



March 2, 2020

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-9926-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted electronically via www.regulations.gov

RE: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021 Proposed Rule—AHIP Comments

Dear Administrator Verma:

On behalf of America's Health Insurance Plans (AHIP)¹, thank you for the opportunity to offer comments in response to the Department of Health and Human Services (HHS) Proposed Notice of Benefit and Payment Parameters for 2021 ("Payment Notice"), published in the *Federal Register* on January 31, 2020 (CMS-9916-P).

Americans deserve a stable market that provides them with access to affordable coverage choices. **We appreciate the Department's work to promote stability and lower administrative burdens, and many of the proposed regulatory changes included in the Payment Notice meet this goal.** For example, we strongly support the proposed clarification on cost-sharing for prescription drug coupons, ensuring that manufacturers do not game the system at the expense of hardworking families and taxpayers. We also appreciate that the Department is looking at ways to expand the availability of value-based care.

At the same time, we are deeply concerned the Department is considering modifications to automatic reenrollment that would create an arbitrary and undue burden on the lowest income enrollees to maintain subsidies that make coverage affordable.

Below is an overview of AHIP's comments on the Proposed 2021 Payment Notice:

- **Automatic Reenrollment: AHIP does not support changes to automatic reenrollment.** Eliminating or reducing advance payments of the premium tax credit (APTC) for enrollees with \$0 premiums would create an arbitrary and discriminatory burden for the lowest income and most vulnerable enrollees. Either option would create unnecessary abrasion and lead to fewer people having coverage. Moreover, it is not clear the Department has authority to set a new APTC

¹ AHIP is the national association whose members provide coverage for health care and related services to millions of Americans every day. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities and the nation. Americans deserve access to comprehensive, quality, affordable coverage. AHIP is committed to advancing policy solutions in support of this goal.

amount unless it is based on updated tax information. We instead ask HHS to rely on existing, well-established program integrity processes.

- **Drug Manufacturer Coupons:** We support finalizing the clarification that health insurance providers may determine whether to apply accumulator programs to drug manufacturer coupons, or other drug manufacturer direct assistance to address high drug prices. We appreciate the Administration's ongoing commitment to lower out-of-control drug prices. We strongly support proposed revisions clarifying that health insurance providers may determine whether to include coupon amounts—or other drug manufacturer direct assistance—in the annual limitation on cost sharing, regardless of whether a generic equivalent is available. Branded manufacturers offer coupons to circumvent patients' cost-sharing for branded drugs and to avoid responsibility for the fundamental reason for higher patient costs – namely, the high price of the drug that is set and controlled solely by manufacturers. The proposed clarification does not prevent patients from using coupons, while also making it clear that plans have the option to employ market-based tools like accumulator programs to negotiate lower drug prices for everyone.
- **HHS-Risk Adjustment:** We recommend adopting changes for the 2021 risk adjustment model, including recalibrating the model based on enrollee-level EDGE data, continuing to apply cost-sharing reduction adjustments, and maintaining the same parameters for the high-cost risk pooling program. In addition, we support the pricing adjustment for the Hepatitis C RXC in order to more accurately reflect the average cost of treatment into the risk adjustment model. With respect to incorporating the use of pre-exposure prophylaxis into the risk adjustment model, we recommend that HHS create an RXC coefficient to ensure adequate capture of risk profiles and adequately compensate plans that disproportionately enroll individuals using this medication. We have concerns about other efforts to update the risk adjustment model—including incorporating hierarchical condition category changes for the 2021 risk adjustment benefit year—and recommend HHS work with stakeholders to continue to assess whether such changes are appropriate in future years.
- **Value-based Insurance Design:** We support efforts that continue to advance access to health plans that leverage the principles of value-based insurance design (V-BID). Ensuring that people can access the care they need, when they need it, at an affordable cost is essential to our mission and the sustainability of American health care. For people with chronic health conditions, value-based design features help them comply with physician recommendations and promote the use of high-value care. Americans should be given meaningful information about benefits and how they may impact their unique health needs to help them make more informed decisions about which coverage is right for them. HHS can support a more informed buying process by organizing plan information in a more consumer-centric way—for example, displaying information by health condition, rather than by identifying plans as V-BID plans.
- **Medical Loss Ratio:** We support meaningful transparency and accurate accounting for health insurance provider administrative costs. We support HHS' recommendation to treat wellness program incentives as quality improvement activities. Regarding HHS' proposals for new reporting related to prescription drug rebates and prices concessions, we provide recommendations below to refine those new requirements to improve alignment between the new requirements and other statutory pharmacy benefit manager (PBM) transparency requirements.

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In our attachment, we provide detailed comments on these and other proposals.

Timing of Final Rule and Significant Policy Changes

With the late publication of the proposed rule, we anticipate a final rule will be published just before health insurance providers begin submitting 2021 products and rates to state regulators. This provides little time for health insurance providers to adapt their products to align with changes in the final rule. Most health insurance providers will have finalized, or nearly finalized, their product offerings and proposed rates for the 2021 plan year by the time the final rule is published. Any major policy changes for the 2021 plan year at this time would be disruptive to both health insurance providers and state regulators. **Thus, we strongly recommend the Department not adopt significant policy changes for the 2021 plan year.**

We appreciate the opportunity to offer comments on the proposed 2021 Payment Notice. We are committed to working with the Administration on policies that ensure high-quality and affordable health insurance options are available for Americans.

Sincerely,

A handwritten signature in cursive script that reads "Jeanette Thornton". The signature is written in black ink and includes a long horizontal flourish extending to the right.

Jeanette Thornton
Senior Vice President, Product, Employer, and Commercial Policy

Attachment

Comments on the Proposed Notice of Benefit and Payment Parameters for 2021

Our detailed comments on the proposed rule are organized into the following sections:

- I. Automatic Reenrollment Process
- II. Cost-Sharing for Drug Manufacturer Coupons
- III. HHS Risk Adjustment
- IV. Medical Loss Ratio
- V. Value-Based Insurance Design
- VI. Other Exchange Establishment Standards (Part 155)
- VII. Other Health Insurance Issuer Standards (Part 156)

I. Automatic Reenrollment Process (85 FR 7119)

In the preamble of the proposed rule, HHS solicits comments on modifying the automatic reenrollment process for Exchange enrollees who would be automatically reenrolled in coverage for the next plan year with advance payments of the premium tax credit (APTC) that would cover their entire premium—fully subsidized enrollees who owe \$0 premium (85 FR 7119). HHS raises concerns that automatic reenrollment may lead to incorrect federal expenditures on APTC, which cannot be fully recovered through the reconciliation process due to statutory caps, and indicates there is a particular risk associated with fully subsidized enrollees who do not need to make a binder payment to maintain coverage.

HHS seeks input on two options for modifying the automatic reenrollment process for fully subsidized enrollees. In the first option, fully subsidized enrollees would be automatically reenrolled without APTC (i.e., they would owe the entire, unsubsidized premium). In the second option, which HHS notes it is considering adopting in the final rule, APTC for fully subsidized enrollees would be reduced such that the enrollee owes a premium greater than \$0 and must make a binder payment to continue coverage (i.e., APTC would be reduced, but not eliminated entirely). Under either scenario, HHS indicates it would conduct outreach and education to notify these enrollees they should return to the Exchange to update their application and actively reenroll to maintain APTC.

Recommendations:

- **HHS should not adopt modifications to eliminate or reduce APTC for fully subsidized enrollees who are automatically reenrolled. Doing so would eliminate a core Exchange process people have come to rely on, create an unequal burden on low-income enrollees to maintain coverage, result in loss of coverage for many low-income enrollees who are among the most vulnerable, and adversely impact the Exchange risk pool. We strongly recommend HHS maintain the current automatic reenrollment process for all Exchange enrollees for the 2021 plan year and beyond.**
- **Many low-income and vulnerable enrollees would lose coverage if they were automatically reenrolled without APTC or with reduced APTC.** Most individuals who are enrolled with \$0 premium have incomes between 100 and 130 percent of the federal poverty level. Losing APTC

would be catastrophic for these individuals and would result in ultimately, if not immediately, terminating coverage due to inability to pay monthly premium. For many of these individuals, if APTC was reduced but not eliminated, even a small premium would be unaffordable. We anticipate reducing APTC would likewise result in losses of coverage due to non-payment of premiums.

- **Eliminating or reducing APTC for fully subsidized enrollees who are automatically reenrolled would reduce overall enrollment, adversely impact the risk pool, and increase premiums for all enrollees.** In a 2019 analysis, Avalere anticipated eliminating automatic reenrollment entirely would increase the average risk in the market and result in higher premiums.² While HHS now proposes to modify automatic reenrollment, not eliminate it altogether, many of the same effects would occur. Fully subsidized enrollees who are automatically reenrolled without APTC would be unable to afford unsubsidized premiums and lose coverage. Those fully subsidized enrollees who actively reenroll would likely be sicker and healthier enrollees would drop coverage, resulting in higher premiums for all enrollees.
- **The proposed changes would drastically alter a core process that enrollees have come to rely on and would create an arbitrary and discriminatory requirement for low-income and vulnerable enrollees to maintain subsidies and coverage.** In Exchanges, as in Medicare and commercial coverage, automatic reenrollment is an essential practice that lowers the barrier for enrollees to maintain coverage year-over-year. Requiring fully subsidized enrollees to return to the Exchange to maintain coverage with the full amount of APTC for which they are eligible would create an undue and unfair burden for the most vulnerable enrollees. Low income enrollees would be required to meet more onerous requirements to maintain APTC than those with higher incomes. Under either proposal, a fully subsidized enrollee with \$0 premium and a subsidized enrollee with \$5 premium would face substantially different requirements to maintain APTC. If both enrollees automatically reenroll, the \$5 premium individual would maintain their APTC while the \$0 individual would lose all or part of the subsidy for which they are eligible. Such an arbitrary requirement for fully subsidized enrollees would put the lowest income enrollees at a disadvantage compared to those who receive APTC that does not cover the entire premium.
- **Automatically reenrolling people with no APTC or a different level of APTC would create an abrasive experience and would introduce a new administrative burden for issuers and Exchanges.** Under current Exchange APTC eligibility requirements, there are scenarios in which enrollees can lose eligibility for APTC during the plan year or upon reenrollment (e.g., periodic data matching or failure to verify income). Through these existing processes, issuers know that loss of APTC is one of the top causes of consumer abrasion. Disruptions in subsidies or continuity of care creates significant confusion and frustration for people. We anticipate that implementing either option would similarly cause consumer abrasion and lead to an increase of questions and complaints directed to issuer and Exchange customer service, creating additional administrative burden (and costs) for issuers and Exchanges.
- **Conflicting communications from the Exchange and issuer about subsidy eligibility would create a confusing consumer experience and would create new administrative burden and costs for issuers and Exchanges during open enrollment.** Under current practice, outdated APTC eligibility information from the current plan year is included in issuer renewal notices.

² Avalere. HHS Proposed Changes Could Reduce ACA Coverage and Increase Premiums. February 18, 2019. <https://avalere.com/press-releases/hhs-proposed-changes-could-reduce-aca-coverage-and-increase-premiums>

Thus, enrollees only see their current APTC eligibility, not the APTC for which they will be eligible in the upcoming plan year. Under the proposed changes, fully subsidized enrollees would continue to see that they are eligible for a \$0 premium. The current renewal notice would not notify fully subsidized enrollees that they owe a premium to maintain coverage. This could be catastrophically misleading for an enrollee who will lose APTC entirely or owe a premium to maintain coverage. HHS indicated it would conduct outreach and education to alert enrollees to the new process and emphasize the importance of returning to the Exchange to update their application. Thus, enrollees could receive a notice from their issuer indicating they are eligible to continue coverage with a \$0 premium but would receive conflicting information from the Exchange about their subsidy eligibility.

We are deeply concerned about the resulting confusion and frustration as well as the burden on issuer and Exchange customer service resources that would result from conflicting notices. As we have learned from other messaging efforts by the Federally-facilitated Exchange (FFE) related to loss of APTC (e.g., periodic data matching), we are concerned that lack of communication—or conflicting communication—would lead to consumer dissatisfaction and may not successfully lead people to the Exchange to reenroll in coverage. Further, the resulting consumer confusion would place strain on issuer and Exchange call centers and enrollment websites to assist enrollees, answer questions, and support higher volume of enrollees actively reenrolling during open enrollment.

- **We recommend HHS more clearly define the extent to which automatic reenrollment, particularly for fully subsidized enrollees, results in incorrect federal spending on APTC.** While the Department has repeatedly raised concerns that automatic reenrollment leads to incorrect federal spending on APTC, it has not yet identified specific risks related to automatic reenrollment for fully subsidized enrollees nor has it identified the potential magnitude of inappropriate federal expenditures. Without a specific description of the problem, it is difficult to provide meaningful comments on risk mitigation strategies or alternative proposals. We recommend HHS and the Department of Treasury report on the extent of incorrect federal expenditures of APTC for those who are automatically enrolled. Such an analysis would allow Exchange and issuers to identify better solutions to promote program integrity with respect to APTC eligibility. With limited information on the scope of the problem, it is challenging to provide feedback on alternatives that would appropriately address HHS' concerns.
- **Data from several issuers does not appear to demonstrate any unique risk associated with fully subsidized enrollees.** Due to the 30-day comment period, we were not able to analyze comprehensive data on \$0 premium enrollees across all issuers, but data from several issuers reveals certain trends. HHS has raised concerns that \$0 premium enrollees are automatically reenrolled without their knowledge. Issuers reported that a strong majority of enrollees actively reenrolled in coverage for the 2019 plan year. Issuers reported about 20-30 percent of \$0 enrollees reenrolled in the same plan (note: for some reporting issuers, this includes both active and passive reenrollments, so automatic reenrollment could be overstated). Looking at utilization, issuers reported a small percentage of \$0 premium enrollees had \$0 allowed claims for the plan year, ranging from 1.5 to 20 percent. For most reporting issuers this rate of \$0 claims was only 1-2 percentage points higher than enrollees with premiums greater than \$0. One issuer reported enrollees with \$0 premiums have lower risk and utilization compared to the rest of their ACA enrollment, meaning a barrier to enrollment for this population could reduce healthy risk and result in higher premiums for everyone.

- **HHS has raised concerns about inappropriate APTC payments, but multiple program integrity controls are already in place to ensure people do not repeatedly automatically reenroll with subsidies without updating their eligibility application.** HHS identified 270,000 people who were automatically reenrolled with zero premium through healthcare.gov in 2019. Existing guidance minimizes the potential for inappropriate payments by removing premium tax credit for certain enrollees who repeatedly automatically reenroll. Specifically, Repeat Passive Reenrollees—enrollees who have not submitted an updated eligibility application for the prior two plan years and for whom the two most recent years of income information is not available from the IRS—cannot be reenrolled with subsidies. Other program integrity checks like periodic data matching are conducted at least once, if not more often, throughout the plan year prior to automatic reenrollment to reduce or prevent reenrollment of individuals who are ineligible for coverage or subsidies.
- **Eliminating or reducing APTC for fully subsidized enrollees could result in higher federal expenditures, the opposite effect of HHS’ stated goal.** If the Department finalizes either proposed option to eliminate or reduce APTC for fully subsidized enrollees, we anticipate two effects that could result in increased federal expenditures on APTC.
 - **First, as discussed above, eliminating or reducing APTC could result in higher premiums for everyone which could lead to increased federal spending on APTC.** Those fully subsidized people who actively reenroll would likely be sicker and healthier enrollees would drop coverage, resulting in higher premiums for all enrollees. An increase in premiums for the second lowest cost silver plan (SLCSP) driven by a sicker risk pool would result in more generous APTC, which would lead to increased federal expenditures.
 - **Second, either option could result in changes to consumer behavior when selecting and enrolling in coverage that could result in greater federal expenditures.** Some subsidy-eligible consumers may have purchased a bronze level qualified health plan (QHP) to optimize the impact of their APTC in order to achieve a \$0 premium. However, under the first proposed option, consumers may be incentivized—or advised by agents/brokers—to purchase a higher metal level QHP so that they owe a small premium upon automatic reenrollment and can avoid automatic reenrollment without APTC that HHS is proposing for enrollees who have \$0 premium. Under current rules, enrollees who select a bronze QHP to achieve a \$0 premium may not need the full APTC amount for which they are eligible in order to fully subsidize their premium. Thus, if these enrollees instead purchase a silver or gold QHP under the proposed change, and maximize their APTC, the federal government could see greater expenditures, rather than lower expenditures, as is the stated goal of this policy.
- **We do not believe the Department has the authority to decrease the amount of APTC for which an enrollee is eligible unless the adjustment is based on updated tax information.** Under the second proposal, which HHS is considering finalizing in a final rule, the Exchange would automatically reenroll a fully subsidized enrollee with decreased APTC so that the enrollee owes a premium greater than \$0 and must pay a binder payment to effectuate coverage. Existing guidance establishes several scenarios in which a subsidized enrollee may be automatically reenrolled without APTC. Enrollees who meet criteria for the Special Notice Group, Opt-Out Group, Failure to File and Reconcile (FTR) Group, and Repeat Passive Reenrollees (RPRs) are at risk for loss of APTC upon automatic enrollment if they if they do not return to the Exchange to

update their application and obtain an updated eligibility determination.³ HHS and the FFE have authority to determine that an enrollee is no longer eligible for APTC if they cannot verify the individual's income for the most recent taxable year for which it is available, as long as the Exchange provides proper notice to the enrollee. However, we do not think HHS has the authority to set a *new* APTC amount that is greater than zero, if it is not based on the tax records of the enrollee.

- **If finalized, HHS should provide flexibility for State-based Exchanges (SBEs) to maintain current automatic reenrollment processes.** SBEs should not be required to adopt either of the proposals to remove or reduce APTC for fully subsidized enrollees. Instead, SBEs should have the flexibility to maintain current automatic reenrollment processes or pursue other approaches to verify subsidy eligibility to promote correct federal spending on APTC.

II. Cost-sharing for Drug Manufacturer Coupons (§156.130(h))

HHS proposes revisions to §156.130(h) clarifying that plans and issuers have the flexibility to determine whether to include coupon amounts, or other drug manufacturer direct assistance, in the annual limitation on cost sharing, regardless of whether a generic equivalent is available. This proposal will not prevent patients from using coupons or other forms of direct or indirect financial assistance at the pharmacy counter.⁴

We strongly support this proposal and we appreciate this Administration's ongoing commitment to lower drug prices. The rising cost of prescription drugs poses financial barriers for seriously ill patients and threatens the affordability of health insurance for everyone. Addressing out-of-control drug prices is a top priority for our members.

Spending on prescription drugs per person in the United States has doubled since the year 2000, with about \$540 spent on average per person in 2000 rising to \$1,200 per person in 2018.⁵ By 2014, half of Americans reported having taken at least one prescription drug in the past 30 days and almost one out of five Americans said they took three or more prescription drugs.⁶ As new therapies are developed for rare diseases, drug manufacturers are debuting drugs with price tags as high as \$2 million for one treatment.⁷ While these treatments are extending or improving life for some patients, American families, employers and taxpayers are straining under the costs of prescription drugs.

For people with commercial health insurance, insurance covers the majority of the total cost for covered prescription drugs. For example, a recent study of employer-sponsored coverage found that insurance

³ CCIIO. Guidance on Annual Eligibility Redetermination and Re-enrollment for Exchange Coverage for 2019 and Later Years. July 13, 2017. <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Guidance-Redetermination-Exchange-2018.pdf>

⁴ Throughout our comments references to "coupons" can be assumed to apply to all forms of direct and indirect financial assistance funded by drug manufacturers to increase utilization of specific drugs. There are many forms of direct and indirect drug manufacturer financial assistance to incent patients to take specific drugs. Examples of other vehicles drug manufacturers and their surrogates use to incent the use of specific drugs include but aren't limited to: pre-paid debit cards for the payment of cost-sharing; and cash or check reimbursement to patients for their cost-sharing for a specific drug.

⁵ <https://data.oecd.org/healthres/pharmaceutical-spending.htm>

⁶ <https://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm>

⁷ <https://www.nytimes.com/2019/08/25/health/drug-prices-rare-diseases.html>

covered 89 percent of the total cost of covered drugs in 2017.⁸ Patients cover the remainder in the form of deductibles, copays or coinsurance. Health insurance coverage helps patients afford medication at the pharmacy, but drug costs account for a large portion of health insurance premiums. Almost \$1 out of every \$5 paid in health insurance premiums is used to cover the portion of drugs costs paid by the health insurance provider.⁹

Coupons, and other forms of direct or indirect drug manufacturer assistance to patients, forgo or reduce patients' payments on drugs without addressing the major driver of higher costs for patients—the high price of the drug. Until drug makers address sky-high prescription drug prices, these coupons will continue to make health care unaffordable for everyone. In fact, the HHS-OIG finds coupons used in government programs to be a violation of the anti-kickback statute as they “induce the purchase of Federal health care program items or services”—that is, the drug manufacturer offering the coupon is directly benefiting from its use at the expense of taxpayers.

Coupons increase premiums because they steer patients and physicians towards more expensive brand-name treatments and increase federal expenditures, such as APTC. This is especially problematic when less costly and equally effective alternatives are available. Coupons enable drug makers to subsidize the patient's share of treatment cost and satisfy their deductible requirements, removing any incentives for patients to consider lower-cost treatment options. In this way, coupons make the true cost of a drug essentially unknowable to consumers and physicians. Meanwhile, health insurance providers are left to foot the bill for the entire treatment cost, which gets passed on to consumers, employers and the taxpayers in the form of higher premiums and, as a result, APTC.

We agree with HHS' statement in the preamble to the proposed 2020 Notice of Benefit and Payment Parameters (2020 Payment Notice) that the intent of current federal law is limits on cost sharing “reflect the actual costs that are paid by the enrollee.” Some health insurance providers have implemented “accumulator programs” to exclude drug manufacturer coupons from calculations of enrollee spending towards deductibles or out-of-pocket maximums. When an accumulator program applies, the patient can still use a drug manufacturer coupon at the pharmacy to cover their out-of-pocket costs, but that amount isn't counted towards their deductible or maximum out-of-pocket as actual costs paid by the enrollee.

Ideally, drug manufacturers would just lower the price of their medications, and coupons or other financial assistance to insured patients for specific drugs would be prohibited altogether—like we already do for federal programs. This would bring down overall spending on drugs and eliminate administrative hassle and financial stress for patients who currently rely on drug manufacturer coupons to afford medications with inflated prices. In the short-term, HHS' proposed clarification is an important step in the right direction as policymakers work to more globally address growing drug costs.

In the 2020 Payment Notice, HHS acknowledged the importance of eliminating disincentives, like coupons, for patients to consider generic drugs and the current §156.130(h) language specifically references generic alternatives. While competition between generics and their brand name equivalents is an important market force that drives prices down, the language in the 2020 Payment Notice did not acknowledge the equally important role competition between brands should play in driving down drug prices. We strongly support the proposed clarification to acknowledge the importance *all* forms of drug competition.

⁸ <https://www.healthsystemtracker.org/brief/tracking-the-rise-in-premium-contributions-and-cost-sharing-for-families-with-large-employer-coverage/>

⁹ https://www.ahip.org/wp-content/uploads/2017/03/HealthCareDollar_FINAL.pdf

Competition between brand drugs that are therapeutic alternatives for treating the same condition can and should drive down the cost of the many brand name drugs that do not have generic equivalents. Drug manufacturers recognize this and spend billions of dollars to dilute the impact of competition by providing coupons for brand drugs that do not have a generic equivalent. One study of drug coupons found almost 80 percent of drugs with coupons did not have a generic equivalent.¹⁰

Current language in §156.130(h)(1) can be interpreted to limit health insurance providers' ability to apply accumulator programs and undermines plan design features to lower out-of-pocket costs for patients who choose equally effective, lower-cost drugs. We support the proposed changes to clarify that health insurance providers are permitted to apply accumulator programs for all drugs, not just those that have a generic equivalent.

Finally, we support the proposal that health insurance providers have the flexibility to decide whether to include or exclude coupon amounts from the annual limitation on cost sharing, rather than being required to do so. In many cases health insurance providers are unaware when drug manufacturer assistance is provided and drug manufacturers change the parameters of assistance programs to conceal this assistance. While health insurance providers are working hard to push back on these misaligned incentives, they are unable to identify all coupons.

Recommendation:

- **The Department should finalize the proposed changes to §156.130(h) but remove the word “direct.”** The proposed change makes it clear health plans and issuers have the flexibility to determine whether to include or exclude coupon amounts, or other drug manufacturer direct assistance, from the annual limitation on cost sharing, regardless of whether a generic equivalent is available. This clarification acknowledges the importance of brand-on-brand drug competition, in addition to the importance of generic competition. We support this change because encouraging all kinds of competition is critical to stemming the rising cost of prescription drugs. The change will not prevent patients from continuing to use drug manufacturer coupons at the pharmacy counter.

While we strongly support the change, the proposed wording references “direct support” from drug manufacturers. Drug manufacturers often incent the utilization of specific drugs through surrogate organizations such as drug-manufacturer-funded condition-advocacy groups. We recommend wording the update of the regulation to allow drug-manufacturer-funded financial assistance to be treated the same way when provided directly and when provided through a surrogate organization.

III. HHS Risk Adjustment

A. HHS Risk Adjustment (§153.320)

The Payment Notice includes several updates and proposed changes to the ACA risk adjustment model including:

- Recalibrating the model based on enrollee-level EDGE data (and discontinuing use of MarketScan data);
- Updating the risk adjustment model recalibration hierarchical condition categories (HCCs);
- Pricing adjustments to the RXC coefficient for Hepatitis C drugs; and

¹⁰ https://healthpolicy.usc.edu/wp-content/uploads/2018/02/2018.02_Prescription20Copay20Coupons20White20Paper_Final-2.pdf

- Incorporating PrEP as a preventive service in the simulation of plan liability in the risk adjustment models.

In addition, HHS solicits comments on several options to modify the risk adjustment models to improve prediction for enrollees without HCCs or enrollees with low actual expenditures.

Recommendations:

- **AHIP supports a number of the proposed changes for the 2021 risk adjustment benefit year.** These include recalibration of the model based on enrollee-level EDGE data, continuing to apply cost-sharing reduction adjustments, and maintaining the same payment parameters for the high-cost risk pooling program. The proposal to recalibrate the risk adjustment model based on enrollee-level EDGE data continues a transition away from MarketScan to data that more accurately represents the actual population enrolled in exchange-plan coverage. Moreover, by proposing an averaged, blended approach, the recalibration included in the proposed rule aims to provide stability for the risk adjustment model while reflecting the most recent years' claims experience. Moreover, we support HHS' proposal to continue including an adjustment for the receipt of CSRs in the risk adjustment models to account for increased plan liability and maintaining the high-cost risk pool parameters (with a threshold of \$1 million and a coinsurance rate of 60 percent). These policies work to promote stability in the risk adjustment program so that it can fulfill its goals of preventing adverse selection while maintaining a level playing field and facilitating fair market competition on the basis of efficiency and quality of care provided.
- **We support the proposal to include pricing adjustment for the Hepatitis C RXC.** Similar to the adjustment included in last year's final 2020 payment notice, we support HHS' proposed pricing adjustment for Hepatitis C coefficient that takes into account the introduction of new Hepatitis C drugs and more precisely reflects the average cost of treatment.
- **We support incorporating the use of pre-exposure prophylaxis (PrEP) as an RXC for the 2021 benefit year.** While the proposed rule would incorporate PrEP as preventive service in the simulation of plan liability in the risk adjustment model, we support creating an RXC coefficient for PrEP to ensure adequate capture of risk profiles. We are concerned that incorporating PrEP into the simulation of plan liability—as contemplated under the proposed rule—does not adequately account for the cost of this service and the potential for adverse selection. Therefore, we support incorporating PrEP into the model as an RXC in order to adequately protect and compensate plans that disproportionately enroll individuals using this medication.
- **We have concerns with HHS' proposal to incorporate hierarchical condition category (HCC) changes for the 2021 risk adjustment models.** We recognize that the current HHS-HCC clinical classification system—which serves as the foundation for the risk adjustment payment transfer model—has not been updated since 2014 and that the proposed changes seek to update the classification system to reflect more recent diagnosis code information and better align HCCs with the newer ICD-10 codes. Before moving ahead with any proposed changes to HCCs, HHS should provide more data and analysis on how these HCC changes would impact statewide average risk scores and payment transfers. Moving ahead with these significant changes to HCCs—all at once and for the 2021 benefit year risk adjustment model—would create considerable uncertainty for issuers that rely on the risk adjustment program. For these reasons, we recommend HHS not move forward with these proposed changes to HCCs for the 2021 benefit year and instead work with stakeholders to continue to assess whether changes are appropriate or warranted in future years. Before finalizing any proposed changes to HCCs, HHS should provide more data and analysis on the following:

- How each specific HCC update would definitively improve the accuracy of identifying risk selection between issuers compared to the existing model;
- How these HCC changes would impact statewide average risk scores and payment transfers; and
- Data on the prevalence of HCCs in each market and state both before and after the proposed HCC changes.

These analyses will help to confirm that the added model complexity improves the identification of risk selection occurring in the market. Moreover, the data would provide issuers with information on how these changes may impact risk scores, which, in turn, can help issuers factor these changes into future premiums.

- **We appreciate HHS' solicitation of comments on proposals to improve risk adjustment model predictions but we are unable to support any of the options under consideration.** Based on our discussions with member plans, there are significant concerns that the approaches under consideration to improve predictive power introduce too much complexity to the risk adjustment model. Moreover, the changes would create uncertainty that would be difficult for plans to incorporate into premium pricing for future years. Moving forward, we recommend HHS continue to engage stakeholders and conduct additional analysis before moving forward with any of these changes aimed at improving risk adjustment model predictions.

B. Risk Adjustment User Fee for 2021 Benefit Year (§153.610(f))

The proposed rule establishes a risk adjustment user fee of \$0.19 per member per month (PMPM) to operate the program. The costs are similar to the 2020 benefit year estimates.

Recommendation:

- **We support the proposed risk adjustment user fee of \$0.19 PMPM to operate and administer the ACA risk adjustment program.**

C. Risk Adjustment Data Validation Requirements when HHS Operates Risk Adjustment (§153.630)

HHS will conduct risk adjustment data validation (RADV) for all 50 states and the District of Columbia for the 2021 benefit year. Beginning with the 2019 benefit year, HHS proposes to amend the outlier identification process. Specifically, an issuer's failure rate for an HCC group will not be considered an outlier if the issuer has fewer than 30 HCCs recorded in the issuer's EDGE server. The data would be included in the calculation of the overall national metrics, but its risk score would not be adjusted for that group.

Recommendation:

- **We support this modification to the application of RADV adjustments as a way to more reliably determine outlier status for issuers with HCCs.** While this proposal will likely have a limited impact, it represents an important first step toward improving the RADV process. We encourage HHS to continue to engage with stakeholders and identify ways to further improve the RADV process—with the goal of reducing volatility and uncertainty.

D. Prescription Drugs for the 2019 Benefit Year Risk Adjustment Data Validation

The proposed rule would allow the 2019 benefit year RADV to function as a second pilot year for the purposes of prescription drug validation.

Recommendation:

- **We support the proposal for an additional pilot year—with the goal of providing issuers more time and experience with the prescription drug data validation process.** However, we encourage HHS to provide additional data and share findings with issuers from the pilot year so that stakeholders can benefit from broader industry lessons learned. This can ensure that the pilot year is successful and lay the foundation for a smooth transition to prescription drug data validation in future years—building on lessons learned from the pilot.

IV. Medical Loss Ratio

A. Reimbursement for Clinical Services Provided to Enrollees (§158.140)

HHS proposes updates to §158.140(b)(1)(i) to require issuers to deduct from incurred claims prescription drug rebates and other price concessions when received by the issuer or by a pharmacy benefit manager (PBM) beginning with the 2021 medical loss ratio (MLR) reporting year (reports submitted in 2022). Currently, issuers are required to deduct rebates received by the issuer. HHS requests comments on whether the proposed effective date allows adequate time for issuers to update their contracts with their PBMs.

We support the goal of providing transparency into drug costs and we understand HHS’ rationale for these updates. Meaningful transparency and accurate accounting for health insurance provider administrative costs requires that costs are reported consistently across issuers and that reported costs truly belong in the categories in which they are reported. In the interest of meaningful and consistent MLR reporting, we recommend below that HHS make changes to two aspects of this proposal: (1) avoid unintentionally double-counting rebates and price concessions retained by the issuer; and (2) define “price concessions” in regulatory text consistent with the PBM transparency statute and related guidance. We also recommend delaying implementation of these requirements until the 2022 plan year to allow issuers time to update their PBM contracts.

Double-Counting Rebates Received by Issuers

Rebates received by issuers have always been excluded from incurred costs, which is appropriate. However, in its conforming change for PBM-retained rebates in 45 CFR 158.140(b)(2)(vii), which requires that PBM-retained rebates be treated as non-claims costs, HHS has unintentionally included rebates received and retained by issuers. Since these are simply price concessions received by the issuer and do not represent an administrative fee paid by the issuer to a third party (as is the case with PBM-retained rebates), these amounts should not be included in non-claims costs of the issuer.

Definition of “Price Concessions”

We are concerned that “price concessions” is not defined in the proposed regulatory text and the definition in the preamble does not clearly exclude bona fide service fees. Without an explicit exclusion for bona fide service fees the proposed regulation could be interpreted inconsistently with the definition of price concessions in the statute on PBM transparency requirements and the recent proposed information collection implementing those requirements for QHPs.¹¹ Without an exclusion for bona fide service fees, some plans might include fees paid by drug manufacturers for services provided to the manufacturer in the health plans’ MLR. Examples of these fees include fees for providing data to the manufacturer or fees for rebate administration on behalf of the manufacturer, which does not affect the plan’s drug costs and so does not constitute a price concession.

¹¹ Sec. 1150A of the Social Security Act (codified at 45 CFR 156.295) and CMS’ Paperwork Reduction Act Notice, 85 Fed. Reg. 4993 (Jan. 28, 2020); see CMS–10725, Pharmacy Benefit Manager Transparency.

The statutory PBM transparency requirements define “price concessions” to exclude bona fide service fees as follows:

“...price concessions (excluding bona fide service fees, which include but are not limited to distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs))...”

In the regulation implementing that statute, 45 CFR 156.295, “prices concessions” are defined to exclude bona fide service fees which are defined in the regulation as follows:

“Bona fide service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.”

The recent information collection request proposes to define “bona fide service fees” as follows and exclude them from “price concessions.”

“Bona fide service fees are fees paid by a manufacturer to an entity that meet all of the following conditions: 1) The fee must be paid for a bona fide, itemized service that is actually performed on behalf of the manufacturer; 2) The manufacturer would otherwise perform or contract for the service in the absence of the service arrangement; 3) The fee represents fair market value; and 4) The fee is not passed on, in whole or in part, to a client or customer of an entity, whether or not the entity takes title to the drug.”

Recommendations:

- **In the final rule, do not include the reference to rebates and price concessions retained “by the issuer” in the update to §158.160(b)(2).** As part of the changes to §158.160(b)(2), Other non-claims costs, HHS is proposing to treat the rebates and price concessions received by the issuer in the same manner as PBM retained rebates and include them as an administrative expense. Treating rebates and price concessions received directly by the issuer as an administrative cost in addition to removing the amount from total claims cost would result in issuer-received rebates and price concessions being double counted and does not follow the logic in the preamble for the treatment of PBM retained rebates.
- **Add a definition of “bona fide service fees” consistent with the final definition of “bona fide service fees” for the PBM QHP Transparency information collection (adopted in regulation at 45 CFR 156.295) and make clear that those fees are excluded from the MLR calculation.** These fees are compensation for services rendered to the drug manufacturer and are not a price concession for purposes of MLR. It’s also important that the definition of “price concessions” is aligned across programs and agencies to minimize administrative cost and burden and ensure policymakers consistently recognize the role of bona fide service fees in efforts across agencies.
- **Implement the new rebate and price concession reporting provisions for MLR beginning with the 2022 plan year, if requirements including a consistent definition of “price concessions” are finalized in 2020.** HHS acknowledged that plans would need to update contracts with their PBMs to implement the new requirements and requested comments on whether the proposed effective date for

the 2021 plan year allows adequate time for issuers to update their contracts with their PBMs. Product design for the 2021 plan year is already underway and health insurance providers will need revisit their contracts with their PBMs in advance of their first year of reporting under the new requirements. Implementing the new rebate and price concession reporting requirements effective for the 2022 plan year will allow plans time to revisit their contracts with PBMs to ensure they can include the new information in their MLR reports.

B. Activities that Improve Health Care Quality (§158.150)

HHS proposes amending §158.150(b)(2)(iv)(A)(5) to clarify that issuers in the individual market may include the cost of certain wellness incentives as quality improvement activities (QIA) expenses in the MLR calculation, which is consistent with the treatment of wellness incentives provided by employers. This change would be effective beginning with the 2021 MLR reporting year (reports submitted in 2022).

Recommendation:

- **Finalize the amendment to §158.150(b)(2)(iv)(A)(5) clarifying that individual market issuers may include the cost of certain wellness incentives as QIA expenses in the MLR calculation as proposed.** In 2019 HHS issued guidance implementing the individual market wellness program demonstration project as required by statute. That guidance cross-references requirements and definitions for employer wellness programs and it makes sense that the incentives provided under individual market programs would also be treated the same as employer wellness programs for MLR purposes. We support this proposal and more broadly we support the option to provide wellness programs in the individual market. We also support provisions in statute and regulations making it clear that offering a wellness program does not eliminate or reduce obligations under the prohibition on discrimination based on pre-existing condition.

V. Promoting Value-based Insurance Design (85 FR 7137)

The Department proposes options issuers could voluntarily adopt to implement value-based insurance design (V-BID) principles for QHPs sold through the Exchanges. While value-based QHPs would not be preferentially displayed on healthcare.gov, HHS seeks input on whether and how to identify value-based QHPs through the certification process and to indicate such plan design to consumers shopping for coverage.

Recommendations:

- **We support enhancing the accessibility of value-based plans to consumers enrolling in QHPs, but recommend not specially designating plans as such on healthcare.gov. Instead, HHS should solicit feedback for future plan years on how to meaningfully inform consumers of value-based insurance design elements in available plan options.** Value-based insurance design is a common-sense and promising way to reduce health care spending while improving outcomes for patients, particularly those with chronic health conditions. AHIP supports expanding utilization of this approach among both private plans and public programs and was involved in developing recommendations for implementing VBID-X plan designs. Among the challenges in that process was determining how to communicate to Exchange consumers that a QHP includes varied cost-sharing amounts depending on whether the item or service has been determined to be of high or low value. Because this challenge remains unresolved, we recommend HHS seek feedback on how to communicate this information to consumers on healthcare.gov for future plan years.

- **Any proposals related to V-BID plans should not be implemented for the 2021 plan year.** We anticipate a final rule would likely be published immediately before many state filing deadlines. This would not give issuers sufficient time to design new plans according to the finalized rule and implement additional requirements in QHPs for the 2021 plan year.
- **We are concerned HHS designating a QHP as “value-based” would result in unintended consequences that could actually hinder value-based designs that do not specifically conform to certification standards.** Certifying select QHPs as “V-BID plans” and displaying them as such to Exchange consumers is not the best way to advance V-BID plan designs moving forward. Designating certain QHPs as V-BID plans presents not only operational challenges for healthcare.gov and SBEs, but would likely be of little benefit to consumers shopping for coverage. There is no obvious and meaningful way to identify a V-BID plan as such on an Exchange website. It is also not clear how HHS or state Exchanges would certify a QHP as a V-BID plan. Many, if not most, QHPs currently available include some design element that borrows from V-BID theory. There are some carriers that have differing views on the high- or low-value nature of items or services (such as whether a certain prescription should be offered without cost-sharing or whether a given service is indeed of low-value).
- **Labeling QHPs as “V-BID Plans” could introduce unnecessary confusion.** Even if a QHP were clearly marked as a V-BID plan, the term “value-based insurance design” is likely one the average person would not recognize. Indeed, people may be further confused by the term, such as thinking the QHP offers fewer benefits. Value-based insurance design centers on the concept of clinical nuance and such a level of nuance requires a substantial amount of information to be relayed to the average consumer shopping for a QHP.
- **We recommend people be offered accessible and meaningful information about their plan options, including how a QHP leveraging V-BID principles would require lower cost-sharing for certain high-value services.** This would be one of many pieces of information about a plan someone should evaluate when selecting a QHP, in addition to important factors like the plan’s provider network and cost-sharing. Healthcare.gov could include a general educational page on V-BID principles. Plan-specific information about how benefits are enhanced for a particular health condition, as well as URLs to the plan’s marketing documents and more detailed information explaining V-BID and the clinical nuance of available plans, could be included on the Plan Details page.
- **We recommend HHS design a free-form text field that would allow issuers to provide information about the V-BID plan features.** This could include a condition-specific drop-down box to best inform consumers about how the plan may offer unique benefits for their condition(s).
- **To ensure meaningful information is communicated to consumers about QHPs that are designed according to V-BID principles, we recommend the Department seek stakeholder feedback to determine the best method for communicating V-BID plan designs and educating consumers on the implications of such plans.** AHIP member health plans currently offer QHPs and other health insurance plans that utilize principles of value-based insurance design and we support ways to expand utilization of high-value services among a broader population. Given the level of detail required to explain those plan details, the risk of unintended consequences, and need for broader agreement on what constitutes value-based insurance design, we recommend HHS solicit feedback for future plan years on how to best educate Exchange consumers about value-based insurance design and empower them to decide which plan best meets their health care needs.

VI. Other Exchange Establishment Standards (Part 155)

A. Eligibility Determinations During a Benefit Year (§155.330)

HHS proposes two changes with respect to periodic data matching (PDM) processes. First, HHS proposes to clarify when exchanges process a voluntary termination for a dual enrollee, Exchanges will not re-determine subsidy eligibility, as would occur under current rules. Second, HHS proposes when an exchange enrollee is identified as deceased through the death PDM, exchanges will not re-determine eligibility for subsidies and will terminate exchange coverage back to the date of death.

Recommendation:

- **We support the proposed change to not redetermine eligibility for enrollees terminated via PDM. We recommend HHS clarify whether eligibility will be redetermined for other members of the policy who are not terminated.** We agree that it makes sense to align termination due to PDM with other enrollee-initiated terminations for the individual being terminated. We recommend HHS clarify whether Exchanges will redetermine subsidy eligibility for enrollees (e.g., dependents) who remain on the policy after the ineligible member is removed.
- **We recommend HHS work with SBEs to ensure they meet timeliness standards for processing information related to life events.** We understand that some SBEs have experienced challenges processing information in a timely manner that could create complications for enrollees if the proposed change is implemented. We urge HHS to work with SBEs to ensure they are meeting life event turnaround times to allow this proposed change to be implemented effectively for enrollees.

B. Special Enrollment Periods (§155.420)

The Department proposes several changes to special enrollment periods (SEPs) throughout §155.420, generally with the objective of streamlining SEP eligibility, limitations, and effective dates.

Exchange enrollees newly ineligible for cost-sharing reductions (§155.420(a)(4)(ii)(B))

HHS proposes to create a new SEP to allow enrollees and their dependents who become newly *ineligible* for CSRs under §155.420(d)(6)(i) or (ii), and are enrolled in a silver metal level QHP, to change to a QHP one metal level higher or lower if they elect to change their QHP enrollment in an Exchange.

Recommendation:

- **We support the proposed change to allow enrollees who become newly ineligible for CSRs to change to a QHP one metal level higher or lower.** We agree that enrollees who become newly ineligible for CSRs should have the opportunity to enroll in a QHP one metal level higher or lower, potentially allowing them to switch to a lower premium plan. However, we note that consumers who use an SEP to enroll in a new QHP mid-plan year could ultimately face higher out-of-pocket costs because their out-of-pocket accumulators will reset. Enrollees should be notified of this potential consequence before switching QHPs to ensure they understand the potential impact for their total annual spending on premiums and out-of-pocket costs.

SEP limitations for enrollees who are dependents (§155.420(a)(4)(iii)(C))

HHS proposes to apply plan category limitations (i.e., metal level restrictions) when a non-dependent household member becomes newly eligible for Exchange coverage through an SEP, allowing them to enroll in the dependent's current QHP.

Recommendation:

- **We support the proposed change to allow consumers who newly gain Exchange coverage through an SEP to be added to a dependent’s existing QHP, or, if business rules prohibit, allow the enrollee and dependents to select a new QHP in the same metal level.** We believe it is appropriate to apply metal level restrictions to this scenario, to mirror existing restrictions when a newly eligible dependent is added to a parent’s existing QHP coverage.

SEP prospective coverage effective dates (§155.420(b)(3))

HHS proposes to revise coverage effective date rules in exchanges using healthcare.gov such that SEPs currently following regular effective date rules would instead be effective on the first of the following month following plan selection (i.e., under an accelerated effective date). If finalized, HHS would make corresponding updates to binder payment rules under §155.400(e)(1)(ii) so that all SEPs with first of the month effective dates are subject to the same binder payment deadline.

Recommendation:

- **We support the proposed change to make coverage effective on the first of the month following plan selection for SEPs currently subject to regular effective dates.** We agree decreasing the amount of time between plan selection and effectuating coverage could reduce gaps in coverage for consumers who are eligible for coverage through the Exchanges. Based on prior experience in processing first of the month effective dates for other SEPs, we do not foresee significant operational challenges in applying this effective date more broadly. However, we encourage HHS to ensure controls are in place to reduce gaming of SEPs. Specifically, we recommend HHS review current SEP verification (SEP-V) processes and make any needed updates to verify eligibility for first of the month effective date SEPs.

SEP retroactive coverage effective dates (§155.420(e)(1)(iii))

HHS now proposes align the retroactive effective date and binder payment rules so that enrollees eligible for retroactive effective dates in all scenarios—including due to an SEP, favorable appeal decision, or SEP verification delay—to have the option to elect a retroactive effective date by paying all months of retroactive premium due through the first prospective month or elect prospective coverage by paying only the premium for one month of coverage. This proposed change eliminates separate payment requirements for enrollees eligible for a retroactive effective date due to a delayed SEP verification.

Recommendations:

- **We support removing the option for “sliding effective dates” for SEP enrollees eligible for a retroactive effective date whose enrollment was pended due to SEP-V.** Based on HHS’ data provided in the preamble demonstrating the timeliness of the SEP-V process, we agree it makes sense to eliminate this special option as few enrollees have elected it.
- **We continue to oppose the requirement that issuers determine an effective date based on the amount of binder payment. This is a deeply flawed policy and places an unnecessary administrative burden on issuers.** We have repeatedly raised significant concerns about the current policy of requiring issuer to manually interpret a coverage effective date based upon the amount of binder payment. There is no other enrollment scenario in which an issuer must interpret an effective date—it is always communicated on the 834. For most issuers, it is not possible to implement an automated process to determine an effective date in this scenario and it has become a challenging manual process that creates excessive administrative burden for issuers. These processes are prone to delays and errors and can create consumer frustration if an effective date other than the one they intended is applied. As we have previously recommended, consumers should indicate at the time of enrollment whether they elect a retroactive effective date and will

pay the entire binder, or if they prefer a prospective effective date and the correct effective date should be communicated to issuers on the 834.

- **Alternatively, HHS should provide issuers flexibility to determine the best consumer experience.** Depending on the issuer, this could involve outreach to consumers or continuing to interpret payment amounts as requests for effective date changes.

Enrollees covered by a non-calendar year plan year QSHERA (§155.420(d)(1)(ii))

HHS now proposes to amend §155.420(d)(1)(ii) to codify that individuals and dependents who are provided a QSEHRA with a non-calendar year plan year may qualify for an SEP. This would align with the SEP provided to employees who newly gain access to an individual coverage HRA to enroll in individual health insurance coverage, or to change to other individual health insurance coverage in order to maximize the use of their individual coverage HRA.

Recommendation:

- **We support the proposed clarification that individuals who are provided a QSHERA with a non-calendar year plan may qualify for an SEP.**

C. Termination of Exchange Enrollment or Coverage (§155.430)

Effective dates for retroactive termination of coverage or enrollment due to Exchange error

HHS proposes to align §155.430(d)(9) with the provisions for enrollee-initiated terminations at §155.430(d)(2) so enrollees who requested a termination, but the termination did not occur because of a technical error, can request to terminate coverage retroactive to the day of the original request. In this scenario, enrollees who experienced technical errors would be able to initiate a termination sooner and not have to provide 14-day notice before a termination is effective.

Recommendation:

- **While we agree with the Department's efforts to minimize impact to a consumer when a technical error delayed a termination, termination should not be retroactively effective if the enrollee incurred claims during that period.** We are particularly concerned about prescription drug claims, which are adjudicated at the point of sale and cannot be recovered. Similar to terminations under the Unauthorized Enrollee Finder File, if an enrollee continues to use the benefits of their policy and incur claims, the issuer should not be required to retroactively terminate coverage.

D. Eligibility Pending Appeal (85 FR 7125)

The Department seeks feedback whether changes to §155.525 are needed to provide greater clarity to Exchanges, issuers, and consumers, when an appellant accepts eligibility pending appeal. HHS specifically discusses whether changes are needed related to:

- Retroactive applicability of eligibility pending appeal
- Timeliness of filing for eligibility pending appeal
- Life events occurring during the pendency of the appeal
- Impact of eligibility decision on eligibility pending appeal
- Eligibility pending appeal and non-payment of premiums

Recommendations:

- **We recommend HHS make data on appeals more transparent so issuers can better understand their members' experience with appeals scenarios HHS describes throughout the preamble.** Currently, issuers do not have access to adequate data on enrollees appealing an

eligibility determination, making it difficult to comment on the questions HHS poses or provide meaningful recommendations for appropriate guardrails. Issuers do not have data on which enrollees are under appeal. Data on appeals would allow issuers to better serve these enrollees during a complicated process. These data would also allow additional analysis, such as whether there is an increase in claims during an appeal process. Based on our limited knowledge of data and trends related to appeals, we provide high level comments for HHS' consideration. We encourage HHS to make appeals data available to issuers before proposing specific changes to the eligibility pending appeals process through future rulemaking.

- **With respect to retroactive applicability of eligibility pending appeal, HHS should consider whether it could create selection issues if an appellant was able to retroactively change plans, products, metal levels or issuer.** Retroactive enrollment changes are typically problematic due to claims reprocessing, changing benefits, and state prompt pay laws. When appellants change benefits retroactively, they could face increased out-of-pocket costs for services they already received.
- **We recommend HHS adopt a timeliness standard for an enrollee to request eligibility pending an appeal.** Specifically, we support a 30-day deadline from the date the appeal is accepted for appellants to request eligibility pending appeal and good cause exceptions to the deadline, consistent with exceptions for filing an appeal by the deadline.
- **Regarding eligibility pending appeal and non-payment of premiums, we recommend the enrollee pay the current billed amount.** If an appeal needs to be submitted within 30 days and resolved within 30 days, this should not be a financial hardship to the enrollee and is within their 90-day grace period.

E. Quality Rating Information Display Standards for Exchanges (§§155.1400 and 155.1405)

For the 2020 open enrollment period, HHS transitioned away from the quality rating system (QRS) pilot to the public display of quality rating information for plan year 2020 for all Exchanges, including SBEs. This included flexibility for SBEs to make some customizations in the way they display QHP quality rating information on their websites. HHS now proposes to amend §§155.1400 and 155.1405 to codify this flexibility and provide SBEs some flexibility to customize the display of quality rating information for their QHPs.

Recommendation:

- **We support codifying flexibility for SBEs in the display of QRS information on their websites.** The 2020 open enrollment period was the first plan year for which QRS information was displayed for all issuers in all states. We encourage HHS to continue working with issuers to evaluate the best way to communicate information on QHP quality to consumers in an easy-to-understand manner. We urge HHS to be transparent in disclosing information on the use of QRS information during plan selection and enrollment, seek input from issuers' experiences when supporting consumers through the plan comparison and selection process, and seek input directly from consumers (e.g., through focus groups) to display QRS information in a meaningful manner.

VII. Other Health Insurance Issuer Standards (Part 156)

A. FFE and SBE-FP user fee rates for the 2021 benefit year (§156.50)

For the 2021 plan year, HHS proposes to maintain the current user fee rates—3 percent for issuers participating in the FFE and 2.5 percent for issuers in State-based Exchanges using the federal platform (SBE-FPs). However, the Department is seeking input on lowering user fees below these rates.

Recommendations:

- **For the 2021 plan year, we support the proposal to maintain or reduce the current user fee rates for issuers in the FFE (3 percent of premiums) and SBE-FPs (2.5 percent of premiums).** As HHS scales back the administrative functions of the FFE and SBE-FP, we agree it is appropriate to maintain or reduce the user fee. Because there is limited transparency into issuer user fee payments or the FFE and SBE-FP administrative costs, it is difficult to provide meaningful comments on whether the current user fee is appropriate to maintain moving forward. However, we would support a further reduction in the user fee if it does not result in further reductions in the level of marketing, outreach, and communication conducted by HHS.
- **For future plan years, we recommend HHS update the user fee methodology so user fees are tied to per capita enrollment, rather than a percent of premiums.** HHS should first conduct a formal study—and publicly disclose the results—of the impact of changing the user fee methodology from a percent of premium to a per capita rate. Under the current approach, user fees rise with medical trend and other factors that inflate rates. Specifically, with the introduction of silver loading to accommodate the loss of CSR funding, premium increases resulted in increased user fees at the same time HHS reduced the budget for marketing and outreach. A capitated user fee methodology would instead generate additional funds to support FFE and SBE-FP operations as enrollment increases, creating a new set of enrollment-based incentives.

B. State selection of EHB benchmark plan for plan years beginning on or after January 1, 2020 (§156.111)

Annual reporting of state-required benefits

Section 1311(d)(3)(B) of the ACA allows states to require that QHPs cover benefits in addition to essential health benefits (EHB), but requires states to defray the cost of those additional state mandated benefits—either through payments to the individual enrollee or to the issuer on behalf of the enrollee. Benefits mandated after December 31, 2011 are considered in addition to EHB, even if mandated benefits are also embedded in the state’s selected EHB benchmark plan. Benefits mandated for purposes of compliance with new federal requirements are not subject to defrayal. States are responsible for identifying which additional state mandated benefits, if any, in addition to EHB and the issuer is responsible for quantifying the costs attributable to each additional required benefit.

The Department now proposes to require states, beginning in plan year 2021, to annually notify HHS of any state-required benefits applicable to QHPs in the individual and/or small group market in addition to EHB. If a state does not notify HHS of state mandated benefits in addition to EHB by the annual reporting deadline, HHS would determine which benefits are in addition to EHB in the state for the applicable plan year and, thus, subject to defrayal.

Recommendations:

- **We support the proposed annual reporting process for states to report state mandated benefits in addition to EHB.** AHIP and its member plans conduct extensive, ongoing tracking of state legislative efforts and newly adopted state mandated benefits. A small number of states have identified state-required benefits—adopted after December 31, 2011—in the individual and/or small group markets that are in addition to EHB and subject to state defrayal of costs. However, it is not clear whether all state-required benefits which rise to the threshold for defrayal as described in Section 1311(d)(3)(B) of the ACA are being defrayed by states. This applies to newly enacted benefit requirements, and whether they are considered new mandates under Section 1311(d)(3)(B), as well as other benefits effectively required by the state, for example through the

QHP filing process when a modification effectively requires a new benefit that is not an EHB or a benchmark benefit.

- **Consistent with prior AHIP comments, we continue to support states, not exchanges, as the entity responsible for identifying and reporting benefit mandates to HHS. However, to mitigate any potential conflict of interest, we recommend HHS require a public comment process to allow stakeholders to provide feedback on the state report of benefit mandates.** States, as the entity responsible for defraying the cost of mandates in addition to EHB, could have a conflict of interest when identifying and reporting new state requirements. Requiring a public comment period would allow issuers and other stakeholders to provide formal input, and create a public record, on which benefit requirements rise to the definition of mandates in addition to EHB that require defrayal by states. A formal public comment process would be an appropriate requirement to promote accountability and could provide additional detail on new and existing benefit mandates issued through state legislation, regulation, or sub-regulatory guidance. HHS should review the record of comments when reviewing state-reported benefit mandates as part of its oversight review when determining whether a state has appropriately identified benefit requirements in addition to EHB that require state defrayal.
- **We urge HHS to provide additional transparency into how it will use state reported information on benefit requirements to enhance its oversight and enforcement of state defrayals under Section 1311(d)(3)(B) of the ACA.** For example, HHS should clarify how it will review state information from prior state activity in the first annual report. For example, will HHS take retroactive action to determine if previous state requirements meet the threshold of defrayal? Regardless of HHS' review of prior state required mandates, we recommend that any requirement for defrayal be prospective. Further, HHS should develop and provide details on how it intends to ensure that states' annual reports are accurate and complete, for example through annual audits of state reports.

States' EHB-benchmark plan options

The Department proposes May 7, 2021, as the deadline for states to submit the required documents for the state's EHB benchmark plan selection or the 2023 plan year. HHS recommends, but does not require, states submit at least 30 days prior to the application deadline to ensure application documents are complete by the proposed deadline. HHS also reminds states that they must complete the required public comment period and submit a complete application by the deadline. The rule would adopt May 7, 2021, as the deadline for states to notify HHS they wish to permit between category benefit substitution for the 2023 plan year.

Recommendation:

- **States should provide ample notification to issuers and other stakeholders of proposed changes to the state's EHB benchmark plan selection and sufficient time to solicit, review, and consider public comment on potential benchmark plan changes.** Updates to a state's EHB benchmark plan to require new benefits, substitute an EHB category from another state or permit between category benefit substitution, or to adopt another state's benchmark could have substantial financial and coverage impacts for issuers and consumers. We strongly urge states to clearly notify stakeholders of these proposed changes and engage in a transparency public comment process prior to submitting an application to HHS.

C. Termination of Coverage or Enrollment for Qualified Individuals (§156.270(b)(1))

The proposed rule would require QHP issuers to send enrollees a termination notice for all termination events described in §155.430(b), including enrollee-initiated terminations.

Recommendation:

- **HHS should not expand the scenarios in which issuers are required to send termination notices to enrollees to include enrollee-initiated terminations or Exchange-initiated terminations.** While some issuers currently send termination notices in these scenarios, not all currently do. Issuers who do not send terminations for enrollee- or Exchange-initiated terminations raised concerns about unnecessary additional administrative costs without added benefit to the enrollee. When an enrollee initiates a termination, they are involved in the process and do not need a termination notice. In fact, a termination notice could be confusing in certain scenarios—for example, if the enrollee switches between QHPs offered by the same issuer during open enrollment or an SEP, a termination notice from their issuer could be confusion and would likely require additional follow-up to ensure they are enrolled in their preferred QHP. When the Exchange initiates the termination, for example due to a change in eligibility, the Exchange should be responsible for sending a notice, not the issuer. An issuer termination notice could prompt the consumer to contact the issuer, but when a termination is due to an updated eligibility determination by the Exchange, the issuer can only direct the consumer to the Exchange, which could create a frustrating consumer experience.