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

On December 5, 2012, the U.S. Office of Personnel Management (OPM) caused to have published in the *Federal Register* a proposed rule to implement the multi-state plan program (MSPP) mandated by section 1334 of the Accountable Care Act (ACA). http://www.gpo.gov/fdsys/pkg/FR-2012-12-05/pdf/2012-29118.pdf **Comments are due on or before January 4, 2013.**

The scope of the proposed rule includes 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.

In general, the proposed MSPP regulations are consistent with those issued by HHS that will apply to qualified health plans (QHPs) and QHP issuers. OPM requests comments on many aspects of the proposed regulations. The areas where comments are requested are included in the following summary in bold type.

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I. BACKGROUND

The ACA directs OPM to contract with private health insurance issuers to offer at least two multi-state plans (MSPs) in each of the Exchanges in the 50 states and the District of Columbia (D.C.). MSPP issuers may phase-in coverage in all states over four years.

The ACA directs OPM to implement the MSPP in a manner similar to its contracting role with the Federal Employees Health Benefits Program (FEHBP). For FEHBP OPM negotiates rates and benefits annually, oversees contract compliance, reviews plan brochures, handles enrollees' complaints, contracts with an external entity for review of disputed claims, and monitors the financial stability of participating carriers, including their reserve funds. Since OPM only negotiates in the large group market for FEHBP, it intends to adjust its process to accommodate differences for operating in the small group and individual markets that will be served by the Exchanges.

OPM will coordinate and cooperate with the States and HHS in administering the MSPP. OPM standards for MSPs are expected to be consistent with those set for QHPs and QHP issuers by HHS and the Exchanges, although in some unique circumstances there may be some differences. OPM states that any differences will be designed to provide neither a competitive advantage nor disadvantage with respect to other plans offered on an Exchange.

In order to assess the level of interest in the MSPP, OPM issued a Request for Information on June 16, 2011. OPM received 19 responses representing 39 groups and organizations.

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 includes 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.

§ 800.20 Definitions.
In general, definitions used in the proposed rule come from the ACA and proposed HHS implementing regulations; the Public Health Service (PHS) Act and regulations; and the Federal Employees Health Benefit Act and regulations.

OPM proposes the following specific definitions (reproduced here verbatim from the proposed regulation text) that should only be read to apply to this rule:

- 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.
- 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.
- 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. Licensing of service marks can take place by private agreement between two or more issuers.
- 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.

SUBPART B – Multi-state Plan Issuer Requirements

§ 800.101 General requirements.

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 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. **OPM seeks comments on unique eligibility and enrollment issues that might affect MSPs.**

§ 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 provision in the ACA, including applicable regulations, listed in Appendix A.

§ 800.103 Authority to contract with issuers.
OPM may contract with issuers to offer MSPs in the State Exchanges and Small Business Health Options Programs (SHOPs) without regard to laws that require competitive bidding. OPM will contact with at least one non-profit entity. 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.
MSPP issuers must offer MSPs in all States (and D.C.), subject to the following phase-in: at least 60% of States (31) in the first year; 70% (36 States) in the second year; 85% (44 States) in the third year; and all States (50 + D.C.) in the fourth year. 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 proposes 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. OPM will evaluate whether the partial coverage locations have been established without regard to racial, ethnic, health status-related, or other factors that exclude high use, high cost, or medically underserved populations. **OPM asks for comment on whether an MSPP issuer should be required to expand to statewide coverage by the fourth year of participation.**

OPM further indicates that it does not believe the requirement in section 1334(c)(1)(D), that requires an MSP to be offered in all States that have adopted adjusted community rating before enactment of the ACA, applies to the phase-in process. Therefore, OPM proposes not to identify any specific states that an MSPP issuer must cover during the phase-in period.

<u>MSPP issuers and SHOP participation.</u> OPM proposes to require that MSPP issuers offer coverage in the State SHOPs as well as in the individual Exchanges. OPM proposes to allow issuers to phase-in SHOP participation.

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. **OPM seeks comments on this approach, including whether SHOP participation should be required from the outset or whether the SHOP phase-in period should be longer than 3 years.**

§ 800.105 Benefits.

OPM proposes 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 HHS requirements as well as any additional standards set by OPM. OPM proposes 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. For the second option, OPM proposes selecting 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 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. **Comments are solicited on these options, including whether either option would encourage or discourage MSPP participation, and whether or not the second option would disrupt a State's level playing field.**

OPM indicates that its research shows that benchmark-eligible plans lack coverage for certain benefits. It therefore is proposing that plans lacking coverage of pediatric oral services or pediatric vision services expand their benefits 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 solicits comments on the provision of pediatric dental services. Under one approach, an MSP would cover pediatric dental services with other benefits in its benefit package. It requests comments on how stand-alone dental plans offered in Exchanges would affect this requirement. It also solicits comments on the advantages and disadvantages of this approach and whether there is legal justification for each approach. It invites comments on other possible approaches.**

OPM would also require MSPP plans to follow the State definition where a State chooses to define habilitative services category. If a State does not define this category, and an OPM-benchmark plan lacks coverage for these services, OPM would define the habilitative services to be covered by the plan.

OPM 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 proposes that if an MSPP issuer chooses the option to use an OPM EHB-benchmark in all states, the issuer would need to use a state-selected benchmark in States that require all plans to offer the same set of benefits to avoid any adverse selection. **OPM seeks comment on this proposal.**

OPM will review MSP benefits packages, including prescription drug lists, and determine if they are substantially equal to an EHB-Benchmark plan. OPM proposes to 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 requests comments on whether MSPP issuers should submit actuarial equivalence evidence to OPM in addition to, or in lieu of, submitting evidence to a State.**

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.

OPM indicates in the preamble to the proposed rule 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. If the proposed and final regulations regarding Certain Preventive Services affect the MSPP, the final rule may include that policy. **OPM seeks comments on this as part of comments on benefits (§800.105.)**

§ 800.106 Cost-sharing limits, premium tax credits, and cost-sharing reductions.
OPM proposes 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 may also issue additional guidance and is soliciting comments on additional standards it should adopt to address unique issues faced by MSPs.**

OPM proposes 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.

§ 800.107 Levels of coverage.
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.

§ 800.108 Assessments and user fees.
OPM proposes to reserve its authority to assess a user fee on MSPP issuers as a condition for participating in the MSPP. The amount of any user fee for a plan year would 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. **OPM seeks comments on using assessments and user fees.**

§ 800.109 Network adequacy.
OPM proposes 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 proposes 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 indicates it will consult with States to set more specific criteria for network adequacy in future guidance. **OPM asks for comments on network adequacy, including issues concerning network adequacy as condition for State licensure, and any issues for MSPs with respect to State-specific network adequacy requirements.**

§ 800.110 Service area.
OPM proposes 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 is also considering 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. If an Exchange permits issuers to define their own service areas, an MSPP issuer

would have to obtain OPM's approval for its proposed service areas. OPM would coordinate with HHS on requests for partial county service areas to align service areas with those of QHPs and prevent any gaming. **OPM invites comments on its approach for service areas.**

§ 800.111 Accreditation requirement.
In general, OPM proposes that an MSPP issuer must 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. **OPM asks for comments on its proposed accreditation requirements.**

§ 800.112 Reporting requirements.
OPM proposes to use the FEHBP model for reporting. Under FEHBP plans are required to report information on finances, premium payments, enrollment and quality assurance. (FEHB carrier reporting requirements may be found at (http://www.opm.gov/carrier/reports/index.asp). 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. As authorized by ACA section 3101(a)(2)(E), OPM proposes to collect data on individuals by race, ethnicity, sex, primary language, and disability status. OPM also proposes to collect other data as it determines necessary for oversight and administration of the MSPP, including claims payment and enrollment data. **OPM will issue further guidance on reporting and requests comments on its approach, including on the types of information it proposes to collect and mechanisms that can reduce unnecessary duplication of data disclosed to OPM, HHS, States, and Exchanges.**

OPM also proposes that MSPP issuers report 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. **OPM requests comments on the unique aspects of accreditation and reporting for MSPs as compared to QHPs.**

§ 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 would have to 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 to meet the needs of MSP enrollees.

OPM proposes that an MSPP issuer 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. OPM also proposes to require MSPs 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 a Memorandum of Understanding (MOU).

OPM proposes to allow 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 states that it expects MSPP issuers to meet State financial requirements including participating in State guaranty funds and meeting State reserving requirements. OPM may execute an MOU with each State regarding participation of MSPP issuers in such funds. **OPM invites 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.**

§ 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 proposes to require an MSPP issuer, with respect to each of its MSPs, to comply with all Federal and State laws in these 13 categories.

§ 800.116 Process for dispute resolution.
OPM proposes a 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 would have to 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 would provide the requester with a copy of any additional information it obtains and provide an opportunity for the requester to respond. OPM would 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 would 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.

In making its decision, OPM would examine whether the State law at issue:

1. Imposes on MSPP issuers or MSPs requirements that differ from those applicable to QHP issuers and QHPs offered in the State;
2. Creates responsibilities, administrative burdens, or costs that impede an MSPP issuer from offering a viable product in the State Exchanges;
3. Creates responsibilities burdens, or costs that deter OPM's effective

implementation of the MSPP; or
4. Prevents an MSPP issuer from offering an MSP in the State's Exchanges.

OPM invites comments on whether to have such a process; its scope; the factors it should consider; and whether the process will be effective. It also invites comments on whether the process should be used by States to raise disputes concerning laws related to the 13 categories listed above.

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

§ 800.201 General requirements.
OPM proposes to 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 would be set on a State-by-State basis. OPM would work with the States to identify and investigate any potentially discriminatory rating practices. OPM proposes to issue guidance, similar to the FEHBP carrier letter, to provide carriers with the information needed to develop rates for the MSPP. Such guidance would follow rating standards generally applicable in a State to the greatest extent practicable.

An MSPP issuer must calculate actuarial value in the same manner as QHP issuers as well as any 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.

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.) OPM proposes that for States with Effective Rate Review Programs, the MSPP issuer would comply with State standards. OPM further proposes that in States where HHS is reviewing rates, HHS would accept of judgment of OPM for MSP rate increases. 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 retains authority to make the final decision to approve rates for participation in the MSPP notwithstanding the absence of State approval. **OPM invites comments on its proposed approach to MSP rate approval, and on the impact of this approach.**

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 would have to comply.

§ 800.202 Rating factors.
OPM proposes that MSPP issuers 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.

§ 800.203 Medical loss ratio.
The ACA authorizes OPM to set a medical loss ratio (MLR) for each MSP, similar to FEHBP. OPM proposes 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. OPM states it does not intend to apply a national aggregate MLR. **OPM requests comments on the proposed MSP-specific MLR and the methodology issuers should use to calculate it.**

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**.**

OPM also has the authority under the ACA section 1334(a)(4) to set profit margins. **OPM has not proposed a standard for profit margins and seeks 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.**

§ 800.204 Reinsurance, risk corridors, and risk adjustment.
OPM proposes that an MSPP comply 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).

SUBPART D – Application and Contracting Procedures

§ 800.301 Application process.

OPM proposes 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.

§ 800.302 Review of applications.

OPM would 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 would establish a standard contract for the MSPP. OPM and the applicant would 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 would 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.

§ 800.304 Term of the contract.

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.

§ 800.305 Contract renewal process.
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 would 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 would be renewed and the existing premiums and benefits for that MSP on that Exchange or Exchanges would 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.

SUBPART E – Compliance

§ 800.401 Contract performance.
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 would 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 poor business practices, as described below.

OPM proposes to define 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 proposes that poor business practices 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.

OPM proposes to establish a performance escrow account for each MSPP issuer and may require the MSPP issuer to pay a "modest" assessment into the escrow account. The account funds could be used to provide a rebate to enrollees in cases of inadequate performance or could be used to reward the plan for meeting performance standards. The accounts could also be used to hold funds paid in response to audit findings, not meeting performance standards, or other issues of noncompliance. **OPM requests comments on the performance escrow account proposal, specifically on how best to collect, hold and release funds. It also requests comments on alternative methods of ensuring contract compliance.**

§ 800.402 Contract quality assurance.
OPM would 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 would 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.

§ 800.403 Fraud and abuse.
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 the agency audit activities. An MSPP issuer must provide any requested information in the form, manner, and timeline prescribed by OPM.

§ 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). If OPM terminates a MSPP contract or withdraws certification for an MSP, the MSPP issuer must comply with requirements imposed by the Exchange on which the MSP was offered, including advance written notification to enrollees. If the Exchange does not require advance written notice of termination, 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.

§ 800.405 Reconsideration of compliance actions.
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 would 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 would 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 would 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

§ 800.501 General requirements.
For purposes of this subpart F, "claim" would mean a request for payment of a health-related bill; or provision of a health-related service or supply. "Adverse benefit determination" would mean an adverse benefit determination as defined in 45 CFR 147.136(a)(2)(i).

This subpart F would 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 processes.
MSPP issuers would be required to comply with the internal claims and appeals processes applicable to QHPs under 45 CFR 147.136(b).

§ 800.503 MSPP issuer internal claims and appeals timeframes and notice of determination.
An MSPP issuer would have to 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).

§ 800.504 External review.
OPM proposes that MSPP issuers comply with OPM's external review process that will meet the standards for State external review processes, and will be similar to that used to review disputed claims for FEHBP. OPM intends to issue further guidance on the external review process.

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.

OPM considered an alternative approach for external review whereby the exclusive method of external review for an MSPP would be use of the Federal external review process that OPM administers with HHS and is used in States without effective processes. OPM also considered a hybrid approach under which OPM would render a final decision in all cases based on medical judgment, and use a process similar the FEHBP disputed claims process for adverse determinations not based on medical judgment. **OPM invites comments on these proposed approaches for external appeals and on the impact of the approaches in providing a level playing field for all plans on the Exchanges.**

§ 800.505 Judicial review.
OPM's written decision under § 800.504(a) would 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 G – Miscellaneous

§ 800.601 Reservation of authority.
OPM would reserve the right to implement and supplement these regulations with written operational guidelines.

§ 800.602 Consumer choice with respect to certain services.
OPM proposes to implement the ACA requirement 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) of the ACA.

OPM also proposes to implement the State opt-out provisions and prohibit an MSP from offering abortion coverage in any State where such coverage of abortion services is prohibited by State law.

II. REGULATORY IMPACT ANALYSIS

OPM determined that the proposed rule is an economically significant regulatory action (economic effects of $100 million or more in any one year) and included a regulatory impact analysis of costs and benefits of regulatory approaches. OPM states that it lacks the information necessary to make assumptions about potential enrollment in MSPs on the Exchanges. **OPM seeks comment on the number of states where MSPs will participate and the influence of current market dynamics on enrollment in MSPs.**

OPM states 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. 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. OPM indicates that it lacks data to quantify benefits, costs, and transfers. It **cannot isolate the effects of MSPs from overall effects of the ACA coverage provisions and request comments on the rule's cost-benefit analysis.**

III. PAPERWORK REDUCTION ACT

OPM determined that the collection of information from MSPP issuers or applicants is exempt from the requirements of the Paperwork Reduction Act because they are considered reporting requirements, and OPM assumes fewer than ten responsible entities will respond to the information collections. **OPM seeks comments on their assumptions regarding the Paperwork Reduction Act requirements.**

IV. REGULATORY FLEXIBILITY ACT

OPM reviewed the Regulatory Flexibility Act and analyzed the impact of the proposed rule on small entities. OPM does not think small businesses or small non-profit organizations will have economies of scale to become MSPP issuers or be part of a group of issuers. The Director of OPM certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities.

V. UNFUNDED MANDATES

OPM reviewed the Unfunded Mandates Reform Act and analyzed the impact of the proposed rule on state, local and tribal governments and the private sector. OPM states that the rule does not place any Federal mandates on State, local, or Tribal governments, or on the private sector because the MSPP is a voluntary federal program.

VI. FEDERALISM

OPM states that the proposed rule has federalism implications because of a 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 believes these implications are substantially mitigated because OPM expects the vast majority of State laws to be consistent. OPM also notes it has engaged in efforts to consult with and work cooperatively with State and local officials. OPM certifies that it has complied with the Federalism Executive Order 13132.

APPENDIX A: Applicable Federal Laws

§800.102 requires an MSPP issuer to comply with the following provisions of part A of title XXVII of the PHS Act:

- Fair Health Insurance Premiums (Sec. 2701);
- Guaranteed Availability of Coverage (Sec. 2702);
- Guaranteed Renewability of Coverage (Sec. 2703);
- Prohibition of Preexisting Condition Exclusions or Other Discrimination Based on Health Status (Sec. 2705);
- Non-Discrimination in Health Care (Sec. 2706);
- Comprehensive Health Insurance Coverage (Sec. 2707 relating to essential benefits, cost-sharing, and child-only plans);
- Prohibition on Excessive Waiting Periods (Sec. 2708);
- Coverage for Individuals Participating in Approved Clinical Trials (Sec. 2709);
- Disclosure of Information (Sec. 2709 [sic]);
- No Lifetime or Annual Limits (Sec. 2711);
- Prohibition on Rescissions (Sec. 2712);
- Coverage of Preventive Health Services (Sec. 2713);
- Extension of Dependent Coverage (Sec. 2714);
- Development and Utilization of Uniform Explanation of Coverage Documents and Standardized definitions (Sec. 2715);
- Provision of Additional Information (Sec. 2715A);
- Ensuring the Quality of Care (Sec. 2717);
- Bringing Down the Cost of Health Care Coverage (Sec. 2718, related to standard hospital charges)
- Appeals Process (Sec. 2719);
- Patient Protections (Sec. 2719A);
- Standards Relating to Benefits for Mothers and Newborns [in the Group Market] (Sec. 2725);
- Mental Health and Substance Use Disorder Parity (Sec. 2726);
- Required Coverage for Reconstructive Surgery Following Mastectomies (Sec. 2727);
- Coverage of Dependent Students on Medically Necessary Leave of Absence (Sec. 2728).

§800.102 requires an MSPP issuer to comply with the following provisions of title I of the ACA:

- Essential Health Benefits (section 1302);
- Special Rules (section 1303);
- Related Definitions (section 1304);
- Affordable Choices of Health Benefits Plans (section 1311);
- Multi-state Plans (section 1334);
- Transitional Reinsurance (section 1341);
- Risk Corridors for Plans in Individual and Small Group Markets (Sec 1342)
- Risk Adjustment (section 1343)
- Premium Assistance for Coverage under a QHP (section 1401);
- Reduced Cost-Sharing for Individuals (section 1402);
- Payment of Premium Tax Credits and Cost-sharing Reductions (section 1412(c));
- Nondiscrimination (Section 1557);
- Pharmacy Benefit Managers Transparency Requirements (Section 6005).

§800.102 requires an MSPP issuer to comply with section 36B of the Internal Revenue Code of 1986 (Section 36B).