

three groupings weighted by total observations of that Super HCC across all issuers' IVA samples, thereby assigning each Super HCC into a high, medium, or low HCC failure rate grouping. This process ensures that all HCCs in a Super HCC are grouped into the same HCC failure rate grouping in HHS-RADV.

Next, an issuer's HCC group failure rate would be calculated as follows:

$$GFR_{G,i} = 1 - \frac{freqIVA_{G,i}}{freqEDGE_{G,i}}$$

Where:

$freqEDGE_{G,i}$ is the number of occurrences of HCCs in group G that are recorded on EDGE for all enrollees sampled from issuer i .

$freqIVA_{G,i}$ is the number of occurrences of HCCs in group G that are identified by the IVA (or SVA, as applicable) for all enrollees sampled from issuer i .

$GFR_{G,i}$ is issuer i 's group failure rate for the HCC group G .

HHS calculates the weighted mean failure rate and the standard deviation of each HCC group as:

$$\mu\{GFR_G\} = 1 - \frac{\sum_i freqIVA_{G,i}}{\sum_i freqEDGE_{G,i}}$$

$$Sd\{GFR_G\} = \sqrt{\frac{\sum_i (freqEDGE_{G,i} * (GFR_{G,i} - \mu\{GFR_G\})^2)}{\sum_i freqEDGE_{G,i}}}$$

Where:

$\mu\{GFR_G\}$ is the weighted mean of $GFR_{G,i}$ of all issuers for the HCC group G weighted by all issuers' sample observations in each group.

$Sd\{GFR_G\}$ is the weighted standard deviation of $GFR_{G,i}$ of all issuers for the HCC group G .

Each issuer's HCC group failure rates will then be compared to the national metrics for each HCC failure rate grouping. If an issuer's failure rate for an HCC failure rate group falls outside of the two-tailed 90 percent confidence interval with a 1.645 standard deviation cutoff based on the weighted mean failure rate for the HCC failure rate group, the failure rate for the issuer's HCCs in that group will be considered an outlier (if the issuer meets the minimum number of HCCs for the HCC failure rate group). Based on issuers' failure rates for each HCC failure rate group, outlier status will be determined for each issuer independently for each issuer's HCC failure rate group such that an issuer may be considered an outlier in one HCC failure rate group but not an outlier in another HCC failure rate group. Beginning with the 2019 benefit year, issuers will not be considered an outlier for an HCC group in which the issuer has fewer than 30 EDGE HCCs. If no issuers' HCC group failure rates in a state market risk pool materially deviate from the national mean of failure rates or if those issuers whose failure rates do materially deviate from the national mean do not also meet the minimum HCC frequency requirement (that is, if no issuers in the state market risk pool are outliers), HHS will not apply any HHS-RADV adjustments to issuers' risk scores or to transfers in that state market risk pool.

Then, once the outlier issuers are determined, we will calculate the GAF taking into consideration the outlier issuer's distance from the confidence interval and limiting calculation of the GAF when if the issuer is a negative error rate outlier with a negative failure rate. The formula⁸⁰ will apply as follows:

If $freqEDGE_{G,i} \geq 30$, then:

⁸⁰ This calculation sequence is expressed here in a revised order compared to how the sequence is published in the 2021 Payment Notice (85 FR at 29196-29198). This change was made to simplify the illustration of how this sequence would be combined with proposals finalized in this rule. The different display does not modify or otherwise change the amendments to the outlier identification process finalized in the 2021 Payment Notice.

If $z_{G,i} < -3.00$ or $z_{G,i} > 3.00$

Then $Flag_{G,i} = \text{"outlier"}$ and

$$GAF_{G,i} = \max\{0, GFR_{G,i}\} - \max\{0, \mu\{GFR_G\}\}$$

Or if $-3 \leq z_{G,i} < -1.645$ or $3 \geq z_{G,i} > 1.645$

Then $Flag_{G,i} = \text{"outlier"}$ and

$$GAF_{G,i} = \max\{0, (disZ_{G,i,r} * Sd\{GFR_G\} + \mu\{GFR_G\})\} - \max\{0, \mu\{GFR_G\}\}$$

If $freqEDGE_{G,i} < 30$ or if $-1.645 \leq z_{G,i} \leq 1.645$

Then $Flag_{G,i} = \text{"not outlier"}$ and $GAF_{G,i} = 0$

Where:

- r indicates whether the GAF is being calculated for a negative or positive outlier;
- a is the slope of the sliding scale adjustment, calculated as:

$$a = \frac{outerZ_r}{outerZ_r - innerZ_r}$$

With $outerZ_r$ defined as the greater magnitude z-score selected to define the edge of the sliding scale range r (3.00 for positive outliers; and -3.00 for negative outliers) and $innerZ_r$ defined as the lower magnitude z-score selected to define the edge of the range r (1.645 for positive outliers; and -1.645 for negative outliers);

- b_r is the intercept of the sliding scale adjustment for a given sliding scale range r , calculated as:

$$b_r = outerZ_r - a * (outerZ_r) = outerZ_r * (1 - a)$$

- $disZ_{G,i,r}$ is the z-score of issuer i 's $GFR_{G,i}$ for HCC failure rate group G discounted according to the sliding scale adjustment for range r , calculated as:

$$disZ_{G,i,r} = a * z_{G,i} + b_r$$

With $z_{G,i}$ defined as the z-score of i issuers' $GFR_{G,i}$:

$$z_{G,i} = \frac{GFR_{G,i} - \mu\{GFR_G\}}{Sd\{GFR_G\}}$$

- $GAF_{G,i}$ is the group adjustment factor for HCC failure rate group G for an issuer i ;
- $Sd\{GFR_G\}$ is the weighted national standard deviation of all issuers' $GFRs$ for HCC failure rate group G ;
- $\mu\{GFR_G\}$ is the weighted national mean of all issuers' $GFRs$ for HCC failure rate group G .

Once an outlier issuer's GAF is calculated, the enrollee adjustment will be calculated by applying the GAF to an enrollee's individual EDGE HCCs. For example, if an issuer has an enrollee with the HIV/AIDS HCC and the issuer's HCC group adjustment rate is 10 percent for the HCC group that contains the HIV/AIDS HCC, the enrollee's HIV/AIDS coefficient would be reduced by 10 percent. This reduction would be aggregated with any reductions to other EDGE HCC risk score coefficients for that enrollee to arrive at the overall enrollee adjustment factor. This value would be calculated according to the following formula for each sample enrollee in strata 1 through 9 with EDGE HCCs:⁸¹

$$Adjustment_{i,e} = \frac{\sum_h (RS_{h,G,i,e} * GAF_{G,i})}{\sum_h (RS_{h,G,i,e})}$$

Where:

$RS_{h,G,i,e}$ is the risk score component of a single HCC h (belonging to HCC group G) recorded on EDGE for enrollee e of issuer i .

$GAF_{G,i}$ is the group adjustment factor for HCC failure rate group G for an issuer i ;

⁸¹ Some enrollees sampled in Strata 1-3 will only have RXCs, which are not considered as part of the determination of an enrollee adjustment factor.

$Adjustment_{i,e}$ is the calculated adjustment amount to adjust enrollee e of issuer i 's EDGE risk scores.

The calculation of the enrollee adjustment factor only considers risk score factors related to the HCCs and ignores any other risk score factors (such as demographic factors and RXC factors). Furthermore, because this formula is concerned exclusively with EDGE HCCs, HCCs newly identified by the IVA (or SVA as applicable) would not contribute to enrollee risk score adjustments for that enrollee and adjusted enrollee risk scores are only computed for sampled enrollees with EDGE HCCs in strata 1 through 9.

Next, for each sampled enrollee with EDGE HCCs, HHS will calculate the total adjusted enrollee risk score as:

$$AdjRS_{i,e} = EdgeRS_{i,e} * (1 - Adjustment_{i,e})$$

Where:

$EdgeRS_{i,e}$ is the risk score as recorded on the EDGE server of enrollee e of issuer i .

$AdjRS_{i,e}$ is the amended risk score for sampled enrollee e of issuer i .

$Adjustment_{i,e}$ is the adjustment factor by which we estimate whether the EDGE risk score exceeds or falls short of the IVA or SVA projected total risk score for sampled enrollee e of issuer i .

The calculation of the sample enrollee's adjusted risk score includes all EDGE server components for sample enrollees in strata 1 through 9 with EDGE HCCs.

After calculating the outlier issuers' sample enrollees with HCCs' adjusted EDGE risk scores, HHS will calculate an outlier issuer's error rate by extrapolating the difference between the amended risk score and EDGE risk score for all enrollees (strata 1 through 10) in the sample. The extrapolation formula will be weighted by determining the ratio of an enrollee's stratum size

in the issuer's population to the number of sample enrollees in the same stratum as the enrollee. Sample enrollees with no EDGE HCCs will be included in the extrapolation of the error rate for outlier issuers with the EDGE risk score unchanged for these sample enrollees. The formulas to compute the error rate using the stratum-weighted risk score before and after the adjustment will be:

$$ErrorRate_i = 1 - \frac{\sum_e (w_{i,e} * AdjRS_{i,e})}{\sum_e (w_{i,e} * EdgeRS_{i,e})}$$

Where:

$$w_{i,e} = \frac{\text{stratum size in population}}{\text{number of sample enrollees of the stratum}}$$

Consistent with 45 CFR 153.350(b), HHS then will apply the outlier issuer's error rate to adjust that issuer's applicable benefit year's plan liability risk score.⁸² This risk score change, which also will impact the state market average risk score, will then be used to adjust the applicable benefit year's risk adjustment transfers for the applicable state market risk pool.⁸³ Due to the budget-neutral nature of the HHS-operated risk adjustment program, adjustments to one issuer's risk scores and risk adjustment transfers based on HHS-RADV findings affect other issuers in the state market risk pool (including those who were not identified as outliers) because the state market average risk score changes to reflect the outlier issuer's change in its plan liability risk score. This also means that issuers that are exempt from HHS-RADV for a given

⁸² Exiting outlier issuer risk score error rates are currently applied to the plan liability risk scores and risk adjustment transfer amounts for the benefit year being audited if they are a positive error rate outlier. For all other outlier issuers, risk score error rates are currently applied to the plan liability risk scores and risk adjustment transfer amounts for the current transfer year. As detailed in Section II.B, we are finalizing the transition to the concurrent application of HHS-RADV results such that issuer risk score error rates for non-exiting issuers will also be applied to the risk scores and transfer amounts for the benefit year being audited beginning with the 2020 benefit year of HHS-RADV.

⁸³ See 45 CFR 153.350(c).

benefit year will have their risk adjustment transfers adjusted based on other issuers' HHS-RADV results if any issuers in the applicable state market risk pool are identified as outliers.

In the proposed rule, we estimated the combined impact of applying the proposed sliding scale adjustment, the proposed negative failure rate constraint and the proposed Super HCC aggregation using 2017 benefit year HHS-RADV results. We performed a similar analysis using 2018 benefit year HHS-RADV results, once the data became available. Table 3 provides a comparison of the national failure rate metrics under the current and new, finalized methodologies using 2017 and 2018 benefit year HHS-RADV results. Additionally, using the 2017 and 2018 HHS-RADV data, Table 4 provides a comparison between the estimated mean error rates using the current methodology for sorting HCCs for HHS-RADV grouping or the finalized Super HCC aggregation for sorting of HCCs for HHS-RADV groupings, with the finalized negative failure rate constraint and the finalized sliding scale adjustment also being applied. As shown in Tables 3 and 4, the analysis of 2018 HHS-RADV results provided roughly the same figures as the 2017 HHS-RADV results, and offers further support for finalizing these refinements to the error rate calculation.

TABLE 3: A Comparison of HHS-RADV National Failure Rate Metrics Based on Prior Benefit Year HHS-RADV data

HHS-RADV Data Benefit Year	Group	Weighted Mean Failure Rate		Weighted Std. Dev		Lower Threshold		Upper Threshold	
		Current Grouping	New Grouping	Current Grouping	New Grouping	Current Grouping & 95% CI	New Grouping & 90% CI	Current Grouping & 95% CI	New Grouping & 90% CI
2017 Data	Low	0.0476	0.0496	0.0973	0.0959	-0.1431	-0.1082	0.2382	0.2074
	Med	0.1549	0.1557	0.0992	0.0994	-0.0395	-0.0078	0.3493	0.3192
	High	0.2621	0.2595	0.1064	0.1065	0.0536	0.0843	0.4706	0.4347
2018 Data	Low	0.0337	0.0369	0.0884	0.0856	-0.1396	-0.1038	0.2070	0.1777
	Med	0.1198	0.1225	0.0862	0.0856	-0.0490	-0.0184	0.2887	0.2633
	High	0.2262	0.2283	0.0919	0.0914	0.0461	0.0779	0.4062	0.3787

TABLE 4: A Comparison of HHS-RADV Error Rate (ER) Estimated Changes Based on Prior Benefit Year⁸⁴ HHS-RADV Data

Scenario	2017 Data				2018 Data			
	Current Sorting Method		New Sorting Method		Current Sorting Method		New Sorting Method	
	Mean Neg ER	Mean Pos ER	Mean Neg ER	Mean Pos ER	Mean Neg ER	Mean Pos ER	Mean Neg ER	Mean Pos ER
Sorting Method Only	-5.68%	9.96%	-5.98%	9.91%	-6.92%	5.43%	-7.06%	5.71%
Sorting Method with Negative Constraint	-3.11%	9.96%	-3.38%	9.91%	-3.35%	5.43%	-3.16%	5.89%
Sorting Method with Sliding Scale ⁸⁵	-2.27%	5.28%	-2.49%	5.32%	-3.07%	2.21%	-3.21%	2.45%
Sorting Method, Sliding Scale & Negative Constraint (Finalized)	-1.50%	5.28%	-1.66%	5.32%	-1.71%	2.21%	-1.86%	2.47%

⁸⁴ These estimates reflect the exclusion from outlier status of those issuers with fewer than 30 HCCs in an HCC group, consistent with the policy finalized in the 2021 Payment Notice (85 FR 29164), which was not in effect for 2017 or 2018 benefit year HHS-RADV. We excluded issuers with fewer than 30 HCCs from outlier status in these estimates to provide a sense of the impact of the proposed changes when compared to the methodology presently in effect for 2019 benefit year HHS-RADV and beyond.

⁸⁵ This analysis reflects the sliding scale policy finalized in Section II.A.2. of this rule which creates a sliding scale adjustment from +/-1.645 to 3 standard deviations.

B. Application of HHS-RADV Results

In the 2014 Payment Notice, HHS finalized a prospective approach for making adjustments to risk adjustment transfers based on findings from the HHS-RADV process.⁸⁶ Specifically, we finalized using an issuer's HHS-RADV error rates from the prior year to adjust the issuer's average risk score in the current benefit year. As such, we used the 2017 benefit year HHS-RADV results to adjust 2018 benefit year risk adjustment plan liability risk scores for non-exiting issuers, resulting in adjustments to 2018 benefit year risk adjustment transfer amounts.^{87,88}

When we finalized the prospective HHS-RADV results application policy in the 2014 Payment Notice, we did not anticipate the extent of the changes that could occur in the risk profile of enrollees or market participation in the individual and small group markets from benefit year to benefit year. As a result of experience with these changes over the early years of the program, and in light of the timeline for the reporting, collection, and disbursement of HHS-RADV adjustments to transfers⁸⁹ and the changes to the risk adjustment holdback policy,⁹⁰ both of which lead to reopening of prior year risk adjustment transfers, we proposed to switch away

⁸⁶ See 78 FR 15410 at 15438.

⁸⁷ See the Summary Report of 2017 Benefit Year HHS-RADV Adjustments to Risk Adjustment Transfers released on August 1, 2019, available at: <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/BY2017-HHSRADV-Adjustments-to-RA-Transfers-Summary-Report.pdf>.

⁸⁸ In the 2019 Payment Notice, we adopted an exception to the prospective application of HHS-RADV results for exiting issuers, whereby risk score error rates for outlier exiting issuers are applied to the plan liability risk scores and transfer amounts for the benefit year being audited. Therefore, for exiting issuers, we used the 2017 benefit year's HHS-RADV results to adjust 2017 benefit year plan liability risk scores, resulting in adjustments to 2017 benefit year risk adjustment transfer amounts. See 83 FR at 16965 - 16966. We updated this policy to only apply HHS-RADV results for exiting issuers that are positive error rate outliers beginning with the 2018 benefit year. See the 2020 Payment Notice, 84 FR at 17503 - 17504.

⁸⁹ See 84 FR at 17504 through 17508.

⁹⁰ See the Change to Risk Adjustment Holdback Policy for the 2018 Benefit Year and Beyond Bulletin (May 31, 2019) (May 2019 Holdback Guidance), available at: <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Change-to-Risk-Adjustment-Holdback-Policy-for-the-2018-Benefit-Year-and-Beyond.pdf>.

from the prospective approach for non-exiting issuers. We proposed to make the transition and apply HHS-RADV results to the benefit year being audited for all issuers starting with the 2021 benefit year of HHS-RADV. We proposed applying HHS-RADV results to the benefit year being audited for all issuers in an effort to address stakeholder concerns about maintaining actuarial soundness in the application of an issuer's HHS-RADV error rate if an issuer's risk profile, enrollment, or market participation changes substantially from benefit year to benefit year.

In the proposed rule, we explained that if we finalized and implemented the policy to adjust the benefit year being audited beginning with the 2021 benefit year HHS-RADV, we would need to adopt transitional measures to move from the current prospective approach to one that applies the HHS-RADV results to the benefit year being audited. More specifically, 2021 benefit year risk adjustment plan liability risk scores and transfers would need to be adjusted first to reflect 2020 benefit year HHS-RADV results, and adjusted again based on 2021 benefit year HHS-RADV results. Then, for the 2022 benefit year of HHS-RADV and beyond, risk adjustment plan liability risk scores and transfers would only be adjusted once based on the same benefit year's HHS-RADV results (that is, 2022 benefit year HHS-RADV results would adjust 2022 benefit year risk adjustment plan liability risk scores and transfers).⁹¹

In order to effectuate this transition, we proposed an "average error rate approach," as set forth in the 2019 RADV White Paper, under which HHS would calculate an average value for the 2021 and 2020 benefit years' HHS-RADV error rates and apply this average error rate to 2021 plan liability risk scores and risk adjustment transfers.⁹² This approach would result in one

⁹¹ As discussed in the May 2019 Holdback Guidance, a successful HHS-RADV appeal may require additional adjustments to transfers for the applicable benefit year in the impacted state market risk pool.

⁹² See Section 5.2 of the 2019 RADV White Paper

final HHS-RADV adjustment to 2021 benefit year plan liability risk scores and risk adjustment transfers, reflecting the average value for the 2021 and 2020 benefit years' HHS-RADV error rates. The adjustments to transfers would be collected and paid in accordance with the 2021 benefit year HHS-RADV timeline.⁹³

However, in an effort to be consistent with our current risk score error rate application and calculation and ensure that both years of HHS-RADV results were taken into consideration in calculating risk adjustment plan liability risk scores, we also proposed an alternative approach: the “combined plan liability risk score option.” Under the combined plan liability risk score option, we would apply 2020 benefit year HHS-RADV risk score adjustments to 2021 benefit year plan liability risk scores, and then apply 2021 benefit year HHS-RADV risk score adjustments to the adjusted 2021 plan liability risk scores. We would then use the final adjusted plan liability risk scores (reflecting both the 2020 and 2021 HHS-RADV adjustments to risk scores) to adjust 2021 benefit year transfers. Under this proposal, HHS would calculate risk score adjustments for 2020 and 2021 benefit year HHS-RADV sequentially and incorporate 2020 and 2021 benefit year HHS-RADV results in one final adjustment amount to 2021 benefit year transfers. We sought comment on both of these approaches to transition from the current prospective approach to one that applies the HHS-RADV results to the benefit year being audited.

We also explained in the proposed rule that the transition to a policy to apply HHS-RADV results to the benefit year being audited for all issuers would remove the need to continue the current policy on issuers entering sole issuer markets finalized in the 2020 Payment Notice.⁹⁴

⁹³ For a general description of the current timeline for reporting, collection, and disbursement of HHS-RADV adjustments to transfers, see 84 FR at 17506 through 17507.

⁹⁴ 84 FR at 17504.

As finalized in the 2020 Payment Notice, new issuer(s) that enter a new market or a previously sole issuer market have their risk adjustment transfers in the current benefit year adjusted if there was an outlier issuer in the applicable state market risk pool in the prior benefit year's HHS-RADV.⁹⁵ We further explained that if the proposal to apply HHS-RADV results to the benefit year being audited for all issuers is finalized, new issuers, including new issuers in previously sole issuer markets, would no longer be impacted by HHS-RADV results from a previous benefit year; rather, the new issuer would only have their current benefit year risk scores (and subsequently, risk adjustment transfers) impacted if there was an outlier issuer in the same state market risk pool.

We also sought comment on an alternative timeline, in which HHS would apply HHS-RADV results to the benefit year being audited for all issuers starting with the 2020 benefit year of HHS-RADV, rather than the 2021 benefit year. We explained that under the alternative timeframe, 2020 benefit year risk adjustment plan liability risk scores and transfers would need to be adjusted twice – first to reflect 2019 benefit year HHS-RADV results and again based on 2020 benefit year HHS-RADV results. Lastly, we sought comment on whether, if we finalized and implemented either of the transition options using the alternative timeline, we should also pilot RXCs for the 2020 benefit year HHS-RADV.

We are finalizing the proposed transition from the current prospective application of HHS-RADV results for non-exiting issuers and will apply HHS-RADV audit findings to the benefit year being audited for all issuers, starting with the 2020 benefit year HHS-RADV, by combining 2019 and 2020 benefit years HHS-RADV results for non-exiting issuers following the average error rate approach. We also reaffirm that, as a result of finalizing these changes, we

⁹⁵ Ibid.

will not need to continue the current policy on issuers entering sole issuer markets after the transition is effectuated. Therefore, if a new issuer entered a state market risk pool in 2020, its risk adjustment plan liability risk score(s) and transfer for 2020 benefit year risk adjustment could be impacted by the new issuer's own 2020 HHS-RADV results and the combined 2019 and 2020 HHS-RADV results of other issuers in the same state market risk pool. For exiting issuers, HHS will continue to adjust only for positive error rate outliers, as opposed to both positive and negative error rate outliers.⁹⁶ Beginning with the 2021 benefit year of HHS-RADV, plan liability risk scores and risk adjustment transfers will only be adjusted once based on the same benefit year's HHS-RADV results (that is, 2021 benefit year HHS-RADV results would adjust 2021 benefit year plan liability risk scores and transfers for all issuers).⁹⁷ Additionally, HHS will continue to pilot RXCs for the 2020 benefit year.

We are finalizing this change to apply HHS-RADV results to the benefit year being audited for all issuers to address stakeholder concerns about maintaining actuarial soundness in the application of an issuer's HHS-RADV error rate if an issuer's risk profile, enrollment, or market participation changes substantially from benefit year to benefit year. In addition, this change has the potential to provide more stability for issuers of risk adjustment covered plans and help them better predict the impact of HHS-RADV results. Once the transition is effectuated, it will also prevent situations in which an issuer who newly enters a state market risk pool, including new market entrants to a sole issuer market, is subject to HHS-RADV adjustments from the prior benefit year for which they did not participate.

⁹⁶ In addition, positive error rate outlier issuers' 2019 and 2020 HHS-RADV results will be applied to the risk scores and transfers for the benefit year being audited. The average error rate approach is not applicable because exiting issuers who participated in 2019 HHS-RADV would not have 2020 benefit year risk scores or transfers to adjust.

⁹⁷ As discussed in the May 2019 Holdback Guidance, a successful HHS-RADV appeal may require additional adjustments to transfers for the applicable benefit year in the impacted state market risk pool.

Comments: The majority of commenters supported switching from the prospective application of the HHS-RADV results to the benefit year being audited. These commenters generally agreed that having a concurrent application would maintain actuarial soundness in the application of an issuer's HHS-RADV error rate, provide stability to HHS-RADV results, and promote fairness in the HHS-RADV process. One commenter suggested that HHS should consider maintaining the current prospective application of HHS-RADV findings; another commenter suggested HHS exempt new issuers from having their transfers adjusted due to HHS-RADV.

Regarding the transition year, some commenters supported switching to the concurrent application in the 2021 benefit year as proposed due to concerns that changing the transition year to the 2020 benefit year of HHS-RADV would heighten the already significant uncertainty surrounding 2020 as a result of COVID-19, with one commenter noting that issuers did not account for this change in their 2020 pricing. However, most commenters supported switching to the concurrent application with the 2020 benefit year, suggesting that it would be most appropriate to transition to a concurrent application as early as possible and one cited to the various changes to the HHS-operated risk adjustment program beginning with the 2021 benefit year as further support for the alternative timeline for the transition. One commenter requested additional information on the 2020 benefit year HHS-RADV timeline.

Response: We are finalizing the proposal to switch from the current prospective application of the HHS-RADV results to the benefit year being audited, starting with the 2020 benefit year. As previously noted, when we finalized the prospective HHS-RADV results application policy, we did not anticipate the extent of changes that could occur in the risk profile of enrollees or market participation by issuers from benefit year to benefit year. As a result of

experience over the early years of the program, we believe that transitioning to apply HHS-RADV results on a concurrent basis for all issuers will provide greater stability, promote fairness, and enhance actuarial soundness, specifically in the event that an issuer's risk profile, enrollment, or market participation changes significantly from benefit year to benefit year. In light of the other changes to HHS-RADV program operations described in this rule which will lead to reopening of prior benefit year risk adjustment transfers,⁹⁸ it is also no longer necessary to apply HHS-RADV results on a prospective basis to allow time to complete the discrepancy and appeals processes to avoid having to reopen prior year transfers. We also agree that we should begin the application of the results on a concurrent basis as soon as possible and will implement the policy starting with the 2020 benefit year. We believe that starting with the 2020 benefit year will add stability in the midst of the COVID-19 pandemic, as the results from the 2019 and 2020 benefit years of HHS-RADV will be averaged together to calculate the adjustment to 2020 benefit year risk adjustment risk scores. We believe this added stability will account for concerns that issuers did not take this proposed change into consideration when setting rates for the 2020 benefit year. We also agree with the commenter who cited the risk adjustment program updates that apply beginning with the 2021 benefit year as further support for effectuating the transition beginning with the 2020 benefit year.⁹⁹

We did not propose and are not finalizing a new exemption from HHS-RADV for new market entrants. The inclusion of new market entrants in HHS-RADV ensures that those issuers' actuarial risk for the applicable benefit year is accurately reflected in risk adjustment transfers, and that the HHS-operated risk adjustment program assesses charges to plans with lower-than-

⁹⁸ Ibid.

⁹⁹ For example, in the 2021 Payment Notice, we finalized several updates to the HHS-HCC clinical classification to develop updated risk factors that apply beginning with the 2021 benefit year risk adjustment models. See 85 FR at 29175.

average actuarial risk while making payments to plans with higher-than-average actuarial risk. However, new market entrants will no longer be impacted by a prior year's HHS-RADV results and will only be impacted by the results from the benefit year under which they participated in the state market risk pool after the transition is effectuated.¹⁰⁰

HHS intends to provide more information on the 2020 benefit year HHS-RADV timeline in the future, but generally anticipates it will commence as usual with the release of samples in May 2021. As previously noted in this rule, HHS has provided details on the updated timeline on the activities for 2019 benefit year HHS-RADV.¹⁰¹

Comments: Most commenters who submitted comments on the options for combining HHS-RADV results during the transition period supported using the average error rate approach, noting that it would provide more stability and transparency than the combined plan liability risk score option. One commenter who expressed a preference for the average error rate approach cited concerns with the amplifying effect of adjusting risk scores twice under the plan liability risk score option. Most commenters who supported the average error rate approach supported effectuating the transition using 2019 and 2020 benefit years' error rate results. These commenters noted that aggregating the results of these 2 years could reduce volatility and smooth over potential challenges issuers may face when conducting HHS-RADV audits for these benefit years due to the COVID-19 public health emergency. A few commenters who supported use of the average error rate approach urged HHS to implement the transition and use 2020 and

¹⁰⁰ As noted above, a new entrant to a state market risk pool in 2020 would see its risk score(s) and transfer impacted by the new issuer's own 2020 HHS-RADV results, the combined 2019 and 2020 HHS-RADV results of other non-exiting issuers in the same state market risk pool, and the 2020 HHS-RADV results for positive error rate outlier exiting issuers in the same state market risk pool. However, a new entrant to a state market risk pool in 2021 would see its risk score(s) and transfer impacted by 2021 HHS-RADV results only.

¹⁰¹ See the "2019 Benefit Year HHS-RADV Activities Timeline"
https://www.regtap.info/uploads/library/HRADV_Timeline_091020_5CR_091020.pdf

2021 benefit years' results, suggesting it would be the most straightforward approach. One commenter requested clarification as to whether the average error rate approach would use a weighted average error rate.

A few commenters supported the combined plan liability risk score option for the transition years of HHS-RADV. One of these commenters believed that the combined plan liability risk score option would be a fairer way to provide consistency, while a different commenter that supported the combined plan liability risk score option was concerned that the average error rate approach would reduce the otherwise applicable HHS-RADV adjustment. Another commenter compared the two alternative approaches, noting that the average error rate would align well with some issuers' practices, while the combined liability risk score option would align better with other issuers' financial reporting.

Response: We are finalizing the use of the average error rate approach to transition to the concurrent application of HHS-RADV results for non-exiting issuers by combining their 2019 and 2020 benefit years' HHS-RADV results. In response to comments we clarify that for simplification purposes, HHS will apply an unweighted average value of the 2019 and 2020 benefit years' HHS-RADV results to adjust 2020 benefit year risk scores and transfers. We proposed using a combined plan liability risk score as an alternative option, believing that it could provide a more consistent transition to a concurrent application of HHS-RADV results. However, the majority of comments on these transition options emphasized the extent to which they believed an average error rate approach will actually provide greater stability and transparency for the HHS-RADV adjustments applied during the transition period. After consideration of comments, we agree that the average error rate approach will be the optimal transitional approach. More specifically, aggregating the 2019 and 2020 benefit years' results for

non-exiting issuers and using the unweighted average value of those benefit years' HHS-RADV results to adjust transfers will allow for more consistency, reduce potential volatility, and better accommodate any potential disparities or challenges due to COVID-19. As noted previously, we also believe the transition to the application of the results on a concurrent basis should be implemented as soon as possible and therefore will start the concurrent application of HHS-RADV results for all issuers starting with the 2020 benefit year. We recognize that there are advantages to the combined plan liability risk score option, which is why we proposed it for combining HHS-RADV results for the transition years. However, for the reasons outlined above, we believe the average error rate method is the more balanced approach to effectuate the transition and combine 2019 and 2020 HHS-RADV results for non-exiting issuers.

Comments: Some commenters suggested HHS cancel either the 2019 or 2020 benefit years of HHS-RADV. One of these commenters expressed concern that the COVID-19 pandemic could potentially skew the 2020 benefit year HHS-RADV results. Other commenters stated that COVID-19 would make it difficult for providers to respond to issuer requests for the medical documentation needed to complete audits, which they noted could skew HHS-RADV results.

Response: We appreciate the concerns related to the potential impact of COVID-19, but are not cancelling HHS-RADV for either the 2019 or 2020 benefit year. We believe that cancelling either year of this program would be detrimental to program integrity and would result in future difficulties monitoring HHS-RADV trends. We acknowledge that the COVID-19 pandemic puts a number of stressors on providers and issuers. Recognizing the impact of the public health emergency on HHS-RADV activities, we postponed the start of 2019 benefit year

HHS-RADV activities.¹⁰² As recently announced, IVA samples for 2019 benefit year HHS-RADV will be released in January 2021 and we anticipate 2020 benefit year HHS-RADV will commence as usual.¹⁰³ We will continue to monitor the COVID-19 public health emergency and will consider whether additional flexibilities for HHS-RADV are appropriate. Further, as noted above, the adoption of the average error rate approach for the transition to the concurrent application of HHS-RADV is intended to help reduce volatility related to potential challenges issuers may face when conducting HHS-RADV audits for these benefit years due to the COVID-19 public health emergency.

Comments: Most commenters supported continuing the pilot of RXCs for the 2020 benefit year. Some of these commenters suggested that continuing to pilot RXCs would allow for more consistency between 2019 and 2020 and support transitioning to the concurrent application of HHS-RADV results starting with the 2020 benefit year, while another commenter believed that it would minimize the amount of changes occurring at once. One commenter noted that extending the RXC pilot would benefit the issuers who are still learning how to conduct HHS-RADV for RXCs. Another commenter did not believe it would be necessary to continue piloting RXCs in 2020, but acknowledged that an additional pilot period would allow issuers to focus on HHS-RADV during the COVID-19 pandemic, rather than adjusting to new aspects of HHS-RADV reporting.

Response: After consideration of comments, we are finalizing the continuation of the pilot for RXCs for the 2020 benefit year. Extending the RXC pilot an additional benefit year will increase consistency between the operations of the 2019 and 2020 benefit years' HHS-RADV

¹⁰² <https://www.cms.gov/files/document/2019-HHS-RADV-Postponement-Memo.pdf>.

¹⁰³ See the "2019 Benefit Year HHS-RADV Activities Timeline"
https://www.regtap.info/uploads/library/HRADV_Timeline_091020_5CR_091020.pdf

and facilitate the combination of the HHS-RADV adjustments for these benefit years as we transition to a concurrent application of HHS-RADV results starting with the 2020 benefit year. We agree with commenters who suggested that an additional pilot year for RXCs would benefit issuers and provide an opportunity to continue to improve their internal process for conducting HHS-RADV for RXCs.

III. 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.*).

Under this final rule, we are finalizing the modifications to the calculation of error rates to modify the HCC failure rate grouping methodology for HCCs that share an HCC coefficient estimation group in the adult risk adjustment models; to calculate and apply a sliding scale adjustment for cases where outlier issuers are near the confidence intervals; and to constrain the error rate calculation for issuers with negative failure rates. We are also finalizing the transition from the current prospective application of HHS-RADV results¹⁰⁴ to apply the results to the benefit year being audited. These are methodological changes to the error estimation used in calculating error rates and changes to the application of HHS-RADV results to risk scores and transfers. Since HHS calculates error rates and applies HHS-RADV results to risk scores and

¹⁰⁴ The exception to the current prospective application of HHS-RADV results is for exiting issuers identified as positive error rate outliers, whose HHS-RADV results are applied to the risk scores and transfer amounts for the benefit year being audited.

transfers, we did not estimate a burden change on issuers to conduct and complete HHS-RADV in states where HHS operates the risk adjustment program for a given benefit year.¹⁰⁵

IV. Regulatory Impact Statement

A. Statement of Need

This rule finalizes standards related to HHS-RADV, including certain refinements to the calculation of error rates and a transition from the prospective application of HHS-RADV results. The Premium Stabilization Rule and other rulemakings noted earlier provided detail on the implementation of HHS-RADV.

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 (the 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 (January 30, 2017).

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

¹⁰⁵ Since the 2017 benefit year, HHS has been responsible for operating risk adjustment in all 50 states and the District of Columbia.

prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule does not reach the economic significance threshold, and thus is not considered a major rule. For the same reason, it is not a major rule under the Congressional Review Act.

C. Regulatory Alternatives Considered

In developing the policies contained in this final rule, we considered numerous alternatives to the presented policies. Below we discuss the key regulatory alternatives considered.

We considered an alternative approach to the sorting of all HCCs that share an HCC coefficient estimation group in the adult models into the same “Super HCC” for HHS-RADV HCC grouping purposes. This alternative approach would have combined all HCCs in the same hierarchy into the same Super HCC for HHS-RADV HCC grouping purposes even if those HCCs had different coefficients in the risk adjustment models. While we did analyze this option, we were concerned that it would not account for risk differences within the HCC hierarchies, and that the finalized approach that focuses on HCCs that share an HCC coefficient estimation group and have the same risk scores in the adult models would better ensure that HHS-RADV results account for risk differences within HCC hierarchies. Additionally, by forcing all HCCs that share a hierarchy into the same HHS-RADV failure rate grouping regardless of whether they have different coefficients, we would not only diminish our ability to allow for differences among various diseases within an HCC hierarchy but would also reduce our ability to recognize differences in the difficulty of providing medical documentation for them.¹⁰⁶

We considered several other options for addressing the payment cliff effect besides the specific sliding scale adjustment that we are finalizing. One option was returning to the original

¹⁰⁶ See 83 FR 16961 and 16965.

methodology finalized in the 2015 Payment Notice, which would have adjusted almost all issuers' risk scores for every error identified as a result of HHS-RADV.¹⁰⁷ The adjustments under the original methodology would have used the issuer's corrected average risk score to compute an adjustment factor, which would have been based on the ratio between the corrected and original average risk scores. However, our analysis indicated that the original methodology generally resulted in less stability, since the vast majority of outlier issuers had their original failure rates applied without the benefit of subtracting the weighted mean difference.¹⁰⁸ In addition, while the original methodology did not specifically result in a payment cliff effect, it would have resulted in more and larger adjustments to transfers.

The second option we considered to mitigate the impact of the payment cliff was to modify the error rate calculation by calculating the issuer's GAF using the HCC group confidence interval rather than the distance to the weighted HCC group mean. As described in the 2019 RADV White Paper and in previous rulemaking,¹⁰⁹ we had concerns that this option would result in under-adjustments based on HHS-RADV results for issuers farthest from the confidence intervals. Thus, although this option could address the payment cliff effect for issuers just outside of the confidence interval, it also could create the unintended consequence of mitigating the payment impact for situations where issuers are not close to the confidence intervals, potentially reducing incentives for issuers to submit accurate risk adjustment data to their EDGE servers.

An additional option suggested by some stakeholders that could address, at least in part, the payment cliff effect that we considered would be to modify the two-sided approach to HHS-

¹⁰⁷ See 79 FR 13755-13770.

¹⁰⁸ See the 2019 RADV White Paper at pages 78-79 and Appendix B.

¹⁰⁹ See 84 FR 17507 – 17508. See also the 2019 RADV White Paper at page 80.

RADV and only adjust issuers who are positive error rate outliers. However, moving to a one-sided outlier identification methodology would not have addressed the payment cliff effect because it would still exist on the positive error rate side of the methodology.¹¹⁰ In addition, the two-sided outlier identification, and the resulting adjustments to outlier issuer risk scores that have significantly better-than-average or poorer-than-average data validation results, ensures that HHS-RADV adjusts for identified, material risk differences between what issuers submitted to their EDGE servers and what was validated by the issuers' medical records during HHS-RADV. The two-sided outlier identification approach ensures that an issuer who is coding well is able to recoup funds that might have been lost through risk adjustment because its competitors are coding badly.

We also considered various other options for the thresholds under the sliding scale option to mitigate the payment cliff effect. For example, we considered as an alternative the adoption of a sliding scale option that would adjust outlier issuers' error rates on a sliding scale between the 95 and 99.7 percent confidence interval bounds (from +/- 1.96 to 3 standard deviations). This alternative sliding scale option would retain the current methodology's confidence interval at 1.96 standard deviations, the full adjustment to the mean failure rate for issuers outside of the 99.7 percent confidence interval (beyond three standard deviations), and the current significant adjustment to the HCC group weighted mean after three standard deviations. Commenters supported this sliding scale option because it addressed the payment cliff issue without increasing the number of issuers identified as outliers. However, while we recognized that this alternative also would mitigate the payment cliff effect, it would weaken HHS-RADV by

¹¹⁰ It is important to note the purpose of HHS-RADV approach is fundamentally different from the Medicare Advantage risk adjustment data validation (MA-RADV) approach. MA-RADV only adjusts for positive error rate outliers, as the program's intent is to recoup Federal funding that was the result of improper payments under the Medicare Part C program.

reducing its overall impact and the magnitude of HHS-RADV adjustments to outlier issuer's risk scores.

When developing a process for implementing the transition from the prospective application of HHS-RADV results to a concurrent application approach, we considered three options for the transition year. In previous sections of this rule, we described two of those options. The third option is the "RA transfer option." The RA transfer option would separately calculate 2019 benefit year HHS-RADV adjustments to 2020 benefit year transfers and 2020 benefit year HHS-RADV adjustments to 2020 benefit year transfers.¹¹¹ Under this option, we would then calculate the difference between each of these values and the unadjusted 2020 benefit year transfers before any HHS-RADV adjustments were applied, and add these differences together to arrive at the total HHS-RADV adjustment that would be applied to the 2020 benefit year transfers. That is, HHS would separately calculate adjustments for the 2019 and 2020 benefit year HHS-RADV results and incorporate 2019 and 2020 benefit year HHS-RADV results in one final adjustment to 2020 benefit year transfers that would be collected and paid in accordance with the 2020 benefit year HHS-RADV timeline.¹¹² However, we believe this alternative is not as consistent with our current risk score error rate application and calculation as the combined plan liability risk score option, or as simple as the average error rate approach being finalized.

V. Regulatory Flexibility Act

The RFA (5 U.S.C. 601, *et seq.*) requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of a proposed rule on small entities, unless the head of

¹¹¹ See section 5.2 of the 2019 RADV White Paper.

¹¹² For a general description of the current timeline for publication, collection, and distribution of HHS-RADV adjustments to transfers, see 84 FR at 17506 –17507.

the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a “small entity” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of “small entity.” HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

In this final rule, we establish standards for HHS-RADV. This program is generally intended to ensure the integrity of the HHS-operated risk adjustment program, which stabilizes premiums and reduces the incentives for issuers to avoid higher-risk enrollees. Because we believe that insurance firms offering comprehensive health insurance policies generally exceed the size thresholds for “small entities” established by the SBA, we do not believe that an initial regulatory flexibility analysis is required for such firms.

We believe that health insurance issuers would be classified under the North American Industry Classification System code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of \$41.5 million or less would be considered small entities for these North American Industry Classification System codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be \$35.0 million or less.¹¹³ We believe that few, if any, insurance companies underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds.

¹¹³ <https://www.sba.gov/document/support--table-size-standards>.

Based on data from MLR annual report¹¹⁴ submissions for the 2017 MLR reporting year, approximately 90 out of 500 issuers of health insurance coverage nationwide had total premium revenue of \$41.5 million or less. This estimate may overstate the actual number of small health insurance companies that may be affected, since over 72 percent of these small companies belong to larger holding groups, and many, if not all, of these small companies are likely to have non-health lines of business that will result in their revenues exceeding \$41.5 million.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule would not affect small rural hospitals. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

VI. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a proposed rule that includes any federal mandate that may result in expenditures in any 1 year by state, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately \$156 million. Although we have not been able to quantify all costs, we expect the combined impact on state, local, or Tribal governments and the private sector to be below the threshold.

VII. Federalism

¹¹⁴ Available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule that imposes substantial direct costs on state and local governments, preempts state law, or otherwise has federalism implications.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policymaking discretion of the states, we have engaged in efforts to consult with and work cooperatively with affected states, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with state insurance officials on an individual basis.

While developing this final rule, we attempted to balance the states' interests in regulating health insurance issuers with the need to ensure market stability and adopt refinements to HHS-RADV standards. By doing so, it is our view that we have complied with the requirements of Executive Order 13132.

Because states have flexibility in designing their Exchange and Exchange-related programs, state decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment program. HHS operates risk adjustment on behalf of any state that does not elect to do so. Beginning with the 2017 benefit year, HHS has operated risk adjustment for all 50 states and the District of Columbia.

In our view, while this final rule would not impose substantial direct requirement costs on state and local governments, it has federalism implications due to direct effects on the distribution of power and responsibilities among the state and Federal Governments relating to

determining standards about health insurance that is offered in the individual and small group markets.

VIII. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771 requires that the costs associated with significant new regulations “to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” This final rule is not subject to the requirements of Executive Order 13771 because it is expected to result in no more than de minimis costs.

IX. Conclusion

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

CMS-9913-F

Dated: November 18, 2020.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: November 23, 2020.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.