Final rule

§ 380.10 [Corrected]

■ 2. On page 61125, in the third column, in § 380.10, in paragraph (a)(2), ''$0.0019'' is corrected to read ''$0.0018''.

Dated: December 3, 2018.

David R. Strickler,

Copyright Royalty Judge.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 153

[CMS–9919–F]

RIN 0938–AT66

Patient Protection and Affordable Care Act; Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program for the 2018 Benefit Year Final Rule

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule adopts the HHS-operated risk adjustment methodology for the 2018 benefit year. In February 2018, a district court vacated the use of statewide average premium in the HHS-operated risk adjustment methodology for the 2014 through 2018 benefit years. Following review of all submitted comments to the proposed rule, HHS is adopting for the 2018 benefit year an HHS-operated risk adjustment methodology that utilizes the statewide average premium and is operated in a budget-neutral manner, as established in the final rules published in the March 23, 2012 and the December 22, 2016 editions of the **Federal Register**.

DATES: The provisions of this final rule are effective on February 8, 2019.

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SUPPLEMENTARY INFORMATION:

I. Background

A. Legislative and Regulatory Overview

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010; the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) was enacted on March 30, 2010. These statutes are collectively referred to as ''PPACA'' in this final rule. Section 1343 of the PPACA established an annual permanent risk adjustment program under which payments are collected from health insurance issuers that enroll relatively low-risk populations, and payments are made to health insurance issuers that enroll relatively higher-risk populations. Consistent with section 1321(c)(1) of the PPACA, the Secretary is responsible for operating the risk adjustment program on behalf of any state that elects not to do so. For the 2018 benefit year, HHS is responsible for operation of the risk adjustment program in all 50 states and the District of Columbia.

HHS sets the risk adjustment methodology that it uses in states that elect not to operate risk adjustment in advance of each benefit year through a notice-and-comment rulemaking process with the intention that issuers will be able to rely on the methodology to price their plans appropriately (see 45 CFR 153.320; 76 FR 41930, 41932 through 41933; 81 FR 94058, 94702 (explaining the importance of setting rules ahead of time and describing comments supporting that practice)).

In the July 15, 2011 **Federal Register** (76 FR 41929), we published a proposed rule outlining the framework for the risk adjustment program. We implemented the risk adjustment program in a final rule, published in the March 23, 2012 **Federal Register** (77 FR 17219) (Premium Stabilization Rule). In the December 7, 2012 **Federal Register** (77 FR 73117), we published a proposed rule outlining the proposed Federally certified risk adjustment methodologies for the 2014 benefit year and other parameters related to the risk adjustment program (proposed 2014 Payment Notice). We published the 2014 Payment Notice final rule in the March 11, 2013 **Federal Register** (78 FR 15409). In the June 19, 2013 **Federal Register** (78 FR 37032), we proposed a modification to the HHS-operated risk adjustment methodology related to community rating states. In the October 30, 2013 **Federal Register** (78 FR 65046), we finalized this proposed modification related to community rating states. We published a correcting amendment to the 2014 Payment Notice final rule in the November 6, 2013 **Federal Register** (78 FR 66653) to address how an enrollee's age for the risk score calculation would be determined under the HHS-operated risk adjustment methodology.

In the December 2, 2013 **Federal Register** (78 FR 72321), we published a proposed rule outlining the Federally certified risk adjustment methodologies for the 2015 benefit year and other parameters related to the risk adjustment program (proposed 2015 Payment Notice). We published the 2015 Payment Notice final rule in the March 11, 2014 **Federal Register** (79 FR 13743). In the May 27, 2014 **Federal Register** (79 FR 30240), the 2015 fiscal year sequestration rate for the risk adjustment program was announced.

In the November 26, 2014 **Federal Register** (79 FR 70673), we published a proposed rule outlining the proposed Federally certified risk adjustment methodologies for the 2016 benefit year and other parameters related to the risk adjustment program (proposed 2016 Payment Notice). We published the 2016 Payment Notice final rule in the February 27, 2015 **Federal Register** (80 FR 10749).

In the December 2, 2015 **Federal Register** (80 FR 75487), we published a proposed rule outlining the Federally certified risk adjustment methodology for the 2017 benefit year and other parameters related to the risk adjustment program (proposed 2017 Payment Notice). We published the 2017 Payment Notice final rule in the March 8, 2016 **Federal Register** (81 FR 12204).

In the September 6, 2016 **Federal Register** (81 FR 61455), we published a proposed rule outlining the Federally certified risk adjustment methodology for the 2018 benefit year and other parameters related to the risk adjustment program (proposed 2018 Payment Notice). We published the 2018 Payment Notice final rule in the December 22, 2016 **Federal Register** (81 FR 94058).

In the November 2, 2017 **Federal Register** (82 FR 51042), we published a proposed rule outlining the federally certified risk adjustment methodology for the 2019 benefit year. In that proposed rule, we proposed updates to the risk adjustment methodology and amendments to the risk adjustment data validation process (proposed 2019 Payment Notice). We published the 2019 Payment Notice final rule in the April 17, 2018 **Federal Register** (83 FR 16930). We published a correction to the 2019 risk adjustment coefficients in the 2019 Payment Notice final rule in the May 11, 2018 **Federal Register** (83 FR 21925). On July 27, 2018, consistent with § 153.320(b)(1)(i), we updated the 2019 benefit year final risk adjustment model coefficients to reflect an additional recalibration related to an

update to the 2016 enrollee-level EDGE dataset.[1]

In the July 30, 2018 **Federal Register** (83 FR 36456), we published a final rule that adopted the 2017 benefit year HHS-operated risk adjustment methodology set forth in the March 23, 2012 **Federal Register** (77 FR 17220 through 17252) and in the March 8, 2016 **Federal Register** (81 FR 12204 through 12352). The final rule provided an additional explanation of the rationale for use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2017 benefit year, including why the program is operated in a budget-neutral manner. That final rule permitted HHS to resume 2017 benefit year program operations, including collection of risk adjustment charges and distribution of risk adjustment payments. HHS also provided guidance as to the operation of the HHS-operated risk adjustment program for the 2017 benefit year in light of publication of the final rule.[2]

In the August 10, 2018 **Federal Register** (83 FR 39644), we published the proposed rule concerning the adoption of the 2018 benefit year HHS-operated risk adjustment methodology set forth in the March 23, 2012 **Federal Register** (77 FR 17220 through 17252) and in the December 22, 2016 **Federal Register** (81 FR 94058 through 94183).

B. The New Mexico Health Connections Court's Order

On February 28, 2018, in a suit brought by the health insurance issuer New Mexico Health Connections, the United States District Court for the District of New Mexico (the district court) vacated the use of statewide average premium in the HHS-operated risk adjustment methodology for the 2014, 2015, 2016, 2017, and 2018 benefit years. The district court reasoned that HHS had not adequately explained its decision to adopt a methodology that used statewide average premium as the cost-scaling factor to ensure that the amount collected from issuers equals the amount of payments made to issuers for the applicable benefit year, that is, a methodology that maintains the budget neutrality of the HHS-operated risk adjustment program for the applicable benefit year.[3] The district court otherwise rejected New Mexico Health Connections' arguments.

C. The PPACA Risk Adjustment Program

The risk adjustment program provides payments to health insurance plans that enroll populations with higher-than-average risk and collects charges from plans that enroll populations with lower-than-average risk. The program is intended to reduce incentives for issuers to structure their plan benefit designs or marketing strategies to avoid higher-risk enrollees and lessen the potential influence of risk selection on the premiums that plans charge. Instead, issuers are expected to set rates based on average risk and compete based on plan features rather than selection of healthier enrollees. The program applies to any health insurance issuer offering plans in the individual, small group and merged markets, with the exception of grandfathered health plans, group health insurance coverage described in 45 CFR 146.145(c), individual health insurance coverage described in 45 CFR 148.220, and any plan determined not to be a risk adjustment covered plan in the applicable Federally certified risk adjustment methodology.[4] In 45 CFR part 153, subparts A, B, D, G, and H, HHS established standards for the administration of the permanent risk adjustment program. In accordance with § 153.320, any risk adjustment methodology used by a state, or by HHS on behalf of the state, must be a federally certified risk adjustment methodology.

As stated in the 2014 Payment Notice final rule, the federally certified risk adjustment methodology developed and used by HHS in states that elect not to operate a risk adjustment program is based on the premise that premiums for that state market should reflect the differences in plan benefits and efficiency—not the health status of the enrolled population.[5] HHS developed the risk adjustment state payment transfer formula that calculates the difference between the revenues required by a plan based on the projected health risk of the plan's enrollees and the revenues that the plan can generate for those enrollees. These differences are then compared across plans in the state market risk pool and converted to a dollar amount based on the statewide average premium. HHS chose to use statewide average premium and normalize the risk adjustment state payment transfer formula to reflect state average factors so that each plan's enrollment characteristics are compared to the state average and the total calculated payment amounts equal total calculated charges in each state market risk pool. Thus, each plan in the state market risk pool receives a risk adjustment payment or charge designed to compensate for risk for a plan with average risk in a budget-neutral manner. This approach supports the overall goal of the risk adjustment program to encourage issuers to rate for the average risk in the applicable state market risk pool, and mitigates incentives for issuers to operate less efficiently, set higher prices, or develop benefit designs or create marketing strategies to avoid high-risk enrollees. Such incentives could arise if HHS used each issuer's plan's own premium in the state payment transfer formula, instead of statewide average premium.

II. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

In the August 10, 2018 **Federal Register** (83 FR 39644), we published a proposed rule that proposed to adopt the HHS-operated risk adjustment methodology as previously established in the March 23, 2012 **Federal Register** (77 FR 17220 through 17252) and the December 22, 2016 **Federal Register** (81 FR 94058 through 94183) for the 2018 benefit year, with an additional explanation regarding the use of statewide average premium and the budget-neutral nature of the HHS-operated risk adjustment program. We did not propose to make any changes to the previously published HHS-operated risk adjustment methodology for the 2018 benefit year.

As explained above, the district court vacated the use of statewide average premium in the HHS-operated risk adjustment methodology for the 2014 through 2018 benefit years on the grounds that HHS did not adequately explain its decision to adopt that aspect of the risk adjustment methodology. The district court recognized that use of statewide average premium maintained the budget neutrality of the program, but concluded that HHS had not adequately explained the underlying decision to adopt a methodology that kept the program budget neutral, that is, a methodology that ensured that amounts

[1] See *Updated 2019 Benefit Year Final HHS Risk Adjustment Model Coefficients.* July 27, 2018. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2019-Updtd-Final-HHS-RA-Model-Coefficients.pdf.*

[2] See *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2017-RA-Final-Rule-Resumption-RAOps.pdf.*

[3] *New Mexico Health Connections* v. *United States Department of Health and Human Services et al.,* No. CIV 16–0878 JB/JHR (D.N.M. Feb. 28, 2018). On March 28, 2018, HHS filed a motion requesting that the district court reconsider its decision. A hearing on the motion for reconsideration was held on June 21, 2018. On October 19, 2018, the court denied HHS's motion for reconsideration. See *New Mexico Health Connections* v. *United States Department of Health and Human Services et al.,* No. CIV 16–0878 JB/JHR (D.N.M. Oct. 19, 2018).

[4] See the definition for ''risk adjustment covered plan'' at § 153.20.

[5] See 78 FR at 15417.

collected from issuers would equal payments made to issuers for the applicable benefit year. Accordingly, HHS provided the additional explanation in the proposed rule.

As explained in the proposed rule, Congress designed the risk adjustment program to be implemented and operated by states if they chose to do so. Nothing in section 1343 of the PPACA requires a state to spend its own funds on risk adjustment payments, or allows HHS to impose such a requirement. Thus, while section 1343 may have provided leeway for states to spend additional funds on their programs if they voluntarily chose to do so, HHS could not have required such additional funding.

We also explained that while the PPACA did not include an explicit requirement that the risk adjustment program be operated in a budget-neutral manner, HHS was constrained by appropriations law to devise a risk adjustment methodology that could be implemented in a budget-neutral fashion. In fact, although the statutory provisions for many other PPACA programs appropriated or authorized amounts to be appropriated from the U.S. Treasury, or provided budget authority in advance of appropriations,[6] the PPACA neither authorized nor appropriated additional funding for risk adjustment payments beyond the amount of charges paid in, and did not authorize HHS to obligate itself for risk adjustment payments in excess of charges collected.[7] Indeed, unlike the Medicare Part D statute, which expressly authorized the appropriation of funds and provided budget authority in advance of appropriations to make Part D risk-adjusted payments, the PPACA's risk adjustment statute made no reference to additional appropriations.[8] Because Congress omitted from the PPACA any provision appropriating independent funding or creating budget authority in advance of an appropriation for the risk adjustment program, we explained that HHS could not—absent another source of appropriations—have designed the program in a way that required payments in excess of collections consistent with binding appropriations law. Thus, Congress did not give HHS discretion to implement a risk adjustment program that was not budget neutral.

Furthermore, the proposed rule explained that if HHS elected to adopt a risk adjustment methodology that was contingent on appropriations from Congress through the annual appropriations process, that would have created uncertainty for issuers regarding the amount of risk adjustment payments they could expect for a given benefit year. That uncertainty would have undermined one of the central objectives of the risk adjustment program, which is to stabilize premiums by assuring issuers in advance that they will receive risk adjustment payments if, for the applicable benefit year, they enroll a higher-risk population compared to other issuers in the state market risk pool. The budget-neutral framework spreads the costs of covering higher-risk enrollees across issuers throughout a given state market risk pool, thereby reducing incentives for issuers to engage in risk-avoidance techniques such as designing or marketing their plans in ways that tend to attract healthier individuals, who cost less to insure.

Moreover, the proposed rule noted that relying on each year's budget process for appropriation of additional funds to HHS that could be used to supplement risk adjustment transfers would have required HHS to delay setting the parameters for any risk adjustment payment proration rates until well after the plans were in effect for the applicable benefit year. The proposed rule also explained that any later-authorized program management appropriations made to CMS were not intended to be used for supplementing risk adjustment payments, and were allocated by the agency for other, primarily administrative, purposes. Specifically, it has been suggested that the annual lump sum appropriation to CMS for program management (CMS Program Management account) was potentially available for risk adjustment payments. The lump sum appropriation for each year was not enacted until after the applicable rule announcing the HHS-operated methodology for the applicable benefit year, and therefore could not have been relied upon in promulgating that rule. Additionally, as the underlying budget requests reflect, the CMS Program Management account was intended for program management expenses, such as administrative costs for various CMS programs such as Medicaid, Medicare, the Children's Health Insurance Program, and the PPACA's insurance market reforms—not for the program payments under those programs. CMS would have elected to use the CMS Program Management account for these important program management expenses, rather than program payments for risk adjustment, even if CMS had discretion to use all or part of the lump sum for such program payments. Without the adoption of a budget-neutral framework, we explained that HHS would have needed to assess a charge or otherwise collect additional funds, or prorate risk adjustment payments to balance the calculated risk adjustment transfer amounts. The resulting uncertainty would have conflicted with the overall goals of the risk adjustment program—to stabilize premiums and to reduce incentives for issuers to avoid enrolling individuals with higher-than-average actuarial risk.

In light of the budget-neutral framework discussed above, the proposed rule explained that we also chose not to use a different parameter for the state payment transfer formula under the HHS-operated methodology, such as each plan's own premium, that would not have automatically achieved equality between risk adjustment payments and charges in each benefit year. As set forth in prior discussions,[9] use of the plan's own premium or a similar parameter would have required the application of a balancing adjustment in light of the program's budget neutrality—either reducing payments to issuers owed a payment, increasing charges on issuers due a charge, or splitting the difference in some fashion between issuers owed payments and issuers assessed charges. Using a plan's own premium would have frustrated the risk adjustment program's goals, as discussed above, of encouraging issuers to rate for the average risk in the applicable state market risk pool, and avoiding the creation of incentives for issuers to operate less efficiently, set higher prices, or develop benefit designs or create marketing strategies to avoid high-risk enrollees. Use of an after-the-fact balancing adjustment is also less predictable for issuers than a

[6] For examples of PPACA provisions appropriating funds, *see* PPACA secs. 1101(g)(1), 1311(a)(1), 1322(g), and 1323(c). For examples of PPACA provisions authorizing the appropriation of funds, *see* PPACA secs. 1002, 2705(f), 2706(e), 3013(c), 3015, 3504(b), 3505(a)(5), 3505(b), 3506, 3509(a)(1), 3509(b), 3509(e), 3509(f), 3509(g), 3511, 4003(a), 4003(b), 4004(j), 4101(b), 4102(a), 4102(c), 4102(d)(1)(C), 4102(d)(4), 4201(f), 4202(a)(5), 4204(b), 4206, 4302(a), 4304, 4305(a), 4305(c), 5101(h), 5102(e), 5103(a)(3), 5203, 5204, 5206(b), 5207, 5208(b), 5210, 5301, 5302, 5303, 5304, 5305(a), 5306(a), 5307(a), and 5309(b).

[7] *See* 42 U.S.C. 18063.

[8] *Compare* 42 U.S.C. 18063 (failing to specify source of funding other than risk adjustment charges), *with* 42 U.S.C. 1395w–116(c)(3) (authorizing appropriations for Medicare Part D risk adjusted payments); 42 U.S.C. 1395w–115(a) (establishing ''budget authority in advance of appropriations Acts'' for Medicare Part D risk adjusted payments).

[9] See for example, September 12, 2011, *Risk Adjustment Implementation Issues White Paper,* available at *https://www.cms.gov/CCIIO/Resources/Files/Downloads/riskadjustment_whitepaper_web.pdf.*

methodology that is established before the benefit year. We explained that such predictability is important to serving the risk adjustment program's goals of premium stabilization and reducing issuer incentives to avoid enrolling higher-risk populations.

Additionally, the proposed rule noted that using a plan's own premium to scale transfers may provide additional incentives for plans with high-risk enrollees to increase premiums in order to receive higher risk adjustment payments. As noted by commenters to the 2014 Payment Notice proposed rule, transfers also may be more volatile from year to year and sensitive to anomalous premiums if they were scaled to a plan's own premium instead of the statewide average premium. In the 2014 Payment Notice final rule, we noted that we received a number of comments in support of our proposal to use statewide average premium as the basis for risk adjustment transfers, while some commenters expressed a desire for HHS to use a plan's own premium.[10] HHS addressed those comments by reiterating that we had considered the use of a plan's own premium, but chose to use statewide average premium, as this approach supports the overall goals of the risk adjustment program to encourage issuers to rate for the average risk in the applicable state market risk pool, and avoids the creation of incentives for issuers to employ risk-avoidance techniques.[11]

The proposed rule also explained that although HHS has not yet calculated risk adjustment payments and charges for the 2018 benefit year, immediate administrative action was imperative to maintain stability and predictability in the individual, small group and merged insurance markets. Without administrative action, the uncertainty related to the HHS-operated risk adjustment methodology for the 2018 benefit year could add uncertainty to the individual, small group and merged markets, as issuers determine the extent of their market participation and the rates and benefit designs for plans they will offer in future benefit years. Without certainty regarding the 2018 benefit year HHS-operated risk adjustment methodology, there was a serious risk that issuers would substantially increase future premiums to account for the potential of uncompensated risk associated with high-risk enrollees. Consumers enrolled in certain plans with benefit and network structures that appeal to higher risk enrollees could see a significant premium increase, which could make coverage in those plans particularly unaffordable for unsubsidized enrollees. In states with limited Exchange options, a qualified health plan issuer exit would restrict consumer choice, and could put additional upward pressure on premiums, thereby increasing the cost of coverage for unsubsidized individuals and federal spending for premium tax credits. The combination of these effects could lead to involuntary coverage losses in certain state market risk pools.

Additionally, the proposed rule explained that HHS's failure to make timely risk adjustment payments could impact the solvency of issuers providing coverage to sicker (and costlier) than average enrollees that require the influx of risk adjustment payments to continue operations. When state regulators evaluate issuer solvency, any uncertainty surrounding risk adjustment transfers hampers their ability to make decisions that protect consumers and support the long-term health of insurance markets.

In response to the district court's February 2018 decision that vacated the use of statewide average premium in the risk adjustment methodology on the grounds that HHS did not adequately explain its decision to adopt that aspect of the methodology, we offered the additional explanation outlined above in the proposed rule, and proposed to maintain the use of statewide average premium in the applicable state market risk pool for the state payment transfer formula under the HHS-operated risk adjustment methodology for the 2018 benefit year. HHS proposed to adopt the methodology previously established for the 2018 benefit year in the **Federal Register** publications cited above that apply to the calculation, collection, and payment of risk adjustment transfers under the HHS-operated methodology for the 2018 benefit year. This included the adjustment to the statewide average premium, reducing it by 14 percent, to account for an estimated proportion of administrative costs that do not vary with claims.[12] We sought comment on the proposal to use statewide average premium. However, in order to protect the settled expectations of issuers that structured their pricing, offering, and market participation decisions in reliance on the previously issued 2018 benefit year methodology, all other aspects of the risk adjustment methodology were outside of the scope of the proposed rule, and HHS did not seek comment on those finalized aspects.

We summarize and respond to the comments received to the proposed rule below. Given the volume of exhibits, court filings, white papers (including all corresponding exhibits), and comments on other rulemakings incorporated by reference in one commenter's letter, we are not able to separately address each of those documents. Instead, we summarize and respond to the significant comments and issues raised by the commenter that are within the scope of this rulemaking.

Comment: One commenter expressed general concerns about policymaking and implementation of the PPACA related to enrollment activity changes, cost-sharing reductions, and short-term, limited-duration plans.

Response: The use of statewide average premium in the HHS-operated risk adjustment methodology, including the operation of the program in a budget-neutral manner, which was the limited subject of the proposed rulemaking, was not addressed by this commenter. In fact, the commenter did not specifically address the risk adjustment program at all. Therefore, the concerns raised by this commenter are outside the scope of the proposed rule, and are not addressed in this final rule.

Comment: Commenters were overwhelmingly in favor of HHS finalizing the rule as proposed, and many encouraged HHS to do so as soon as possible. Many commenters stated that by finalizing this rule as proposed, HHS is providing an additional explanation regarding the operation of the program in a budget-neutral manner and the use of statewide average premium for the 2018 benefit year consistent with the decision of the district court, and is reducing the risk of substantial instability to the Exchanges and individual and small group and merged market risk pools. Many commenters stated that no changes should be made to the risk adjustment methodology for the 2018 benefit year because issuers' rates for the 2018 benefit year were set based on the previously finalized methodology.

Response: We agree that a prompt finalization of this rule is important to ensure the ongoing stability of the individual and small group and merged markets, and the ability of HHS to continue operations of the risk adjustment program normally for the 2018 benefit year. We also agree that finalizing the rule as proposed would maintain stability and ensure predictability of pricing in a budget-neutral framework because issuers relied on the 2018 HHS-operated risk adjustment methodology that used

[10] 78 FR 15410, 15432.

[11] *Id.*

[12] See 81 FR 94058 at 94099.

statewide average premium during rate setting and when deciding in calendar year 2017 whether to participate in the market(s) during the 2018 benefit year.

Comment: Several commenters agreed with HHS's interpretation of the statute as requiring the operation of the risk adjustment program in a budget-neutral manner; several cited the absence of additional funding which would cover any possible shortfall between risk adjustment transfers as supporting the operation of the program in a budget-neutral manner. One commenter highlighted that appropriations can vary from year to year, adding uncertainty and instability to the market(s) if the program relied on additional funding to cover potential shortfalls and was not operated in a budget-neutral manner, which in turn would affect issuer pricing decisions. These commenters noted that any uncertainty about whether Congress would fund risk adjustment payments would deprive issuers of the ability to make pricing and market participation decisions based on a legitimate expectation that risk adjustment transfers would occur as required in HHS regulations. Other commenters noted that without certainty of risk adjustment transfers, issuers would likely seek rate increases to account for this further uncertainty and the risk of enrolling a greater share of high-cost individuals. Alternatively, issuers seeking to avoid significant premium increases would be compelled to develop alternative coverage arrangements that fail to provide adequate coverage to people with chronic conditions or high health care costs (for example, narrow networks or formulary design changes). Another commenter pointed to the fact that risk adjustment was envisioned by Congress as being run by the states, and that if HHS were to require those states that run their own program to cover any shortfall between what they collect and what they must pay out, HHS would effectively be imposing an unfunded mandate on states. The commenter noted there is no indication that Congress intended risk adjustment to impose such an unfunded mandate. Another commenter expressed that a budget-neutral framework was the most natural reading of the PPACA, with a different commenter stating this framework is implied in the statute.

However, one commenter stated that risk adjustment does not need to operate as budget neutral, as section 1343 of the PPACA does not require that the program be budget neutral, and funds are available to HHS for the risk adjustment program from the CMS Program Management account to offset any potential shortfalls. The commenter also stated that the rationale for using statewide average premium to achieve budget neutrality is incorrect, and that even if budget neutrality is required, any risk adjustment payment shortfalls that may result from using a plan's own premium in the risk adjustment transfer formula could be addressed through pro rata adjustments to risk adjustment transfers. This commenter also stated that the use of statewide average premium is not predictable for issuers trying to set rates, especially for small issuers which do not have a large market share, as they do not have information about other issuers' rates at the time of rate setting. Conversely, many commenters noted that, absent an appropriation for risk adjustment payments, the prorated payments that would result from the use of a plan's own premium in the risk adjustment methodology would add an unnecessary layer of complexity for issuers when pricing and would reduce predictability, resulting in uncertainty and instability in the market(s).

Response: We acknowledged in the proposed rule that the PPACA did not include a provision that explicitly required the risk adjustment program be operated in a budget-neutral manner; however, HHS was constrained by appropriations law to devise a risk adjustment methodology that could be implemented in a budget-neutral fashion. In fact, Congress did not authorize or appropriate additional funding for risk adjustment beyond the amount of charges paid in, and did not authorize HHS to obligate itself for risk adjustment payments in excess of charges collected. In the absence of additional, independent funding or the creation of budget authority in advance of an appropriation, HHS could not make payments in excess of charges collected consistent with binding appropriations law. Furthermore, we agree with commenters that the creation of a methodology that was contingent on Congress agreeing to appropriate supplemental funding of unknown amounts through the annual appropriations process would create uncertainty. It would also delay the process for setting the parameters for any potential risk adjustment proration until well after rates were set and the plans were in effect for the applicable benefit year. In addition to proration of risk adjustment payments to balance risk adjustment transfer amounts, we considered the impact of assessing additional charges or otherwise collecting additional funds from issuers of risk adjustment covered plans as alternatives to the establishment of a budget-neutral framework. All of these after-the-fact balancing adjustments were ultimately rejected because they are less predictable for issuers than a budget-neutral methodology which does not require after-the-fact balancing adjustments, a conclusion supported by the vast majority of comments received. As detailed in the proposed rule, HHS determined it would not be appropriate to rely on the CMS Program Management account because those amounts are designated for administration and operational expenses, not program payments, nor would the CMS Program Management account be sufficient to fund both the payments under the risk adjustment program and those administrative and operational expenses. Furthermore, use of such funds would create the same uncertainty and other challenges described above, as it would require reliance on the annual appropriations process and would require after-the-fact balancing adjustments to address shortfalls. After extensive analysis and evaluation of alternatives, we determined that the best method consistent with legal requirements is to operate the risk adjustment program in a budget-neutral manner, using statewide average premium as the cost scaling factor and normalizing the risk adjustment payment transfer formula to reflect state average factors.

We agree with the commenters that calculating transfers based on a plan's own premium without an additional funding source to ensure full payment of risk adjustment payment amounts would create premium instability. If HHS implemented an approach based on a plan's own premium without an additional funding source, after-the-fact payment adjustments would be required. As explained above, the amount of these payment adjustments would vary from year to year, would delay the publication of final risk adjustment amounts, and would compel issuers with risk that is higher than the state average to speculate on the premium increase that would be necessary to cover an unknown risk adjustment payment shortfall amount. We considered and ultimately declined to adopt a methodology that required an after-the-fact balancing adjustment because such an approach is less predictable for issuers than a budget-neutral methodology that can be calculated in advance of a benefit year. This included consideration of a non-budget neutral HHS-operated risk adjustment methodology that used a plan's own premiums as the cost-scaling

factor, which we discuss in detail later in this preamble. Modifying the 2018 benefit year risk adjustment methodology to use a plan's own premium would reduce the predictability of risk adjustment payments and charges significantly. As commenters stated, the use of a plan's own premium would add an extra layer of complexity in estimating risk adjustment transfers because payments and charges would need to be prorated retrospectively based on the outcome of risk adjustment transfer calculations, but would need to be anticipated in advance of the applicable benefit year for use in issuers' pricing calculations. We do not agree with the commenter that statewide average premium is less predictable than a plan's own premium, as the use of statewide average premium under a budget-neutral framework makes risk adjustment transfers self-balancing, and provides payment certainty for issuers with higher-than-average risk.

After considering the comments submitted, we are finalizing a methodology that operates risk adjustment in a budget-neutral manner using statewide average premium as the cost scaling factor and normalizing the risk adjustment payment transfer formula to reflect state average factors for the 2018 benefit year.

Comment: The majority of the comments supported the use of statewide average premium in the HHS-operated risk adjustment methodology for the 2018 benefit year. Some commenters stated that the risk adjustment program is working as intended, by compensating issuers based on their enrollees' health status, that is, transferring funds from issuers with predominately low-risk enrollees to those with a higher-than-average share of high-risk enrollees. One commenter stated that the program has been highly effective at reducing loss-ratios and ensuring that issuers can operate efficiently, without concern for significant swings in risk from year to year. Although some commenters requested refinements to ensure that the methodology does not unintentionally harm smaller, newer, or innovative issuers, a different commenter noted that the results for all prior benefit years of the risk adjustment program do not support the assertion that the risk adjustment methodology undermines small health plans. This commenter noted that the July 9, 2018 ''Summary Report on Permanent Risk Adjustment Transfers for the 2017 Benefit Year'' found a very strong correlation between the amount of paid claims and the direction and scale of risk adjustment transfers.[13] It also pointed to the American Academy of Actuaries' analysis of 2014 benefit year risk adjustment results, in which 103 of 163 small health plans (those with less than 10 percent of market share) received risk adjustment payments and the average payment was 27 percent of premium.[14] This commenter cited these points as evidence that risk adjustment is working as intended for small issuers. This commenter also cited an Oliver Wyman study that analyzed risk adjustment receipts by health plan member months (that is, issuer size) and found no systematic bias in the 2014 risk adjustment model.[15]

A few commenters stated that use of statewide average premium to scale risk adjustment transfers tends to penalize issuers with efficient care management and lower premiums and rewards issuers for raising rates. One of the commenters also stated that the HHS-operated risk adjustment methodology does not reflect relative actuarial risk, that statewide average premium harms issuers that price below the statewide average, and that the program does not differentiate between an issuer that has lower premiums because of medical cost savings from better care coordination and an issuer that has lower premiums because of healthier-than-average enrollees. The commenter suggested that HHS add a Care Management Effectiveness index into the risk adjustment formula. This commenter also stated that use of a plan's own premium rather than statewide average premium could improve the risk adjustment formula, stating that issuers would not be able to inflate their premiums to ''game'' the risk adjustment system due to other PPACA requirements such as medical loss ratio, rate review, and essential health benefits, as well as state insurance regulations, including oversight of marketing practices intended to avoid sicker enrollees.

However, other commenters opposed the use of a plan's own premium in the risk adjustment formula based on a concern that it would undermine the risk adjustment program and create incentives for issuers to avoid enrolling high-cost individuals. Some commenters noted the difficulty of determining whether an issuer's low premium was the result of efficiency, mispricing, or a strategy to gain market share, and that the advantages of using statewide average premium outweigh the possibility that use of a plan's own premium could result in better reflection of cost management. One commenter noted that encouraging issuers to set premiums based on market averages in a state (that is, using statewide average premium) promotes market competition based on value, quality of care provided, and effective care management, not on the basis of risk selection. Other commenters strongly opposed the use of a plan's own premium, as doing so would introduce incentives for issuers to attract lower-risk enrollees because they would no longer have to pay their fair share, or because issuers that traditionally attract high-risk enrollees would be incentivized to increase premiums in order to receive larger risk adjustment payments. Others stated that the use of a plan's own premium would add an extra layer of complexity in estimating risk adjustment transfers, and therefore in premium rate setting, because payments and charges would need to be prorated retrospectively based on the outcome of risk adjustment transfer calculations, but would need to be anticipated prospectively as part of issuers' pricing calculations.

One commenter expressed concern that the risk adjustment payment transfer formula exaggerates plan differences in risk because it does not address plan coding differences.

Response: We agree with the majority of commenters that use of statewide average premium will maintain the integrity of the risk adjustment program by discouraging the creation of benefit designs and marketing strategies to avoid high-risk enrollees and promoting market stability and predictability. The benefits of using statewide average premium as the cost scaling factor in the risk adjustment state payment transfer formula extend beyond its role in maintaining the budget neutrality of the program. Consistent with the statute, under the HHS-operated risk adjustment program, each plan in the risk pool receives a risk adjustment payment or charge designed to take into account the plan's risk compared to a plan with average risk. The statewide average premium reflects the statewide average cost and efficiency level and acts as the cost scaling factor in the state payment transfer formula under the HHS-operated risk adjustment methodology. HHS chose to use statewide average premium to encourage issuers to rate for the average risk, to automatically

[13] Available at *https://downloads.cms.gov/cciio/Summary-Report-Risk-Adjustment-2017.pdf.*

[14] American Academy of Actuaries, ''Insights on the ACA Risk Adjustment Program,'' April 2016. Available at *http://actuary.org/files/imce/Insights_on_the_ACA_Risk_Adjustment_Program.pdf.*

[15] Oliver Wyman, ''A Story in 4 Charts, Risk Adjustment in the Non-Group Market in 2014,'' February 24, 2016. Available at *https://health.oliverwyman.com/2016/02/a_story_in_four_char.html.*

achieve equality between risk adjustment payments and charges in each benefit year, and to avoid the creation of incentives for issuers to operate less efficiently, set higher prices, or develop benefits designs or create marketing strategies to avoid high-risk enrollees.

HHS considered and again declined in the 2018 Payment Notice to adopt the use of each plan's own premium in the state payment transfer formula.[16] As we noted in the 2018 Payment Notice, use of a plan's own premium would likely lead to substantial volatility in transfer results and could result in even higher transfer charges for low-risk, low-premium plans because of the program's budget neutrality. Under such an approach, high-risk, high-premium plans would require even greater transfer payments. If HHS applied a balancing adjustment in favor of these plans to maintain the budget-neutral nature of the program after transfers have been calculated using a plan's own premium, low-risk, low-premium plans would be required to pay in an even higher percentage of their plan-specific premiums in risk adjustment transfer charges due to the need to maintain budget neutrality. Furthermore, payments to high-risk, low-premium plans that are presumably more efficient than high-risk, high-premium plans would be reduced, incentivizing such plans to inflate premiums. In other words, the use of a plan's own premium in this scenario would neither reduce risk adjustment charges for low-cost and low-risk issuers, nor would it incentivize issuers to operate at the average efficiency. Alternatively, application of a balancing adjustment in favor of low-risk, low-premium plans could have the effect of under-compensating high-risk plans, increasing the likelihood that such plans would raise premiums. In addition, if the application of a balancing adjustment was split equally between high-risk and low-risk plans, such an after-the-fact adjustment, would create uncertainty and instability in the market(s), and would incentivize issuers to increase premiums to receive additional risk adjustment payments or to employ risk-avoidance techniques. As such, we agree with the commenters that challenges associated with pricing for transfers based on a plan's own premium would create pricing instability in the market, and introduce incentives for issuers to attract lower-risk enrollees to avoid paying their fair share. We also agree that it is very difficult to determine the reason an issuer has lower premiums than the average, since an issuer's low premium could be the result of efficiency, mispricing, or a strategy to gain market share. In all, the advantages of using statewide average premium outweigh the possibility that the use of a plan's own premium could result in better reflection of care or cost management, given the overall disadvantages, outlined above, of using a plan's own premium. HHS does not agree that use of statewide average premium penalizes efficient issuers or that it rewards issuers for raising rates.

Consistent with the 2018 Payment Notice,[17] beginning with the 2018 benefit year, this final rule adopts the 14 percent reduction to the statewide average premium to account for administrative costs that are unrelated to the claims risk of the enrollee population. While low cost plans are not necessarily efficient plans,[18] we believe this adjustment differentiates between premiums that reflect savings resulting from administrative efficiency from premiums that reflect healthier-than-average enrollees. As detailed in the 2018 Payment Notice,[19] to derive this parameter, we analyzed administrative and other non-claims expenses in the Medical Loss Ratio (MLR) Annual Reporting Form and estimated, by category, the extent to which the expenses varied with claims. We compared those expenses to the total costs that issuers finance through premiums, including claims, administrative expenses, and taxes, and determined that the mean administrative cost percentage in the individual, small group and merged markets is approximately 14 percent. We believe this amount represents a reasonable percentage of administrative costs on which risk adjustment should not be calculated.

We disagree that the HHS-operated risk adjustment methodology does not reflect relative actuarial risk or that the use of statewide average premium indicates otherwise. In fact, the risk adjustment models estimate a plan's relative actuarial risk across actuarial value metal levels, also referred to as ''simulated plan liability,'' by estimating the total costs a plan is expected to be liable for based on its enrollees' age, sex, hierarchical condition categories (HCCs), actuarial value, and cost-sharing structure. Therefore, this ''simulated plan liability'' reflects the actuarial risk relative to the average that can be assigned to each enrollee. We then use an enrollee's plan selection and diagnoses during the benefit year to assign a risk score. Although the HHS risk adjustment models are calibrated on national data, and average costs can vary between geographic areas, relative actuarial risk differences are generally similar nationally. The solved coefficients from the risk adjustment models are then used to evaluate actuarial risk differences between plans. The risk adjustment state payment transfer formula then further evaluates the plan's actuarial risk based on enrollees' health risk, after accounting for factors a plan could have rated for, including metal level, the prevailing level of expenditures in the geographic areas in which the enrollees live, the effect of coverage on utilization (induced demand), and the age and family structure of the subscribers. This relative plan actuarial risk difference compared to the state market risk pool average is then scaled to the statewide average premium. The use of statewide average premium as a cost-scaling factor requires plans to assess actuarial risk, and therefore scales transfers to actuarial differences between plans in state market risk pool(s), rather than differences in premium.

We have been continuously evaluating whether improvements are needed to the risk adjustment methodology, and will continue to do so as additional years' data become available. We decline to amend the risk adjustment methodology to include the Care Management Effectiveness index or a similar adjustment at this time. Doing so would be beyond the scope of this rulemaking, which addresses the use of statewide average premium and the operation of the risk adjustment program in a budget-neutral manner. A change of this magnitude would require significant study and evaluation. Although this type of change is not feasible at present, we will examine the feasibility, specificity, and sensitivity of measuring care management effectiveness through enrollee-level EDGE data for the individual, small group and merged markets, and the benefits of incorporating such measures in the risk adjustment methodology in future benefit years, either through rulemaking or other opportunities in which the public can submit comments. We believe that a robust risk adjustment program encourages issuers to adopt incentives to improve care management effectiveness, as doing so would reduce plans' medical costs. As we stated above, use of statewide average

[16] 81 FR 94100.

[17] 81 FR 94099.

[18] If a plan is a low-cost plan with low claims costs, it could be an indication of mispricing, as the issuer should be pricing for average risk.

[19] 81 FR 94100.

premium in the risk adjustment state payment transfer formula incentivizes plans to apply effective care management techniques to reduce losses, whereas use of a plan's own premium could be inflationary as it benefits plans with higher-than-average costs and higher-than-average premiums.

We are sympathetic to commenters' concerns about plan coding differences, and recognize that there is substantial variation in provider coding practices. We are continuing to strengthen the risk adjustment data validation program to ensure that conditions reported for risk adjustment are accurately coded and supported by medical records, and will adjust risk scores (and subsequently, risk adjustment transfers) beginning with 2017 benefit year data validation results to encourage issuers to continue to improve the accuracy of data used to compile risk scores and preserve confidence in the HHS-operated risk adjustment program.

Comment: Some commenters provided suggestions to improve the risk adjustment methodology, such as different weights for metal tiers, multiple mandatory data submission deadlines, reducing the magnitude of risk scores across the board, and fully removing administrative expenses from the statewide average premium. One commenter stated that, while it did not conceptually take issue with the use of statewide average premium, the payment transfer formula under the HHS-operated risk adjustment methodology creates market distortions and causes overstatement of relative risk differences among issuers. This commenter cited concerns with the use of the Truven MarketScan® data to calculate plan risk scores under the HHS risk adjustment models, and suggested incorporating an adjustment to the calculation of plan risk scores until the MarketScan® data is no longer used.

A few commenters stressed the importance of making changes thoughtfully and over time, and one encouraged HHS to actively seek improvements to avoid unnecessary litigation. Several commenters, while supportive of the proposed rule and its use for the 2018 benefit year, generally stated that the risk adjustment methodology should continue to be improved prospectively. Another commenter stated that the proposed rule did not do enough to improve the risk adjustment program, and encouraged HHS to review and consider suggestions to improve the risk adjustment methodology in order to promote stability and address the concerns raised in lawsuits other than the New Mexico case. One commenter further requested that HHS reopen rulemaking proceedings, reconsider, and revise the Payment Notices for the 2017 and 2019 benefit years under section 553(e) of the Administrative Procedure Act.

Response: We appreciate the feedback on potential improvements to the risk adjustment program, and will continue to consider the suggestions, analysis, and comments received from commenters for potential changes to future benefit years. This rulemaking is intended to provide additional explanation regarding the operation of the program in a budget-neutral manner and the use of statewide average premium for the 2018 benefit year, consistent with the February 2018 decision of the district court. It also requires an expedited timeframe to maintain stability in the health insurance markets following the district court's vacatur of the use of statewide average premium in the HHS-operated risk adjustment methodology for the 2018 benefit year. We intend to continue to evaluate approaches to improve the risk adjustment models' calibration to reflect the individual, small group and merged markets actuarial risk and review additional years' data as they become available to evaluate all aspects of the HHS-operated risk adjustment methodology. We also continue to encourage issuers to submit EDGE server data earlier and more completely for future benefit years. However, the scope of the proposed rule was limited to the use of statewide average premium and the budget-neutral nature of the risk adjustment program for the 2018 benefit year, and consequently, we decline to adopt the various suggestions offered by commenters regarding potential improvements to the 2018 benefit year HHS-operated risk adjustment methodology as to other issues because they are outside the scope of this rule.

We reiterate that HHS is always considering possible ways to improve the risk adjustment methodology for future benefit years. For example, in the 2018 Payment Notice, based on comments received for the 2017 Payment Notice and the March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting Discussion Paper,[20] HHS made multiple adjustments to the risk adjustment models and state payment transfer formula, including reducing the statewide average premium by 14 percent to account for the proportion of administrative costs that do not vary with claims, beginning with the 2018 benefit year.[21] HHS also modified the risk adjustment methodology by incorporating a high-cost risk pool calculation to mitigate residual incentive for risk selection to avoid high-cost enrollees, to better account for the average risk associated with the factors used in the HHS risk adjustment models, and to ensure that the actuarial risk of a plan with high-cost enrollees is better reflected in risk adjustment transfers to issuers with high actuarial risk.[22] Other recent changes made to the HHS-operated risk adjustment methodology include the incorporation of a partial year adjustment factor and prescription drug utilization factors.[23] Furthermore, as outlined above, HHS stated in the 2019 Payment Notice that it would recalibrate the risk adjustment model using 2016 enrollee-level EDGE data to better reflect individual, small group and merged market populations.[24] We also consistently seek methods to support states' authority and provide states with flexible options, while ensuring the success of the risk adjustment program.[25] We respond to comments regarding options available to states with respect to the risk adjustment program below. We appreciate the commenters' input and will continue to examine options for potential changes to the HHS-operated risk adjustment methodology in future notice with comment rulemaking.

The requests related to the 2017 and 2019 benefit year rulemakings are outside the scope of the proposed rule and this final rule, which is limited to the 2018 benefit year.

Comment: One commenter suggested that states should have broad authority to cap and limit risk adjustment transfers and charges as necessary, stating that the requirements associated with the flexibility HHS granted to states to request a reduction to risk adjustment transfers beginning in 2020 are too onerous and unclear. The commenter noted that state regulators know their markets best and should have the discretion and authority to implement their own remedial measures without seeking HHS's permission. Conversely, one commenter specifically supported the state flexibility policy set forth in § 153.320(d). A few commenters requested that states be allowed to establish alternatives to statewide

[20] *https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf.*

[21] See 81 FR 94100.

[22] See 81 FR 94080.

[23] See 81 FR at 94071 and 94074.

[24] See 83 FR 16940.

[25] *Id.* and 81 FR 29146.

average premium, with one suggesting that this change begin with the 2020 benefit year, and providing as an example the idea that HHS could permit states to aggregate the average premiums of two or more distinct geographic markets within a state.

Response: HHS continually seeks to provide states with flexibility to determine what is best for their state markets. Section 1343 of the PPACA provides states authority to operate their own state risk adjustment programs. Under this authority, a state remains free to elect to operate the risk adjustment program and tailor it to its markets, which could include establishing alternatives to the statewide average premium methodology or aggregating the average premiums of two or more distinct geographic markets within a state. If a state does not elect to operate the risk adjustment program, HHS is required to do so.[26] No state elected to operate the risk adjustment program for the 2018 benefit year; therefore, HHS is responsible for operating the program in all 50 states and the District of Columbia.

In the 2019 Payment Notice, HHS adopted § 153.320(d) to provide states the flexibility, when HHS is operating the risk adjustment program, to request a reduction to the otherwise applicable risk adjustment transfers in the individual, small group, or merged markets by up to 50 percent.[27] This flexibility was established to provide states the opportunity to seek state-specific adjustments to the HHS-operated risk adjustment methodology without the necessity of operating their own risk adjustment programs. It is offered beginning with the 2020 benefit year risk adjustment transfers and, since it involves an adjustment to the transfers calculated by HHS, it will require review and approval by HHS. States requesting such reductions must substantiate the transfer reduction requested and demonstrate that the actuarial risk differences in plans in the applicable state market risk pool are attributable to factors other than systematic risk selection.[28] The process will give HHS the necessary information to evaluate the flexibility requests. We appreciate the comments offered on this flexibility, but note that they are outside the scope of the proposed rule, which was limited to the 2018 benefit year and did not propose any changes to the process established in § 153.320(d). However, we will continue to consider commenter feedback on the process, along with any lessons learned from 2020 benefit year requests.

HHS has consistently acknowledged the role of states as primary regulators [29] of their insurance markets, and we continue to encourage states to examine local approaches under state legal authority as they deem appropriate.

Comment: One commenter detailed the impact of the HHS-operated risk adjustment methodology on the commenter, the CO–OP program's general struggles, and the challenges faced by some non-CO–OP issuers, stating that this is evidence that the HHS-operated risk adjustment methodology is flawed. The commenter urged HHS to make changes discussed above to the methodology to address what it maintains are unintended financial impacts on small issuers that are required to pay large risk adjustment charges, and also challenged the assertion that the current risk adjustment methodology is predictable.

Response: HHS previously recognized and acknowledged that certain issuers, including a limited number of newer, rapidly growing, or smaller issuers, owed substantial risk adjustment charges that they did not anticipate in the initial years of the program. HHS has regularly discussed with issuers and state regulators ways to encourage new participation in the health insurance markets and to mitigate the effects of substantial risk adjustment charges. Program results discussed earlier have shown that the risk adjustment methodology has worked as intended, that risk adjustment transfers correlate with the amount of paid claims rather than issuer size, and that no systemic bias is found when risk adjustment receipts are analyzed by health plan member months. We created an interim risk adjustment reporting process, beginning with the 2015 benefit year, to provide issuers and states with preliminary information about the applicable benefit year's geographic cost factor, billable member months, and state averages such as monthly premiums, plan liability risk score, allowable rating factor, actuarial value, and induced demand factors by market. States may pursue local approaches under state legal authority to address concerns related to insolvencies and competition, including in instances where certain state laws or regulations differentially affect smaller or newer issuers. In addition, as detailed above, beginning with the 2020 benefit year, states may request a reduction in the transfer amounts calculated under the HHS-operated methodology to address state-specific rules or market dynamics to more precisely account for the expected cost of relative risk differences in the state's market risk pool(s).

Finally, HHS has consistently sought to increase the predictability and certainty of transfer amounts in order to promote the premium stabilization goal of the risk adjustment program. Statewide average premium provides greater predictability of an issuer's final risk adjustment receivables than use of a plan's own premium, and we disagree with comments stating that the use of a plan's own premium in the risk adjustment transfer formula would result in greater predictability in pricing. As discussed previously, if a plan's own premium is used as a scaling factor, risk adjustment transfers would not be budget neutral. After-the-fact adjustments would be necessary in order for issuers to receive the full amount of calculated payments, creating uncertainty and lack of predictability.

III. Provisions of the Final Regulations

After consideration of the comments received, this final rule adopts the HHS-operated risk adjustment methodology for the 2018 benefit year which utilizes statewide average premium and operates the program in a budget-neutral manner, as established in the final rules published in the March 23, 2012 and the December 22, 2016 editions of the **Federal Register**.

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*).

V. Regulatory Impact Analysis

A. Statement of Need

The proposed rule and this final rule were published in light of the February 2018 district court decision described above that vacated the use of statewide average premium in the HHS-operated risk adjustment methodology for the 2014–2018 benefit years. This final rule adopts the HHS-operated risk adjustment methodology for the 2018 benefit year, maintaining the use of statewide average premium as the cost-scaling factor in the HHS-operated risk adjustment methodology and the

[26] See section 1321(c) of the PPACA.

[27] See 83 FR 16955.

[28] See § 153.320(d) and 83 FR 16960.

[29] See 83 FR 16955. Also see 81 FR 29146 at 29152 (May 11, 2016), available at *https://www.gpo.gov/fdsys/pkg/FR-2016-05-11/pdf/2016-11017.pdf.*

continued operation of the program in a budget-neutral manner, to protect consumers from the effects of adverse selection and premium increases that would result from issuer uncertainty. The Premium Stabilization Rule, previous Payment Notices, and other rulemakings noted above provided detail on the implementation of the risk adjustment program, including the specific parameters applicable for the 2018 benefit year.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year).

OMB has determined that this final rule is ''economically significant'' within the meaning of section 3(f)(1) of Executive Order 12866, because it is likely to have an annual effect of $100 million in any 1 year. In addition, for the reasons noted above, OMB has determined that this final rule is a major rule under the Congressional Review Act.

This final rule offers further explanation of budget neutrality and the use of statewide average premium in the risk adjustment state payment transfer formula when HHS is operating the permanent risk adjustment program established by section 1343 of the PPACA on behalf of a state for the 2018 benefit year. We note that we previously estimated transfers associated with the risk adjustment program in the Premium Stabilization Rule and the 2018 Payment Notice, and that the provisions of this final rule do not change the risk adjustment transfers previously estimated under the HHS-operated risk adjustment methodology established in those final rules. The approximate estimated risk adjustment transfers for the 2018 benefit year are $4.8 billion. As such, we also incorporate into this final rule the RIA in the 2018 Payment Notice proposed and final rules.[30] This final rule is not subject to the requirements of Executive Order 13771 (82 FR 9339, February 3, 2017) because it is expected to result in no more than *de minimis* costs.

Dated: November 16, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 19, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–26591 Filed 12–7–18; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

RIN 0648–XG025

Pacific Island Pelagic Fisheries; 2018 U.S. Territorial Longline Bigeye Tuna Catch Limits for American Samoa

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

ACTION: Announcement of a valid specified fishing agreement.

SUMMARY: NMFS announces a valid specified fishing agreement that allocates up to 1,000 metric tons (t) of the 2018 bigeye tuna limit for the Territory of American Samoa to identified U.S. longline fishing vessels. The agreement supports the long-term sustainability of fishery resources of the U.S. Pacific Islands, and fisheries development in American Samoa.

DATES: December 7, 2018.

ADDRESSES: NMFS prepared environmental analyses that describe the potential impacts on the human environment that would result from the action. The analyses, identified by NOAA–NMFS–2018–0026, are available from *https://www.regulations.gov/docket?D=NOAA-NMFS-2018-0026,* or from Michael D. Tosatto, Regional Administrator, NMFS Pacific Islands Region (PIR), 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818.

The Fishery Ecosystem Plan for Pelagic Fisheries of the Western Pacific (Pelagic FEP) is available from the Western Pacific Fishery Management Council (Council), 1164 Bishop St., Suite 1400, Honolulu, HI 96813, tel 808–522–8220, fax 808–522–8226, or *http://www.wpcouncil.org.*

FOR FURTHER INFORMATION CONTACT: Rebecca Walker, NMFS PIRO Sustainable Fisheries, 808–725–5184.

SUPPLEMENTARY INFORMATION: In a final rule published on October 23, 2018, NMFS specified a 2018 limit of 2,000 t of longline-caught bigeye tuna for the U.S. Pacific Island territories of American Samoa, Guam, and the CNMI (83 FR 53399). NMFS allows each territory to allocate up to 1,000 t of the 2,000 t limit to U.S. longline fishing vessels identified in a valid specified fishing agreement.

On November 19, 2018, NMFS received from the Council a specified fishing agreement between the government of American Samoa and Quota Management, Inc. (QMI). The Council's Executive Director advised that the specified fishing agreement was consistent with the criteria set forth in 50 CFR 665.819(c)(1). NMFS reviewed the agreement and determined that it is consistent with the Pelagic FEP, the Magnuson-Stevens Fishery Conservation and Management Act, implementing regulations, and other applicable laws.

In accordance with 50 CFR 300.224(d) and 50 CFR 665.819(c)(9), vessels identified in the agreement may retain and land bigeye tuna in the western and central Pacific Ocean under the American Samoa limit. NMFS will begin attributing bigeye tuna caught by vessels identified in the agreement to American Samoa starting on December 10, 2018. This is seven days before December 17, 2018, which is the date NMFS forecasted the fishery would reach the CNMI bigeye tuna allocation limit. If NMFS determines that the fishery will reach the American Samoa 1,000-t attribution, we would restrict the retention of bigeye tuna caught by vessels identified in the agreement, unless the vessels are included in a subsequent specified fishing agreement with another U.S. territory, and we would publish a notice to that effect in the **Federal Register**.

Authority: 16 U.S.C. 1801 *et seq.*

[30] 81 FR 61455 and 81 FR 94058.