collected by OPM.

Comments: Some commenters were opposed to the imposition of user fees in State-based Exchanges citing operational challenges in collecting fees.

Response: We have considered the comments received and agree that operational complexities for collecting any user fee from MSP issuers on State-based Exchanges exist. We will not be collecting or imposing user fees on MSP issuers operating on State-based Exchanges in plan year 2016. Therefore, the changes to § 800.108 will be accepted as proposed.

Network Adequacy (§ 800.109)

In § 800.109(b), OPM proposed to codify the requirement that MSP issuers must comply with any additional provider directory standards that may be set by HHS.

Comments: Commenters generally supported the proposed change, noting that incorporating HHS standards for

provider directories would improve the quality of information consumers receive. Some commenters suggested OPM defer to State requirements where they exist.

Response: It has been OPM's intention that an MSP issuer comply with appropriate Federal, and where applicable, State requirements for provider directories. OPM did not intend for the proposed changes to § 800.109(b) to alter that framework. After further consideration of the proposed change to subsection (b), we decided that the proposed language is unnecessary. We are, therefore, removing the proposed addition to subsection (b) from the regulatory text. Again, we intend for MSP issuers to comply with any additional regulations promulgated by HHS for QHP issuers, and where applicable, State requirements for provider directories.

Accreditation (§ 800.111)

In the proposed rule, we proposed to revise the reference to the specific section in the Code of Federal Regulations to 45 CFR 156.275(a)(1) to be more precise. We received no comments on this proposed change, and are finalizing the text as proposed.

Level Playing Field (§ 800.115)

In § 800.115, we proposed to revise the regulatory text to clarify that all areas listed under section 1324(b) of the Affordable Care Act are subject to § 800.114. In addition, we made a technical correction to § 800.115(l) to change a reference to 45 CFR part 162 to 45 CFR part 164. We received no comments on these changes and are finalizing as proposed.

Subpart D—Application and Contracting Procedures

In subpart D of 45 CFR part 800, OPM set forth procedures for processing and evaluating applications from issuers seeking participation in the MSP Program. Subpart D also establishes processes pertaining to executing contracts to offer MSP coverage. In particular, this subpart includes sections that address an application process, review of applications, MSP Program contracting, term of a contract, contract renewal process, and nonrenewal. OPM did not receive any comments pertaining to this subpart, except for § 800.301. We are finalizing Subpart D as proposed.

Application Process (§ 800.301)

In § 800.301, OPM proposed a technical correction that it would consider annual applications from health insurance issuers to participate in the MSP Program. We also specified that an existing MSP issuer could submit a renewal application to OPM annually. This correction is intended to clarify the distinction between new and renewal applications.

Comment: Commenters recommended that renewal applicants should be required to complete a full (not streamlined) application.

Response: Renewal applications require comprehensive and detailed responses to adequately inform OPM about whether to renew its contract with the issuer. OPM has, and will continue to use its experience in the FEHB Program to inform and guide its contracting process with MSP issuers to the extent such experience is applicable to the individual and small group markets within which the MSP Program operates. We are finalizing our proposal.

Subpart E—Compliance

In subpart E of 45 CFR part 800, OPM set forth standards and requirements with which MSP issuers must comply. This subpart also contains a non-exhaustive list of actions OPM may utilize in instances of non-compliance and the process by which OPM may reconsider any compliance actions we decide to take. In particular, this subpart includes sections regarding contract performance, contract quality assurance, fraud and abuse, compliance actions, and reconsideration of compliance actions. OPM did not receive any comments pertaining to this subpart, except for § 800.404. We are finalizing Subpart E as proposed.

Compliance Actions (§ 800.404)

In § 800.404(a)(4), OPM proposed to clarify that we may initiate a compliance action against an MSP issuer for violations of applicable law or the terms of its contract pursuant to OPM's authority under §§ 800.102 and 800.114. In § 800.404(b)(2), OPM clarified that compliance actions may include withdrawal of certification of an MSP option or options. We also added nonrenewal of participation as a compliance action in order to be consistent with the new paragraph under § 800.306(a)(2). In § 800.404(d), OPM clarified that requirements pertaining to notices to enrollees are triggered when one of the following occurs: The MSP Program contract is terminated, OPM withdraws certification of an MSP option, or if a State-level issuer's participation is not renewed.

Comment: Commenters suggested that OPM should establish a Federal standard to ensure a seamless transition for enrollees when a plan is terminated or an enrollee is transferred to another issuer and enrolled in a new plan.

Response: To the extent that the MSP issuer is providing health insurance coverage in a Federally-facilitated Exchange, Federal requirements regarding notice to enrollees must be followed. MSP coverage offered in a State-based Exchange must meet the requirements of that specific State or Exchange to the extent there is no conflict with Federal law. This delineation is consistent with the approach for applicable requirements across the MSP Program. Therefore, we are adopting this section as final, with no changes.

Subpart G—Miscellaneous

In subpart G of 45 CFR part 800, OPM set forth requirements pertaining to coverage and disclosure of non-excepted abortion services and data-sharing with State entities.

Consumer Choice With Respect to Certain Services (§ 800.602)

We proposed adding a new paragraph (c) to § 800.602 that would require an MSP issuer to provide notice of coverage or exclusion of non-excepted abortion services in an MSP option. Under our proposal, an MSP issuer must disclose to consumers prior to enrollment the exclusion of non-excepted abortion services in a State where coverage of such abortion services is permitted by State law. We also proposed that if an MSP issuer provides an MSP option that covers non-excepted abortion services, in addition to an MSP option that excludes coverage, notice of coverage would also need to be provided to consumers prior to enrollment. Finally, OPM reserved the authority to review and approve these MSP notices and materials. OPM requested comments on the form and manner of these disclosures.

Comments: In general, commenters supported the proposed notice requirements. However, commenters expressed concern that consumers would receive notice that an MSP option excludes coverage of non-excepted abortion services only if the MSP option is offered in a State that permits coverage of non-excepted abortion services. Commenters argued that consumers may not know if their State permits coverage of non-excepted abortion services.

Response: We agree that it is in the best interests of consumers for an MSP issuer to provide notice if an MSP option excludes non-excepted abortion services from coverage in every State, not just the States that would permit coverage of such services. We have

amended the regulatory text to reflect this change.

Comments: Commenters also generally supported our proposal that an MSP issuer who offers an MSP option with coverage of non-excepted abortion services must provide notice of coverage of such services to consumers. We proposed that MSP issuers must provide this notice of coverage in a manner consistent with 45 CFR 147.200(a)(3) to meet the requirements of 45 CFR 156.280(f). Commenters offered a variety of suggestions on the form and manner of notices of coverage of non-excepted abortion services.

Response: We believe adding the disclosure and notice requirements will assist consumers in making informed decisions about their coverage options. Consumers should have accurate information on an MSP option's covered benefits, exclusions, and limitations. Therefore, we are finalizing this section as proposed, with changes to improve readability and clarity.

Disclosure of Information (§ 800.603)

OPM proposed this new section to clarify that OPM may use its discretion and authority to disclose information to State entities, including State Departments of Insurance and Exchanges, in order to keep such entities informed about the MSP Program and its issuers.

Comments: Commenters expressed concern that the language in the new section gives OPM but not States discretion to withhold information. Others supported the language in the new section, indicating that it will assist States in being better primary regulators.

Response: This section has been added to the rule to make it easier for States to obtain information from OPM on the MSP Program. This provision does not address disclosure of information from States to OPM, and therefore, this provision does not dictate information that a State may or may not withhold from OPM. We are finalizing this section as proposed.

Executive Orders 13563 and 12866; Regulatory Review

OPM has examined the impact of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993) and Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any 1 year adjusted for inflation). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more in any one year or adversely affect in a material way a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal government or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

OPM will continue to generally operate the MSP Program as it previously had in plan year 2014. The regulatory changes in this final rule are for purposes of policy clarification, and any changes will have minimal impact on the administration of the Program. Administrative costs of the rule are generated both within OPM and by issuers offering MSP options. The costs that MSP issuers may incur are the same as those of QHPs, and as stated in 45 CFR part 156, will include: Accreditation, network adequacy standards, and quality reporting. The costs associated with MSP certification offset the costs that issuers would face were they to be certified by the State, or HHS on behalf of the State, to offer QHPs through the Exchange. For the 2014 plan year, there are approximately 371,000 consumers enrolled in MSP options and with an estimated average monthly premium of $350, premiums collected by MSP issuers for consumers enrolled in MSP options are approximately $1.4 billion this year. While the overall regulation and Program have a significant economic impact, this final rule provides for no substantial changes to the Program and is not economically significant.

We received one comment suggesting that the proposed rule could potentially have an economic impact of $100 million or more per year. The commenter recommended OPM perform a full regulatory impact analysis.

Based on the analysis presented in our proposed rule and acknowledged above, the economic impact of this rule is not expected to exceed the $100 million threshold.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 [6] requires that the U.S. Office of Management and Budget (OMB) approve all collections of information by a Federal agency from the public before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number. OPM is not requiring any additional collections from MSP issuers or applicants seeking to become MSP issuers in this final rule. OPM continues to expect fewer than ten responsible entities to respond to all of the collections noted above. For that reason alone, the existing collections are exempt from the Paperwork Reduction Act.[7]

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) [8] requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of a 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 ''small entity'' as—(1) A proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a not-for-profit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of ''small entity.''

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a proposed rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, small non-profit organizations, and small government jurisdictions. Small businesses are those with sizes below thresholds established by the SBA. With respect to most health insurers, the SBA size standard is $38.5 million in annual receipts.[9] Issuers

[6] 44 U.S.C. chapter 35; see 5 CFR part 1320.

[7] 44 U.S.C. 3502(3)(A)(i).

[8] 5 U.S.C. 601 *et seq.*

[9] According to the SBA size standards, entities with average annual receipts of $38.5 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 July 14, 2014, U.S. Small Business Administration, available at *http://www.sba.gov*).

could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be $32.5 million or less.

OPM does not think that small businesses with annual receipts less than $38.5 million would likely have sufficient economies of scale to become MSP issuers or be part of a group of MSP issuers. Similarly, while the Director must enter into an MSP Program contract with at least one non-profit entity, OPM does not think that small non-profit organizations would likely have sufficient economies of scale to become MSP issuers or be part of a group of MSP issuers. OPM does not think that this final rule would have a significant economic impact on a substantial number of small businesses with annual receipts less than $38.5 million, because there are only a few health insurance issuers that could be considered small businesses. Moreover, while the Director must enter into an MSP contract with at least one non-profit entity, OPM does not think that this final rule would have a significant economic impact on a substantial number of small non-profit organizations, because few health insurance issuers are small non-profit organizations.

OPM incorporates by reference previous analysis by HHS, which provides some insight into the number of health insurance issuers that could be small entities. Based on HHS data from Medical Loss Ratio (MLR) annual report submissions for the 2013 MLR reporting year, approximately 141 out of 500 issuers of health insurance coverage nationwide had total premium revenues of $38.5 million or less.[10] HHS estimates this data may overstate the actual number of small health insurance companies, since 77 percent of these small companies belong to larger holding groups, and many if not all of these small companies are likely to have non-health lines of business that would result in their revenues exceeding $38.5 million. OPM concurs with this HHS analysis, and, thus, does not think that this final rule would have a significant economic impact on a substantial number of small entities.

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

[10] 79 FR 70747.

Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) [11] 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 governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold is approximately $154 million. UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of costs, mainly those ''Federal mandate'' costs resulting from: (1) Imposing enforceable duties on State, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs.

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

Federalism

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have ''substantial direct effects'' on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with State and local officials, and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

This final rule has federalism implications because it has direct effects on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among various levels of government. However, these sections of the regulation were not modified.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the States, OPM has engaged in efforts to consult with and work cooperatively with affected State and local officials, including attending meetings of the NAIC and consulting with State insurance officials on an individual basis. It is expected OPM will continue to act in a similar fashion in enforcing the Affordable Care Act requirements. Throughout the process of administering the MSP Program and developing this final regulation, OPM has attempted to balance the States' interests in regulating health insurance issuers, and the statutory requirement to provide two MSP options in all Exchanges in the each States and the District of Columbia. By doing so, it is OPM's view that it has complied with the requirements of Executive Order 13132.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signature affixed to this final regulation, OPM certifies that it has complied with the requirements of Executive Order 13132 for the attached regulation 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 care, Health insurance, Reporting and recordkeeping requirements.

Office of Personnel Management.

Katherine Archuleta,

Director.

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

[11] Public Law 104–4.

PART 800—MULTI-STATE PLAN PROGRAM

Subpart A—General Provisions and Definitions

Subpart B—Multi-State Plan Program Issuer Requirements

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

Subpart D—Application and Contracting Procedures

Subpart E—Compliance

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

Subpart G—Miscellaneous

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

Subpart A—General Provisions and Definitions

§ 800.10 Basis and scope.

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

(1) *1001.* Amendments to the Public Health Service Act.

(2) *1302.* Essential Health Benefits Requirements.

(3) *1311.* Affordable Choices of Health Benefit Plans.

(4) *1324.* Level Playing Field.

(5) *1334.* Multi-State Plans.

(6) *1341.* Transitional Reinsurance Program for Individual Market in Each State.

(7) *1342.* Establishment of Risk Corridors for Plans in Individual and Small Group Markets.

(8) *1343.* Risk Adjustment.

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

§ 800.20 Definitions.

For purposes of this part:

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

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

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

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

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

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

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

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

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

Group of issuers means:

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

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

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

Health insurance issuer or *issuer* means an insurance company, insurance service, or insurance organization (including a health maintenance organization) that is required to be licensed to engage in the business of insurance in a State and that is subject to State law that regulates insurance (within the meaning of section 514(b)(2) of the Employee Retirement Income Security Act (ERISA)). This term does not include a group health plan as defined in 45 CFR 146.145(a).

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

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

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

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

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

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

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

Non-profit entity means:

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

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

OPM means the United States Office of Personnel Management.

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

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

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

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

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

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

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

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

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

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

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

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

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

Subpart B—Multi-State Plan Program Issuer Requirements

§ 800.101 General requirements.

An MSP issuer must:

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

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

(c) *Required levels of coverage.* Offer levels of coverage as required by § 800.107 of this part;

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

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

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

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

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

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

§ 800.102 Compliance with Federal law.

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

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

§ 800.103 Authority to contract with issuers.

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

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

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

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

§ 800.104 Phased expansion, etc.

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

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

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

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

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

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

that State pursuant to § 800.110 of this part.

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

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

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

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

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

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

§ 800.105 Benefits.

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

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

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

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

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

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

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

(c) *OPM selection of benchmark plans.* (1) The OPM-selected EHB-benchmark plans are the three largest Federal Employees Health Benefits (FEHB) Program plan options, as identified by HHS pursuant to section 1302(b) of the Affordable Care Act, and as supplemented pursuant to paragraphs (c)(2) through (5) of this section.

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

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

(4) An MSP issuer must follow the definition of habilitative services and devices as follows:

(i) An MSP issuer must follow the Federal definitions where HHS specifically defines habilitative services and devices if the State does not define the term, if the State defines the term in a conflicting way, or if the State definition is less stringent than the Federal definition.

(ii) An MSP issuer must follow State definitions where the State specifically defines the habilitative services and devices category pursuant to 45 CFR 156.110(f) and the State definition is not in conflict with the Federal definition or goes above the standards set in the Federal definition.

(iii) In the case of any State that does not define this category and absent a clearly applicable Federal definition, if any OPM-selected EHB-benchmark plan lacks coverage of habilitative services and devices, OPM may determine what habilitative services and devices are to be included in that EHB-benchmark plan.

(5) Any EHB-benchmark plan selected by OPM under paragraph (c)(1) of this section must include, for each State, any State-required benefits enacted before December 31, 2011, that are included in the State's EHB-benchmark plan as described in paragraph (b)(1)(i) of this section, or specific to the market in which the plan is offered.

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

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

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

(a) *Cost-sharing limits.* For each MSP option it offers, an MSP issuer must ensure that the cost-sharing provisions of the MSP option 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 option it offers, an MSP issuer must ensure that an eligible individual receives the benefit of advance payments of premium tax credits under section 36B of the Internal Revenue Code and the cost-sharing reductions under section 1402 of the Affordable Care Act. An MSP issuer must also comply with any applicable standards set by OPM or HHS.

§ 800.107 Levels of coverage.

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

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

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

(d) *Plan variations for the reduction or elimination of cost-sharing.* An MSP

issuer must comply with section 1402 of the Affordable Care Act, as well as any applicable standards set by OPM or HHS.

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

§ 800.108 Assessments and user fees.

(a) *Discretion to charge assessment and user fees.* Beginning in plan year 2015, OPM may require an MSP issuer to pay an assessment or user fee as a condition of participating in the MSP Program.

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

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

§ 800.109 Network adequacy.

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

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

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

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

(b) *Provider directory.* An MSP issuer must make its provider directory for an MSP option available to the Exchange for publication online pursuant to guidance from the Exchange and to potential enrollees in hard copy, upon request. In the provider directory, an MSP issuer must identify providers that are not accepting new patients.

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

§ 800.110 Service area.

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

§ 800.111 Accreditation requirement.

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

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

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

§ 800.112 Reporting requirements.

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

(b) *Quality and quality improvement standards.* An MSP issuer must comply with any standards required by OPM for reporting quality and quality improvement activities, including but not limited to implementation of a quality improvement strategy, disclosure of quality measures to enrollees and prospective enrollees, reporting of pediatric quality measures, and implementation of rating and enrollee satisfaction surveys, which will be similar to standards under section 1311(c)(1)(E), (H), and (I), (c)(3), and (c)(4) of the Affordable Care Act.

§ 800.113 Benefit plan material or information.

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

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

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

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

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

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

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

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

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

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

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

§ 800.114 Compliance with applicable State law.

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

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

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

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

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

§ 800.115 Level playing field.

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

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

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

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

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

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

(f) *Fraud and abuse.* Comply with all Federal and State fraud and abuse laws;

(g) *Licensure.* Be licensed in every State in which it offers an MSP option;

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

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

(j) *Prompt payment.* Comply with applicable State law in negotiating the terms of payment in contracts with its providers and in making payments to claimants and providers;

(k) *Appeals and grievances.* Comply with Federal standards under section 2719 of the PHS Act for appeals and grievances relating to adverse benefit determinations, as described in subpart F of this part;

(l) *Privacy and confidentiality.* Comply with all Federal and State privacy and security laws and requirements, including any standards required by OPM in guidance or contract, which will be similar to the standards contained in 45 CFR part 164 and applicable State law; and

(m) *Benefit plan material or information.* Comply with Federal and State law, including § 800.113 of this part.

§ 800.116 Process for dispute resolution.

(a) *Determinations about applicability of State law under section 1334(b)(2) of the Affordable Care Act.* In the event of a dispute about the applicability to an MSP option or MSP issuer of a State law, the State may request that OPM reconsider a determination that an MSP option or MSP issuer is not subject to such State law.

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

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

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

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

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

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

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

(3) OPM will issue a written decision within 60 calendar days after receiving the written request, or after the due date for a response under paragraph (c)(2) of this section, whichever is later, unless a different timeframe is agreed upon.

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

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

§ 800.201 General requirements.

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

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

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

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

(e) *OPM rate review process.* An MSP issuer must participate in the rate review process established by OPM to negotiate rates for MSP options. The rate review process established by OPM will be similar to the process established by HHS pursuant to section 2794 of the

PHS Act and disclosure and review standards established under 45 CFR part 154.

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

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

§ 800.202 Rating factors.

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

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

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

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

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

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

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

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

§ 800.203 Medical loss ratio.

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

(1) The medical loss ratio (MLR) required under section 2718 of the PHS Act and regulations promulgated by HHS; and

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

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

§ 800.204 Reinsurance, risk corridors, and risk adjustment.

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

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

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

Subpart D—Application and Contracting Procedures

§ 800.301 Application process.

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

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

§ 800.302 Review of applications.

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

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

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

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

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

§ 800.303 MSP Program contracting.

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

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

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

(d) *Package of benefits.* OPM must approve the applicant's package of benefits for its MSP option.

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

(1) Are in the interests of MSP enrollees; or

(2) OPM determines to be appropriate.

(f) Certification to offer health insurance coverage.

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

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

§ 800.304 Term of the contract.

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

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

§ 800.305 Contract renewal process.

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

(b) *OPM decision.* Subject to paragraph (c) of this section, OPM will renew the MSP Program contract of an MSP issuer who timely submits the information described in paragraph (a).

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

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

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

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

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

§ 800.306 Nonrenewal.

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

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

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

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

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

Subpart E—Compliance

§ 800.401 Contract performance.

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

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

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

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

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

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

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

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

(c) *Prudent business practices.* OPM will consider an MSP issuer's specific circumstances and facts in using its discretion to determine compliance with paragraph (b)(5) of this section. For purposes of paragraph (b)(5) of this section, prudent business practices include, but are not limited to, the following:

(1) Timely compliance with OPM instructions and directives;

(2) Legal and ethical business and health care practices;

(3) Compliance with the terms of the MSP Program contract, regulations, and statutes;

(4) Timely and accurate adjudication of claims or rendering of medical services;

(5) Operating a system for accounting for costs incurred under the MSP Program contract, which includes segregating and pricing MSP option medical utilization and allocating indirect and administrative costs in a reasonable and equitable manner;

(6) Maintaining accurate accounting reports of costs incurred in the administration of the MSP Program contract;

(7) Applying performance standards for assuring contract quality as outlined at § 800.402; and

(8) Establishing and maintaining a system of internal controls that provides reasonable assurance that:

(i) The provision and payments of benefits and other expenses comply with legal, regulatory, and contractual guidelines;

(ii) MSP funds, property, and other assets are safeguarded against waste, loss, unauthorized use, or misappropriation; and

(iii) Data is accurately and fairly disclosed in all reports required by OPM.

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

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

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

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

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

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

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

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

§ 800.402 Contract quality assurance.

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

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

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

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

§ 800.403 Fraud and abuse.

(a) *Program required.* An MSP issuer must conduct a program to assess its vulnerability to fraud and abuse as well as to address such vulnerabilities.

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

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

§ 800.404 Compliance actions.

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

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

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

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

(4) Such other violations of law or regulation as OPM may determine, including pursuant to its authority under §§ 800.102 and 800.114.

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

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

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

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

(iii) Performance incentives;

(iv) Reduction of service area or areas;

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

(vi) Nonrenewal of participation

(vii) Nonrenewal of contract; and

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

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

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

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

(d) *Notice to enrollees.* If the contract is terminated, if OPM withdraws certification of an MSP option, or if a

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

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

§ 800.405 Reconsideration of compliance actions.

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

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

(2) Nonrenewal of participation

(3) Nonrenewal of contract; or

(4) Termination of the MSP Program contract.

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

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

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

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

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

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

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

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

§ 800.501 General requirements.

(a) *Definitions.* For purposes of this subpart:

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

(2) *Claim* means a request for:

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

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

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

§ 800.502 MSP issuer internal claims and appeals.

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

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

§ 800.503 External review.

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

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

(c) *Issuer obligation.* An MSP issuer must pay a claim or provide a health-related service or supply pursuant to OPM's final decision or the final decision of an independent review organization without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

§ 800.504 Judicial review.

(a) OPM's written decision under the external review process established under § 800.503(a) of this part 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 of this part, OPM will ensure that at least one of the MSP issuers on each Exchange in each State offers at least one MSP option that does not provide

coverage of services described in section 1303(b)(1)(B)(i) of the Affordable Care Act.

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

(c) *Notice to Enrollees*—(1) *Notice of exclusion.* The MSP issuer must provide notice to consumers prior to enrollment that non-excepted abortion services are not a covered benefit in the form, manner, and timeline prescribed by OPM.

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

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

§ 800.603 Disclosure of information

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

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

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

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

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

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 101206604–1758–02]

RIN 0648–XD731

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic; 2015 Commercial Run-Around Gillnet Closure

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements an accountability measure (AM) through this temporary rule for commercial harvest of king mackerel in the Florida west coast southern subzone of the eastern zone of the Gulf of Mexico (Gulf) exclusive economic zone (EEZ) using run-around gillnet gear. NMFS has determined that the commercial annual catch limit (ACL; commercial quota) for king mackerel using run-around gillnet gear in the Florida west coast southern subzone of the Gulf EEZ will be reached on February 20, 2015. Therefore, NMFS closes the Florida west coast southern subzone to commercial king mackerel fishing using run-around gillnet gear in the Gulf EEZ. This closure is necessary to protect the Gulf king mackerel resource.

DATES: The closure is effective 12:01 p.m., eastern standard time, February 20, 2015, until 6 a.m., eastern standard time, January 19, 2016.

FOR FURTHER INFORMATION CONTACT: Susan Gerhart, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *susan.gerhart@noaa.gov.*

SUPPLEMENTARY INFORMATION: The fishery for coastal migratory pelagic fish (king mackerel, Spanish mackerel, and cobia) is managed under the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic (FMP). The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

Gulf migratory group king mackerel's Florida west coast subzone of the Gulf eastern zone is divided into northern and southern subzones, each with separate commercial quotas. From November 1 through March 31, the southern subzone encompasses an area of the EEZ south of a line extending due west of the Lee and Collier County, FL, boundary on the Florida west coast, and south of a line extending due east of the Monroe and Miami-Dade County, FL, boundary on the Florida east coast, which includes the EEZ off Collier and Monroe Counties, FL. From April 1 through October 31, the southern subzone is reduced to the EEZ off Collier County, and the EEZ off Monroe County becomes part of the Atlantic migratory group area (50 CFR 622.384(b)(1)(i)(C)).

On January 30, 2012 (76 FR 82058, December 29, 2011), NMFS implemented a commercial quota for the Gulf migratory group king mackerel in the Florida west coast southern subzone of 551,448 lb (250,133 kg) for vessels using run-around gillnet gear (50 CFR 622.384(b)(1)(i)(B)(*1*)), for the current fishing year, July 1, 2014, through June 30, 2015.

Regulations at 50 CFR 622.8(b) require NMFS to close any segment of the king mackerel commercial sector when its quota has been reached, or is projected to be reached, by filing a notification with the Office of the Federal Register. NMFS has determined that the commercial quota of 551,448 lb (250,133 kg) for Gulf group king mackerel for vessels using run-around gillnet gear in the Florida west coast southern subzone will be reached on February 20, 2015. Accordingly, commercial fishing using such gear in the Florida west coast southern subzone is closed at 12:01 p.m., eastern standard time, February 20, 2015, until 6 a.m., eastern standard time, January 19, 2016, the beginning of the next fishing season, *i.e.,* the day after the 2016 Martin Luther King, Jr. Federal holiday. Accordingly, the operator of a vessel that has been issued a Federal commercial permit to harvest Gulf migratory group king mackerel using run-around gillnet gear in the Florida west coast southern subzone must have landed ashore and bartered, traded, or sold such king mackerel prior to 12:01 p.m., eastern standard time, February 20, 2015.

Persons aboard a vessel for which a commercial permit for king mackerel has been issued, except persons who also possess a king mackerel gillnet permit, may fish for or retain Gulf group king mackerel harvested using hook-and-line gear in the Florida west coast southern subzone unless the commercial quota for hook-and-line gear has been met and the hook-and-line