Submitted electronically via *www.regulations.gov*

March 1, 2024

The Honorable Xavier Becerra
Secretary, Department of Health and Human Services

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services

Meena Seshamani, MD, Ph.D.
Director, Center for Medicare
U.S. Department of Health and Human Services
Attention: CMS-2024-0006
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on the Advance Notice of Methodological Changes for Calendar Year (CY) 2025 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (CMS-2024-0006)

Dear Secretary Becerra, Administrator Brooks-LaSure, and Director Seshamani:

Thank you for the opportunity to respond to the Advance Notice of Methodological Changes for Calendar Year (CY) 2025 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, released on January 31, 2024.

CVS Health serves millions of people through our local presence, digital channels, and our nearly 300,000 dedicated colleagues – including more than 40,000 physicians, pharmacists, nurses, and nurse practitioners. CVS Health offers Medicare Advantage Prescription Drug (MAPD) plans in 46 states and D.C. Aetna also offers robust standalone prescription drug plans (PDPs) to individuals in all 50 states and D.C. Our unique healthcare model gives us an unparalleled insight into how health systems may be improved to help consumers navigate the healthcare system–as well as their personal healthcare–by eliminating disparities, improving access, lowering costs, and being a trusted partner for every meaningful moment of health. And we do it all with heart, each and every day.

For years, we have championed combining population-level health management with innovative solutions to provide people-centered care through care coordination, reduced cost-sharing, and our supply of supplemental benefits addressing gaps in care. Our comprehensive approach to the delivery of care has helped improve health outcomes and deepen patient engagement with their healthcare. As more individuals choose Medicare Advantage (MA), we believe it is critical for the Centers for Medicare & Medicaid Services

(CMS) to enact stable payment policies that allow MA plans to continue providing affordable, consistent and high-quality benefits to Medicare beneficiaries year after year.

As a leading healthcare solution company, we are committed to working the Department of Health and Human Services (HHS) to formulate rules that advance Medicare beneficiaries' top priorities. The MA and Part D programs are a shining example of how the private sector can partner with CMS to provide cost-effective, person-centered care that is focused on prevention. Seniors are responding to this coverage option, and MA is growing in popularity.

We appreciate that CMS has not proposed large and new policy changes to the program, particularly in light of the major changes to the Part D program that were required to implement the Part D benefit redesign pursuant to the Inflation Reduction Act of 2022 (IRA). As we have previously commented, the MA and Part D programs benefit from consistent policies that promote CMS' and CVS Health's shared goal of improved health and healthcare for beneficiaries. We encourage CMS to use its authority to maintain a predictable and stable payment environment, so MA and Part D plans can continue to meet the needs of Medicare beneficiaries and avoid a significant disruption in benefits. However, we are concerned that some proposals could create unnecessary disruption in the MA, MAPD and PDP markets.

Inadequate reimbursement rates also destabilize the program. MA and Part D plans may have to increase premiums and/or cost sharing or decrease important and needed supplemental benefits currently offered to beneficiaries. Seniors and disabled individuals relying on Medicare are already struggling with the rising cost of living. CMS' calculations for the growth rate and normalization do not adequately account for the costs MA and Part D plans are facing. We understand Congress is very close to enacting legislation that would increase Medicare physician payments for the rest of CY 2024 *(details still being negotiated)*. If Congress passes the bill, we urge CMS to incorporate the increase for physician payments into the final growth rate calculation and MA benchmarks for all future periods. MA Benchmarks should reflect the best estimate for anticipated unit cost levels for all service categories.

- **CMS should reexamine its proposed growth rate and utilization**. We strongly believe that CMS is underestimating the projected utilization of services, especially in consideration of beneficiaries' use of new Alzheimer and other medical pharmacy treatments, not incorporating Q4 2023 experience into the baseline, and expected additional medical cost associated with induced utilization from Part D redesign.
- **CMS should reconsider its normalization factors for CMS-HCC risk adjustment models.** The proposed calculation of the normalization factor appears to be overly influenced by one-time trends observed during the COVID-19 pandemic. We can support CMS' new multi-linear regression methodology, if it incorporates a variable and gradually declining COVID factor, to produce both a better fit for observed risk scores and more durable post-COVID-19 pandemic Fee-for-Service (FFS) risk score trends. See the attached Appendix II with further detail and analysis.

CVS Health has provided more detailed comments on CMS' Part D Redesign Program Instructions in a separate letter. As we indicate in that letter, it is important that CMS take steps to create stability and a level playing field in the MA-PD and PDP programs, especially as they relate to the IRA. **Therefore, we ask CMS to use its statutory authority under section 402 of the Social Security Act to narrow the risk corridors for 2025 and later plan years. Doing so would alleviate the risk of unanticipated liability plans face in light of the dramatic changes to the Part D program and uncertain impacts of market responses in the upcoming plan years.** Also, to the extent CMS feels they do not have the authority to address the Total Beneficiary Cost (TBC) concerns outlined below, **we recommend that CMS narrow the risk corridors AND address TBC using the authority from section 402 of the Social Security Act.**

We have significant concerns with the calculation of the IRA Part D redesign impact and timing of guidance on TBC for 2025. The 2025 Part D benefit redesign will have a significant impact on the Out-of-Pocket Cost (OOPC) model, and we are looking for CMS to provide timely guidance. **Specifically, we recommend:**

- **CMS issues guidance as soon as practically feasible** to either (1) retain the current total beneficiary cost calculation but increase the TBC threshold with a calculation to reflect the standard Part D benefit improvement under the IRA; or (2) adjust the total beneficiary calculation to include Part D benefit improvements under the IRA and the corresponding reduction to beneficiary cost. We are concerned that if the enriched Part D cost-sharing benefits under the IRA are not reflected as a decrease in TBC, an increase in TBC will be an inaccurate reflection of a reduction in benefits. Not appropriately applying this enrichment in Part D costs into the TBC calculation may result in the inability of plans to adequately offset the additional cost on existing plan offerings, leading to member disruption and plan terminations.
- **CMS releases the OOPC models no later than April 1, 2024** and provide guidance on how the reduction to beneficiary cost sharing under the 2025 Part D benefit redesign will be reflected in the calculation of TBC. In addition, we have detailed recommendations on how CMS should consider, and provided guidance for, enhanced alternative Part D plans.

We appreciate that CMS has not proposed major directional changes in the Star Ratings (Part C and D) program. **Even so, we urge CMS to strengthen the Star Ratings program to protect the program's future stability.** CVS Health believes strongly that CMS must foster a stable Star Ratings program and use its regulatory authority to reduce as much volatility in the program as possible. We urge CMS to work with stakeholders to consider the Star Ratings program as a whole and to avoid yearly piecemeal changes that do not address the underlying causes of beneficiary and plan challenges. CMS should consider adopting system-wide changes that are necessary to ensure that the Star Ratings program continues to advance CMS' strategic pillars of advancing equity, expanding access, engaging partners, driving innovation, protecting the Medicare program, and fostering excellence. Nonetheless, under the Advance Notice, we support some of CMS' Star Ratings proposals. For example, we fully support reducing the weight of patient experience and complaints.

We also support the concept of the Health Equity Index (HEI) Reward to incentivize plans to reduce disparities in health. However, we strongly believe that CMS should align that incentive for all plans that serve members with social risk factors (SRFs). CMS currently sets an arbitrary threshold (around 21%) before plans can earn that HEI Reward. We believe that reward should be on a sliding scale starting at zero and increase as the proportion of SRF membership increases.

As we have urged CMS before, we believe that the Medicare Plan Finder (MPF) Price Accuracy Measure does not work as intended and, rather than continuing to modify the measure, CMS should abandon it. CMS should alternatively address the MPF's fundamental challenges by investigating solutions to reflect "real time prices" on a website that currently accepts only bi-weekly updates from plans. We are also concerned that CMS' voluntary disenrollment measure would penalize plans with expanded special enrollment periods.

Finally, given the uncertainty caused by the IRA changes, as well as the significant utilization headwinds faced by MA, MAPD, and PDP plans**, if CMS decides to finalize any or all of these proposals, it should phase-in certain changes incrementally over the next few plan years.**

We provide more details of our recommendations in the attached Appendices I and II.

Thank you for considering our recommendations and comments. CVS Health is committed to collaborating with CMS as it formulates rules and policies that promote affordable, comprehensive care and provides beneficiaries with innovative coverage choices to meet their needs. We welcome any follow-up questions you may have.

Sincerely,

Melissa Schulman
Senior Vice President, Government & Public Affairs
CVS Health

Appendix I

Advance Notice of Methodological Changes for Calendar Year (CY) 2025 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies

I.   MA Payment Changes

A.   Growth Rate Calculation and Utilization

The effective growth rate is the national average of the expected change in per capita costs, with CMS adjustments related to medical education costs that reduce the effective growth rate. For 2025, CMS has estimated the effective growth rate for the non-End-Stage Renal Disease rates to be 2.44 percent (%).

CVS Health, like other MA plans, is concerned that CMS' estimates underestimate increased healthcare costs and fail to account for increased utilization of healthcare, particularly in the past year. While we appreciate that CMS was not able to include fourth quarter (Q4) data in its growth rate calculation—we urge CMS to include that data in the final growth rate. Even before Q4, MA plans were experiencing significant utilization increases that we believe are not adequately reflected in CMS' projection.[1] Utilization patterns are subject to seasonality trends, and services are not uniform throughout the calendar year (for example, Q4 2023 saw an increase in RSV related visits and COVID vaccines relative to Q1-Q3). Therefore, this data should be included in the baseline for future year projections.

More seniors than ever before receive their Medicare benefits through MA plans. MA plans are undergoing a significant increase in utilization of outpatient care and late 2023 inpatient

---

[1] Humana Form 8-K, Jan. 18, 2024 ("Actual fourth quarter results reflect an additional increase in Medicare Advantage medical cost trends, driven by higher than anticipated inpatient utilization, primarily for the months of November and December, as well as a further increase in non-inpatient trends, predominantly in the categories of physician, outpatient surgeries and supplemental benefits …"), https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/0000049071/000004907124000005/hum-20240118.htm; Healthcare Dive, Centene echoes Humana's concerns about a proposed MA rate drop, Feb. 6. 2024 ("UnitedHealth and Humana, which together hold almost half of total MA market share, say that seniors are continuing to seek outpatient care in droves, including procedures like orthopedic surgeries and seasonal needs like vaccinations for the flu or respiratory virus RSV. Both also reported higher inpatient utilization, though UnitedHealth blamed expensive COVID-19 admissions while Humana said it was seeing more short stays in hospitals across the board. Though outpatient care has remained elevated, Centene didn't see an increase in inpatient care in the fourth quarter, according to management."), https://www.healthcaredive.com/news/centene-medicare-advantage-rate-drop-2023-earnings/706620/; Modern Healthcare, Aetna forecasts higher Medicare Advantage costs, Feb. 7, 2024, (""Outpatient trend accelerated slightly in the fourth quarter," CVS CFO Tom Cowhey said on a call with investors Wednesday morning. Cowhey attributed the increase to more seniors receiving orthopedic procedures and utilizing supplemental benefits like dental and vision care, along with more vaccinations for RSV. Elevated utilization appears to be carrying into 2024.") https://www.modernhealthcare.com/insurance/cvs-health-medicare-advantage-utilization-2024; Healthcare Dive, Medicare Advantage plans could see rates dip slightly in 2025, Feb. 1. 2024 ("MA insurers are struggling with a number of headwinds in the program, including seniors utilizing more care than anticipated. The trend, which started last year, is expected to continue in 2024"), https://www.healthcaredive.com/news/medicare-advantage-rate-notice-proposed-2025/706261/.

admissions. MA plans have also experienced rising costs due to an increased number of office visits as beneficiaries seek out seasonal vaccinations from their medical providers such as the Respiratory Syncytial Virus (RSV) vaccine covered at $0 member cost share under Part D. And while much of the country has rebounded from COVID, seniors and other vulnerable beneficiaries may be continuing to "catch up" on deferred care or may be experiencing more serious ancillary effects from prior COVID infections. MA plans continue to find innovative ways to provide quality, accessible care, and with greater options to receive treatment—including through telehealth. Therefore, utilization may initially increase as beneficiaries receive care that they may have previously entirely foregone. And as CMS is aware, its calculations are based upon nationwide averages. Local conditions, including cost and utilization, may differ dramatically from these nationwide averages. Plans must be reimbursed at a rate that properly reflects healthcare inflation and appropriately accounts for increased utilization of services.

At the same time, Medicare beneficiaries need more support than ever. For instance, we identified an increase of twenty-seven percent (27%) of our MA plan enrollees who are considered at-risk populations. COVID and RSV are particularly challenging for most Medicare beneficiaries; not only are they generally more physically vulnerable, any steps they may take to protect themselves may lead to isolation, loneliness, or reduced self-care. In short, in our experience and view, Medicare beneficiaries are continuing to recover from the pandemic, and when added to other physical and social risk factors, they often need more care and support than one may have predicted absent the pandemic.

Finally, we note that this projection downward (for 2024 and 2025) seems entirely inconsistent with predicted developments. We are concerned that CMS has not adequately accounted for underlying utilization and claim trends when factoring in the additional pressure from beneficiaries' use of new Alzheimer treatments (over $4 PMPM in 2025 per OACT estimates) and other Part B medical pharmacy treatments.

We urge CMS to reconsider its proposed growth rate calculation. CMS does not adequately account for the utilization MA plans are experiencing now and are projected to continue to experience in 2025. We hope that CMS will carefully review its assumptions both about healthcare costs (and trends), as well as the trend of increased utilization, and will adjust its final effective growth rate accordingly. In addition, as CMS has done in the past, including last year, CMS should include Q4 in its final effective growth rate calculation to accurately capture increased utilization and associated elevated expenses.

Lastly, we understand Congress is very close to enacting legislation that would increase Medicare physician payments for the rest of CY 2024 *(details still being negotiated)*. If Congress passes the bill, we urge CMS to incorporate the increase for physician payments into the final growth rate calculation and MA benchmarks for all future periods. MA Benchmarks should reflect the best estimate for anticipated unit cost levels for all service categories.

> **Recommendations:**
> - o **Include utilization data from fourth quarter (Q4) of 2023 in calculation of the growth rate.**
> - o **Reconsider the data and assumptions underlying health costs and utilization to accurately reflect increases in the use and cost of healthcare.**
> - o **Incorporate any increase for physician payments into the final growth rate calculation and MA benchmarks for all future periods.**

B.   Indirect and Direct Medical Education (IME)

To smooth the year over year impact to the marketplace, consistent with how CMS handled the original IME Phase-Out per section 1853(k)(4)(B)(ii) of the Social Security Act, we recommend CMS phase-in this change over several more years or, at a minimum, skip the adjustment for CY 2025. These changes are significant and combined with the recent v.28 risk adjustment changes will create disruption in the MA market. This disruption may affect beneficiaries in the form of higher premiums and/or reduced benefits.

> **Recommendation: Phase-in the IME adjustment over a longer period of time or, at a minimum, skip the adjustment for CY 2025.**

C.   Calculation of the Normalization Factor

For 2023 and 2024, CMS excluded 2021 average risk score data from the calculation of the FFS normalization factor for the CMS Hierarchical Condition Category (CMS-HCC) models to account for the impact of the COVID-19 pandemic on the risk score trend. For 2025, CMS' proposed methodology does not require exclusion of any years of data because CMS said that excluding data years under the current methodology "does not produce reasonable projections." Instead, CMS proposes a multiple regression model that CMS says would consider the distinct trends and risk score levels for the pre- and post-COVID-19 periods when projecting to future plan years.

These changes to the normalization factor calculation can be substantial in consideration of other market changes MA plans experience and CMS' decision to split the normalization factor to calculate Part D separately. Beneficiaries' experience may be disrupted if MA plans are required to issue higher premiums and/or reduce benefits in reaction to these changes.

We agree with CMS that the pandemic caused significant uncertainty in the risk score trend. We note that more beneficiaries have been choosing MA plans, and we are unable to determine whether the proposed change in the normalization factor accurately reflects the increased volume of healthcare. CMS has previously recognized the importance of

adjusting normalization factors due to utilization and enrollment changes and should do so again here.[2]

We reviewed the multiple linear regression methodology and coefficients CMS proposed. While we support CMS exploring alternative approaches to calculating the risk adjustment model normalization factors, we believe that improvements can be made to the proposed multiple linear regression models to produce a better fit for the 2019-2023 observed risk scores, and more durable post-COVID-19 pandemic FFS risk score trends for 2024-2025.

We propose using a variable and gradually declining COVID factor, from 1.0 in 2021 to 0.7 in 2022, 0.5 in 2023, and 0.4 in 2024 and 2025. These factors are consistent with a slowing reduction in the COVID bounce back, which closely fits the observed risk score trends, and reflects the lower but remaining COVID impacts through 2025. The multiple linear regression methodology with these factors produces a better fit to the 2019-2023 historical FFS risk scores and higher adjusted R-square value.

> ➤ **Recommendation: CMS should revise the proposed models to better fit observed risk scores, including by using a variable and declining COVID factor. Please see Appendix II for the technical details supporting our recommendation.**

II.   Part D Payment Policy Changes

A.   Risk Adjustment

CVS Health appreciates CMS proposal to apply separate normalization factors for MA-PD and standalone PDP, supports the inclusion of most recent available PDE data in the model, and shares the desire to improve prediction of Part D expenditures. We are concerned, however, that CMS may not have accounted for the shift in MAPD toward DSNPs— specifically, that there is a larger number of plans that cover dually eligible individuals—and that this population change is not adequately reflected in CMS' models. Please clarify how CMS has considered this trend and how did CMS adjust to account for MAPD covering a larger percentage of dually eligible beneficiaries in the re-sloping between MAPD and PDP plans.

While we generally agree with CMS' comment on page 106 in the advance notice that

---

[2] "Under any model, the average risk score can change from year to year for a number of reasons, including changes in demographics, disease prevalence, coding practices, and utilization." CMS, CY 2022 Rate Notice (Jan. 15. 2021); "the risk scores were too low and resulted in a predicted payment year risk score that was too low" so CMS changed the normalization factors in 2016. CMS, CY 2017 Rate Notice and Final Call Letter (Apr. 4, 2016); "We have calculated the normalization factors for 2015 in order to better account for the effect of baby boomer enrollment." Fact Sheets Strengthening Medicare Advantage, CMS.GOV (Apr. 7, 2014) https://www.cms.gov/newsroom/fact-sheets/strengthening-medicare-advantage.

"[b]y using separate normalization factors for MA-PD plans and PDPs, risk scores will more accurately reflect Part D costs in each of these two sectors of the Part D market that are driven by a variety of market-based variables, including the overall benefits that they are able to manage, the lack of an ability of PDPs to affect the submission of diagnoses in FFS, and available strategies used to manage Part D costs."

We note that pharmacy network DIR impacted Part D costs present in 2022 data that has been effectively eliminated as of January 1, 2024. It is possible that network DIR programs were present to a lesser extent in the MAPD market than the PDP market; i.e., all else equal, PDP point of sale costs may have been higher than MAPD. This may skew the relative value of gross expenditures and point of sale prices in the PDP vs. MAPD markets. The impact of the DIR changes should be normalized out of PDP and MAPD gross expenditures, otherwise the unadjusted data may not be appropriate for 2025 PDP and MAPD risk score and normalization factor development. It is also possible that there are different formulary coverage strategies deployed in the PDP market that drive higher brand dispensing and manufacturer rebates which would again lead to higher gross, but not necessarily net, expenditures in the PDP market.

If CMS is committed to separate normalization factors across MAPD and PDP, please consider a phase-in approach so that the impact can be reversed if new data or analysis related to DIR becomes available. For example, under the proposed 2021/22 calibration model, the normalization factors when calculated separately are 1.073 and 0.955, and for sake of illustration assume that this is 1.018 if they were combined. Under a three-year phase in, we suggest CMS weight the separated normalization factors by 33%, 66% and 100% for 2025, 2026 and 2027, respectively. The MAPD Part D normalization factor for 2025 would be 33% x 1.073 + 67% x 1.018 = 1.036 rather than 1.073.

We continue to be concerned that the RxHCC model does not account for several significant areas of projected higher plan liability and is not sufficient to ensure long-term stability of the Part D program. We understand CMS may not be able to make major changes in the model for 2025, but we believe at least some adjustments could be made that would ameliorate the conditions in 2025, and that a more robust process for comprehensive changes in 2026 should be undertaken.

As we have commented in the past, **CMS should use Part D claims data when no medical diagnosis is available to address high drug costs**. The model relies on historical data, and there is no adjustment to reflect the material changes in pharmacy direct or indirect remuneration (DIR) in 2025. As a result, negotiated prices will be lower in 2025 than in previous years. We are also concerned that the model does not address selection issues or anticipated changes in utilization as a result of the Part D redesign in 2025. For example, the $2,000 cap on out-of-pocket costs will create an incentive for beneficiaries to take more and more expensive drugs in order to reach that cap as quickly as possible.

- ➢ **Recommendations:**
    - o **CMS should update the Part D risk score model to reflect the changes in the CY 2025 plan design so that risk adjustment payments better reflect anticipated plan costs for the year.**
    - o **CMS should confirm that DSNPs were correctly reflected in CMS' models and, if not, should not move forward with implementation until DSNPs are appropriately accounted for in the models.**
    - o **If CMS did appropriately account for DSNPs, it should phase in the risk adjustment model over multiple years.**
    - o **For CY 2025, CMS should update the model to reflect risk selection and the impact of induced utilization that is expected to occur as a result of the new Part D plan design.**
    - o **For 2026:**
        - ▪ CMS should look for ways to improve the fit of the Part D risk score model, including looking for ways to address high pharmacy cost where there may not be a medical diagnosis.
        - ▪ CMS should incorporate the impact of the elimination of post-POS pharmacy price concessions into the risk score model. Using historical drug costs prior to the change in treatment of post-POS pharmacy price concessions can distort some drug classes and not reflect current pricing.
        - ▪ CMS should incorporate the impacts of recent reductions in manufacturer list prices (i.e., WAC) in certain drug categories.
        - ▪ CMS should incorporate the anticipated negotiated drug prices for 2026 and future years instead of relying on historical costs for these drugs.
        - ▪ Further, the entire RxHCC model should be developed and calibrated separately for PD plans and PDP plans, as it is unlikely that differences in recording of medical diagnosis is consistent across HCCs.

B.   Part D Risk Sharing

CMS notes that the Part D benefit is changing in 2025 in ways that will increase plan costs and liability, and that widening the risk corridor would increase the risk associated with providing the Part D benefit and reduce the risk sharing amounts provided (or recouped) by CMS. This would suggest that CMS should narrow the risk corridors for 2025. However, CMS states that the statute does not permit it to do so relative to the CY 2011 thresholds.

We strongly support narrowing the risk corridors for 2025 in light of the new benefit design and significantly higher plan liability. This will help Part D plans cope with the major changes in the benefit structure and increase the stability of the Part D program. While we understand that the statute states in sections 1860D-15(e)(3)(C)(i)(III) and (C)(ii)(III) that the risk corridors may be "no less" than 5 and 10 percent respectively, we respectfully disagree that that the statute prohibits CMS from narrowing the corridors. Specifically, we believe

that CMS may rely on its demonstration authority in section 402 of the statute to waive these statutory provisions. CMS proposed to rely on this authority for precisely this purpose in 2019 when it sought to address the greater financial exposure that Part D sponsors would face if its proposal to require rebates to be reflected at POS was implemented. We recommend a voluntary multi-year demonstration to test an efficient transition for beneficiaries and plans due to the unprecedented level of change in the Part D program due to the IRA.

Narrowing the risk corridors will increase stability and protections. As currently proposed, shifting the catastrophic responsibility from 20% to 60% for plan sponsors will lead to significant financial risk that some plans may be ill-equipped to manage. The 2025 defined standard benefit design with the $2,000 MOOP represents a substantial level of benefit enhancement. Part D sponsors and their actuaries will make best efforts to accurately price for the impact of benefit enhancement and induced utilization, but there may not be sufficient market data or similar sizable events available for study and development of reliable and reasonable assumptions. Furthermore, it is unclear to what extent the Individual Market will continue to offer enhanced alternative MAPDs and PDPs in 2025 or beyond due to the IRA, and for those that do, what the impact of enhanced benefits accumulating toward the $2,000 MOOP will have on bidders' projections of catastrophic spend. If there are substantially fewer EA plans available in the market, unanticipated enrollment and population shifts are unlikely to have been fully contemplated or captured in basic bid projections. The Medicare Prescription Payment Plan (MPPP or M3P) also takes effect in 2025. This program may increase utilization, especially of expensive medications. The general implementation of this program will increase non-benefit expenses. Plans will also need to assume in their bid pricing the number of beneficiaries who will enroll in M3P and also estimate bad debt incurred under the program as a non-benefit expense built into premiums. As a result of yet another change due to IRA, we expect there will be inconsistencies in Part D pricing assumptions across industry bidders which could lead to substantial selection effects on certain plans or carriers that threaten longer term stability of the Part D program.

It is notable in the 2023 Medicare Trustees Report that, "for 2026 and later, this $2,000 limit will be increased by the annual percentage increase used for other Part D benefit parameters." Table V.E2 of that same report estimates that the catastrophic threshold will remain roughly flat or *decrease* over time, moving from $2,000 in 2025 down to only $1,800 in 2031. We are concerned that member premiums, particularly in the Standalone PDP market, will be pressured in 2025 and over time, that the increased financial risk to plans will result in fewer plans being offered. (Depending on CMS guidance related to TBC, the same outcome of fewer plans may also emerge in the MAPD market.) As premiums increase, non-utilizing or generally healthy low-cost utilizers may have little to no incentive to enroll in a PDP, either opting out of the Part D program entirely or by choosing a low or no premium MAPD, exposing the PDP market to additional cost and sustainability pressures.

We strongly recommend a multi-year demonstration approach as the Part D market dynamics, member behaviors, catastrophic threshold, manufacturer pipeline and drug pricing trends evolve.

➢ **Recommendation: CMS should use its Section 402 demonstration authority to narrow the risk corridors for 2025 in recognition of the greater financial exposure of Part D plans under the Part D redesign. Also, to the extent CMS feels they do not have the authority to address the Total Beneficiary Cost (TBC) concerns outlined below, we recommend that CMS narrow the risk corridors and address TBC using the authority from section 402 of the Social Security Act.**

C.   Total Beneficiary Cost

CVS Health has significant concerns with the calculation and timing of guidance on TBC for 2025 and implementation of the IRA. The IRA introduces major changes to the Part D program in 2025 for both the PDP and MAPD markets. It is crucial that plans have as much information as early as possible for product planning, strategy and execution for 2025 bids. For 2025, the IRA will introduce significant reductions to beneficiary cost-sharing through the redesign of the standard Part D benefit, including a $2,000 limit on beneficiary out-of-pocket costs. We anticipate the 2025 Part D benefit redesign will have a significant impact on the Out-of-Pocket Cost (OOPC) model and are looking for CMS to provide timely guidance on: (a) how the new defined standard, as well as any enhanced Part D benefits that accumulate towards the $2,000 max OOP, will be reflected in the calculation of TBC; and (b) how the increase in plan sponsor cost beyond the catastrophic benefit threshold, which increases standard bid amounts and beneficiary premiums, will be reflected.

We understand the 2025 OOPC models, including TBC values and guidance, are expected to be released in April 2024; we are concerned that this does not provide Part D Plans with sufficient time to understand the model and make necessary adjustments prior to the 2025 bid submission deadline of June 3.

In the Final CY 2024 Standards for Part C Benefits, Bid Review, and Evaluation memo, CMS states: "the change in TBC from one year to the next captures the combined financial impact of premium changes and benefit design changes (i.e., cost sharing changes) on plan enrollees; an increase in TBC is indicative of a reduction in benefits." We are concerned that if the enriched Part D cost-sharing benefits under the IRA are not reflected as a decrease in TBC, then any increase in TBC will be an inaccurate reflection of a reduction in benefits. Not appropriately applying this enrichment in Part D costs into the TBC calculation may result in the inability of plans to adequately offset the additional cost on existing plan offerings, leading to member disruption and plan terminations.

➢ **Recommendations:**
   o **At a minimum, provide guidance on how the reduction to beneficiary cost sharing under the 2025 Part D benefit redesign will be reflected in the calculation of TBC.**

- o **Release the 2025 OOPC models as soon as possible, no later than April 1 2024.**
- o **Specifically, will the lower beneficiary costs under the Part D benefit redesign for the IRA be reflected as a benefit improvement in the OOPC model, offsetting any other changes in benefits?**
- o **How will enhanced alternative Part D plans be reflected given that enhanced benefits accumulate to the MOOP and may reduce actual OOP maximum to something less than $2,000?**
- o **CMS should take one of the following approaches in providing guidance:**
    1. Keep the current TBC calculation but increase the TBC threshold to reflect the improvement of the standard Part D benefit under the IRA. Apply the TBC threshold as currently calculated (OOPC + Premium) and implement an additional adjustment to the TBC threshold calculation to reflect the standard Part D benefit improvement under the IRA, including basic premium impact of the increased plan sponsor liability beyond the catastrophic threshold; or
    2. Adjust the current TBC calculation of benefits to include the improvement of the standard Part D benefit under the IRA. Recognize a flat dollar value for the Part D benefit improvement under the IRA and add to the otherwise established TBC benefit calculation, applying this adjustment across all plans.
- o **CMS should adjust both approaches for enhanced alternative Part D plans under the IRA, e.g., enhanced benefits which accumulate to the MOOP.**
- o **As part of either of these two approaches, we also recommend that CMS recognize a further additional flat dollar value for Part D plans that are filed as enhanced alternatives.**

III.   Star Ratings (Part C and D)

A.   Alternative Star Ratings Models

CVS Health supports CMS' efforts to create a resilient, high-value healthcare system that promotes quality outcomes, safety, equity, and accessibility for all beneficiaries. We believe the Star Ratings system—and connecting Star Ratings to MA plan reimbursement—have transformed the MA marketplace. The Star Ratings program demonstrates that a consistent, shared set of quality metrics can drive rapid quality improvement. We encourage CMS to continue its transparency and stability efforts that allow MA plans to invest efficaciously in quality improvements. A transparent and stable ratings program allows MA plans to work with network providers to align quality incentives throughout the entire care continuum. We look forward to continuing working with CMS on these issues.

As we have previously drawn to CMS' attention, yearly stop-gap adjustments to cut points and guardrails do not and cannot address the larger methodological issues raised by CMS' benchmark-based Star Ratings program. Volatile and unpredictable scores are inherent in the current model. We urge CMS to make efforts to ensure stability in the program.

CMS should consider alternative models to measure performance. We would welcome the opportunity to work with CMS in developing alternatives that reward plans that consistently provide quality, safe, equitable, and accessible benefits. For example, CMS could move toward defined cut points for a set of long-tenured measures with defined excellence standards (i.e., 4- and 5-star cut point) backed by years of clinical data, experience, and best practices. CVS Health recommends the following measures for consideration as core measures and welcomes further conversation with CMS on this approach, which we believe is aligned with the goals of CMS' Universal Foundation:

- Breast cancer screening
- Colorectal cancer screening
- Osteoporosis Management in Women who had a Fracture
- Diabetes Care – Eye Exam
- Diabetes Care – Blood Sugar Controlled
- Medication Adherence for Diabetes Medications (formerly Part D Medication Adherence for Oral Diabetes Medications)
- Medication Adherence for Hypertension (RAS antagonists) (formerly Part D Medication Adherence for Hypertension (ACE or ARB))
- Medication Adherence for Cholesterol (Statins) (formerly Part D Medication Adherence for Cholesterol (Statins))

For new measures or measures that demonstrate instability over time, CVS Health encourages CMS to continue to explore other classification methods such as Isolation Forest, DBSCAN, or k-means clustering and to engage a Technical Expert Panel to review and reconsider long-term solutions and implications of varying methods for Star Ratings assignment.

Our comments on CMS' specific proposals follow.

B.   Universal Foundation

CVS Health supports a Universal Foundation of quality measures aligned across CMS quality and value-based care programs. We agree that aligning health plans and providers on a streamlined set of quality measures has the potential to reduce administrative burden and ensure that CMS and MA plans are working toward the same patient goals and outcomes. We appreciate that CMS is adding measures to its "Universal Foundation" of aligned measurements.

As we previously suggested, in addition to establishing the initial sets of core quality measures, we encourage CMS to begin working with stakeholders on implementation of the

Universal Foundation measures within CMS programs and models. While alignment on the measures themselves is important, CMS should also ensure alignment on implementation timelines and incentives. For example, if a core quality measure were to move from a display page measure to inclusion in the Star Ratings score, CMS should ensure that the comparable measure(s) under other CMS quality programs and models are also factored into the provider's quality performance score. Where possible, CMS should ensure that implementation timelines are aligned so that any new measure/measure goal is introduced across programs for the same performance years. This will ensure that incentives are aligned as plans and providers work together to improve patient quality and outcomes.

> ➤ **Recommendation: Establish core quality measures and align implementation timelines and incentives.**

C.   Medicare Plan Finder (MPF) Drug Pricing Measure

CMS has solicited feedback on its efforts to create a new measure intended to improve the accuracy of sponsors' pricing information listed on the MPF in the years following 2025. Under the existing measurement, MPF and Prescription Drug Event (PDE) data is only measured from January 1 to September 30. From October 1 through the end of the calendar year, the MPF displays projected costs for the following plan year to support the Medicare Annual Enrollment Period (AEP). CMS states that it is concerned that some plans may be submitting artificially high or low prices to display on the MPF during AEP, and that it is considering developing a new measure that would evaluate whether Part D sponsors are engaging in these pricing tactics by evaluating whether plans are substantially increasing or decreasing the MPF prices for drugs following AEP.

CMS asks a number of questions related to comparing a drug's price between AEP and the plan year. Specifically, CMS asked:

> *How will CMS calculate a plan sponsor's MPF prices during AEP for the purpose of comparing to prices during the plan year?*

We believe the most accurate option of those proposed by CMS would be to take an average of prices displayed during AEP, October through December, rather than a weighted average. Using a weighted average approach may result in inaccurate overall averages. Moreover, Part D sponsors have no idea when the higher traffic weeks are, nor are their price adjustments made based on this.

> *When comparing a drug's price between AEP and the plan year, should pricing data be aggregated to a single price for a drug prior to comparison?*

We do not believe pricing data should be aggregated to a single price for a drug before comparing them. Pricing is complicated and often varies by type of pharmacy. The average unit cost for a drug should be calculated, at a minimum, by type of pharmacy, day supply, and plan. Additional criteria would be preferred and more accurate.

Is it more important that AEP prices are stable (relative to a sponsor's prices displayed on MPF during the plan year) or reliable (compared to a sponsor's PDEs during the plan year)?

Because prices are subject to changes outside plan control, measuring for stability may be unreliable. It would make more sense to assess reliability during the year. Implementing a measurement similar to the MPF accuracy measure currently in place would be preferable to using an average. CMS could assign an AEP MPF price to each PDE throughout the plan year and then calculate the magnitude and frequency of any differences.

We believe CMS' pricing comparison proposal is overly simplified. Averaging unit costs from a drug across the entire contract/plan/segment/pharmacy/ pharmacy service type/days of supply combination and proposing to use this average to determine whether costs during AEP, compared to January through September, are the "same" is a meaningless comparison.

CMS has also not explained how it would account for shifting factors that impact prescription drug costs that are outside of Part D sponsors' control, such as Average Wholesale Price (AWP) changes.

CMS asks whether it should, "[u]tilize a methodology to identify outlier contracts, instead of defining allowed thresholds for price changes." It is not clear what CMS means by this and we ask CMS to provide more information in order for us to comment on this.

CMS should revisit this proposal. We have significant concerns that the measures the proposed MPF program relies on will ultimately be arbitrary and produce little tangible benefit for enrollees. Nuances exist within MPF price accuracy CMS methodology that negatively impact measure performance and are not within a Part D sponsor's control. For example, pricing differences between MPF and Point of Sale (POS) adjudication can occur because of natural fluctuations in the market price that occur outside of the CMS updates to MPF. In addition, pricing differences can be a result of differences in reporting at the reference rather than the expanded National Drug Code (NDC) level. MPF limits submission of pricing data to every two weeks. This timeframe creates delays in information supply to beneficiaries and creates the gap between the price on MPF and the price beneficiaries see in a provider's office or pharmacy.

The introduction of a frequency component further magnified the flaws in the measurement of pricing differences. The frequency measurement has a disproportionate impact for drugs that have a high level of utilization, which makes this measure even more misleading to beneficiaries. Namely, the use of Formulary Reference Files in MPF in comparison to the Expanded NDC pricing used at point of sale is not a true indicator of a pricing inaccuracy. It is a comparison of a reference NDC to an expanded NDC. Our analysis has shown that on average, over 60 percent (%) of mismatched claims are attributable to this crosswalk. As a result, much of the MPF Price Accuracy measure is not under the control of the plan.

Furthermore, under the projection's component of the MPF, no real-world pricing data would be compared.

CVS Health agrees with CMS that the existing MPF needs improvement to enhance enrollee experience. However, rather than implementing this proposal, CMS should consider creation of a real-time price tracking tool. We also recommend that CMS explore alternative display measures for Star Ratings to promote price transparency. For example, tracking drug prices may be better suited for a section 402 demonstration than the Star Ratings program. Moving forward with the proposal, as is, will increase administrative burden on MA plans without achieving the objective of providing accurate pricing data to beneficiaries.

> **Recommendation: CMS should not finalize the proposed changes to the MPF. Monitoring MPF in this manner does not align with CMS' triple aim of improving patient experiences, the health of populations, and reducing healthcare costs. There are opportunities to identify improper or misleading pricing strategies, which better align with the goals CMS has set forth as the foundation of quality and Star Ratings, such as monitoring member complaints and Complaints Tracking Module (CTM) cases.**

D.   Health Outcomes Survey (HOS) Measure Changes

CMS requests feedback on its proposal to broaden the HOS questions by replacing the existing questions with questionnaires in the future. CMS is simultaneously seeking OMB approval to conduct a field test to evaluate these new survey items and ways to deliver the questions (e.g., web-based in addition to mail with telephone follow-up for mail non-respondents). These questionnaires would include the following topics: Patient-Reported Outcomes Measurement Information System (PROMIS) Physical Function items, Generalized Anxiety Disorder 2 (GAD-2) matters, and Health-Related Social Needs (HRSN) issues. These topics cover a broad array of subjects – such as functional impairment, more expansive assessments of mental health (such as by measuring anxiety in addition to depression), and the social determinants of health (e.g., transportation availability or housing insecurity).

CMS should not proceed with this proposal due to the lack of evidence-based measures. There is minimal evidence to support that these survey-based questions accurately assess MA plan improvement. If CMS wishes to revisit the HOS measures, we recommend CMS select measures that are data driven and support examination of a MA plan's quality of care over years. The healthcare many individuals receive cannot be accurately assessed within one plan year.

In particular, the proposed questions relating to the Physical Functioning Activities of Daily Living and Health-Related Social Needs can be particularly challenging to measure through a survey response. For example, aging populations generally do not improve physical function naturally. A survey response measuring improvement on this measure without

considering other healthcare supports and services would fail to accurately evaluate the overall improvements in care a MA plan is accomplishing.

> ➤ **Recommendation: Cease implementation of surveys dependent on enrollees' response and focus on evidence-driven measurements for the HOS evaluation. Measurements assessing beneficiaries' experience should also be evaluated over multiple-years.**

IV.   Employer Group Waiver Plan (EGWP) Prospective Reinsurance Amount

CMS makes prospective reinsurance payments to Part D calendar year EGWP sponsors based on the average per member-per month (PMPM) actual reinsurance amounts paid to Part D calendar year EGWP sponsors for the most recently reconciled payment year (which is 2022 for 2025). For 2025, CMS has proposed to update the methodology to ensure that Part D calendar year EGWPs are paid a more appropriate prospective reinsurance amount. CMS will calculate the prospective reinsurance payments to all Part D calendar year EGWP sponsors using a weighted average of PMPM prospective reinsurance amounts submitted by Part D sponsors for Enhanced Alternative (EA) plans as part of the Part D bid submissions for the payment year in question.

We generally support CMS' changes to promote a robust EGWP program. However, it is unclear to what extent the Individual Market will continue to offer EA plans in 2025 due to the IRA, and for those that do, what the impact of enhanced benefits accumulating toward the $2,000 OOP will have on bidders' projections of catastrophic spend (e.g., pricing impact of potentially unprecedented levels of induced utilization). Given the magnitude of change it is unlikely that 2025 EA bids will reasonably reflect claims experience and risk scores consistent with the 2025 EGWP population. Furthermore, waiting until late July or early August to understand the impact on cash flow and budget projections will be especially disruptive for public sector Part D EGWP sponsors who contract with CMS or MAOs and self-fund their Part D program.

We recommend that CMS **does not** update the methodology for 2025 and announce the prospective payment amount this spring, consistent with prior years. CMS may use their authority to hold the monthly prospective reinsurance payment at the same amount for plan year 2024 ($71.09) or select and announce another reasonable amount in the spring, to promote stability and predictability for the upcoming plan year. Given the substantial changes to the Part D program for 2025 and additional changes that will take effect from direct negotiation in 2026, we recommend that CMS continues to review actual EA results and revisits the proposal to use EA bid reinsurance for EGWP prospective payments in future plan years.

> ➤ **Recommendation: CMS should announce the prospective EGWP reinsurance payment in the spring and reevaluate the proposal in future years.**

Appendix II – Technical Details Normalization Comments

This section is in response to the proposed normalization factors for the Part C CMS-HCC Models published in the CY2025 Advance Notice, specifically page 64 of the Advance Notice. Here, CMS encourages "feedback on all normalization calculation approaches, including both the linear slope and multiple linear regression approaches, and how they serve our goal of effective normalization and payment accuracy."

We reviewed in detail the multiple linear regression methodology and coefficients proposed in the Advance Notice. While we support CMS exploring alternative approaches to calculating the risk adjustment model normalization factors, we believe that improvements can be made to the proposed multiple linear regression models to produce a better fit for the 2019-2023 observed risk scores, and more durable post-COVID-19 pandemic FFS risk score trends for 2024-2025.

We believe the methodology proposed in the Advance Notice, specifically holding the COVID factor constant at 1.0 for 2021 and beyond, should be adjusted to account for a variable yearly COVID effect. The variable effect would reflect the acceleration and bounce back of utilization and risk scores as healthcare delivery nationwide gradually shifts out of the COVID pandemic.

We propose using a variable and gradually declining COVID factor, from 1.0 in 2021 to 0.7 in 2022, 0.5 in 2023, and 0.4 in 2024 and 2025. These factors are consistent with a slowing reduction in the COVID bounce back, which closely fits the observed risk score trends, and reflects the lower but remaining COVID impacts through 2025. The multiple linear regression methodology with these factors produces a better fit to the 2019-2023 historical FFS risk scores and higher adjusted R-square value.

Below you will find an examination of the multiple linear regression methodology proposed by CMS in the Advance Notice and our proposed alternative multiple linear regression methodology that improves both the fit to historical risk scores and predictive ability for future year projected risk scores.

Section I. Post-COVID-19 Pandemic FFS Risk Score Trend

Table I-1 below shows the 2017-2023 observed average FFS risk scores under both the 2024 and 2020 CMS-HCC Models, as provided in Table II-10 on page 65 in the Advance Notice, along with the 2024 and 2025 projected FFS risk scores, calculated using each model's multiple linear regression model coefficients, as proposed in the Advance Notice. The 2025 projected risk scores of 1.045 and 1.153, as calculated, match those shown on page 65 of the Advance Notice, validating the calculation. The right-hand side of Table I-1 below was added to display the observed and projected year over year risk score trends under each model.

Table I-1. 2017-2023 Observed and 2024-2025 Projected FFS Risk Scores Using Multiple Linear Regression Models Proposed in the CY2025 Advance Notice

2017-2023 Observed/ 2024-2025 Projected FFS Risk Scores			2017-2023 Observed/2024-2025 Projected FFS Risk Score Trends	
Year	2024 CMS-HCC Model	2020 CMS-HCC Model	2024 CMS-HCC Model	2020 CMS-HCC Model
2016	-	1.020	-	-
2017	0.969	1.031	-	1.1%
2018	0.980	1.049	1.1%	1.7%
2019	0.990	1.064	1.0%	1.4%
2020	1.000	1.079	1.0%	1.4%
2021	0.968	1.048	-3.2%	-2.9%
2022	0.992	1.079	2.5%	3.0%
2023	1.009	1.104	1.7%	2.3%
2024 Projection	1.027	1.128	1.8%	2.2%
2025 Projection	1.045	1.153	1.8%	2.2%

First, we note that the 2022 and 2023 observed FFS risk scores indicate 2023 over 2022 observed FFS risk score trends of +1.7% on the 2024 CMS-HCC Model and +2.3% on the 2020 CMS-HCC Model. Second, we note that the 2024-2025 projected FFS risk scores imply 2024 over 2023, and 2025 over 2024, projected risk score trends of +1.8% on the 2024 CMS-HCC Model and +2.2% on the 2020 CMS-HCC Model, very close to the 2023 over 2022 observed risk score trends of +1.7% and +2.3%.

From this, we conclude the multiple linear regression models, as proposed, inherently assume that the 2023 over 2022 observed FFS risk score trends will continue into 2024-2025 as the post-COVID-19 pandemic long-term FFS risk score trends.

We believe the 2023 over 2022 observed FFS risk score trends are not a good indicator of post-COVID-19 pandemic long-term FFS risk score trends. To understand why we believe this, consider the effects of the COVID-19 pandemic on 2021-2023 risk scores:

- 2021 risk scores (based on 2020 utilization and diagnosis) were severely suppressed by the impact of lockdowns and deferred care in 2020
- 2022 risk scores (based on 2021 utilization and diagnosis) reflected a "partial bounce back" relative to 2021 risk scores as utilization increased relative to 2020 levels. However, the 2022 risk scores continued to contain some level of suppression as vaccines were not widely available until late spring of 2021, and seniors remained

hesitant to fully utilize the healthcare system due to the emergence of new variants and other factors.

- 2023 risk scores (based on 2022 utilization and diagnosis) returned to a more normal level, resulting in another "partial bounce back" relative to the still partially suppressed 2022 risk scores.

To summarize, we believe that the 2023 over 2022 FFS risk score trends are elevated above normal long-term levels due to the continued suppression on the 2022 risk scores, which are based on 2021 utilization, in the denominator of the trend calculation.

As an alternative long-term post-COVID-19 pandemic risk score trend, we note the pre-COVID-19 pandemic underlying morbidity risk score trends from 2018-2020 averaged +1.1% under the 2024 CMS-HCC Model and +1.5% under the 2020 CMS-HCC Model. We believe these to be more appropriate long-term risk score trends as we emerge out of the COVID-19 pandemic.

Section II. Multiple Linear Regression Methodology – Model Fit

Page 64 in the Advance Notice states that the proposed multiple linear regression methodology, with proposed coefficients, "is a good fit to the actual average FFS risk score data. Under the proposed method we are able to reasonably reflect the underlying patterns in the historical FFS risk scores in both pre-and post-COVID-19 periods."

To test the fit of the proposed methodology and coefficients, we calculated the predicted risk scores for the 2019-2023 historical period using the proposed multiple linear regression models and coefficients for both the 2024 and 2020 CMS-HCC Models and compared to the observed risk scores over this period.

Tables II-1 and II-2 below provide this predicted versus actual comparison, for the 2024 and 2020 CMS-HCC Model risk scores, using each model's proposed coefficients (as published on page 65 of the Advance Notice with COVID-19 flag of 0 for years before CY 2021 and 1 for CY 2021 and onwards) and comparing to the observed "actual" FFS risk scores from Table II-10 on page 65 in the Advance Notice.

Table II-1. 2024 CMS-HCC Model Predicted versus Actual FFS Risk Score, 2019-2023

Year	Predicted FFS Risk Score	Actual FFS Risk Score	Predicted vs Actual FFS Risk Score
2019	0.986	0.990	-0.4%
2020	1.004	1.000	0.4%
2021	0.971	0.968	0.3%
2022	0.990	0.992	-0.2%
2023	1.008	1.009	-0.1%
2019-2023 Average	0.992	0.992	0.0%

Table II-2. 2020 CMS-HCC Model Predicted versus Actual FFS Risk Score, 2019-2023

Year	Predicted FFS Risk Score	Actual FFS Risk Score	Predicted vs Actual FFS Risk Score
2019	1.059	1.064	-0.5%
2020	1.084	1.079	0.5%
2021	1.052	1.048	0.4%
2022	1.077	1.079	-0.2%
2023	1.102	1.104	-0.2%
2019-2023 Average	1.075	1.075	0.0%

We observe that yearly comparison of predicted versus actual FFS risk scores range from -0.4% to +0.4% under the 2024 CMS-HCC Model, and -0.5% to +0.5% under the 2020 CMS-HCC Model. We also observe that the yearly variances swing from negative to positive to negative over the five-year time frame, with no consistent over- or under- prediction. We recognize that over the five-year time frame the predicted risk score approximately equals the actual risk score under each model. However, the five-year average comparison does not to recognize the yearly variance within the five-year time frame.

In order to test the proposed method's ability to "reasonably reflect the underlying patterns in the historical FFS risk scores in both pre-and post-COVID-19 periods", we converted the predicted and actual risk scores to predicted and actual risk score trends over the five-year time frame. Tables II-3 and II-4 below provide this predicted versus actual risk score trend comparison for the 2024 and 2020 CMS-HCC Model risk scores.

Table II-3. 2024 CMS-HCC Model Predicted versus Actual FFS Risk Score Trends, 2019-2023

Year	Predicted FFS Risk Score Trend	Actual FFS Risk Score Trend	Predicted vs Actual FFS Risk Score Trend
2020 / 2019	1.8%	1.0%	0.8%
2021 / 2020	-3.3%	-3.2%	-0.1%
2022 / 2021	2.0%	2.5%	-0.5%
2023 / 2022	1.8%	1.7%	0.1%
2019-2023 Average	0.6%	0.5%	0.1%

Table II-4. 2020 CMS-HCC Model Predicted versus Actual FFS Risk Score Trends, 2019-2023

Year	Predicted FFS Risk Score Trend	Actual FFS Risk Score Trend	Predicted vs Actual FFS Risk Score Trend
2020 / 2019	2.4%	1.4%	1.0%
2021 / 2020	-3.0%	-2.9%	-0.1%
2022 / 2021	2.4%	3.0%	-0.6%
2023 / 2022	2.3%	2.3%	0.0%
2019-2023 Average	1.0%	1.0%	0.1%

We observe that under each CMS-HCC risk score model (2024 and 2020) the proposed method over predicted risk score trend for the only pre-COVID-19 two-year period, 2019-2020 (+0.8% under the 2024 CMS-HCC Model and +1.0% under the 2020 CMS-HCC Model). Then, chronologically moving forward, the 2021 over 2020 predicted risk score trends closely matched the actual risk score trends.

We observe the following year-over-year trend patterns under each CMS-HCC risk score model (2024 and 2020):

Pre-COVID-19 Period:
  o 2020 / 2019: The proposed method over-predicted risk score trend for the only pre-COVID-19 two-year period (+0.8% under the 2024 CMS-HCC Model and +1.0% under the 2020 CMS-HCC Model)

Post-COVID-19 Periods:

- 2021 / 2020: The predicted risk score trends closely matched the actual risk score trends under each model, appearing to correctly capture the initial suppression in the 2021 risk scores.
- 2022 / 2021: The proposed method under-predicted risk score trends (-0.5% under the 2024 CMS-HCC Model and -0.6% under the 2020 CMS-HCC Model), appearing to not fully capture the initial bounce back on 2022 risk scores relative to 2021.
- 2023 / 2022: The predicted risk score trends closely matched the actual risk score trends under each model.

We also observe that the predicted risk score trends are approximately 1.8% under the 2024 CMS-HCC Model and approximately 2.3% under the 2020 CMS-HCC Model for all two-year periods outside of 2020-2021. However, the actual risk score trends were considerably lower during the 2020/2019 pre-COVID-19 two-year period, and then trended downward from historically high trends in 2022/2021 to lower trends in 2023/2022. The predicted risk score trends do not accurately capture the lower pre-COVID-19 trends, nor the decline in trends for 2023/2022 relative to historically high trends for 2022/2021 as we transition out of the peak COVID-19 impacted years.

From this, we conclude that the proposed method and coefficients do not accurately reflect the underlying year over year patterns in the historical FFS risk scores in both pre-and post-COVID-19 periods. Rather, we believe the proposed method and coefficients over-fit to the 2023 observed risk scores and risk score trend while failing to accurately capture the year over year impact that the COVID-19 pandemic has had on utilization and risk scores.

Section III. Proposed Alternative Multiple Linear Regression Methodology

As stated in the introduction, we believe improvements can be made to the proposed multiple linear regression models to produce a better fit for the 2019-2023 observed risk scores and produce more durable post-COVID-19 pandemic FFS risk score trends for 2024-2025. We believe that the key issue in the methodology proposed in the Advance Notice is assuming a 1.0 COVID-19 flag for all years 2021 and onward. For reasons stated previously, the COVID-19 pandemic has had varying impacts on each year's risk scores, from peak suppression in 2021 (based on 2020 utilization) to partial bounce backs in 2022 and 2023 as utilization gradually returned to normal levels.

As an alternative to the methodology proposed in the Advance Notice, we propose varying the COVID-19 flag to mirror the impact of COVID-19 on each year's risk scores. We explored several iterations of this approach, basing on the same 2019-2023 average FFS risk scores used by CMS to develop the methodology proposed in the Advance Notice. After much evaluation, we propose the use of the multiple linear regression methodology outlined in the Advance Notice, but with varying COVID-19 flags as outlined in Table III-1 below:

Table III-1. COVID-19 Flag (x_2) by Year

Year	x_2
2019	0.0
2020	0.0
2021	1.0
2022	0.7
2023	0.5
2024	0.4
2025	0.4

Table III-2 below shows the resulting regression coefficients (rounded to eight decimals) for both the 2024 and 2020 CMS-HCC models, developed using the same 2019-2023 average FFS risk scores as was used by CMS combined with the varying yearly COVID-19 flag provided in Table III-1.

Table III-2. Proposed Alternative 2024 and 2020 CMS-HCC Model Regression Coefficients

Coefficient	2024 CMS-HCC Model	2020 CMS-HCC Model
Intercept (β_0)	-19.39314783	-31.33326584
Average Change in FFS Risk Scores (β_1)	0.01009565	0.01604596
COVID-19 Flag (β_2)	-0.04173913	-0.04732919

We believe the varying yearly COVID-19 flag outlined in Table III-1, along with the regression coefficients in Table III-2, accurately captures the year over year impact that the COVID-19 pandemic has had on FFS risk scores from 2021-2023 and provides a better yearly fit to the 2019-2023 historical FFS risk scores than do the models and coefficients proposed on page 65 in the Advance Notice. Tables III-3 and III-4 demonstrate the improved fit under both the 2024 and 2020 CMS-HCC models.

Table III-3. Proposed Alternative Predicted versus Actual FFS Risk Score, 2024 CMS-HCC Model

Year	Predicted FFS Risk Score	Actual FFS Risk Score	Predicted vs Actual FFS Risk Score
2019	0.990	0.990	0.0%
2020	1.000	1.000	0.0%
2021	0.968	0.968	0.0%
2022	0.991	0.992	-0.1%
2023	1.009	1.009	0.0%

2019-2023 Average	0.992	0.992	0.0%

Table III-4. Proposed Alternative Predicted versus Actual FFS Risk Score, 2020 CMS-HCC Model

Year	Predicted FFS Risk Score	Actual FFS Risk Score	Predicted vs Actual FFS Risk Score
2019	1.064	1.064	0.0%
2020	1.080	1.079	0.1%
2021	1.048	1.048	0.0%
2022	1.079	1.079	0.0%
2023	1.104	1.104	0.0%
2019-2023 Average	1.075	1.075	0.0%

Table III-5 below offers a direct side-by-side comparison of each year's predicted versus actual FFS risk scores, under the Proposed Alternative model compared to the CMS model proposed in the Advance Notice (for both the 2024 and 2020 CMS-HCC model risk scores).

Table III-5. Predicted vs Actual FFS Risk Score, Proposed Alternative Model vs CMS Advance Notice

Year	2024 CMS-HCC Model		2020 CMS-HCC Model	
	CMS Advance Notice	Proposed Alternative	CMS Advance Notice	Proposed Alternative
2019	-0.4%	0.0%	-0.5%	0.0%
2020	0.4%	0.0%	0.5%	0.1%
2021	0.3%	0.0%	0.4%	0.0%
2022	-0.2%	-0.1%	-0.2%	0.0%
2023	-0.1%	0.0%	-0.2%	0.0%

Tables III-3, III-4 demonstrate that the Proposed Alternative model, with varying yearly COVID-19 flag and corresponding regression coefficients, provide a very good fit to the 2019-2023 historical FFS average risk scores. Table III-5 demonstrates that this is an improved fit over the model proposed by CMS in the Advance Notice with non-varying 1.0 COVID-19 flag for all years 2021 and onward. To further demonstrate the improved fit of the Proposed Alternative model, table III-6 below compares the Adjusted R-squared values.

Table III-6. Adjusted R-Squared, Proposed Alternative Model vs CMS Advance Notice

2024 CMS-HCC Model		2020 CMS-HCC Model	
CMS Advance Notice	Proposed Alternative	CMS Advance Notice	Proposed Alternative
0.8879	0.9971	0.9146	0.9990

We believe that tables III-1-6 demonstrate that the Proposed Alternative model results in an improved fit to the 2019-2023 historical average FFS risk scores.

Shifting toward the projection period, the Proposed Alternative model prescribes a gradual reduction of the COVID-19 flag from a peak of 1.0 in 2021 to 0.7 in 2022; 0.5 in 2023; and 0.4 for both 2024 and 2025. This gradual reduction of the COVID-19 flag results in a gradual decline in the projected risk score trend, mirroring the decline observed in the actual FFS risk score trends from 2021 to 2023, and continuing to return to a pre-COVID-19 pandemic long-term underlying morbidity risk score trend for 2025 over 2024, closely matching the trend observed in the most recent pre-COVID-19 two-year period (2019 to 2020). Tables III-7 and III-8 demonstrate the gradual return approximately equal to pre-COVID-19 trend levels for 2025 under both the 2024 and 2020 CMS-HCC Models.

Table III-7. Proposed Alternative Predicted Risk Score Trends versus Actual, 2024 CMS-HCC Model

Year	Predicted FFS Risk Score	Predicted FFS Risk Score Trend	Actual FFS Risk Score	Actual FFS Risk Score Trend
2019	0.990	-	0.990	-
2020	1.000	1.0%	1.000	1.0%
2021	0.968	-3.2%	0.968	-3.2%
2022	0.991	2.4%	0.992	2.5%
2023	1.009	1.8%	1.009	1.7%
2024	1.024	1.5%	n/a	n/a
2025	1.034	1.0%	n/a	n/a

Table III-8. Proposed Alternative Predicted Risk Score Trends versus Actual, 2020 CMS-HCC Model

Year	Predicted FFS Risk Score	Predicted FFS Risk Score Trend	Actual FFS Risk Score	Actual FFS Risk Score Trend
2019	1.064	-	1.064	-
2020	1.080	1.5%	1.079	1.4%
2021	1.048	-3.0%	1.048	-2.9%

2022	1.079	3.0%	1.079	3.0%
2023	1.104	2.3%	1.104	2.3%
2024	1.125	1.9%	n/a	n/a
2025	1.141	1.4%	n/a	n/a

Section IV. Conclusion

In conclusion, we support CMS exploring alternative approaches to the long-standing linear trend methodology in calculating the risk adjustment model normalization factors. We believe a multiple linear regression methodology can improve the accuracy of the predicted FFS risk scores and normalization factors. However, we believe an alternative approach, with variable yearly COVID-19 flags and corresponding model coefficients, results in a model that more closely matches the historical FFS risk scores and provides greater predictive ability.

Tables IV-1 and IV-2 below compare the 2019-2025 predicted average FFS risk scores using the multiple linear regression methodology and corresponding model coefficients as proposed on page 65 of the Advance Notice, compared to the Proposed Alternative methodology outlined in Section III of this document.

Table IV-1. Predicted FFS Risk Score, Proposed Alternative Methodology vs CMS Advance Notice Methodology, 2024 CMS-HCC Model

Year	CMS Advance Notice	Proposed Alternative
2019	0.986	0.990
2020	1.004	1.000
2021	0.971	0.968
2022	0.990	0.991
2023	1.008	1.009
2024	1.027	1.024
2025	1.045	1.034

Table IV-2. Predicted FFS Risk Score, Proposed Alternative Methodology vs CMS Advance Notice Methodology, 2020 CMS-HCC Model

Year	CMS Advance Notice	Proposed Alternative
2019	1.059	1.064
2020	1.084	1.080
2021	1.052	1.048
2022	1.077	1.079

2023	1.102	1.104
2024	1.128	1.125
2025	1.153	1.141

As stated in Section III, the Proposed Alternative methodology, with varying yearly COVID-19 Flag, produces an improved fit with greater predictive value than does the methodology outlined by CMS in the Advance Notice. We believe an approach similar to the alternative proposed in this document will improve the CMS predicted average FFS score scores for 2024-2025 and result in more durable FFS normalization factor trends as we transition out of the peak COVID-19 impacted years.

We welcome any follow-up questions you may have.