screenings? If yes, please explain the scheduling issue that is a barrier and provide recommendations for how it could be overcome.

6. Does concern about the confidentiality of medical information pose a barrier to participation? If this is a barrier, then please provide recommendations or suggestions for how it can be overcome.

7. Does concern that the early identification of dust-related lung disease might adversely affect a miner's career (*e.g.,* prevent career advancement or the ability to get a new coal mining job) pose a barrier to participation? If this is a barrier, then please provide recommendations or suggestions for how it can be overcome.

8. Does concern that early identification of dust-related lung disease might affect subsequent eligibility for compensation through Federal or State programs pose a barrier to participation? If this is a barrier, then please describe the specific compensation programs and how eligibility for them can be affected by early detection of dust-related lung disease. Please also provide recommendations or suggestions for how this barrier could be overcome.

9. Does concern that personal finances will require a miner to continue working despite early identification of dust-related lung disease pose a barrier to participation? If this is a barrier, please provide recommendations or suggestions for how it can be overcome.

10. Are there any other barriers to participation that NIOSH should be aware of?

Interested parties may participate in this activity by submitting written views, opinions, recommendations, and data. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you do not wish to be disclosed. Although your name, contact information, or other information that identifies you in the body of your comments will be on public display, NIOSH will review all submissions and may choose to redact or withhold submissions containing private or proprietary information such as Social Security numbers, medical information, and/or inappropriate language. Comments may be submitted on any topic related to this action. All public comments will be posted in the docket for this action at *https://www.regulations.gov.*

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2018–24700 Filed 11–9–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2416–N]

Basic Health Program; Final Administrative Order

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of Final Administrative Order.

SUMMARY: This notice serves to announce that a Final Administrative Order related to the Basic Health Program (BHP) was issued to the States of New York and Minnesota on August 24, 2018.

DATES: The Final Administrative Order was effective August 24, 2018.

FOR FURTHER INFORMATION CONTACT: Christopher Truffer, (410) 786–1264; Meg Barry, (410) 786–1536.

SUPPLEMENTARY INFORMATION:

I. Background and Provisions of the Notice

The CMS Administrator issued a Final Administrative Order to set forth the revised payment methodology that applies to the Basic Health Program for 2018 *only* (HHS Revised BHP Payment Methodology). The Administrative Order is an agency action under 5 U.S.C. 551(13), issued pursuant to 5 U.S.C. 555(b) and (e).

The HHS Revised BHP Payment Methodology modifies the existing methodology for 2018, which is set forth in the payment notice entitled ''Basic Health Program; Federal Funding Methodology for Program Years 2017 and 2018'' (81 FR 10091, February 29, 2016) (February 2016 Payment Notice). The modification involves the application of a Premium Adjustment Factor (PAF) that considers the premium increases in other states that became effective after the Centers for Medicare & Medicaid Services (CMS), an operating division of the U.S. Department of Health and Human Services (HHS), discontinued payments to issuers for cost-sharing reductions (CSRs) provided to enrollees in qualified health plans (QHPs) offered on health insurance Exchanges.

On July 6, 2018, pursuant to an amended stipulated order issued in *State of New York* v. *U.S. Department of Health and Human Services,* 18–cv–00683 (S.D.N.Y. filed Jan. 26, 2018), CMS issued a Draft Administrative Order on which New York and Minnesota (the States) had an opportunity to comment. The States each submitted comments on August 6, 2018. CMS considered those comments in issuing the Final Administrative Order, which adopts the HHS Revised BHP Payment Methodology for 2018 as set forth in the Draft Administrative Order.

II. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, 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.*) is not required.

III. Addendum

We are publishing the Final Administrative Order as an addendum to this Notice.

Dated: November 2, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

BILLING CODE 4120–01–P

ADDENDUM

FINAL ADMINISTRATIVE ORDER

August 24, 2018

The Administrator for the Centers for Medicare & Medicaid Services issues this Administrative Order to set forth the revised payment methodology that applies to the Basic Health Program for 2018 *only* (HHS Revised BHP Payment Methodology). This Administrative Order is an agency action under 5 U.S.C. § 551(13), issued pursuant to 5 U.S.C. §§ 555(b) and (e).

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On July 6, 2018, pursuant to an amended stipulated order issued in *State of New York, et al, v. U.S. Department of Health and Human Services*, 18-cv-00683 (S.D.N.Y. filed Jan. 26, 2018), CMS issued a Draft Administrative Order on which New York and Minnesota (the States) had an opportunity to comment. The States each submitted comments on August 6, 2018. CMS has considered those comments in issuing this Final Administrative Order. For the reasons set forth below—including in our responses to the States' comments—this Final Administrative Order adopts the HHS Revised BHP Payment Methodology for 2018 as set forth in the Draft Administrative Order.

The result of applying the HHS Revised BHP Payment Methodology to enrollment data provided by the State of New York is $422,206,235 in additional payment to New York for the first, second, and third quarters of 2018.

The result of applying the HHS Revised BHP Payment Methodology to enrollment data provided by the State of Minnesota is $46,276,090 in additional payment to Minnesota for the first, second, and third quarters of 2018.

The structure of the HHS Revised BHP Payment Methodology and its application to New York and Minnesota are set forth in greater detail below.

I. Statutory and Regulatory Framework

Section 1331 of the Patient Protection and Affordable Care Act (Pub. L. No. 111-148, enacted March 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. No. 111-152, enacted March 30, 2010) (collectively referred to as the Affordable Care Act (ACA)) provides states with an option to establish a Basic Health Program (BHP). New York and Minnesota elected to operate BHPs for 2018.

The amount of federal funding for a state's BHP is the amount the Secretary determines is equal to 95 percent of the premium tax credits (PTC) under section 36B of the Internal Revenue Code of 1986 (IRC), and the CSRs under ACA § 1402 that would have been provided for the year to eligible individuals enrolled in standard health plans in the state if such eligible individuals were allowed to enroll in a QHP through the state's health insurance Exchange. ACA § 1331(d)(3)(A)(i).

In calculating the BHP payment amount, "[t]he Secretary shall make the determination … on a per enrollee basis and shall take into account all relevant factors necessary to determine the value of the [PTCs] and [CSRs] that would have been provided" to the eligible individuals. ACA

§ 1331(d)(3)(A)(ii). Relevant factors may include "the age and income of the enrollee, whether the enrollment is for self-only or family coverage, geographic differences in average spending for health care across rating areas, the health status of the enrollee …, and whether any reconciliation of the [PTC] or [CSRs] would have occurred if the enrollee had been so enrolled." *Id.* "This determination ***shall take into consideration the experience of other States with respect to participation in an Exchange and such [PTCs] and [CSRs] provided to residents of the other States***, with a special focus on enrollees with income below 200 percent of poverty." *Id.* (emphasis added).

On March 12, 2014, CMS published a final rule implementing ACA § 1331. *Basic Health Program: State Administration of Basic Health Programs; Eligibility and Enrollment in Standard Health Plans; Essential Health Benefits in Standard Health Plans; Performance Standards for Basic Health Programs; Premium and Cost Sharing for Basic Health Programs; Federal Funding Process; Trust Fund and Financial Integrity*, 79 FR 14112 (March 12, 2014) (BHP Final Rule). The BHP Final Rule establishes standards for administering BHPs—including provisions about eligibility and enrollment, benefits, cost-sharing requirements, and oversight activities—but does not contain the specific information necessary to determine BHP payments. Instead, the BHP Final Rule informs states that the development and publication of the payment methodology, including any data sources, will be addressed in separate annual BHP Payment Notices.

On February 29, 2016, CMS published a final Payment Notice setting forth the BHP payment methodology for 2017 and 2018. *Basic Health Program; Federal Funding Methodology for Program Years 2017 and 2018*, 81 FR 10091 (Feb. 29, 2016) (February 2016 Payment Notice). Thereafter, as indicated in the February 2016 Payment Notice, CMS published a bulletin setting forth the updated factors it would consider when making the BHP payments to states for 2018.

CMCS Informational Bulletin, *Basic Health Program; Federal Funding Methodology for Program Year 2018* (May 17, 2017).

In October 2017, in response to an inquiry from HHS and the Treasury Department, the Attorney General concluded "that the best interpretation of the law is that the permanent appropriation for 'refunding internal revenue collections,' 31 U.S.C. § 1324, cannot be used to fund the CSR payments to insurers authorized by 42 U.S.C. § 18071." Letter from Attorney Gen. Jefferson B. Sessions III to Sec'y of Treasury Steven Mnuchin & Acting Sec'y of HHS Don Wright at 1 (Oct. 11, 2017). The next day, HHS sent a memorandum to CMS explaining that "CSR payments are prohibited unless and until a valid appropriation exists." Memorandum from Acting Sec'y of HHS Eric Hargan to Adm'r of CMS Seema Verma, Payments to Issuers for Cost-Sharing Reductions (CSRs), at 1 (Oct. 12, 2017).[1] Because to date no CSR appropriation has been enacted, CMS is prohibited from making further payments of the CSR component of any BHP payment.

II. Procedural Background

Starting with the payment for the first quarter (Q1) of 2018 (which began on January 1, 2018), CMS stopped paying the CSR component of the quarterly BHP payments to New York and Minnesota. The States then sued the Secretary for declaratory and injunctive relief in the United States District Court for the Southern District of New York. *See State of New York, et al, v. U.S. Department of Health and Human Services*, 18-cv-00683 (S.D.N.Y. filed Jan. 26, 2018). HHS understands the States' complaint to seek to compel HHS to either pay the CSR component of their 2018 BHP payments as calculated under the methodology set forth in the February 2016 Payment

[1] The Attorney General's letter and the subsequent memorandum from the Acting HHS Secretary are available at https://www.hhs.gov/sites/default/files/csr-payment-memo.pdf.

Notice, or take other actions that would ostensibly yield BHP payments for 2018 that are greater than what CMS has paid.

On May 2, 2018, the parties filed a stipulation requesting a 60-day stay of the litigation so that HHS may issue an administrative order revising the 2018 BHP payment methodology. As a result of the stipulation, the court dismissed the BHP litigation, although it retained jurisdiction to enforce the stipulation and re-open the docket. On June 8, 2018, the parties revised their stipulation to amend the dates by which HHS would issue an administrative order.

III. The HHS Revised BHP Payment Methodology for 2018

The HHS Revised BHP Payment Methodology, which applies only for 2018, modifies the existing methodology for 2018 set forth in the February 2016 Payment Notice. The modification involves the application of a premium adjustment factor (PAF) to calculate the PTC portion of the BHP payment rates.

Consistent with the February 2016 Payment Notice and prior years, the HHS Revised BHP Payment Methodology for 2018 determines the States' BHP payments based on multiple rate cells[2] applied to estimated BHP enrollment. CMS calculates the BHP payment rate for each rate cell in two parts. The first part equals 95 percent of the estimated PTC that would have been paid if a BHP enrollee in that rate cell had instead enrolled in a QHP through the State's Exchange. The second part equals 95 percent of the estimated CSR payment that would have been made if a BHP enrollee in that rate cell had instead enrolled in a QHP through the State's Exchange.

[2] Each rate cell represents a unique combination of age range, geographic area, coverage category (for example, self-only or two-adult coverage through BHP), household size, and income range as a percentage of FPL. There is a distinct rate cell for individuals in each coverage category within a particular age range who reside in a specific geographic area and are in households of the same size and income range. In addition, the HHS Revised BHP Payment Methodology aligns with a state's rules on age rating. Thus, in the case of a state that does not use age as a rating factor on the Exchange, the BHP payment rates will not vary by age.

CMS uses the following equation from the February 2016 Payment Notice for the PTC part of the BHP payment rate calculation for each rate cell:

$$PTC_{a,g,c,h,i} = \left[ARP_{a,g,c} - \frac{\sum_j I_{h,i,j} \times PTCF_{h,i,j}}{n}\right] \times IRF \times 95\%$$

The definitions for the variables in this equation are:

- $PTC_{a,g,c,h,i}$ = PTC portion of BHP payment rate
- a = Age range
- g = Geographic area
- c = Coverage status (self-only or applicable category of family coverage) obtained through BHP
- h = Household size
- i = Income range (as percentage of the federal poverty level (FPL))
- $ARP_{a,g,c}$ = Adjusted reference premium (modified by PAF)
- $I_{h,i,j}$ = Income (in dollars per month) at each 1 percentage-point increment of FPL
- $j = j^{th}$ percentage-point increment FPL
- n = Number of income increments used to calculate the mean PTC
- $PTCF_{h,i,j}$ = PTC formula percentage
- IRF = Income reconciliation factor

The HHS Revised BHP Methodology for 2018 modifies the equation for the PTC part of the BHP payment rate calculation by incorporating the PAF into the adjusted reference premium ($ARP_{a,g,c}$). Under that modification, the $ARP_{a,g,c}$ equals the reference premium ($RP_{a,g,c}$) multiplied by the BHP population health factor (PHF) multiplied by the PAF. In other words:

$$ARP_{a,g,c} = RP_{a,g,c} \times PHF \times PAF$$

We understand that CSR loading in 2018 premiums may have influenced enrollee behavior in terms of metal tier selection. For future years, CMS may consider modifications to

the payment formula based on consideration of the experience of other states regarding enrollee participation in metal tiers.

The total BHP payment rate for each rate cell equals the sum of the PTC and CSR parts. CMS multiplies the rate for each rate cell by the number of BHP enrollees in that cell—that is, the number of enrollees that meet the criteria for each rate cell ($E_{a,g,c,h,i}$)—to calculate the total monthly BHP payment to the state (PMT). The equation for this calculation is:

$$PMT = \sum \left[(PTC_{a,g,c,h,i} + CSR_{a,g,c,h,i}) \times E_{a,g,c,h,i} \right]$$

In this equation, CMS assigns a value of zero to the CSR part of the BHP payment rate calculation ($CSR_{a,g,c,h,i}$) because there is presently no available appropriation from which CMS can make the CSR portion of any BHP payment.[3]

Determination of the PAF

The PAF considers the premium increases in other states that took effect after CMS discontinued payments to issuers for CSRs provided to enrollees in QHPs offered on state insurance Exchanges. The PAF is authorized by ACA § 1331(d)(3)(A)(ii), which says that the determination of the BHP payment amount "shall take into consideration the experience of other States with respect to participation in an Exchange and such [PTCs] and [CSRs] provided to residents of the other States."

CMS has calculated the PAF for each BHP state for 2018 as follows:

- CMS sought to collect QHP issuer information from QHP issuers in each state and the District of Columbia, and then determine the premium adjustment that the responding QHP

[3] In the event that an appropriation for CSRs for 2018 is made, CMS would reconsider whether to zero-out the CSR part of the BHP payment rate calculation ($CSR_{a,g,c,h,i}$) and to include the PAF in the HHS Revised BHP Methodology.

issuers made to each silver level plan in 2018 to account for the discontinuation of CSR payments to QHP issuers.

- Based on the data collected, CMS estimated the median adjustment for silver level QHPs nationwide (excluding those in the two BHP states). To the extent that QHP issuers made no adjustment (or the adjustment was 0), this counted as 0 in determining the median adjustment made to all silver level QHPs nationwide. If the amount of the adjustment was unknown—or CMS determined that it should be excluded for methodological reasons (*e.g.*, the adjustment is negative, an outlier, or unreasonable)—then CMS did not count the adjustment towards determining the median adjustment.
- For each of the two BHP states, CMS determined the median adjustment for all silver level QHPs in that state.
- The PAF for each BHP state equals 1 plus the nationwide median adjustment divided by 1 plus the state median adjustment for the BHP state. In other words,

  PAF = (1 + Nationwide Median Adjustment) ÷ (1 + State Median Adjustment).
- For New York, the PAF is: **1.188.**
- For Minnesota, the PAF is: **1.188.**

Reconciliation of BHP Payments for 2018

In addition to using the HHS Revised BHP Methodology to calculate the remaining 2018 quarterly payments, CMS will remit any additional payments (true-up payments) to the States that are necessary to ensure New York and Minnesota receive the total BHP payments calculated under the HHS Revised BHP Methodology for the first, second, and third quarters of 2018. CMS will make any necessary true-up payments for these quarters on or before September 7, 2018.

In general, CMS has determined these specific true-up payments by calculating the total BHP payments for the first, second, and third quarters of 2018 under the HHS Revised BHP Methodology set forth in this Final Order and subtracting the amounts of the payments already made for those quarters (including the Q2 supplemental payments made to the states on or about May 14, 2018). If a state already received a total quarterly BHP payment exceeding the quarterly payment that CMS calculated under the HHS Revised BHP Methodology set forth in this Final Order, then CMS will offset the overpayment against the next quarterly payment to the state.

CMS will make any future reconciliation payments (*i.e.*, those payments calculated retrospectively and based on final BHP enrollment for 2018, as compared to the quarterly payments based on estimated enrollment) using the HHS Revised BHP Methodology set forth in this Final Order, and otherwise consistent with the February 2016 Payment Notice.

IV. Facts and Data

To determine the PAF described above, CMS requested information from QHP issuers in each state serviced by a Federally-facilitated Exchange (FFE) to determine the premium adjustment those issuers made to each silver level plan offered through the Exchange in 2018 to account for the end of CSR payments. Specifically, CMS requested information showing the percentage change that QHP issuers made to the premium for each of their silver level plans to cover benefit expenditures associated with the CSRs, given the lack of CSR payments in 2018. This percentage change was a portion of the overall premium increase from 2017 to 2018.

According to CMS records, there are 1,233 silver-level QHPs operating on Exchanges in 2018. Of these 1,233 QHPs, 318 QHPs (25.8 percent) responded to CMS's request for the percentage adjustment applied to silver-level QHP premiums in 2018 to account for the discontinuance of the CSRs. These 318 QHPs operated in 26 different states with 10 of those

states running state-based exchanges (SBEs) or SPEs, which were exchanges in states that worked in partnership with CMS to implement the FFE in their state in 2018. Thirteen of these 318 QHPs were in New York (and none were in Minnesota). Excluding these 13 QHPs from the analysis, the nationwide median adjustment was 20.0 percent. Of the 13 QHPs in New York that responded, the state median adjustment was 1.0 percent. CMS believes that this is an appropriate adjustment for QHPs in Minnesota as well. CMS thus calculated the PAF as (1 + 20%) ÷ (1 + 1%) (or 1.20/1.01), which results in a value of 1.188.

The PAF, therefore, will be set to 1.188 in the formulas described above for New York and Minnesota. This adjustment reflects CMS' estimates that the QHP premiums in Minnesota and New York would have been 18.8 percent higher in 2018 due to the discontinuance of the CSR payments if the States were not operating BHPs.

V. The States' Comments on the Draft Order and CMS' Responses

Comments from New York with Responses from CMS

In its comments submitted to CMS on August 6, 2018, New York maintains that its proposed approach results in a more accurate calculation of the PTC subsidy amount that would have been provided to BHP-eligible individuals in response to the silver-loading that occurred following HHS's decision to stop paying CSR subsidies.[4]

CMS does not have any basis to evaluate the accuracy of the state's proposed approach, and therefore has not adopted it. While we believe the state offered this approach in good faith, New York provided no support, analysis, or detail that would allow CMS to determine if the rates the state proposed accurately reflected premium rate increases issuers would have imposed in 2018 in the absence of the BHP program. In addition, it is unknown whether New York's approach "take[s] into consideration the experience of other States with respect to participation in an

[4] New York first submitted proposed 2018 premium rates for CMS to use to calculate 2018 BHP payments on November 22, 2017, and reiterated this approach in a submission dated May 22, 2018, which the state incorporated into its August 6, 2018 comments to CMS.

Exchange and such [PTCs] and [CSRs] provided to residents of the other States," as required by ACA § 1331(d)(3)(A)(ii).

New York's enumerated comments submitted on August 6, 2018 and CMS' responses follow:

1. The methodology fails to detail how HHS accounts for the experiences of other states in estimating the median adjustment for silver-level QHPs nationwide. Specifically, the methodology does not set forth how CMS accounted for relative distributions of income, differences in rating rules, actual claims experiences, and differential approaches to adjust for the loss of CSRs.

   Response: The methodology described in the Draft Order adequately accounts for the experience of other states with regard to the discontinuance of the CSR payments to QHPs. By surveying QHPs, we have taken into account the experience of states in the aggregate. Accounting for the impact of the discontinuance in each state at the level of detail New York suggests would be impractical, if not impossible, given (i) the multitude of state-specific factors noted above and (ii) the lack of clarity and transparency in how individual QHP issuers took these factors into account in making any adjustments to the QHP premiums.

2. On page 7 of the Draft Administrative Order, CMS outlines how it will determine the PAF and claims that it will "collect QHP issuer information from QHP issuers in each state and the District of Columbia" to account for the discontinuation of CSR payments to QHP issuers. However, page 9 of the Draft Administrative Order indicates that CMS only requested information from QHP issuers in states serviced by Federally-facilitated Exchanges ("FFEs"). As CMS itself seems to recognize, it cannot exclude states with State-based Exchanges ("SBEs") – particularly since the BHPs are only in states with SBEs. CMS must provide clarity on whether it only reached out to QHP issuers in FFEs – and if so, provide an explanation as to why it did so and how that impacts its ability to accurately establish a nationwide median.

   Response: We disagree that surveying QHP issuers participating in SBEs is required to accurately establish a nationwide median, as we do not believe that QHP issuers in SBEs responded to the discontinuation of CSR payments differently than QHP issuers in FFEs. That is, we do not believe that the mere type of entity managing the Exchange, standing alone, affected QHP issuer behavior.

   Based on our survey of QHP issuers, we found that the mean premium adjustments by state ranged from 3.9 percent to 29.6 percent in states operating SBEs or SPEs in 2018 (9 states, excluding New York) and the median of these was 15.0 percent. The mean premium adjustments by state for states with FFEs in 2018 (15 states) were 9.25 percent to 32.5 percent, and the median of these was 19.9 percent. We believe that these mean premium rate increase ranges and medians are reasonably similar between the SBE/SPE states and FFE states, and that there is no apparent bias between the results. We also note to the

extent there is any difference between the premium rate increases and medians found in SBE/SPE states and FFE states, the rate increases were *lower* in SBE/SPE states.

CMS was able to compile this rate increase data because CMS requested information from all QHP issuers participating in FFEs and SPEs. Because many of these issuers also offered QHPs in SBEs, they also reported adjustments for those QHPs to CMS. Thus, while CMS did not directly solicit information from issuers that only offered QHPs on SBEs, CMS did receive adjustment information for QHPs offered on SBEs. Therefore, we do not believe that this approach impacted our ability to accurately establish a nationwide median.

3. The Draft Order states that the PAF is derived only from a very small pool of silver-level QHPs (25.8%) and does not provide information regarding how many different states that represents. Relying on a small fraction of issuers' rate adjustments from an unspecified number of states does not appear to be sufficient to calculate a "nationwide median adjustment" as provided for in the Proposed Methodology. CMS should provide additional information on the issuers whose information was considered and why that survey is adequate to establish a nationwide median.

Response: We disagree that the PAF is derived from a "very small pool" of silver-level QHPs. On the contrary, QHP issuers representing 26 different states responded to our request for information, including 10 states that operated SBEs/SPEs in 2018. We do not believe, and have no reason to believe, there is any difference in the premium adjustments made by QHP issuers that did report and those that did not report.

The QHPs (and the states) represented in the sample are reasonably representative of the nationwide results. Fundamentally, QHPs faced similar costs in each state's Exchange, because the underlying actuarial values of the silver-level plans and the CSRs were the same. While there may be some underlying variations state-to-state (for example, the relative number of people receiving CSRs compared to those not receiving CSRs) and some states may have provided different instructions to QHPs, we received a range of results that adequately captured the experience across the states and various QHPs.

Also, the results of the survey based on the responses that we received were generally consistent with public domain information regarding QHP issuers' adjustments to premiums to account for the discontinuance of CSR payments. For example, the Kaiser Family Foundation surveyed QHP issuers in October 2017 and found that silver-level QHP premiums were adjusted between 0 and 38 percent for 2018 due to the discontinuance of the CSR payments, with a median adjustment of about 15 percent. (See Kaiser Family Foundation, "How the Loss of Cost-Sharing Subsidy Payments is Affecting 2018 Premiums," October 2017; http://files.kff.org/attachment/Issue-Brief-How-the-Loss-of-Cost-Sharing-Subsidy-Payments-is-Affecting-2018-Premiums).

In short, the response rate was sufficient to develop the nationwide median adjustment for use in the payment methodology.

4. In describing the PAF, CMS states that "outlier" QHPs were not included in the factor. However, the Draft Order does not define "outlier" or provide any guidance as to when an adjustment would be excluded on such grounds. "Outlier" should be defined.

   Response: CMS considered outliers to be adjustments that were (1) negative or (2) excessively high (for example, above 100 percent). Of the responses CMS received, we considered only 1 an outlier (reporting a 2,000 percent increase), and we suspect this was a typographical error in reporting.

5. CMS states that QHP issuers that made no CSR adjustment will count as "0" in determining the median adjustment made to all silver-level QHPs nationwide. New York disagrees with this determination because including these QHP issuers in the adjustment is contrary to the purpose of the BHP payment methodology. Only issuers that adjusted premiums in response to the CSR defunding should be included in the calculation of the PAF factor, as this is the relevant comparison group when adjusting for the experience of other states. By including issuers with no CSR adjustments, HHS is not calculating the PTC subsidy amount that "would have been provided" to BHP-eligible individuals in New York if they had enrolled in QHPs, as required by statute. *See* 42 U.S.C. § 18051(d)(3)(A)(i); 42 C.F.R. § 600.605(a)(1)-(2).

   Response: CMS, in accordance with ACA § 1331, sought to account for all states' experience in developing the PAF adjustment. No QHP issuers reported an adjustment of 0 for silver-level QHPs on Exchanges, and therefore no 0 adjustments were included in the calculation. That said, some states allowed or required QHP issuers to make no adjustment to 2018 premium amounts to account for the discontinuation of CSR payments. So we believe that "0%" adjustments would be acceptable because they reflect the experience of issuers in other states. Again, though, CMS made no such adjustments.

6. The Proposed Methodology does not address issuance of quarterly payment letters to states. Payment letters providing the states with details on how the payment methodology is applied to the state's estimated enrollment submission for the following quarter should resume in August 2018 for quarter 4.

   Response: CMS intends to provide quarterly payment letters to the States, as it has done in the past, for future quarters starting with Q4 of 2018.

Comments from Minnesota with Responses from CMS

1. In section IV of the draft order, under the heading "Facts and Data," CMS explains that it requested information from issuers in each state serviced by a federally-facilitated marketplace. From the 25.8% of those issuers that responded, CMS calculated a median nationwide adjustment of 20 percent. It appears that CMS did not attempt to obtain data from issuers in state-based marketplaces and in state-partnership marketplaces. The draft order does not explain whether and how CMS plans to obtain data from issuers in these states to include in the calculation of the nationwide median adjustment. We recommend

that CMS survey all issuers, especially those in state-based marketplaces, before finalizing the value of the premium adjustment factor. As is, the lack of representation from the plans in state-based and partnership marketplaces that are more representative of Minnesota's individual insurance market is likely masking the nationwide experience.

Response: We disagree that surveying QHP issuers participating in SBEs or SPEs is required to accurately establish a nationwide median, as we do not believe that QHP issuers in SBEs or SPEs responded to the discontinuation of CSR payments differently than QHP issuers in FFEs. That is, we do not believe that the mere type of entity managing the Exchange, standing alone, affected QHP issuer behavior.

Based on our survey of QHP issuers, we found that the mean premium adjustments by state ranged from 3.9 percent to 29.6 percent in states operating SBEs or SPEs in 2018 (9 states, excluding New York) and the median of these was 15.0 percent. The mean premium adjustments by state for states with FFEs in 2018 (15 states) were 9.25 percent to 32.5 percent, and the median of these was 19.9 percent. We believe that these mean premium rate increase ranges and medians are reasonably similar between the SBE/SPE states and FFE states, and that there is no apparent bias between the results. We also note to the extent there is any difference between the premium rate increases and medians found in SBE/SPE states and FFE states, the rate increases were *lower* in SBE/SPE states.

CMS was able to compile this rate increase data because CMS requested information from all QHP issuers participating in FFEs and SPEs. Because many of these issuers also offered QHPs in SBEs, they also reported adjustments for those QHPs to CMS. Thus, while CMS did not directly solicit information from issuers that only offered QHPs on SBEs, CMS did receive adjustment information for QHPs offered on SBEs. We do not believe that this approach impacted our ability to accurately establish a nationwide median.

QHP issuers representing 26 different states responded to our request for information, including 10 states that operated SBEs or SPEs in 2018. We do not believe, and have no reason to believe, there is any difference in the premium adjustments made by QHP issuers that did report and those that did not report.

Also, the results of the survey based on the responses that we received were generally consistent with public domain information regarding QHP issuers' adjustments to premiums to account for the discontinuance of CSR payments. For example, the Kaiser Family Foundation surveyed QHP issuers in October 2017 and found that silver-level QHP premiums were adjusted between 0 and 38 percent for 2018 due to the discontinuance of the CSR payments, with a median adjustment of about 15 percent. (See Kaiser Family Foundation, "How the Loss of Cost-Sharing Subsidy Payments is Affecting 2018 Premiums," October 2017; http://files.kff.org/attachment/Issue-Brief-How-the-Loss-of-Cost-Sharing-Subsidy-Payments-is-Affecting-2018-Premiums). In short, the response rate was sufficient to develop the nationwide median adjustment for use in the payment methodology.

2. Further, it is especially important that the factor determined for 2018 is based on data from a population including all the silver-level issuers nationwide, and that the 1.188 forms the base for the future adjustments because QHP issuers will not be able to continue calculating the difference in premiums before and after the CSR loss after the 2018 coverage year. If it is not CMS' intent to obtain data from all issuers or from a more representative sample of issuers, then we suggest that the final methodology should itemize the exclusions and justify the resulting adjustment factor as a reasonable approximation of the experience in other states, including those not sampled.

   Response: The QHPs (and the states) represented in the sample are reasonably representative of the nationwide results. Fundamentally, QHPs faced similar costs in each state exchange, because the underlying actuarial values of the silver-level plans and the CSRs were the same. While there may be some underlying variations state-to-state (for example, the relative number of people receiving CSRs compared to those not receiving CSRs) and some states may have provided different instructions to QHPs, we received a range of results that adequately captured the experience across the states and various QHPs.

   CMS has not committed to a methodology for 2019 or beyond at this point in time.

3. On page 7 of the draft order, CMS notes that issuers that reported a zero increase were counted in the calculation of the median, but that CMS reserves the right to exclude reported amounts that are negative, outliers, or unreasonable. Including zero increases is inconsistent with the purpose of this adjustment factor, given that a zero increase is likely the result of decisions some states made to the detriment of policyholders. Also, for those amounts that were determined to be "outliers" or "unreasonable," CMS should itemize and explain those amounts that were excluded.

   Response: CMS, in accordance with ACA § 1331, sought to account for all states' experience in developing the PAF adjustment. No QHP issuers reported an adjustment of 0 for silver-level QHPs on Exchanges, and therefore no 0 adjustments were included in the calculation. That said, some states allowed or required QHP issuers to make no adjustment to 2018 premium amounts to account for the discontinuation of CSR payments. So we believe that "0%" adjustments would be acceptable because they reflect the experience of issuers in other states. Again, though, no such adjustments were made.

   CMS considered outliers to be adjustments that were (1) negative or (2) excessively high (for example, above 100 percent). Of the responses CMS received, we considered only 1 an outlier (reporting a 2,000 percent increase), and we suspect this was a typographical error in reporting.

4. Finally, we urge CMS to finalize the payment methodology for 2019 as soon as possible.

   Response: CMS concurs, and CMS is at work on the 2019 and 2020 BHP payment methodologies.

VI. BHP Payments for Q1-Q3 2018 Under The HHS Revised Payment Methodology

Using the HHS Revised BHP Payment Methodology with PAF values of 1.188 for both New York and Minnesota as finalized in this Administrative Order and with enrollment data previously provided by the States, CMS calculates the States' BHP payments for the first three quarters of 2018 as listed in the tables below. These tables include the quarterly BHP payments CMS has made for Q1-Q3 2018 to New York and Minnesota, payment amounts for the same periods calculated under the HHS Revised Payment Methodology, Q2 supplemental payments paid to the States in May 2018, and the resulting true-up payments CMS will make to the States by September 7, 2018.

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Table 1. Payment Adjustments to New York BHP for 2018

Quarter	Original Payment	Revised Payment	Difference
2018 Q1	$833,521,555	$1,015,683,868	$182,162,313
2018 Q2	$884,765,140	$1,078,636,836	$193,871,696
2018 Q3	$903,794,710	$1,101,841,936	$198,047,226
Total	$2,622,081,405	$3,196,162,640	$574,081,235
Q2 2018 Supplemental Payment			$151,875,000
True-Up Payment			$422,206,235

Table 2. Payment Adjustments to Minnesota BHP for 2018

Quarter	Original Payment	Revised Payment	Difference
2018 Q1	$97,670,055	$120,707,821	$23,037,766
2018 Q2	$84,307,519	$104,193,418	$19,885,899
2018 Q3	$87,345,273	$107,947,698	$20,602,425
Total	$269,322,847	$332,848,937	$63,526,090
Q2 2018 Supplemental Payment			$17,250,000
True-Up Payment			$46,276,090

These amounts are calculated using the previously submitted enrollment data used to develop the original 2018 BHP payment rates and amounts. CMS will also provide the updated BHP monthly

payment rates to the States.

We are finalizing these revised payment amounts for the first three quarters of 2018 in this Final Administrative Order. In addition, CMS will use the finalized monthly BHP payment rates determined under the HHS Revised BHP Payment Methodology finalized in this Administrative Order to develop the States' reconciled BHP payments (using actual enrollment data the States submit after the close of the benefit year).

Ordered this 24th day of August, 2018.

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

[FR Doc. 2018–24673 Filed 11–9–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2017–N–0558; FDA–2017–N–1315; FDA–2011–N–0776; FDA–2018–N–3038; FDA–2018–N–0405; FDA–2014–N–1048; FDA–2011–N–0908; FDA–2011–N–0920; and FDA–2018–N–1857]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *http://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Disclosures in Professional and Consumer Prescription Drug Promotion	0910–0860	9/30/2020
Experimental Study of Risk Information Amount and Location in Direct-to-Consumer Print Ads	0910–0861	9/30/2020
Reclassification Petitions for Medical Devices	0910–0138	9/30/2021
Request for Samples and Protocols	0910–0206	9/30/2021
Medical Device Recall Authority	0910–0432	9/30/2021
Food Safety, Health, and Diet Survey	0910–0345	10/31/2020
Medical Device Labeling Regulations	0910–0485	10/30/2021
GFI: Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees	0910–0581	10/31/2021
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food	0910–0751	10/31/2021
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals	0910–0789	10/31/2021

Dated: November 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24609 Filed 11–9–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4100]

Drug Development Tool Process Under the 21st Century Cures Act and Prescription Drug User Fee Act VI; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a public meeting entitled ''Drug Development Tool Process under the 21st Century Cures Act and PDUFA VI.'' This public meeting is intended to fulfill commitments made by FDA under the sixth authorization of the Prescription Drug User Fee Act (PDUFA VI) and the 21st Century Cures Act (Cures Act) by soliciting comments on Drug Development Tool Qualification at FDA related to the qualification process under section 507 of the Federal Food, Drug, and Cosmetic Act (FD&C Act); discussing taxonomy for biomarkers and related concepts used in drug development; and planning activities to define a framework with appropriate standards and scientific approaches to support qualification for a specified context of use.

DATES: The public meeting will be held on December 11, 2018, from 9 a.m. to 5 p.m. Submit either electronic or written comments on this public meeting by January 31, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503A (the Great Room), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments may not be considered. For timely consideration we request that electronic comments be submitted on or before January 31, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time on January 31, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your