ESTABLISHMENT OF THE MULTI-STATE PLAN PROGRAM FOR THE AFFORDABLE INSURANCE EXCHANGES
SUMMARY OF FINAL RULE
RIN: 3206-AM47

On March 1, 2013, the U.S. Office of Personnel Management (OPM) put on public display a final rule to implement the multi-state plan program (MSPP) mandated by section 1334 of the Accountable Care Act (ACA). This final rule is published in the March 11, 2011 issue of the *Federal Register.*

OPM received about 350 comments on the corresponding proposed rule published December 5, 2012, of which 105 were unique comment letters; the others were form letters, including letters requesting an extension of the 30-day comment period. The final rule is largely unchanged from what was originally proposed. The final rule is generally effective on May 10, 2013, except for provisions relating to external review, which will take effect on the effective date of regulations implementing section 2719 of the Public Health Service (PHS) Act, which will address external review and other matters that apply to all non-grandfathered group health plans and health insurance issuers, including MSPP issuers.

Table Of Contents

	Page
Overarching Comments	1
SUBPART A –General Provisions and Definitions	2
SUBPART B – Multi-state Plan Issuer Requirements	3
SUBPART C – Premiums, Rating Factors, Medical Loss Ratios, and Risk Adjustment	14
SUBPART D – Application and Contracting Procedures	17
SUBPART E – Compliance	19
SUBPART F – Appeals by Enrollees for Denials of Claims for Payment or Service	23
SUBPART G – Miscellaneous	25
Regulatory Review, Paperwork Reduction Act, Regulatory Flexibility Act, Unfunded Mandates, Federalism, Congressional Review Act	25

I. RESPONSES TO COMMENTS

Overarching Comments

OPM acknowledges that many commenters requested an extension of the 30-day comment period, but says that the comment period was consistent with the Administrative Procedure Act and Executive Orders 12866 and 13563, and that other opportunities for input were also provided, including a Request for

Information issued on June 16, 2011, a draft MSPP application issued on September 21, 2012, and meetings and phone calls with numerous stakeholders.

OPM also disagrees with one commenter who argued that church plans meet the requirements necessary for OPM to offer them under an MSPP contract, noting that church plans, by themselves, do not meet the definition of health insurance issuer; section 1334(a)(1) of the ACA explicitly requires OPM to enter into contracts for Multi-State Plans (MSPs) with health insurance issuers.

PART 800 MULTI-STATE PLAN PROGRAM (MSPP)

SUBPART A –General Provisions and Definitions

§ 800.10 Basis and Scope.

These regulations are based on the following sections of the ACA: 1001; 1302; 1311; 1324; 1334; 1341; 1342; and 1343.

The scope of the proposed rule included establishing standards for health insurance issuers wishing to contract with OPM to participate in the MSPP; issuer appeal of a decision by OPM to either non-renew or terminate an issuer's contract; and MSP enrollees' appeals of denials of payment or services by an MSPP issuer. OPM received no comments on §800.10 and adopts it as final, with no changes.

§ 800.20 Definitions.

In general, the definitions in the proposed rule are finalized without change, including the definitions of the following terms:

- Applicant means an issuer or group of issuers that submitted an application to OPM to be considered for participation in the MSPP.
- Benefit plan material or information means explanations or descriptions, whether printed or electronic, that describes a health insurance issuer's products. The term does not include a policy or contract for health insurance coverage.
- Group of issuers means (1) a group of health insurance issuers who are either affiliated by common ownership and control or by common use of a nationally licensed service mark, or (2) an affiliation of health insurance issuers and an entity who is not an issuer but who owns a nationally licensed service mark.
- Licensure means the authorization obtained from the appropriate State official or regulatory authority to offer health insurance coverage in the State.
- MSPP means the program administered by OPM pursuant to section 1334 of the ACA.
- MSPP issuer means a health insurance issuer or group of issuers that has a contract with OPM to offer health plans pursuant to section 1334 of the ACA and meets the requirements of this part.

- Nationally licensed service mark means a word, name, symbol, or device, or any combination thereof, that an issuer or group of issuers uses consistently nationwide to identify itself.
- Non-profit entity means: (1) an organization that is incorporated under State law as a non-profit entity and licensed under State law as a health insurance issuer, or (2) a group of health insurance issuers licensed under State law, a substantial portion of which are incorporated under State law as non-profit entities.
- 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.
- Rating means the process, including rating factors, numbers, formulas, methodologies, and actuarial assumptions, used to set premiums for a health plan.
- State insurance commissioner means the commissioner or other chief insurance regulatory official of a State.

OPM rejects comments requesting that the definition of "group of issuers" not include "an affiliation of health insurance issuers and an entity who is not an issuer but who owns a nationally licensed service mark." OPM similarly rejects a comment requesting that the definition of "non-profit entity" not include "a group of health insurance issuers licensed under State law a substantial portion of which are incorporated under State law as non-profit entities." In both instances, OPM argues that the definitions are consistent with the manner in which OPM administers the Federal Employees Health Benefits Program (FEHBP).

The final rule revises the definition of "MSP" to clarify that an MSP is offered under contract with OPM via an MSPP issuer, as noted below:

- MSP means a health plan that is offered under a contract with OPM pursuant to section 1334 of the ACA and meets the requirements of this part.

In response to comments, the final rule deletes definitions for the terms "Indian" and "Indian Plan Variation."

SUBPART B – Multi-state Plan Issuer Requirements

§ 800.101 General requirements.

In the proposed rule, OPM specified that an MSPP issuer must be licensed in each State where it offers coverage; have a contract with OPM; offer plans with levels of coverage as required under §800.107 (below); meet the same requirements that apply to Qualified Health Plans (QHPs) and QHP issuers regarding eligibility and enrollment; ensure its MSPs meet requirements; comply with the regulations in part 800; comply with OPM direction and with other applicable law; meet other requirements determined appropriate by OPM; comply

with applicable nondiscrimination laws; and with respect to its MSPs, not discriminate based on race, color, national origin, disability, age, sex (including pregnancy and gender identity), or sexual orientation.

In the final rule, OPM revises the non-discrimination language at §800.101(i) to ensure consistency with the prohibition on discrimination with respect to essential health benefits (EHB) in 45 CFR 156.125 and the non-discrimination standards applicable to qualified health plans (QHPs) under 45 CFR 156.200(e). More specifically, §800.101(i) specifies that MSPs and MSPP issuers must comply with applicable Federal and State non-discrimination laws, including the standards set forth in 45 CFR 156.125 and 156.200(e). Section 156.125 prohibits discrimination based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions (but does not prevent an issuer from appropriately utilizing reasonable medical management techniques). Section 156.200(e) prohibits a QHP issuer, with respect to its QHP, from discriminating on the basis of race, color, national origin, disability, age, sex, gender identity, or sexual orientation.

OPM emphasizes that this non-discrimination requirement clearly bars discrimination against certain health care providers of the MSPP issuer (but declines to list specific types of providers so protected). OPM adds that an MSPP issuer would not violate the non-discrimination requirements by contracting with health care providers who are authorized or directed by law to serve specific populations, such as Indian health providers. The remainder of proposed §800.101 is adopted as final, with no changes.

In response to comments, OPM encourages States to identify consumer protections and regulatory procedures that go above and beyond Federal standards so that it can consider and address them through a memorandum of understanding (MOU) with the State(s) and, if appropriate, in its contracts with MSPP issuers.

§ 800.102 Compliance with federal law.

In order to contract with OPM for the MSPP, issuers must comply with provisions of title XXVII of the PHS Act and applicable provisions in the ACA. The proposed rule included two appendices listing such provisions but the final rule omits them, with OPM saying that it was concerned that the lists might not necessarily be comprehensive or could change over time. The final rule also omits another appendix relating to §36B of the Internal Revenue Code because OPM has concluded that this section does not set forth responsibilities of issuers. In response to comments, OPM agrees that section 1312 of the ACA (relating to consumer choice, risk pools, and related matters) applies to MSSP issuers.

§ 800.103 Authority to contract with issuers.

OPM adopts this proposed section without change. Thus, OPM may contract with issuers to offer at least two MSPs in the State Exchanges and Small

Business Health Options Programs (SHOPs) without regard to laws that require competitive bidding. OPM will contract with at least one non-profit entity. Further, a contract may be with a group of issuers (defined above). Contracts will provide for both individual coverage and coverage for small employers.

§ 800.104 Phased expansion.
As originally proposed, MSPP issuers must offer MSPs in all States (and D.C.), subject to the following phase-in: at least 60% of States in the first year; 70% in the second year; 85% in the third year; and all States in the fourth year. The proposed rule had referred to the minimum number of States for each of these phases but the final rule omits these references because section 1334(e) of the ACA refers to percentages, not specific numbers of States. OPM also declines to identify specific States that MSPP issuers should cover during phased expansion. As originally proposed, MSPP issuers must be licensed in each State in which they offer an MSP, and must make a good faith effort to become licensed in every State by the end of the phase-in period.

OPM proposed to allow an MSPP issuer to offer coverage in only part of a State, provided the issuer provides OPM with a plan for expanding to statewide coverage. The final rule maintains this policy. In response to comments, including those worried that allowing partial State coverage could lead to red-lining by MSPP issuers or adverse selection resulting in MSSP issuers avoiding certain populations, OPM says that it will pay special attention to service areas that are medically underserved, such as rural areas and American Indian/Alaska Native populations, as it reviews MSPP issuer applications. OPM adds that it intends to encourage issuers to offer coverage statewide where they have the capacity to do so. Further, OPM will evaluate MSPP issuers to ensure that the locations in which they propose to offer MSP coverage have been established without regard to racial, ethnic, language, 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.

<u>MSPP issuers and SHOP participation.</u> OPM proposed to require that MSPP issuers offer coverage in the State SHOPs as well as in the individual Exchanges, but also allow issuers to phase-in SHOP participation. Under this proposal, MSPP issuers may offer coverage in the individual Exchanges and not in the SHOPs throughout the 3 year phase-in period, so long as the issuers provide OPM their plan for expanding coverage to the SHOPs in all States. The final rule generally preserves this flexibility. However, since the HHS Payment Notice adopted a provision stating that a QHP issuer applicant will participate in a Federally-facilitated SHOP based on an issuer applicant's current small group market share (with a threshold of 20 percent market share used to determine whether a small group market issuer is subject to the tying provision for QHPs in the Federally-facilitated SHOPs), this policy is extended to MSPP issuers. OPM notes that this standard can be met if a State-level MSPP issuer or any other issuer in the same issuer group affiliated with an MSPP issuer provides coverage

on the Federally-facilitated SHOP. In response to comments, OPM also clarifies that an MSPP issuer must offer coverage for both individuals and small groups in a State with a merged individual and small group market.

§ 800.105 Benefits.

OPM finalizes its proposal that each MSPP issuer offer a benefits package for each MSP that is uniform within a state, but not necessarily uniform among states. Benefits packages must comply with Department of Health and Human Services (HHS) requirements as well as any additional standards set by OPM. In response to comments discussing the need for national MSPs for American Indians/Alaska Natives, OPM says that reciprocity of coverage among MSPs in States is an issue it intends to take up in contract negotiations with MSPP issuers.

OPM proposed two options for MSP benefits: a plan that is substantially equal to each State's essential health benefits (EHB)-benchmark plan; or (2) any EHB-benchmark plan selected by OPM, and finalizes this policy. For the second option, OPM finalizes its proposal to select the three largest FEHBP plans by enrollment: Blue Cross Blue Shield (BCBS) Standard Option, BCBS Basic Option; and the Government Employees Health Association (GEHA) Standard Option. An issuer generally must choose one option to use uniformly in all states; MSPP issuers would not be allowed use a state benchmark plan in some states and the OPM benchmark option in other states. However, the final rule provides one exception to this policy; in a State that does not allow substitution of benchmark benefits, or that has standard benefit designs, an MSSP issuer that has chosen to use an OPM-selected EHB-benchmark plan must use the State's EHB-benchmark plan.

OPM also finalizes its proposal that any OPM-selected EHB benchmark plan lacking coverage of pediatric oral services or pediatric vision services be expanded to include the entire category of benefits from the largest Federal Employee Dental and Vision Insurance Program (FEDVIP) plan (MetLife Federal Dental Plan High Option and FEP BlueVision High Option, respectively). OPM solicited comments on whether and how stand-alone dental plans offered on the Exchanges should affect the requirement that MSPs cover pediatric oral services, but says it is not promulgating any further regulatory provisions regarding coverage of pediatric oral services but will be mindful of the issue during MSPP contract negotiations, an approach which OPM believes would allow greater flexibility on benefit designs.

As originally proposed, OPM will require MSPs to follow the State definition of habilitative services and devices, where a State chooses to define this service category. Alternatively, if an OPM-benchmark plan lacks coverage for these services, OPM will define the habilitative services and devices to be covered.

OPM also finalizes without change the proposed requirement that EHB-benchmark plans must include, for each State, any State-required benefits enacted prior to December 31, 2011 that are included in the State's EHB-benchmark plan. Any State required benefits enacted after 2011 would be in addition to the EHB and, as required by the ACA, the state must assume the cost of those benefits and make payments either to the enrollee or on behalf of the enrollee to the plan issuer. MSPP issuers must calculate and report the costs of such benefits.

OPM will review MSP benefits packages, including prescription drug lists, and determine if they are substantially equal to an EHB-Benchmark plan. As originally proposed, OPM will follow the HHS approach (45 CFR 156.115, 156.120, and 156.125), including the proposed requirement to allow issuers to make benefit substitutions and submit evidence of actuarial equivalence of substituted benefits to a State. OPM requested comments on whether MSPP issuers should submit actuarial equivalence evidence to OPM in addition to, or in lieu of, submitting evidence to a State. In the final rule, OPM says that it "will work collaboratively with State regulatory officials during the MSPP application process to ensure they receive evidence of actuarial equivalence of substituted benefits."

As it did in the proposed rule, OPM indicates that it will review MSP benefit packages for discriminatory benefit design, and will work closely with HHS and the States to identify and investigate potentially discriminatory benefit packages.

In the preamble to the proposed rule, OPM said that one or more issuers of an MSP could be required or incentivized to provide contraceptive coverage to enrollees covered under certain religious organizations' self-insured plans to accommodate those organizations' religious objections to such coverage. This matter is not discussed in the final rule.

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

OPM finalizes the proposal that each MSP's cost-sharing provisions comply with the limits in section 1302(c) of the ACA as well any applicable regulatory standards set by HHS (45 CFR 156.170).

OPM also finalizes the proposal that each MSP must make available to an eligible individual the premium tax credits under section 36B of the Internal Revenue Code of 1986, and the cost-sharing reductions under section 1402 of the ACA, and must comply with any applicable HHS or OPM standards.

In response to comments, OPM says it intends to require MSPP issuers to follow HHS rules regarding cost-sharing except when State laws impose stricter requirements for their Exchanges. OPM also says that in some circumstances, it may require MSPP issuers to provide in-network benefits for services from

certain out-of-network providers but would do so through contract negotiation, not rulemaking.

§ 800.107 Levels of coverage.
As originally proposed, an MSPP issuer must offer at least one MSP at the silver level of coverage and one MSP at the gold level of coverage on each Exchange in which it is certified by OPM to offer coverage. An MSPP issuer may offer, pursuant to a contract with OPM, one or more MSPs at the bronze level of coverage, or the platinum level of coverage, or both, on any Exchange, or SHOP in any State. For each level of coverage, the MSPP issuer must offer a child-only plan at the same level of coverage, for individuals who, at the beginning of the plan year, have not attained age 21. An MSPP issuer must comply with reductions or elimination of cost-sharing as provided in section 1402 of the ACA, as well as any applicable HHS or OPM standards. Levels of coverage plans and plan variations must be submitted to OPM for review and approval.

In response to comments, OPM says it intends to direct MSPP issuers to comply with State requirements related to the offering of levels of coverage, including but not limited to standardized benefit designs and tiers. However, OPM will not require bronze coverage through this regulation, and adds that it does not have authority to require MSPP issuers to participate in Medicaid.

§ 800.108 Assessments and user fees.
In the final rule, OPM preserves its discretion to assess a user fee on MSPP issuers as a condition for participating in the MSPP and clarifies that it will not begin doing so any earlier than 2015. OPM adds that it will issue further guidance in advance of collecting any user fees. As originally proposed, the amount of any user fee for a plan year will be determined by OPM as the amount necessary to meet OPM's administrative costs for MSPP functions, including, but not limited to, contracting, certifying, recertifying, decertifying, and overseeing MSPs and MSPP issuers for that plan year.

In response to comments, OPM states that any OPM-imposed user fee would not be a substitute for any user fee or assessment imposed by a State-based Exchange or Federally-facilitated exchange. OPM instead intends for any MSPP user fee it collects to be offset against any State-based Exchange or Federally-facilitated Exchange user fee that the MSPP issuer must pay. This would have the effect of preserving a level playing field for MSPP issuers; they would pay the same total assessment or user fee as all other QHPs but a portion of their payments would be retained by OPM. However, the final rule does not speculate on the amount of any OPM-imposed fee or how it might compare to similar user fees imposed by Exchanges.

§ 800.109 Network adequacy.
OPM finalizes the proposal to adopt for the MSPP the same network adequacy standards as the HHS standards in 45 CFR 156.230. An MSPP issuer would

have to ensure that the provider network for each of its MSPs is sufficient in number and types of providers to assure that all services will be accessible without unreasonable delay; is consistent with network adequacy standards of section 2702(c) of the PHS Act; and includes essential community providers in compliance with 45 CFR 156.235.

OPM also finalizes the proposal that an MSPP issuer would have to make its provider directory available to the Exchange for publication online pursuant to guidance from the Exchange, and to potential enrollees in hard copy upon request. In the provider directory, an MSPP issuer would have to identify providers that are not accepting new patients. OPM adds that it will consider, during MSPP contract negotiations, the comment recommending that an MSPP issuer should maintain a dedicated email address for changes in provider directory information.

In response to comments, OPM says that the non-discrimination standards set forth in §800.101 and §800.102 adequately prohibit discrimination against specific provider types. OPM also assures commenters that it considers §800.109(a) and §800.114 to require MSPP issuers to comply with State "any willing provider" laws. With regard to comments recommending that OPM require MSPP issuers to adopt a standard Indian Addendum for contracting with tribal health care providers, OPM notes that the Centers for Medicare & Medicaid Services (CMS) has not required that QHP issuers use the Addendum, and adds that it thinks it more appropriate to address this issue in its contract negotiations.

With respect to network adequacy, the final rule states that OPM has adopted an approach under which the MSPP will establish a uniform standard for network adequacy using time and distance standards that are based on those published by CMS for Medicare Advantage plans (for providers and facilities) and Medicare Part D (for retail pharmacies). OPM also says that more information is available in its final MSPP application that was published on January 18, 2013, on the Federal Business Opportunities website at www.FBO.gov under solicitation number OPM35-12-R-0006, Multi-State Plan Program.

Finally, OPM says that in the first year of the MSPP, it will apply only the MSPP standard for MSPP issuer networks, and in future years may require an MSPP issuer to meet State network standards, "if appropriate and in the best interest of MSP enrollees."

§ 800.110 Service area.

OPM finalizes the proposal that MSPP issuers offer an MSP within one or more service areas in a State, as defined by each Exchange pursuant to 45 CFR 155.1055, but does not require an MSP to be offered in all service areas during the phase-in period. OPM considered permitting an MSP to be offered in a portion of a service area during the phase-in period, so long as it is not discriminatory, but the final rule clarifies that MSPs will be required to comply

with the service area requirements applicable to all QHPs in a State; OPM is not making any additional requirements regarding partial rating regions or geographic service areas in States with certain licensure laws that determine service area. Further, as originally proposed, if an Exchange permits issuers to define their own service areas, an MSPP issuer will have to obtain OPM's approval for its proposed service areas.

In response to comments, OPM appears to say that it is removing (as it did in §800.104) the requirement in the proposed rule that, for each State in which the MSPP issuer does not offer coverage in all service areas, the MSPP issuer would submit a plan on expanding coverage throughout the State. But this requirement was not removed from §800.104 and the preamble even emphasizes its retention. Thus, what OPM appears to mean is that it is removing an arguably duplicative requirement from §800.110. In any event, OPM says it intends to encourage MSPP issuers to expand coverage and will assess their capacity to do so through the MSPP contract negotiations.

§ 800.111 Accreditation requirement.
OPM finalizes the proposal requiring an MSPP issuer to be or become accredited consistent with the requirements for QHP issuers specified in section 1311 of the ACA and in 45 CFR 156.275(a). An MSPP issuer must authorize its accrediting entity 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. An MSPP issuer that is not accredited as of the date that it enters into a contract with OPM must become accredited within the timeframe established by OPM.

§ 800.112 Reporting requirements.
As originally proposed, OPM will specify the data and information that must be reported by an MSPP issuer, as well as the form, manner, frequency and process for reporting. OPM may also require that MSPP issuers submit claims payment and enrollment data to facilitate OPM's oversight and administration of the MSPP in a manner similar to the FEHBP.

OPM also finalizes the proposal requiring MSPP issuers to 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, similar to standards under section 1311(c)(1)(E), (H), and (I), (c)(3), and (c)(4) of the ACA.

In response to comments, OPM notes the following:

- §800.115(c) requires MSPP issuers to comply with all Federal and State quality improvement and reporting requirements.

- OPM intends to enter into MOUs with States to streamline data collection and reduce duplicate reporting requirements; the final rule does not address specifics of how OPM will collect data (for example, whether OPM would use a centralized health claims data warehouse for the MSPP or adopt a decentralized approach), and its method for data collection will be developed in future policy guidance, in consultation with HHS.
- Pharmacy Benefit Manager (PBM) transparency standards will be established through the MSPP contract.
- Specific reporting issues are more appropriately addressed through contract negotiations, rather than the final rule.
- Although the final rule does not provide for any specific demographic data collection, OPM's authority to administer MSPP contracts includes collection of demographic data, if it decides to do so in the future.
- With respect to quality reporting under the MSPP, OPM expects to begin with the performance measurement approach used under the FEHBP, where plans report their performance through Healthcare Effectiveness Data and Information Set (HEDIS) metrics and Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys.

§ 800.113 Benefit plan material or information.
OPM defines benefit plan material information narrowly, to include explanations or descriptions of an issuer's products, but not to include a policy or contract for coverage. MSPP issuers must comply with Federal and State laws relating to benefit plan material or information, as well as OPM's standards, process, and timeline for approval of benefit plan materials. An MSPP issuer must provide all applications and notices to enrollees with limited English proficiency and those with disabilities in accordance with the standards for QHPs described in at 45 CFR 155.205(c). OPM may establish additional standards for MSPP applications and notices. In response to comments requesting clearer guidance on language access policies, OPM says that limited English language proficiency guidance will be addressed through the MSPP contract negotiation process.

As originally proposed, an MSPP issuer will be responsible for the accuracy of its benefit plan material or information. All benefit plan material or information must be written in plain language, be truthful, not be misleading, and not contain material omissions. MSPs are also required to comply with law and regulations related to uniform explanation of coverage documents and standardized definitions that apply to QHPs. MSPP issuers must also comply with requirements that allow standardized benefit information to be displayed on HHS or Exchange web portals.

OPM reserves the right to review and approve benefit plan material or information to ensure that an MSPP issuer complies with Federal and State laws, and the standards prescribed by OPM, but does not expect to review and approve all benefit plan material or information. It will request from issuers the materials it wishes to review. OPM will work with the States on benefit plan

material review and may define respective roles through an MOU. The final rule notes that State approval of a policy form is not a precondition of OPM approval; OPM expects that few disagreements will arise between OPM and a State regarding form review and, if they do, OPM "will work with the State to successfully resolve the discrepancy in a manner that is acceptable to both OPM and the particular State."

OPM finalizes the proposal allowing an MSPP issuer to include a statement in its benefit plan material or information that OPM has certified the MSP as eligible to be offered on the Exchange and that OPM monitors the MSP for compliance with all applicable law. OPM does not believe this violates State anti-endorsement laws or regulations because it is a recitation of fact.

§ 800.114 Compliance with applicable State law.
In general, this section requires an MSPP issuer, with respect to each of its MSPs, to comply with State law pursuant to section 1334(b)(2) of the ACA. However, as specified in the ACA, MSPs and MSPP issuers need not comply with State laws that (1) are inconsistent with section 1334 of the ACA or its regulations; (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 ACA. OPM reserves the right to determine, in its judgment, whether particular state laws fall into these categories.

OPM proposed to use a list of four factors to determine whether a State law fits into one of the above categories: (1) whether the law in question imposes a requirement that differs from those applicable to QHPs and QHP issuers on one or more Exchanges in the State; (2) whether the law creates responsibilities, administrative burdens, or costs that would significantly deter or impede the MSPP issuer from offering a viable product on one or more Exchanges; (3) whether the law creates responsibilities, administrative burdens, or costs that significantly deter or impede OPM's effective implementation of the MSPP; or (4) whether the law prevents an MSPP issuer from offering an MSP on one or more Exchanges in the State. In light of comments expressing concerns about these factors, including that they were too broad and vague, OPM has dropped them from the final rule. However, OPM notes that by removing them, it does "not disavow them as relevant considerations" but does "not wish to give the impression that they are any more or less important than any other factor that may be relevant." OPM adds that it intends to pursue MOUs with each State in which the MSPs are being offered. OPM also intends to consult with States during the process of making a determination of inconsistency regarding a State law; the final rule modifies §800.114(b) to expressly state this intention. In response to a comment, OPM also says that it will not automatically apply a determination of inconsistency to more than one State law without consulting with the State regulatory agencies and Exchange(s) and thoroughly evaluating the unique facts and circumstances in each State.

In the proposed rule, OPM stated that it expects MSPP issuers to meet State financial requirements including participating in State guaranty funds and meeting State reserving requirements. OPM added that it may execute an MOU with each State regarding the participation of MSPP issuers in such funds. OPM also invited comments on participation of MSPP issuers in State guaranty funds, as well as comments on how it may further ensure the stability of MSPP issuers across State lines. The final rule does not specifically address these matters. However, OPM emphasizes that it intends MSPs and MSPP issuers to be subject to all of the same standards and requirements as QHPs and QHP issuers, except where deviations are authorized by law. Nonetheless, OPM rejects comments indicating that MSPP issuers should be required to enter into a contract with Exchanges, saying this would circumvent section 1334(d) of the ACA, which vests certification authority for MSPs in OPM; MSPs offered under a contract with OPM are deemed to be certified by an Exchange. OPM adds that it considers active or selective contracting models employed by Exchanges to be operational processes rather than QHP standards, and it will not direct MSPP issuers to participate in such processes.

§ 800.115 Level playing field.
The level playing provision in the ACA (Section 1324(b)) specifies that health insurance coverage provided by a private issuer shall not be subject to any Federal or State laws related to 13 categories, if a plan operated under the Consumer Operated and Oriented Plan (CO-OP) program, a community health insurance option under section 1323, or a nationwide QHP under section 1333(b)) is not subject to such law. The 13 categories include guaranteed renewal, rating, preexisting conditions, non-discrimination, quality improvement and reporting, fraud and abuse, solvency and financial requirements, market conduct, prompt payment, appeals and grievances, privacy and confidentiality, licensure, and benefit plan material or information.

In order to maintain a level playing field, OPM finalizes the proposal to require an MSPP issuer, with respect to each of its MSPs, to comply with all Federal and State laws in these 13 categories. In response to comments, OPM argues that while it (and not the States) will administer the external review process for MSPs, MSPs will be subject to, and comply with, the same law on external review as other issuers.

§ 800.116 Process for dispute resolution.
OPM finalizes the proposed process for resolving disputes about the applicability of State laws not related to the 13 categories specified above. Under the process, a State may request that OPM reconsider a determination that an MSP or MSPP issuer is not subject to a State law. The State making a request must demonstrate that the State law at issue is not inconsistent with section 1334 of the ACA or these regulations, and does not prevent the application of a requirement of part A of title XXVII of the PHS Act or a requirement of title I of the ACA.

The request must be in such form, contain such information, and be submitted in such manner and within such timeframe as OPM may prescribe. The requester may submit to OPM any relevant information to support its request. 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. OPM will issue a written decision within 60 calendar days after receiving the written request, or after the due date for the response, whichever is later, unless a different timeframe is agreed upon. OPM's written decision will constitute final agency action that is subject to review under the Administrative Procedure Act (APA) in the appropriate U.S. district court. Such review would be limited to the record that was before OPM when OPM made its decision.

OPM rejects a comment requesting a decision timeframe of less than 60 days, saying that 60 days is "an appropriate period within which written decisions must be issued" but adding that it intends to resolve each dispute "as quickly as possible after it arises."

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

§ 800.201 General requirements.
As originally proposed, OPM will review rating practices and negotiate MSP premiums annually with an MSPP issuer, and those premiums would remain in effect for the consecutive 12 month plan year. Premiums will be set on a State-by-State basis. OPM will work with the States to identify and investigate any potentially discriminatory rating practices.

An MSPP issuer must calculate actuarial value in the same manner as QHP issuers and comply with applicable standards set by OPM or HHS. An MSPP issuer must participate in the OPM rate review process, which will be similar to the process established by HHS. OPM intends to follow state rating standards, and work closely with each State in approving a rate for the MSPs. However, the final decision on MSP premium rates rests with OPM. OPM would share with each State its rate review analysis for each MSP operating within the State.

As originally proposed, the final rule specifies that an MSPP issuer is subject to a State's rate review process, including a State's Effective Rate Review program established by HHS (45 CFR part 154.) Further, for States with Effective Rate Review Programs, the MSPP issuer must comply with State standards. In addition, in States where HHS is reviewing rates, HHS would accept the judgment of OPM for MSP rate increases.

The proposed rule stated that in the event that a State withholds approval of an MSP rate for reasons that OPM determines, in its discretion, to be arbitrary, capricious, or an abuse of discretion, OPM would retain authority to make the

final decision to approve rates for participation in the MSPP notwithstanding the absence of State approval. The final rule removes the “arbitrary, capricious, or an abuse of discretion” language but otherwise preserves OPM’s final authority to approve MSP rates. OPM says that it expects that the OPM Director will rarely, if ever, have to exercise this authority to disapprove or approve MSP rates over the approval or non-approval of a State. The final rule also specifies that MSPP issuers must allow the rate review process in States, including administrative and judicial remedies, to proceed unless the timeline for administration of the MSPP is threatened. Thus, OPM would exercise its discretion to approve MSP rates (notwithstanding the status of the State approval process) only in the event that the State’s action would impede the Federal objective by preventing OPM from operating the MSPP.

As originally proposed, an MSPP issuer must consider all enrollees in an MSP to be in the same risk pool as all enrollees in all other non-grandfathered health plans in the individual market or small group market, respectively, in compliance with section 1312(c) of the ACA, 45 CFR 156.80, and any applicable Federal or State laws and regulations. If a State elects to combine its individual and small group markets, an MSPP issuer will have to comply. In response to a comment, OPM affirms that MSPP issuers will pool risk within a State and not across States.

§ 800.202 Rating factors.
As originally proposed, MSPP issuers must comply with the HHS regulations for health insurance premiums. An MSPP issuer must use only the rating factors permitted under section 2701 of the PHS Act: family composition, geographic area, age, and tobacco use within limits. Rating variations for age and tobacco use must be applied based on the portion of the premium attributable to each family member covered under the coverage. For age rating, an MSPP issuer must use the ratio established by the State in which the MSP is offered if it is less than 3:1. An MSPP issuer must use the uniform age bands, and age curves, established under the HHS regulations. An MSP must use the rating areas appropriate to the State in which the MSP is offered and established under HHS or State regulations.

In response to comments, OPM:

- Clarifies that its intent is for an MSPP issuer to use any age curve established by a State pursuant to 45 CFR 147.103(e); if a State does not establish an age curve, the MSPP issuer would use the standard age curve established by HHS.
- Agrees that MSSP issuers must comply with PHS Act section 2705 and its implementing regulations on incentives for nondiscriminatory wellness programs in group health plans (adding a paragraph (f) to §800.202 to this effect).
- Acknowledges that the final rule does not specify the minimum categories of family members that must be rated in a family policy, but adds that it

encourages MSPs to provide the same benefits for all family compositions, including but not limited to same-sex domestic partners and their children.

§ 800.203 Medical loss ratio.
The ACA authorizes OPM to set a medical loss ratio (MLR) for each MSP, similar to FEHBP. OPM finalizes the proposal to require MSPP issuers to attain the MLR required under section 2718 of the PHS Act and regulations promulgated by HHS (80% in the small group and individual markets, or higher percentage if required under state law.) OPM reserves the authority to impose a different, MSP-specific MLR if it is in the best interests of MSP enrollees, or is necessary to be consistent with a State's requirements with respect to MLRs. In response to comments, OPM emphasizes that, as a matter of policy, it does not foresee exercising this authority and would only do so under extraordinary and rare circumstances, and after consulting with the State. OPM also says that MSPP issuers must calculate MLR on a State-by-State basis as well as pool MSP and non-MSP experience within a State.

As originally proposed, if an MSPP issuer fails to attain the required MLR, OPM may take any appropriate action including intermediate sanctions, such as suspension of marketing. In the case of widespread, repeated failures, sanctions may include, but not be limited to, decertifying an MSP in one or more States or terminating an MSPP issuer's contract**.** In response to a comment, OPM clarifies that it would only decertify an MSP mid-year under unusual circumstances, such as widespread and repeated failure to comply with the legal or MSPP contractual requirements, and before decertifying an MSP, would consult with a State and/or HHS, as appropriate, to avoid market disruption and protect consumers.

In response to a comment regarding the treatment of MSPP user fees in MLR calculations, OPM says that MSPP user fees will not be included in the MLR calculation, noting that technical guidance document CCIIO 2012-002, released by HHS on April 20, 2012, specifies that Exchange user fees are subtracted from premiums in the MLR calculation, as are all other Federal and State regulatory and licensing fees. OPM also points to §800.108 of the final rule, which clarifies that MSPP user fees will be part of the State-based Exchange or Federally-facilitated Exchange user fee (as noted above).

The proposed rule noted that OPM has the authority under the ACA section 1334(a)(4) to set profit margins. OPM has not proposed a standard for profit margins and sought comments on whether it should set such a standard, and the impact such a standard would have on Exchanges and State requirements concerning profit margins. This matter is not discussed in the final rule.

§ 800.204 Reinsurance, risk corridors, and risk adjustment.
OPM finalizes the proposal to require MSPP issuer compliance with applicable Federal or State laws and regulations pertaining to implementation of the

transitional reinsurance program for the individual market (section 1341 of the ACA); the temporary risk corridors program (section 1342 of the ACA); and the risk adjustment program (section 1343 of the ACA). OPM notes that the majority of comments on the proposed rule supported this policy.

SUBPART D – Application and Contracting Procedures

§ 800.301 Application process.

OPM adopts as final its proposal to use a model similar to the one it uses for FEHBP, and use an application process rather than a request for proposals. This allows OPM to contract with as many issuers as meet the requirements. Applications will be considered annually; OPM may also issue a notice that it is not going to consider new applications for an upcoming year if it determines that would not be beneficial. Applications must contain the information requested by OPM, and be submitted to OPM in the form and manner, and in accordance with the timeline specified by OPM.

OPM again refers readers to the final paper application, available at www.FBO.gov under solicitation number OPM35-12-R-006, Multi-State Plan Program. OPM says this solicitation notes that OPM expects to begin receiving application material from issuers in February 2013, and instructs issuers to submit a notice of intent to apply to receive access to the MSPP Portal, through which issuers will submit the requested information to OPM electronically. OPM adds that it is not establishing rigid timelines for submission and review of applications, contracting, and renewal of contracts in the final rule but will evaluate and address these matters through guidance.

§ 800.302 Review of applications.

As originally proposed, OPM will determine if an applicant meets MSPP requirements, and may request additional information from the applicant in order to do so. If OPM determines that an applicant meets the requirements, OPM may accept the applicant to enter into contract negotiations with OPM to participate in the MSPP, or it may decline to enter contract negotiations. If OPM declines to enter into contract negotiations with an applicant, OPM would inform the applicant in writing of the reasons for that decision. A decision to decline an application will not preclude the applicant from submitting an application to participate in the MSPP for a subsequent year.

§ 800.303 MSPP contracting.

To become an MSPP issuer, the applicant and the OPM Director or his designee must sign a contract that meets the regulatory requirements. OPM will establish a standard contract for the MSPP. OPM and the applicant will negotiate the premiums and benefit packages for each MSP for each plan year. OPM may elect to negotiate with an applicant such additional terms, conditions, and requirements as are in the interests of MSP enrollees, or that OPM determines to be appropriate.

For each plan year, an MSPP contract will contain a certification that specifies the Exchanges in which the MSPP issuer is authorized to offer an MSP, as well as the specific benefit packages authorized to be offered on each Exchange and the premiums to be charged for each benefit package on each Exchange. An MSPP issuer could not offer an MSP on an Exchange unless its MSPP contract with OPM includes a certification authorizing the MSPP issuer to offer the MSP on that Exchange.

In response to comments, OPM says it will address specific terms of the MSPP standard contract through a development process following the publication of the final rule. OPM also acknowledges the unique concerns of Indian Health Service, tribes and tribal organizations, and urban Indian organizations (I/T/Us) and says it intends to address them, to the extent practicable, through contractual terms. OPM declines to specifically list State laws with which MSPP issuers must comply.

§ 800.304 Term of the contract.
As originally proposed, the term of the contract will be for the plan year, defined as a consecutive 12-month period during which an MSP provides coverage for health benefits. A plan year may be a calendar year or otherwise. In response to a comment, OPM says that it anticipates that all MSPP issuers will participate in the program "for many contract terms."

§ 800.305 Contract renewal process.
As originally proposed, applications to continue participating in the MSPP must contain the information requested by OPM, and be submitted to OPM in the form and manner, and in accordance with the timeline specified by OPM. OPM will renew the contract of an MSPP issuer who timely submits the required information if the issuer is in compliance with all legal requirements.

OPM may decline to renew the contract of an MSPP issuer if OPM and the MSPP issuer fail to agree on premiums and benefits for an MSP for the subsequent plan year; if the MSPP issuer has engaged in conduct that is cause for compliance action as described in § 800.404(a); or if OPM determines that the MSPP issuer will be unable to comply with a material provision of section 1334 of the ACA or this part.

If an MSPP issuer and OPM fail to agree on premiums and benefits for an MSP on one or more Exchanges for the subsequent plan year by the date required by OPM, either party may provide notice of nonrenewal or OPM may in its discretion withdraw the certification of that MSP on the Exchange or Exchanges for that plan year. In addition, in the event of no action (no notice of nonrenewal or renewal) by either party, the MSPP contract will be renewed and the existing premiums and benefits for that MSP on that Exchange or Exchanges will remain in effect for the subsequent plan year. OPM intends to ensure that premium and benefit information will be submitted to each Exchange in compliance with the

Exchange's timeline.

§ 800.306 Nonrenewal.
"Nonrenewal" means a decision by either OPM or an MSPP issuer not to renew an MSPP contract. Either OPM or an MSPP issuer may decline to renew an MSPP contract by providing a written notice of nonrenewal to the other party. An MSPP issuer's written notice of nonrenewal must be made in accordance with its MSPP contract with OPM, and must also adhere to any QHP termination requirements imposed by an Exchange including a requirement to provide advance written notice of termination to enrollees. If an Exchange does not have requirements about advance written notice of termination to enrollees, the MSPP issuer must inform current MSP enrollees in writing of the termination no later than 90 days prior to termination, unless OPM determines that there is good cause for less than 90 days' notice. OPM acknowledges that some commenters recommended lengthening the period of notice to enrollees of nonrenewal to 180 days, but responds that the 90-day period was taken from the same requirement in the FEHBP. OPM emphasizes that the 90-day requirement would only take effect in the absence of an Exchange rule requiring a different notice period.

SUBPART E – Compliance

§ 800.401 Contract performance.
OPM adopts the proposed §800.401 as final, with no changes except for minor technical edits. In general, an MSPP issuer must perform an MSPP contract with OPM in accordance with the requirements of the ACA and these regulations and must continue to meet such requirements while under an MSPP contract with OPM.

The following additional requirements will apply to each MSPP issuer:

- It must have, in the judgment of OPM, the financial resources to carry out its obligations under the MSPP;
- It must keep such reasonable financial and statistical records for each MSP and furnish them to OPM as requested by OPM;
- It must permit representatives of OPM (including the OPM Office of Inspector General), the U.S. Government Accountability Office (GAO), and any other applicable Federal auditing entities to audit and examine its records and accounts which pertain, directly or indirectly, to the MSP at such reasonable times and places as may be designated by OPM or the GAO;
- It must timely submit to OPM a properly completed and signed novation or change of-name agreement in accordance with subpart 42.12 of title 48 CFR;
- It must perform the MSPP contract in accordance with prudent business practices, as described below; and
- It must not engage in poor business practices, as described below.

As originally proposed, OPM defines prudent business practices to include, but not be limited to, the following:

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

OPM further defines poor business practices to include, but not be limited to, the following:

- Using fraudulent or unethical business or health care practices or otherwise displaying a lack of business integrity or honesty;
- Repeatedly or knowingly providing false or misleading information in the rate setting process;
- Failing to comply with OPM instructions and directives;
- 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;
- Failing to assure that the MSP properly pays or denies claims, or if applicable, provides medical services that are inconsistent with standards of good medical practice; and
- Entering into contracts or employment agreements with providers, provider groups, or health care workers that include provisions or financial incentives that directly or indirectly create an inducement to limit or restrict communication about medically necessary services to any individual covered under the MSPP. Financial incentives are defined as bonuses, withholds, commissions, profit sharing or other similar adjustments to basic compensation (e.g., service fee, capitation, salary) which have the effect of limiting or reducing communication about appropriate medically

necessary services.

In response to a comment expressing concern that the definition of poor business practices might interfere with delivery system reforms, OPM notes that limitation of communication about medically necessary services to enrollees is not an innovative payment arrangement or delivery model, and is not a feature of an accountable care organization (ACO) or a Patient-Centered Medical Home (PCMH).

The final rule also states that OPM may require MSPP issuers to pay an assessment into an escrow account to ensure contract compliance and benefit MSP enrollees. In response to comments, OPM reports that it continues to explore establishing a performance escrow account to use in enforcement of MSPP contracts. OPM adds that it may develop more specific policies to begin using such an account no sooner than 2015 and will issue specific guidance on the operations of such an account well in advance of the date on which it takes effect.

§ 800.402 Contract quality assurance.
As originally proposed, OPM will periodically evaluate each contractor's system of internal controls under the quality assurance program required by the contract and acknowledge in writing whether or not the system is consistent with the contract requirements. OPM's reviews do not diminish the contractor's obligation to implement and maintain an effective and efficient system to apply the internal controls. OPM will also issue specific performance standards for MSPP contracts and inform MSPP issuers of the applicable performance standards prior to negotiations for the contract year. OPM may benchmark its standards against standards generally accepted in the insurance industry, or may authorize nationally recognized standards to be used to fulfill this requirement. MSPP issuers must comply with the performance standards issued under this section.

In response to a comment recommending that OPM require MSPP issuers to meet States' quality assurance standards and requirements and contract with each State, in addition to contracting with OPM, OPM again says that requiring MSPP issuers to enter into a contract with Exchanges would circumvent section 1334(d) of the ACA, which vests certification authority for MSPs in OPM. OPM adds that it intends to hold MSPs to performance standards that are comparable to those set for QHPs by States and Exchanges.

§ 800.403 Fraud and abuse.
As originally proposed, an MSPP issuer must have a program to assess its vulnerability to fraud and abuse as well as to address such vulnerabilities. An MSPP issuer must operate a system designed to detect and eliminate fraud and abuse by its employees and subcontractors, by providers furnishing goods or services to MSP enrollees, and by MSP enrollees. An MSPP issuer must provide to OPM (including its Office of Inspector General) such information or assistance

as may be necessary for agency audit activities. An MSPP issuer must provide any requested information in the form, manner, and timeline prescribed by OPM. OPM notes that it intends to set forth specific standards and requirements for systems to detect and eliminate fraud and abuse in the model MSPP contract.

§ 800.404 Compliance actions.

OPM may impose a compliance action against an MSPP issuer for failure by the MSPP issuer to meet the contract performance requirements; for sustained failure to perform the MSPP contract in accordance with prudent business practices; for a pattern of poor conduct or evidence of poor business practices; or for such other violations of law or regulation as OPM may determine.

OPM may impose a compliance action against an MSPP issuer at any time during the contract term if it determines that the MSPP issuer is not in compliance with applicable law, regulations, or the terms of its contract with OPM. Compliance actions may include, but are not limited to:

- Establishment and implementation of a corrective action plan;
- Imposition of intermediate sanctions such as suspension of marketing;
- Performance incentives;
- Reduction of service area or area(s);
- Withdrawal of the certification of the MSPP issuer to offer the MSP on one or more Exchanges;
- Nonrenewal of the MSPP contract; and
- Withdrawal of approval or termination of the MSPP contract.

OPM must notify an MSPP issuer in writing of any specific compliance action undertaken and the reason for the compliance action. For compliance actions involving withdrawal of certification to offer an MSP, contract nonrenewal, or contract termination, the notice must include a statement that the MSPP issuer is entitled to ask for a reconsideration (see §800.405 below).

In response to a comment, the final rule revises the proposed text for §800.404 to provide that OPM will notify State and/or Exchange officials when it reduces the service area or areas of an MSP in the State, withdraws certification for an MSP in the State, declines to renew the MSPP contract under which an MSP is offered in the State, or terminates the MSPP contract under which an MSP is offered in the State.

Under §800.404(d), which is slightly revised from the proposed rule to add clarity, if OPM terminates an MSPP issuer's MSPP contract with OPM, or OPM withdraws the MSPP issuer's certification to offer the MSP on an Exchange, the MSPP issue must comply with any requirements regarding the termination of a plan that are applicable to a QHP offered on an Exchange on which the MSP was offered, including a requirement to provide advance written notice of termination to enrollees. If an Exchange does not have requirements about advance written notice of termination to enrollees, the MSPP issuer must inform

current MSP enrollees in writing of the nonrenewal of the MSP no later than 90 days prior to termination of coverage, unless OPM determines that good cause justifies less than 90 days' notice.

§ 800.405 Reconsideration of compliance actions.
OPM finalizes the proposed §800.405 with no changes. Under this section, an MSPP issuer may request that OPM reconsider a determination to impose one of the following compliance actions:

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

An MSPP issuer with a right to request reconsideration may request a hearing in which OPM will reconsider its determination to impose a compliance action. A request under this section must be in writing and contain such information, and be submitted in such manner, as OPM may prescribe. The request must be received by OPM within 15 calendar days after the date of the MSPP issuer's receipt of the notice of compliance action. The MSPP issuer may request that OPM's reconsideration allow a representative of the MSPP issuer to appear personally before OPM. A request must include a detailed statement of the reasons that the MSPP issuer disagrees with the compliance action, and may include additional information that will assist OPM in rendering a final decision. OPM may obtain additional information relevant to the request from any source it deems necessary. OPM will provide the MSPP issuer with a copy of any additional information it obtains and provide the MSPP issuer an opportunity to respond.

OPM's reconsideration, and hearing if requested, may be conducted by the OPM Director or a designated representative who did not participate in the initial decision that is the subject of the request for review. OPM will notify the MSPP issuer, in writing, of OPM's final decision and the specific reasons for that final decision. OPM's written decision will constitute final agency action that is subject to review under the APA 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 for Denials of Claims for Payment or Service

The final rule notes that the enrollee appeals standards and timeframes under the MSPP will be administratively similar to the disputed claims process employed within the FEHBP. OPM notes that the MSPP external review process will include binding final decisions by independent review organizations (IROs) on enrollee disputes that involve medical judgment (including, but not limited to, those based on medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit).

In response to comments, OPM agrees that MSPP issuer notices to enrollees should include contact information for Consumer Assistance Programs (CAPs) and Ombudsman offices available to assist consumers in filing appeals.

§ 800.501 General requirements.
OPM adopts proposed §800.501 as final, with no changes. For purposes of this subpart F, “claim” will mean a request for payment of a health-related bill; or provision of a health-related service or supply. “Adverse benefit determination” will mean an adverse benefit determination as defined in 45 CFR 147.136(a)(2)(i).

This subpart F will apply to enrollees and to other individuals or entities who are acting on behalf of an enrollee and who have the enrollee’s specific written consent to pursue a remedy of an adverse benefit determination.

§ 800.502 MSPP issuer internal claims and appeals.
In the final rule, OPM combines proposed §800.502 and §800.503 into a single section numbered 800.502 without making any substantive changes to what was proposed. MSPP issuers must comply with the internal claims and appeals processes applicable to QHPs under 45 CFR 147.136(b). An MSPP issuer must provide written notice to an enrollee of its determination on a claim brought under § 800.502 according to the timeframes and notification rules under 45 CFR 147.136(b) and (e), including the timeframes for urgent claims. If the MSPP issuer denies a claim (or a portion of the claim), the enrollee may appeal the adverse benefit determination to the MSPP issuer in accordance with 45 CFR 147.136(b).

§ 800.503 External review.
Proposed §800.504 has been finalized with only one change and renumbered §800.503 in the final rule. OPM will conduct external review of adverse benefit determinations using a process similar to OPM review of disputed claims under the FEHBP, subject to the standards and timeframes set forth in 45 CFR 147.136(d). In the proposed rule, OPM had referred to the State external review process under standards in 45 CFR 147.136(c)(2). OPM now says that the standards outlined in paragraph (c)(2) apply only to a State external review process, and would be inconsistent with the national approach OPM was proposing, which OPM says more appropriately falls under 45 CFR 147.136(d). OPM adds that it wishes to clarify that it intended the State external review standards in paragraph (c)(2) to serve as a model for the consumer protections that OPM would incorporate into its proposed external review process.

Under the finalized §800.503, notices to MSP enrollees regarding external review must comply with 45 CFR 147.136(e), including cultural and linguistic appropriateness standards, as well as adequately describing enrollee rights and obligations. Notices are subject to review and approval by OPM.

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

§ 800.504 Judicial review.
Proposed §800.505 is adopted as final, with one change, and renumbered as §800.504. While OPM's written decision under § 800.503(a) will constitute final agency action that is subject to review under the APA in the appropriate U.S. district court, as originally proposed, OPM emphasizes that final decisions on adverse benefit determinations related to medical judgment will be made by IROs; these decisions will be final, OPM will not be responsible for their approval, and such decisions cannot be considered final agency action subject to judicial review. In any event, under the finalized §800.504, judicial review is limited to the record that was before OPM when it made its decision.

SUBPART G – Miscellaneous

§ 800.601 Reservation of authority.
As originally proposed, OPM reserves the right to implement and supplement these regulations with written operational guidelines.

§ 800.602 Consumer choice with respect to certain services.
As originally proposed, OPM will ensure that at least one of the MSPP issuers on each Exchange in each State offers at least one MSP that does not provide coverage of abortion services described in section 1303(b)(1)(B)(i) of the ACA. Further, an MSP may not offer abortion coverage in any State where such coverage of abortion services is prohibited by State law.

In response to comments, OPM says that if an MSP is offered in a State that requires coverage of abortion services described in section 1303(b)(1)(B)(i), OPM will discuss options for compliance with State and Federal laws in contract negotiations with MSPP applicants.

II. EXECUTIVE ORDERS 13563 AND 12866; REGULATORY REVIEW

OPM treats the final rule as an economically significant regulatory action because its economic impact may exceed the $100 million threshold. Therefore, OPM assesses the costs and benefits of the final rule but acknowledges that it lacks data to quantify most of the benefits, costs, and transfers.

In the proposed rule, OPM sought comments on the number of States where MSPs will participate and the influence of the current market dynamics on enrollment in MSPs, but received none. Also, since OPM has not yet begun contract negotiations with potential MSPP issuers or closed the application

process, it notes that it does not have any more information on projected MSP enrollment than it had at the time of the proposed rule.

In any event, OPM states, as it did in the proposed rule, that the benefits of health insurance coverage include improved health, increased longevity, and improved financial security. It also may encourage inefficiency in terms of the tendency to purchase more care than is necessary. Further, administrative costs will be generated within OPM as well as by issuers. These costs will offset costs that would otherwise be incurred by States or by HHS. There will also be transfers between members of society.

III. PAPERWORK REDUCTION ACT

OPM acknowledges that it will have several information collections from MSPP issuers or applicants seeking to become MSPP issuers, but says it has determined that they are exempt from the requirements of the Paperwork Reduction Act because they are considered reporting requirements, and because OPM assumes fewer than ten responsible entities will respond to these information collections.

IV. REGULATORY FLEXIBILITY ACT

OPM concludes that the final rule will not have a significant economic impact on a substantial number of small entities because there are only a few health insurance issuers that could be considered small businesses or small non-profit organizations.

V. UNFUNDED MANDATES

OPM finds that the final rule does not place any Federal mandates on State, local, or tribal governments, or on the private sector.

VI. FEDERALISM

OPM states that the final rule has federalism implications due to its direct effect on the States, in particular, because OPM may deem a State law to be inconsistent with section 1334 of the ACA, and thus inapplicable to an MSP or an MSPP issuer. However, OPM expects that the vast majority of States have laws that are consistent with section 1334 of the ACA. OPM respectively disagrees with a comment arguing that OPM is not in compliance with Executive Order 13132 because it does not defer to more consumer-protective State standards, and asserts that it defers to such standards. OPM certifies that it has complied with the Federalism Executive Order 13132.

VII. CONGRESSIONAL REVIEW ACT

OPM notes that the final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Act of 1996, and says that it has, therefore, transmitted the rule to Congress and the Comptroller General for review.