America's Health Insurance Plans
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February 19, 2019

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 2019 Proposed Rule—AHIP Comments

Dear Administrator Verma:

On behalf of America's Health Insurance Plans (AHIP), 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 2020 ("Payment Notice"), published in the *Federal Register* on January 24, 2019 (CMS-9926-P).

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.

We appreciate the Department's continued efforts to promote stability in regulatory requirements and lower administrative burdens related to implementing the Affordable Care Act (ACA). HHS specifically proposes solutions to lower costs for consumers, ensure accuracy of core ACA programs including risk adjustment and premium tax credits, and promote transparency. We share these goals and our recommendations aim to balance these objectives with ensuring Americans have access to affordable, comprehensive coverage. However, we are concerned some of the changes proposed by the Department would undermine stability of the individual market, decrease enrollment, and make coverage less affordable for Americans.

Because of the later than usual timeline for publication of the proposed Payment Notice, we urge the Department to issue the final rule as soon as possible. Health insurance providers will be in the end stages of finalizing products and rates for the 2020 plan year when the final rule is published. At that late stage it will be difficult for insurance providers to adapt product offerings

to accommodate significant policy changes. Thus, we recommend HHS not implement major policy changes for the 2020 plan year in the final rule. In our detailed comments, we specifically note proposals that would be difficult to accommodate for 2020.

Overview of AHIP Comments on Key Issues in the Proposed Rule:

Our comments and recommendation reflect AHIP's commitment to continue our partnership with the Administration to develop policy solutions that will support a more stable individual market, ensure access to comprehensive coverage, and promote affordability. Below we summarize AHIP's comments and recommendations on key issues proposed in the proposed Payment Notice for 2020:

- **Direct Enrollment: Continue to expand the availability of streamlined consumer shopping experiences through enhanced direct enrollment.** We strongly support HHS' ongoing efforts to improve the consumer experience when shopping for and enrolling in coverage through the exchange. We greatly appreciate HHS' ongoing partnership with private stakeholders to develop and implement enhanced direct enrollment. Changes proposed in this rule will build on ongoing efforts by HHS and health insurance providers to make available innovative consumer experiences for enrollment in exchange coverage.

- **Special Enrollment Periods: Allow consumers enrolled in minimum essential coverage to qualify for a special enrollment period (SEP) to enroll in subsidized coverage through the exchange when they newly qualify for premium tax credits.** HHS proposes a new SEP that would create a path to enroll in subsidized coverage for consumers who are already enrolled in other minimum essential coverage off-exchange but become newly eligible for premium tax credits due to a decrease in income mid-year. This SEP will be especially critical for consumers who do not qualify for premium tax credits and enroll in off-exchange coverage to avoid higher premiums due to silver loading, but later become eligible for subsidies.

- **User Fee: Reduce the user fee for health insurance providers in the federally-facilitated exchanges (FFEs) and state-based exchanges using the to reflect the evolving administrative functions of exchanges.** We greatly appreciate HHS' proposal to reduce the user fee rates for health insurance providers in FFEs for the 2020 plan year. As the administrative functions of the exchanges continue to evolve, especially with the increased emphasis on direct enrollment, and exchanges become increasingly efficient, it is appropriate to reduce these user fees. We further recommend HHS reallocate user fee funds to re-invest in consumer outreach, education, and marketing for open enrollment.

- **Risk Adjustment Program:** Support HHS' proposal to continue recalibrating the risk adjustment model based on EDGE data—which reflects the actual data from insurers individual and small-group populations. In addition to promoting a more accurate model,

HHS' approach to risk adjustment model recalibration can help promote predictability and stability by reducing year-to-year changes in risk scores. In addition, AHIP supports maintaining the categories included in the risk adjustment model for the 2020 benefit year while adding a pricing adjustment to more accurately reflect changing drug prices. While supportive of many of the proposed updates to the risk adjustment methodology, AHIP has serious concerns with the proposal to make EDGE data publicly available via a limited data set file. To safeguard commercially sensitive and proprietary data, we recommend that EDGE data should only be used for internal government purposes including administering the risk adjustment program and making updates to the actuarial value calculator.

- **Proposals Related to Prescription Drugs: Continue the commitment to identifying broader solutions to address out-of-control prescription drug prices.** While we greatly appreciate HHS' emphasis on promoting generic drugs, the proposals in the rule are worded very narrowly and could have the unintended consequences of precluding several other standard practices to reduce spending on drugs and promote effective high-value care. We disagree with the assertion that current uniform modification rules prohibit mid-year formulary changes and provide further rationale on that point in the detailed comments.

    - **Spend more time working with stakeholders to explore broader approaches to reducing the cost of prescription drug benefit in the commercial market.** In the meantime, HHS should clarify that the policies proposed in the NBPP are not intended to limit the flexibility that health insurance providers currently have.

    - **Do not finalize the proposed changes to the rule at this time.** But if changes are finalized, we recommend HHS broaden the description of instances in which health insurance providers can employ the practices proposed in the rule and clarify that nothing would preclude health insurance providers from continuing current formulary practices.

- **Premium Adjustment Percentage: Do not adopt changes to the premium adjustment percentage that would make coverage less affordable for consumers and result in coverage losses.** HHS projects that including individual market premiums in the premium adjustment percentage would reduce enrollment through the exchanges by 100,000 people in 2020 and reduce eligibility for premium tax credits. As a result, the federal government would spend $900 million on subsidies to make coverage more affordable for low-income Americans. The proposed change would negatively impact the individual market and we strongly oppose it.

- **Silver Loading: Continue to defer to state authority on oversight of rate approval, permitting states to continue the practice of silver loading if the state determines it is**

the most appropriate solution to the loss of funding for the cost sharing reduction (CSR) benefit. Despite the cessation of federal funding for the CSR benefit, eligible consumers with incomes up to 250 percent of the federal poverty level (FPL) continue to be eligible for reduced cost-sharing benefits. Absent an appropriation by Congress, there needs to be a solution to allow health insurance providers to continue providing this benefit. HHS should continue to provide states the flexibility to permit silver loading to ensure eligible consumers receive CSR benefits.

- **Auto Reenrollment: Maintain current auto reenrollment processes to promote continuous coverage, reduce burdens on consumers, and control administrative costs.** Consumers rely on auto reenrollment to maintain coverage from year-to-year and avoid gaps in coverage that could limit their access to medical care. HHS has invested significant resources and worked tirelessly in partnership with health insurance providers to make this a smooth experience for consumers, to minimize gaps in coverage, and mitigate administrative burdens for exchanges and health insurance providers. We strongly urge HHS to continue to leverage these efforts and maintain auto reenrollment. A recent analysis by Avalere demonstrated that eliminating auto reenrollment could reduce effectuated enrollments by 1 million and result in an increase in premiums of 5.7 percent for people who remain enrolled. We understand one of HHS' concerns is minimizing improper federal expenditures on premium tax credits. We recommend targeted improvements to existing periodic data matching and other program integrity efforts to achieve this goal.

We appreciate the opportunity to offer comments on the proposed 2020 Payment Notice. We remain committed to working with the Administration and other stakeholders to bring greater stability to the individual and small group markets to improve affordability and choice.

Sincerely,

Keith Fontenot
Executive Vice President
Policy and Strategy

Comments on the Proposed Notice of Benefit and Payment Parameters for 2020

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

I. Updates to Risk Adjustment Model

II. Risk Adjustment Data Validation (RADV)

III. Prescription Drug Benefits

IV. Premium Adjustment Percentage

V. Auto Reenrollment

VI. Silver Loading

VII. Executive Summary Requests for Comment

VIII. Other Exchange Establishment Standards (Part 155)

IX. Other Health Insurance Issuer Standards (Part 156)

I. Updates to Risk Adjustment Model

A. HHS risk adjustment (§153.320)

The draft payment notice includes several updates and proposed changes to the ACA risk adjustment model, including updates to the risk adjustment model recalibration. Specifically, the draft payment notice proposes to recalibrate the model by blending the two most recent years of enrollee-level EDGE data (2016 and 2017) with the most recent year of MarketScan data (2017). Beginning in the 2021 benefit year, HHS expects to propose solely using enrollee-level EDGE data for model recalibration.

The draft payment notice does not propose to make changes to the categories included in the ACA risk adjustment models for the 2020 benefit year. However, HHS proposes a pricing adjustment for one RXC coefficient (Hepatitis C) for the 2020 benefit year adult models.

Finally, the draft Payment notice proposes to maintain the same parameters for the high-cost risk pooling program and maintains the cost-sharing reduction factors finalized in the 2019 payment notice.

Recommendations:

- **We support HHS' proposal to continue recalibrating the risk adjustment model based on EDGE data—which reflects the actual data from insurers individual and small-group populations.** Specifically, AHIP supports the proposal to blend the two most recent years of enrollee-level EDGE data (2016 and 2017) with the most recent year of MarketScan data. HHS proposed approach of incorporating the most recent years' claims experience can help promote predictability and stability by reducing year-to-year changes in risk scores. And, by continuing to transition away from MarketScan data toward using insurers actual data, this approach can help promote a more accurate risk adjustment model.

- **We support HHS' proposal to maintain the categories included in the HHS risk adjustment model for the 2020 benefit year—with the addition of a pricing adjustment for one RXC coefficient for the 2020 benefit year adult models.** The draft payment notice proposes a pricing adjustment to the Hepatitis C coefficient to more accurately reflect the expected costs of Hepatitis C drugs. AHIP supports this change as a way to more precisely adjust the coefficient to reflect changing drug prices and to mitigate against the potential for misaligned incentives such as overprescribing. In addition, we also note that the U.S. Preventive Services Task Force (USPSTF) recently issued a draft recommendation statement addressing pre-exposure prophylaxis (PrEP) for the prevention of HIV infection. Based on its review of the evidence, the Task Force recommends that clinicians offer pre-exposure prophylaxis (PrEP)—a daily pill that helps prevent HIV—to all people at high risk of HIV. This is a new Grade A recommendation. While the timing of the final recommendation is uncertain, we recommend that HHS consider future model changes to reflect this development.

- **We support maintaining payment parameters under the high-cost risk pooling program with a threshold of $1 million and a coinsurance rate of 60 percent across all states.** By maintaining the same payment parameters for the 2020 benefit year, HHS can help promote stability and predictability for insurers in their rate setting.

- **We support the proposal on receipt of cost-sharing reductions consistent with the approach finalized in the 2019 payment notice.** This approach can help ensure that the risk adjustment models account for the increased utilization of health care services by lower-income individuals receiving CSR subsidies. Moreover, maintaining the cost-sharing reduction factors finalized in the 2019 payment notice helps promote certainty for insurers participating in the exchange market.

B. Overview of payment transfer formulas (§153.320)

The draft payment notice does not propose changes to the risk adjustment transfer formula but does include an extended discussion about the decision to operate the program in a budget

neutral manner and using statewide average premium as the cost-scaling factor in the state payment transfer formula.

Recommendation:

- **We agree with HHS' detailed explanation in the proposed rule regarding the use of the statewide average premium and the budget neutral nature of the program—expanding on the policy rationale articulated in previous final regulations.** We believe that HHS' rationale for administering the risk adjustment program in budget neutral manner and using statewide average premiums is well-reasoned and supported by the statutory provisions of the ACA for establishing the permanent risk adjustment program. As we have stated previously, the use of statewide average premiums, which is a critical component of the risk adjustment payment methodology, results in balanced payment transfers in a state and helps advance the market stabilizing goals of the program.[1] Other approaches such as using a plan's own premiums are impractical and would work at cross-purposes with the goals and intent of the risk adjustment program. For all these reasons, AHIP supports maintaining the current risk adjustment payment transfer formula for the 2020 benefit year and concurs with HHS' policy rationale for administering the program in a budget neutral manner using statewide average premiums.

  We welcome the opportunity to work with HHS as it considers longer-term improvements to the risk adjustment program on a prospective basis and for future years (e.g., 2021 benefit year and beyond) based on the experience of and learnings from the program's five years of operation.

C. Risk adjustment issuer data requirements (§§153.610, 153.710)

The draft payment notice proposed to make available a limited data set file based on enrollee-level EDGE data submissions used to administer the risk adjustment program that could be used for research, public health or health care operations purposes. HHS proposes to make this information available upon request to increase cost transparency for consumers and other stakeholders. HHS also discusses the extraction of state and rating area from edge data for HHS to use for risk adjustment model recalibration, AV calculator updates, and other ACA programs.

Recommendation:

- **We have serious concerns with making EDGE data publicly available via a limited data set file as proposed in the draft payment notice.** In order to safeguard commercially sensitive and proprietary data, we believe that EDGE data should only be used for internal government purposes including administering the ACA risk adjustment

[1] AHIP Comments on Patient Protection and Affordable Care Act; Adoption of Methodology for the HHS-Operated Permanent Risk Adjustment Program for the 2018 Benefit Year Proposed Rule. September 7, 2018.

program (including model recalibration) and for making updates to the actuarial value (AV) calculator. This approach can help maintaining the integrity of the distributed data collection approach (via plan EDGE data submissions) and guard against unauthorized disclosures that could have negative impacts on the marketplace. The disclosure of such information—via a limited data set file available to researchers and others upon request—could erode insurer confidence in the operations of the risk adjustment program. Further, we do not support the combining of EDGE data with other plan data such as state and rating area data.

D. Risk adjustment user fee for 2020 benefit year (§153.610(f))
The draft payment notice proposes to establish a risk adjustment user fee to operate the program set at $2.16 per billable member per year or $0.18 PMPM. The user fee is established to cover the administrative costs for operating the ACA risk adjustment program—estimated at $50 million.

Recommendation:

- **We support the draft payment notice proposed user fee amount of $2.16 per billable member per year, or $0.18 PMPM.** The proposed increase is reasonable in order to cover the administrative costs of operating the ACA risk-adjustment program.

II. Risk Adjustment Data Validation (RADV)

A. Varying initial validation audit sample size (§153.630(b))
HHS seeks comments on several different approaches for varying the initial validation audit sample size, including approaches that uses HCC failure rates to determine sample size or an alternative approach what would increase sample size based on insurer size alone.

Recommendation:

- **We do not support the proposal to increase audit sample size at this time.** We recommend HHS maintain the current sample size limit of 200 enrollees statewide and not finalize the approaches included in the draft payment notice. Increasing the audit sample size would create undue administrative burden on plans without improving the quality of the outcomes.

B. Second validation audit and error rate discrepancy reporting (§153.630(d)(2))
HHS proposes to shorten the window to confirm the findings of the second validation audit from 30 calendar days to 15 calendar days.

Recommendation:

- **We do not support the proposal to shorten the window to confirm findings from the second validation audit to within 15 calendar days.** While we appreciate the need for timely resolution of discrepancies prior to the release of the summary report on risk adjustment results by the end of June, we would encourage HHS to examine alternative ways to condense and revise timeframes to meet this goal.

C. Error estimation for prescription drugs

HHS proposes to incorporate RXCs into the error estimation methodology beginning with the 2018 benefit year risk adjustment data validation error estimation. HHS is also considering several alternatives for adding RXCs into the risk adjustment data validation error estimation methodology.

Recommendation:

- **We recommend HHS not adopt this proposal to incorporate RXCs into the error estimation methodology.** We believe this proposal would add a significant amount of complexity to the to the RADV process while doing little to improve the error estimation methodology. As such, we recommend HHS maintain the current process for error estimation methodology and not expanding this process to include RXCs. Alternatively, we recommend that RADV audits for RXCs be pursed as a pilot program for at least two years where RXC errors would be treated similar to an EDGE data discrepancy currently used for demographic and enrollment checks. During this pilot, HHS and insurers can gain valuable experience in how best to evaluate RXC errors and understand potential implications as part of the overall RADV process.

D. Risk adjustment data validation adjustments in exiting and single issuer markets and negative error rate outlier markets

The draft payment notice proposes to amend existing policy so that if an exiting insurer is found to have a negative error rate outlier, HHS would not adjust that insurer's risk score and its associated risk adjustment transfers as a result of this negative error rate outlier finding. HHS also seeks comments on the impact of the current approach under the error estimation methodology and the outlier adjustment policy for negative error outlier issuers, or issuers with significantly lower-than-average HCC failure rates, on other issuers in a state market risk pool.

Recommendation:

- **We support HHS proposal to not make adjustments to an exiting insurer's risk score and its associated risk adjustment transfers if it is found to be a negative error rate outlier.** This policy aims to avoid the need for HHS to retroactively reopen a risk pool and potentially adjust other insurers transfers—based on an exiting insurer's

negative error rate. Under this policy, an exiting insurer's risk score and payment transfers would only be reopened if it was found to have a positive error rate (and was overpaid or undercharged based on RADV results).

- **We appreciate HHS soliciting stakeholder feedback on the current error estimation methodology for RADV.** AHIP strongly supports policies that ensure market stability, and we recommend HHS explore ways to help ensure and promote stability in the risk adjustment program and its components. In addition, HHS should consider convening a joint industry stakeholder workgroup to develop effective solutions to ensure the risk adjustment process achieves its goals and fulfils its intended purpose. By bringing industry experts together to work with HHS, this collaborative approach holds promise in developing a more workable and effective approach to risk adjustment, including RADV. This industry workgroup could also support HHS as it considers risk adjustment modifications.

E. Exemptions from risk adjustment data validation

The proposed Payment Notice proposes additional exemptions from RADV requirements—including exempting insurers currently in liquidation or that will soon enter liquidation.

Recommendations:

- **We do not support HHS proposal to exempt insurers currently in liquidation or entering liquidation from RADV requirements.** We have significant concerns that allowing such an exemption could provide incentive for some plans to find ways to take advantage of the exemption without entering liquidation.

- **We support the codification of a materiality threshold policy.** Setting a flat materiality threshold across all markets would not account for variations across markets. An alternative approach would be to exempt plans that account for less than a certain percentage of premiums in a market. If the threshold is set at $15 million for all markets, that number should be updated in future years to account for changes in market conditions, particularly in premium amounts.

III. Prescription Drug Benefits

We strongly support HHS' commitment to addressing the high cost of prescription drugs. Approximately 23% of health insurance premiums are spent on prescription drugs.[2] Controlling these costs is critical to making coverage affordable for all Americans. While we appreciate HHS' emphasis on promoting generic drugs, the proposals in the rule are worded very narrowly and could have the unintended consequences of precluding several other standard industry practices to reduce spending on drugs and promote effective high-value care.

[2] https://www.ahip.org/health-care-dollar/

We recommend that more time should be spent working with stakeholders to explore broader approaches to reducing the cost of prescription drug benefit in the commercial market. In the meantime, HHS should clarify that the policies proposed in the NBPP are not intended to limit the flexibility that issuers currently have.

Promoting Generics

HHS proposes a number of changes to make it clear that formularies and benefit design that promote the use of newly released generic drugs are permitted. They also propose changes to allow reference pricing and not counting drug manufacturers' coupons towards deductibles and out-of-pocket maximums when a generic equivalent to a brand name drug is available. We agree that promoting the use of generic drugs is a proven way to reduce spending on drugs and appreciate HHS recognizing in this rule that plan features that promote generic drugs are permitted.

Today health plans employ many strategies to promote lower-cost generics over their higher-cost branded versions and mitigate increases in drug costs. Health plans typically place generics on lower formulary tiers compared to branded versions, so that patients have lower out-of-pocket costs when they choose generics. Some plans include zero-cost generics as part of a value-based formulary designed to target specific chronic conditions within a population. Other health plan tools to promote generics include (but aren't limited to): mandatory generic-substitution policies, step-therapy, and dispense as written penalties.

Preserving Other Tools to Address Spending on Prescription Drugs

Generic drug promotion is one very important tool to lower spending on drugs. But we are very concerned that the proposals in the rule would preclude several other standard industry practices to reduce spending on drugs and promote effective high-value care.

Drug companies can raise prices at any time and there are many egregious examples of them doing exactly that.[3] To promote clinically effective drugs, protect patients and fight back the premium increases that arise from drug manufacturers' ad hoc price increases, health plans should continue to have the flexibility to make mid-year formulary changes and not count coupons towards accumulators[4] for instances including but not limited to when:

- A biosimilar drug is available; or
- A lower-priced brand-name therapeutic equivalent or authorized generic is available; or

[3] See New York Times article, "Drug Goes From $13.50 a Tablet to $750, Overnight," September 20, 2015. Accessed at: https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html?module=inline. See also New York Times article, "Outcry Over EpiPen Prices Hasn't Made Them Lower," June 4, 2017. Accessed at https://www.nytimes.com/2017/06/04/business/angry-about-epipen-prices-executive-dont-care-much.html?_r=0&module=inline

[4] Accumulators are the operational mechanism issuers use to track enrollee out-of-pocket spending and determine when an enrollee has met their deductibles or annual out-of-pocket max for the plan year.

- A brand-name drug changes its price; or
- An over-the-counter (OTC) version of the drug is available; or
- The issuer becomes aware of a patient safety issue with a drug; or
- There is a shortage of a preferred generic drug; or
- New evidence becomes available about the efficacy of a drug or that expands the indications of a drug; or
- A new drug that is clinically effective becomes available.

Health plan features to incentivize consumers to consider biosimilars is one example of a tool that may be precluded if the rule is finalized as proposed. AHIP strongly supports many of the major elements of the FDA's Biosimilars Action Plan[5] and applauds the FDA for its efforts to foster a more competitive and vibrant market. Our detailed recommendations to support the development and adoption of biosimilars can be found in our response to the Drug Blueprint.[6]

If the provisions in the rule are finalized as proposed, the rule may have the unintended consequence of increasing spending on drugs by inadvertently restricting issuers to controlling costs only when a generic equivalent is available for a brand name drug. To avoid this, we recommend HHS not finalize the proposed changes to the rule at this time. If changes are finalized, we recommend HHS broaden the description of instances in which issuers can employ the practices proposed in the rule and clarify that nothing would preclude issuers from continuing current formulary practices.

A. Clarification of Uniform Modification Rules

In the preamble to the rule HHS asserts that mid-year formulary changes are currently prohibited under uniform modification rules. We disagree with this interpretation of the existing uniform modification rules. The general consensus amongst health plans, consumer groups, and states appears to have been that preamble language in the 2016 Notice of Benefit and Payment Parameters did not prohibit issuers from making mid-year formulary changes. CMS recognized that there could be instances where mid-year formulary changes related to the availability of drugs in the market may be necessary and appropriate.

The preamble commentary reads as follows:

> We are also concerned about issuers making mid-ear formulary changes, especially changes that negatively affect enrollees. We are monitoring this issue to consider whether further standards are needed. We also note that, under guaranteed renewability requirements and the definitions of "product" and "plan," issuers generally may not make

[5] Facilitating Competition and Innovation in the Biological Products Marketplace; Public Hearing; Request for Comments [Docket no. FDA-2018-N-2689]

[6] https://www.ahip.org/wp-content/uploads/2018/07/AHIP-Letter-to-Secretary-Azar-and-Detailed-Comments-RE-FR-Doc.-201810435-HHS-Blueprint-to-Lower-Drug-Prices-and-Reduce-Out-of-Pocket-Costs-FIN.pdf

> plan design changes, including changes to drug formularies, other than at the time of plan renewal. We recognize that certain mid-year changes to drug formularies related to the availability of drugs in the market may be necessary and appropriate.[7]

In August 2016, Consumers Union interpreted this preamble language to indicate that it did not prohibit mid-year formulary changes and made recommendations to both HHS and states to act to limit these changes.[8] Some states have since done so. In the intervening period, health insurance providers have complied with any state restrictions on mid-year formulary changes and FFE QHP issuers have provided information on specific mid-year formulary changes to CMS in the monthly formulary updates they provide as required under §156.122(d)(2).

While we support HHS making it explicit that health insurance providers are able to make mid-year formulary changes to recognize mid-year introduction of generics, we do not agree that changes to formularies mid-year are prohibited by guaranteed renewability or uniform modification provisions in statute.

The current rules governing guaranteed renewability do not explicitly prohibit mid-year formulary changes.[9] The rules provide the circumstances under which health insurance issuers in the specified market may modify health insurance coverage upon coverage renewal consistent with state law and effective on a uniform basis. Formulary changes are not identified as modifications that may only occur upon renewals.

Health insurance coverage is defined elsewhere in the PHSA as "benefits consisting of medical care…" Notably, this statute does not speak to the particular subject at hand – which is whether a health insurance issuer may make a mid-year formulary change. We do not believe that issuers are prohibited under this statute from making mid-year formulary changes nor is HHS directed to promulgate narrow exceptions to permit only generic substitution. HHS has discretion to interpret this language and we describe the policy reasons below that warrant a broader set of circumstances under which mid-year formulary changes are warranted and should continue to be permitted.

B. Mid-Year Formulary Changes (§§146.152, 147.106, 148.122, 156.122)

HHS proposes updates to guaranteed renewability rules under §146.152 (group market), §147.106 (individual, small and large group markets) and §148.122 (individual market) to allow mid-year formulary changes when a generic drug becomes available. Issuers would be permitted to add a newly available generic drug to their formulary mid-year and to remove the associated brand name drug or move it to a higher formulary tier.

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[7] 80 Federal Register at 10822

[8] See https://advocacy.consumerreports.org/wp-content/uploads/2016/08/Promoting-Access-to-Affordable-Prescription-Drugs_Aug-2016.pdf

[9] See §146.152 (group market), §147.106 (individual, small and large group markets) and §148.122 (individual market).

Under the proposed rule, issuers would be required to provide enrollees the option to request the brand name drug under the appeals process specified in §147.136 and the exceptions process specified in §156.122(c). Issuers would also be required to notify all plan enrollees of the formulary change in writing a minimum of 60 days before the change and include specified data elements in the notice. Updates are also proposed to §156.122 to require FFE issuers to report mid-year formulary changes to the Department.

In the commercial insurance market, all decisions about formulary changes are made based on the recommendations of a Pharmacy and Therapeutics Committee (P&T Committee). P&T Committees consist of practicing physicians, practicing pharmacists and other practicing health care professionals who are licensed to prescribe drugs. Committee members are required to be free of conflicts of interest with drug manufacturers and insurance companies. The committee reviews new evidence about drugs as the evidence emerges and meets at least quarterly. The committee may recommend a mid-year formulary change when the committee agrees that sufficient evidence has emerged to demonstrate a new drug is effective or there is a patient safety issue with an old drug. This long-standing practice is explicitly required for plans subject to essential health benefits (EHB) rules under §156.122(a)(3). These committees bring a wide knowledge of clinical issues and concern for patient safety to their recommendation and do not make mid-year formulary change recommendations lightly.

Recommendations:

- **Do not finalize proposed language to limit mid-year formulary changes narrowly to instances in which a new generic is available for a brand name drug.** Defining this option so narrowly in the rule text could preclude many current industry practices to reduce spending on drugs and promote effective high-value care. Mid-year formulary changes should be permitted more broadly, as they are today, to allow issuers to continue to incent patients to consider the most cost-effective drug options and to allow issuers to respond to mid-year drug prices increases, clinical innovations and newly identified patient safety issues.

- **For any mid-year formulary change notification requirement included in the final rule, allow issuers to provide notice to "impacted enrollees" rather than all enrollees and only require notice when the impacted member's drug is being removed from the formulary or moved to a higher tier.** Issuers and PBMs have data and tools to identify enrollees who are taking specific drugs. In fact, in the PRA request released alongside the proposed rule, CMS acknowledges that they would expect issuers to identify affected enrollees using claims data.[10] Standard practice in the group market is

[10] See PRA CMS-10696, available at: https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10696.html?DLPage=2&DLEntries=10&DLSort=1&DLSortDir=descending

for issuer to look back at who has used a drug within the last 120 days when enrollees need to be notified about changes to drug coverage. Issuers have found that this look-back period is adequate to capture the vast majority of enrollees affected by a drug coverage change.

Consumers want targeted communication from their insurance companies to focus on issues that affect them, not every medical condition covered under their plan. Receiving mail about drugs they have never taken for conditions they don't have will confuse and frustrate consumers. Similarly, advance notification of mid-year formulary changes should not be required when the impacted enrollee's cost-sharing will be reduced the next time they fill their prescription. Consumers will welcome those changes and the administrative expense of notifying them in advance is unnecessary.

- **For any mid-year formulary change notification requirement included in the final rule, require notification within 30 days of the change taking effect**.

- **In lieu of creating new formulary change reporting requirements for FFE QHP issuers under §156.122, use the data already being provided in the machine-readable formulary files to gather data on mid-year formulary changes.** FFE QHP issuers already provide monthly updates on their formularies to CCIIO. To minimize regulatory burden and expense, use that data to support the Departments' interest in mid-year formulary changes.

- **In the final rule, clarify that any requirement for FFE issuers to report mid-year formulary changes to HHS applies only to QHPs sold on the FFE.** As drafted, the reference to §147.106, which applies to all individual, small group and large group plans, in the reporting requirement added to §156.122 could be interpreted to mean that FFE QHP issuers must report on all lines of business. The supporting statement for PRA CMS-10696 implies that this was not HHS intent and that the intent was that the requirement apply to FFE QHPS only. Applying the requirement to all lines of business for FFE QHP issuers would create an administrative burden and expense tied to FFE participation that could make issuers that participate in the FFE less competitive in other markets, such as the large group market.

C. Cost-sharing requirements and annual and lifetime dollar limitations (§156.130)

HHS proposes several policy changes related to cost-sharing requirements to promote the use of generic drugs, including: what is included as EHB, which effects the annual out-of-pocket limit under Public Health Service Act (PHS) section 2707(b) and the prohibition on annual lifetime dollar limits under section 2711. Because non-grandfathered group health plans and health insurance issuers are subject to section 2707(b) and all group health plans and group health insurance issuers are subject to section 2711, these policy proposals are applicable to all health coverage and plans.

Reference Pricing
HHS proposes a definitional change to what is considered EHB and proposes that for plans that cover both a brand prescription drug and its generic equivalent plans may consider the brand drug to not be EHB if the generic drug is available and medically appropriate for the enrollee (unless coverage of the brand drug is determined to be required under an exception process). HHS acknowledges that this approach to permitting reference pricing would mean that brand name drugs that have a generic equivalent are not treated as EHB and do not qualify for advance premium tax credits (APTC).

Recommendations:

- **Do not reclassify all brand drugs for which a generic equivalent is available as non-EHB.** We have concerns that the operational and consumer impacts of this unilateral reclassification could outweigh the benefits of reference pricing for those drugs. In some instances, an issuer may wish to cover brand drugs that have a generic equivalent, based on factors such as cost and clinical effectiveness. If these drugs are treated as non-EHB, consumers who receive APTC will experience higher premiums and for those enrollees who currently pay no premium they would now receive a premium bill for the premium attributable to these drugs, causing confusion and frustration.

  Practically speaking, this reclassification cannot be operationalized for the 2020 plan year as what is considered EHB and non-EHB must be reflected in federal and state filing guidelines and templates and those templates cannot be revised in time to meet quickly approaching filing deadlines.

- **We support the option for issuers to include reference pricing for brand name drugs for which a generic equivalent is available but oppose a requirement to do so.** Generic drugs are more cost-effective way to treat many conditions and benefit design that promotes utilization of generic drugs should be permitted. However, issuers need flexibility to design plans that meet consumers' needs in the markets they serve, and cover treatment based on the most current clinical evidence. New benefit design mandates will reduce consumer options and tie issuers' hands as they respond to emerging issues in drug pricing.

  Finally, until patent-gaming issues—such as patent hopping, evergreening, use of patent estates—are addressed, a unilateral prohibition on insurers covering brand name drugs for which a generic drug is available will only drive pharmaceutical manufacturers to more aggressively game to extend patents. Our recommendations to address patent gaming can be found in our response to the Drug Blueprint.[11]

[11] https://www.ahip.org/wp-content/uploads/2018/07/AHIP-Letter-to-Secretary-Azar-and-Detailed-Comments-RE-FR-Doc.-201810435-HHS-Blueprint-to-Lower-Drug-Prices-and-Reduce-Out-of-Pocket-Costs-FIN.pdf

- **We support HHS exploring additional policies to promote reference pricing for drugs and look forward to providing input.**

Cost Sharing & Coupons

We commend HHS for addressing the issue of drug cost-sharing coupons (coupons). Coupons forgo or reduce patients' payments on drugs without addressing a major driver of higher costs for patients – the high price of the actual drug. Until drug makers address sky-high prescription drug prices, these coupons will continue to make health care unaffordable for everyone.

Coupons increase premiums because they steer patients 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 patients' share of treatment cost and satisfy their deductible requirements, removing any incentives for patients to consider lower-cost treatment options. In this way, the coupons make the true cost of a drug essentially unknowable to consumers. Meanwhile, insurers 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 APTC.

For plan years beginning on or after January 1, 2020, HHS proposes that amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to insured patients to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have a generic equivalent are not required to be counted toward the annual limitation on cost sharing.

As noted above, we have concerns that the proposed language will restrict issuers ability to address coupons to only when a generic is available for a brand name drug and only instances where the coupon is provided by a drug manufacturer. We agree with HHS' statement in the preamble that the intent of PPACA was that limits on cost sharing "reflect the actual costs that are paid by the enrollee." Limiting issuers' ability to exclude coupons from counting towards accumulators to only brand name drugs for which there is a generic available would prevent issuers from taking appropriate steps to make sure coupons are not counted as enrollee spending. Such a limitation would also interfere with efforts to have consumers consider taking other drugs in a therapeutic class that are equally effective and lower cost.

HHS asks about operational considerations in excluding coupons from accumulators. Today, there are significant challenges to identifying instances when a coupon has been used. Some issuers can identify coupons, most notably for drugs obtained through a specialty or mail order pharmacy. In most instances, issuers have no way to know when a coupon has been used in a retail pharmacy. To further complicate the issue, coupons often come from entities primarily funded by pharmaceutical manufacturers, such as condition-specific patient groups, not the drug manufacturer. Issuers are working to overcome these challenges and we recommend that the

language in the final rule be broad enough to empower issuers to address coupons generally as they identify ways to do so. In addition, HHS should explore avenues to mandate transparency from manufacturers, entities funded by manufacturers, and pharmacies so that issuers will be made aware when coupons are being used.

Recommendations:

- **The final rule should include language to allow the exclusion of all cost-sharing coupons from accumulators, whether provided by a drug manufacturer or entity primarily funded by drug manufacturers, for all markets.** This is more consistent with the intent of PPACA as described by HHS, that cost-sharing limits reflect actual costs paid by the enrollee.

- **Issuers should be permitted but not required to exclude coupons from accumulators.** Significant operational issues make it impossible to identify and exclude all coupons from accumulators. As part of its price transparency initiatives, HHS should explore ways to compel manufacturers, entities funded by manufacturers, and pharmacies to be transparent about when coupons are used.

- **Federal rules allowing coupons to be excluded from accumulators should pre-empt state rules.**

D. Therapeutic Substitutions

HHS specifically requested comments on therapeutic substitutions, defined as substituting a chemically different compound within one drug class for another drug. Significant savings are possible when plans include incentives for consumers to consider a clinically effective, lower-cost therapeutic equivalent before a high-cost brand name drug. Researchers estimated that $73 billion could be saved in the United States if lower cost therapeutic equivalents were consistently chosen over higher cost brand name drugs.[12] States including Arkansas, Idaho and Kentucky have passed state laws to permit therapeutic substitutions by pharmacies.

A lower-cost therapeutic equivalent might be a generic of a different drug but could also be a chemically different, lower cost brand name drug or a biosimilar. We encourage HHS to continue permitting plan design features, insurer practices and state policies that promote lower cost therapeutic equivalents.

[12] Johansen ME, Richardson C. Estimation of potential savings through therapeutic substitution. JAMA Intern Med. 2016;176(6):769-75. https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2520679

Recommendations:

- **Most urgently, we strongly recommend that HHS not finalize proposed rule text that could be interpreted as a new prohibition on existing plan features that promote therapeutic substitution.**

- **As HHS consider future policies to promote therapeutic substitution, we recommend that policies permit but not require health plans to promote therapeutic equivalents.**

IV. Premium Adjustment Percentage

A. Premium Adjustment Percentage (§156.130)

This annual premium adjustment percentage is a measure of premium growth for health insurance covered compared to 2013. Beginning with the 2020 benefit year, HHS proposes to calculate the premium adjustment percentage using CMS Office of the Actuary (OACT) estimates of projected private and individual market health insurance measure, excluding Medigap and property and casualty. Until now, it has been calculated using average per enrollee employer-sponsored premiums. The proposed premium adjustment percentage for 2020 would be 1.2969271275, which is an increase in private health insurance premiums of approximately 29.7 percent from 2013 to 2019.

Recommendations:

- **We strongly oppose changes to the premium adjustment percentage that would make coverage less affordable for consumers, result in coverage losses, and further destabilize the exchange markets.** The Department's regulatory impact assessment anticipates the proposed change in calculation of premium adjustment percentage would result in a faster premium growth rate, increasing the amount of premium individuals owe, decreasing eligibility for premium tax credits, and make it less likely that consumers with an offer of employer sponsored coverage would be eligible for premium tax credit. HHS estimates 100,000 fewer consumers would enroll in coverage through the exchanges in 2020 and federal spending on premium tax credits would decrease by $900 million.

- **Use of historical individual market premiums would not accurately reflect market trends, but would instead capture volatility driven by market reforms and policy changes in a market that has yet to stabilize.** In the 2015 Payment Notice final rule, HHS finalized a premium adjustment calculation based on employer-sponsored insurance premiums due to fluctuations and risk pricing practices in the individual market in the early years of implementing market reforms. HHS contemplated proposing a new methodology once individual market premium trends stabilized. We understand the logic of including individual market data to measure growth in individual market premiums. However, most of the individual market's premium increases from 2013 through 2018

reflect historical fluctuations due to ongoing policy changes. Premium growth over this period is not necessarily indicative of cost fluctuations in an established market. Specifically, including premium growth beginning in 2013 would reflect the significant impact of the ACA's market reforms, including pre-existing condition protections, more comprehensive covered benefits, ongoing adjustments to exchange policy requirements throughout the early years of implementation, and most recently the loss of cost sharing reduction (CSR) funding and subsequent practice of silver loading. The individual market continues to experience volatility as it adjusts to the introduction of new policy changes like the recent expansion of other coverage options like short term plans and association health plans and the zeroing out of the individual mandate for the 2019 tax year. Using individual market premiums from 2013 onward would not be a true reflection of premium growth, but rather a measure of the impact of significant policy changes, and we strongly oppose this proposal.

- **If the Department finalizes the proposal to include individual market premiums it should adjust the index for policy changes that directly impacted benefit packages, cost-sharing, or morbidity**. Since 2013 the individual market has experienced significant statutory and regulatory changes that have affected premiums. In fact, HHS noted as justification for its decision to exclude individual market from the premium adjustment percentage index in the 2015 NBPP final rule "individual market premiums are likely to be affected by significant changes in benefit design and composition."[13] The Department should continue to exclude from the premium adjustment percentage index changes to premium that are related to key policy changes such as the introduction of guaranteed issue, essential health benefits, or ending of Federal payments for cost-sharing reductions. By including an adjustment, HHS would continue to align the premium adjustment percentage index with premium increases rather than changes in benefit design and composition. As currently proposed, the index captures one-time policy changes rather than reflect underlying medical trends. If this is not technically feasible to make these adjustments at this time, we support the use of employer-sponsored insurance premiums when measuring growth, as it is a better reflection of overall increases in medical costs without the volatility of major policy changes, until such adjustments are possible.

B. Reduced maximum annual limitation on cost sharing (§156.130)

Based on the proposed premium adjustment percentage of 1.2969721275, HHS proposes the 2020 annual limitation on cost sharing would be $8,200 for self-only coverage and $16,400 for other than self-only coverage. This would be a 3.8 percent increase from the 2019 limits of $7,900 for self-only and $15,800 for other than self-only.

[13] 79 FR 13802

To ensure the cost-sharing limits do not result in the actuarial value (AV) of health plans to exceed statutorily-defined metal level limits (i.e., 73, 87, or 94 percent), HHS proposes to reduce the maximum annual limitation on cost sharing for enrollees with household incomes between 200 and 250 percent FPL and 100 and 200 percent FPL.

Recommendation:

- **Due to the timing for publication of the final 2020 Payment Notice, we recommend a safe harbor that would allow issuers to use the proposed MOOP amounts of $8,200 for self-only coverage and $16,400 for other than self-only coverage.** We anticipate the final rule will be published at the same time as most issuers are required to submit form and rate filings to their state regulators. This would give little time for issuers to adjust plan designs if a the final 2020 MOOP values differ from those proposed. A safe harbor would allow issuers to finalize product designs and meet state deadlines.

VI. Auto Reenrollment (84 FR 229)

HHS does not propose changes to the auto reenrollment process (also known as batch auto reenrollment, or BAR, in the FFE). However, the Department discusses several potential challenges with auto reenrollment, including potential eligibility errors, tax credit miscalculations, unrecoverable federal spending, and consumer confusion. HHS seeks input on auto reenrollment processes as well as other policies and processes to reduce eligibility errors and potential government misspending.

Recommendations:

- **We strongly encourage the Department to continue the practice of auto reenrollment in the exchanges to promote a smooth consumer experience, encourage continuous coverage from year to year, and reduce administrative burden for QHP issuers and exchanges. Instead of eliminating auto reenrollment, HHS should enhance existing program integrity measures to promote accuracy of federal expenditures on premium tax credits.**

Affordability

- **Eliminating auto reenrollment would increase premiums for consumers who remain in the market by 5.7 percent by 2025.** [14] A recent Avalere analysis anticipates the decrease in enrollment resulting from eliminating auto reenrollment would result in higher premiums for consumers who remain in the market. Avalere projects eliminating exchange auto reenrollment beginning in 2021 would increase the average risk in the market—many people would lose coverage due to failure to reenroll, and those that

[14] 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

maintain coverage would likely be sicker. As premiums increase due to a sicker risk pool, healthier people would exit the market due to higher premiums. Based on these factors, Avalere projects premiums would increase by 5.7 percent by 2025 compared to current policy. We anticipate additional factors weighed in setting actuarially sound premiums, including significant administrative costs, would likely result in even higher increases.

- **Consumers who do not actively enroll in coverage may be reenrolled off-exchange without subsidies.** Absent auto reenrollment through the exchanges, issuers would continue to be subject to guaranteed renewability and would be required to reenroll consumers off-exchange without subsides. Without premium tax credits to lower monthly premiums or subsidies to lower out-of-pocket costs, most consumers would likely not be able to afford monthly premiums and lose coverage. Consumers may not be able to pay the first month's premium, thus not effectuating coverage, or may terminate for non-payment after attempting to pay the full unsubsidized premium for a few months. Thus, while guaranteed renewability may result in consumers being reenrolled off-exchange, most consumers would effectively lose access to affordable coverage and therefore lose access to important health care services.

- **Auto reenrollment is an important factor in promoting a balanced risk pool.** Consumers who regularly use health care services, for example to manage a chronic condition or fill a prescription drug, are more likely to ensure they maintain coverage through the exchanges. Without auto reenrollment, these consumers would be more likely to actively enroll than young, healthy individuals who do not currently use health care or do not anticipate using it in the coming year. Avalere's analysis anticipates eliminating auto reenrollment and increasing barriers to maintain coverage, would lead to a less balanced risk pool and higher premiums for consumers who remain in the market.

Consumer Impact

- **Recent analysis estimates that eliminating auto reenrollment would lead to 1 million fewer consumers enrolled in the individual market by 2025 compared to current policy.** Avalere analyzed the impact of eliminating auto reenrollment on effectuated coverage and premiums in the individual market. Avalere found eliminating auto reenrollment would lead to substantial reductions in effectuated exchange coverage compared to current auto reenrollment practices with future healthy people exiting the individual market. If HHS eliminates auto-reenrollment beginning in 2021, Avalere projects 1 million fewer effectuated enrollments by 2025 compared to current policy.

- **As a core function of the exchange, consumers rely on auto reenrollment for to maintain coverage through the exchanges and subsidies to make coverage more affordable.** As HHS noted in the preamble, auto reenrollment is common practice in other insurance markets to promote continuity of coverage and reduce administrative burdens. As in Medicare and commercial markets, auto reenrollment creates a pathway

for consumers to maintain coverage without taking action. Consumers may choose auto reenrollment for a range of options—they may be happy with their plan and choose to stay in it; they may have reviewed other plan options, including through consultation with an agent or assister, and decided not to change plans; and/or or they may not have any income or household changes to report. Consumers who enroll in coverage through exchanges have come to expect and rely on auto reenrollment as an easy way to maintain coverage through exchanges and subsidies that help make coverage more affordable. If auto reenrollment was eliminated, consumers who rely on this process could lose coverage and access to subsidies and face gaps in coverage, which can impede access to care. This becomes critically important for consumers who experience a major health event or other extenuating circumstances that make them unable to participate in open enrollment. Even if consumers are auto reenrolled off-exchange under guaranteed renewability, they would be renewed without subsidies. Many would not be able to afford unsubsidized premiums. Consumers who lose coverage or access to subsidies would not have access to health care services or prescription drugs that they rely on and would have to wait until the next open enrollment period to enroll, unless they experience a qualifying life event.

- **Ending auto reenrollment would generate considerable consumer abrasion and significantly increase consumer burden during open enrollment.** Without auto reenrollment, all consumers enrolled in coverage through the exchange would be required to return to healthcare.gov to update the eligibility application, select a plan, and enroll in coverage. For consumers who have not experienced household or income changes or do not want to change coverage, this is an unnecessary step. During 2018 open enrollment, HHS reported a quarter of consumers maintained coverage through auto reenrollment.[15] Individual issuers report approximately half of their enrollees maintain coverage through auto reenrollment, some reporting rates as high as 70 percent. Auto reenrollment reduces, by millions, the number of consumers who need to access healthcare.gov, contact the healthcare.gov call center or issuer call centers, or seek assistance from agents, brokers, and enrollment assisters. It also generates a pre-populated exchange application, which can be accessed and updated by the consumer, exchange, or assister, which substantially reduces the amount of time to update eligibility information. Without auto reenrollment, customer service channels would face significantly higher volumes and consumers would experience long waits to receive assistance and enroll in coverage.

Administrative Costs

- **Auto reenrollment processes significantly lower administrative burden for QHP issuers and exchanges and have been painstakingly implemented and iteratively improved each open enrollment period, at significant cost to issuers and exchanges.** Auto reenrollment is standard practice in Medicare and commercial lines of business. Not

[15] CMS. Health Insurance Exchanges 2018 Open Enrollment Period Final Report. April 3, 2018.

only does it lower burdens on consumers, but it significantly lowers administrative costs for issuers and exchanges. If all consumer were required to actively reenroll in coverage each year, issuers and exchanges would need to make significant investments to implement changes to their IT systems, expand website capacity, and implement modified enrollment and billing processes. In October, AHIP conducted a survey of member plans' costs related to auto reenrollment. We received feedback from seven issuers. Individual issuers' total investments to implement processes related to auto reenrollment ranged from $300,000 to nearly $15 million. Sunk costs to date vary significantly based on the issuer's market share and IT infrastructure. Annual costs to support BAR and OE range from $150,000 to $40 million per issuer. Variable costs vary by issuer's market, target population, and outreach efforts (i.e., sales, marketing/outreach, in-person assistance). These investments would be lost and issuers and exchanges would face steep new administrative costs to overhaul the reenrollment process.

- **QHP issuers and exchanges would need to make significant investments in marketing, outreach, and education to ensure consumers understand they must actively enroll to maintain coverage and subsidies through the exchange.** Many consumers expect to rely on auto reenrollment to maintain coverage and subsidies through the exchanges. To ensure consumers are aware of the new requirement to actively enroll in coverage every open enrollment period, issuers and exchanges would have to make significant investments in marketing, outreach, and education including updating notices and increasing customer service resources. Exchanges and issuers would have to develop additional supports for consumers enrolled off-exchange due to guaranteed renewability to explain the differences in coverage—most importantly, the lack of premium tax credits and CSRs, if applicable, to make coverage more affordable, but also policy changes such as the shorter grace period for non-payment of premiums. Exchanges would need to develop new processes to notify issuers of enrollees who would lose coverage so issuers could renew off-exchange and begin outreach and notification efforts.

Program Integrity

- **Rather than eliminating annual auto reenrollment, we recommend HHS increase program integrity checks to ensure only individuals eligible for exchange coverage are reenrolled and, if applicable, limit inappropriate premium tax credit payments**. In the preamble, the Department raised several concerns that auto reenrollment could lead to eligibility errors, tax credit miscalculations, or expenditures on premium tax credits that cannot be recovered through the reconciliation of APTC through individual federal tax returns. HHS identified 270,000 consumers who were auto reenrolled with zero premium—that is, fully subsidized—through healthcare.gov in 2019. For these consumers, auto reenrollment is an important tool to promote continuity of coverage. There are existing program integrity controls in place to remove premium tax credit for

certain consumers who auto reenroll repeatedly.[16] Specifically, consumers who have not submitted a updated eligibility application for the prior two plan years and for whom the two most recent years of income information is not available from IRS may not be reenrolled with subsidies.

However, the Department raises concerns that auto reenrollment discourages enrollees from returning to the exchange to update household and income information, which would result in inappropriate APTC payments. Issuer and exchange notices provide multiple reminders encouraging consumers to return to the exchange to update their application and confirm their plan selection. Issuers report that up to three quarters of auto reenrolled consumers update or cancel their auto reenrollment, indicating that many consumers respond to issuer and exchange notifications encouraging them to update their exchange eligibility application. Issuers have provided extensive feedback to the Department to work together to improve the timing and content of consumer notices. We welcome the opportunity to continue refining consumer notices to encourage consumers to take action.

HHS also raises concerns about inappropriate APTC payments—specifically, consumers who receive APTC during the year for which they are not eligible but are not required to repay under the ACA's repayment limits. For the 2018 filing season, Treasury reported approximately $3.7 billion, or about 14 percent of the total $27 billion APTC, exceeded the amount of premium tax credit to which taxpayers were entitled. Of that amount, $1 billion, or four percent of total APTC, is above the maximum reconciliation amount and will not be repaid. Treasury reported this is significantly lower than APTC amounts not subject to repayment in prior years.[17] Neither HHS nor Treasury has demonstrated that eliminating auto reenrollment would increase the accuracy of APTC payments and reduce APTC amounts not repaid.

While we strongly oppose eliminating auto reenrollment, we agree with the Department that additional measures should be adopted to promote program integrity and mitigate auto reenrollment of consumers who are not eligible for coverage through exchanges or, if applicable, premium tax credits. We supported changes proposed in recent Exchange Program Integrity proposed rule to require more frequent periodic data matching (PDM) verifications to identify consumers dually enrolled in coverage through the exchanges and Medicare, Medicaid, and the basic health plan. We strongly encourage the Department to finalize those additional PDM requirements for all exchanges. We

[16] 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

[17] Treasury Inspector General for Tax Administration. Results of the 2018 Filing Season. December 19, 2018. https://www.treasury.gov/tigta/auditreports/2019reports/201940013fr.pdf

additionally recommend HHS adopt PDM to remove deceased persons from coverage. Automatic reenrollment of deceased enrollees has been a concern for several years, and was recently highlighted in a GAO report, but has not yet been addressed through exchange program integrity processes.[18,19]

V. Silver Loading (84 FR 283)

HHS does not propose any changes to silver loading for the 2020 benefit year. In the preamble HHS notes the Administration supports a legislative solution to appropriate CSR payments, thus ending silver loading. However, in the absence of legislative action, HHS seeks comments on potential regulatory action to address silver loading in future rulemaking, not applicable earlier than the 2021 plan year.

Recommendations:

- **We strongly recommend HHS continue to defer to defer to states on the approval of rates and continue to permit states to allow silver loading without placing new restrictions on rating practices.** Despite the loss of federal funding for CSR subsidies, consumers with income below 250 percent FPL continue to be eligible for these benefits. A solution is needed to allow issuers to continue to lower out-of-pocket costs for eligible consumers to make coverage more affordable. Following the federal government's announcement that CSR payments to issuers would cease, most states allowed or required issuers to adjust premium rates to account for the loss of CSR funding. Because issuers were still required to provide CSR benefits to eligible individuals, despite lack of payments from the federal government, this approach limited adverse impacts of the loss of CSR payments on most consumers but had the unintended consequence of increasing premiums tax credit spending. Most states took the approach of silver loading whereby issuers incorporated the CSR impact onto silver metal level premiums only. Some states adopted "broad loading", in which the CSR impact was distributed *across premiums for all metal levels* (though some of these states subsequently switched to silver loading). The Department should continue to defer to states in approving rating practices to ensure affordable coverage for its consumers. Restricting states' ability to allow silver loading would increase the number of uninsured and result in consumer-facing premium increases for both those eligible for premium tax credits and those ineligible.

- **We support policies implemented by HHS to provide additional options for consumers ineligible for premium tax credits to mitigate the impacts of silver loading.** As a result of silver loading, consumers who are ineligible for premium tax credits face higher silver level premiums on-exchange. To provide these consumers

[18] *Federal Health Insurance Marketplace: Analysis of Plan Year 2015 Application, Enrollment, and Eligibility-Verification Process.* GAO-18-169. Washington, D.C. December 2017.
[19] We understand CMS is considering implementing a death PDM processes but does not plan to adopt this verification for several more years.

additional options, some states encouraged or required issuers to create "mirror" options off-exchange without a CSR load, providing a lower silver level premium. In August 2018, the Centers for Medicare and Medicaid Services (CMS) issued guidance encouraging this practice. It is impractical, and would be significant administrative costs, to create off-exchange non-silver loaded mirror plans for every variation of metal level, provider network, and cost-sharing. But, offering limited off-exchange alternatives in states that allow the practice, would provide unsubsidized consumers options for lower premiums. As discussed later in our comments, we support the proposed special enrollment period that would allow consumers enrolled in off-exchange coverage to enroll in exchange coverage if they become eligible for premium tax credits due to a decrease in income. For consumers who enroll off-exchange to avoid silver loaded premiums, this creates a path to more affordable coverage if they have a change in income.

- **We strongly discourage requiring states to implement broad loading instead of silver loading, as doing so would disproportionately increase premiums for middle class Americans.**

    - **Broad loading places an unequitable burden on unsubsidized enrollees.** Silver loading provides non-subsidized consumers an option to enroll in less costly bronze or gold coverage, whose premiums exclude CSR loading. Nearly six million unsubsidized exchange enrollees selected a bronze or gold plan during 2018 open enrollment and would likely see double digit premium increases if the Administration requires states to move from a silver load to a broad load.[20]

    - **A switch to broad loading would adversely impact a significant portion of subsidized exchange enrollees, particularly those earning between 250-400% FPL[21]** as it would result in significant premium increases for gold and bronze plans. At the same time, premium subsidies would decrease. Two million subsidized consumers received APTC and selected bronze or gold plans in 2018. These consumers would see exponential increases in their net out-of-pocket premium spending if silver loading is replaced with broad loading.[22]

    - **Under broad loading, premiums for unsubsidized enrollees are projected to increase by 10 percent nationwide compared to premiums under silver**

[20] Enrollment by metal level and APTC status can be found in the 2018 PUF File at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Marketplace-Products/2018_Open_Enrollment.html
[21] For a family of four in the contiguous United States, these are families earning between $62,750 and $100,400 annually.
[22]Enrollment by metal level and APTC status can be found in the 2018 PUF File at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Marketplace-Products/2018_Open_Enrollment.html

loading.[23] A recent analysis by Oliver Wyman estimated premiums for consumers without access to tax credits would increase by 10 percent versus silver loading. The analysis also projected approximately 900,000 fewer consumers would be enrolled in coverage in the individual market in FFE and SBE states.

VII. Executive Summary Requests for Comment (84 FR 229)

A. Transparency Requirements

In the Executive Summary of the proposed rule, the Department seeks comment on ways to provide additional cost-sharing and pricing transparency to consumers including on how to further implement QHP Transparency in Coverage requirements related to enrollee cost-sharing information at §156.220(d) and (2) options to disclose consumer out-of-pocket cost-sharing.

Recommendations:

- **We support providing meaningful information to increase cost-sharing and pricing transparency to help consumers make informed health care decisions.** HHS should seek input from stakeholders on specific transparency data elements ensure information displayed to consumers is meaningful and actionable that builds upon existing data tools that health plans already make available to their enrollees. Transparency data should not add complexity or create confusion for the consumer plan selection experience and should instead be accessed by consumers when they are using their health insurance or seeking care. We encourage the Department to collect the minimum necessary data to support transparency requirements and not impose new administrative costs on issuers. Data collections be narrowly tailored to gather accurate information that is useful to consumers and not impose an undue burden on issuers.

- **We support measures that would provide patients and consumers with as much information as possible to aid in decision-making, plan for care, and anticipate financial responsibility.** For situations when out-of-network care is probable or likely, patients should be informed by their health care provider or facility of the possibility they may be treated unwillingly by an out-of-network provider, what that could mean for their total costs, and their legal rights and care options. Health insurance providers continue to publicize anticipated costs for known treatments, both through the SBC and price estimators and cost-transparency tools voluntarily developed by health plans. Too often, services and drugs come with prices into which neither patients nor plans have insight. As purchasers of health care services, we know that greater transparency about the actual cost of care, including prescription drugs, is essential and would aid both health plans and our member patients in making health planning decisions.

[23] Oliver Wyman. Impact on Members and Premiums of Covering the Cost of the Unfunded Cost Sharing Reduction Program. February 15, 2019. https://avalere.com/press-releases/hhs-proposed-changes-could-reduce-aca-coverage-and-increase-premiums

In certain situations, individuals seeking medical care or other health care services have the opportunity to truly be a consumer, making decisions about which providers, facilities, and pharmacies will provide the best value at the lowest cost. This requires tools that can inform and empower consumers to shop for services and clear disclosure of anticipated costs, including cost-sharing requirements.

B. Surprise Billing

In some circumstances, patients lack any meaningful opportunity to act as a health care consumer, including when treated at a hospital for emergency care or treated at an in-network hospital for any care by an out of network provider they did not request and, often, with whom they never interacted. The latter scenario presents a challenge to disclosing the consumer's anticipated costs, as health plans are often unaware of the network status of many providers treating a member patient. These instances result in what are frequently called "surprise medical bills" and while they increase overall costs and can lead to substantial financial hardship for individual and families, they also prevent health plans from being able to pre-determine or even estimate the financial responsibility of a member patient.

For example, a common scenario would be one such as a patient who schedules a colonoscopy at a hospital they know to participate in their insurance network and with a colorectal surgeon who also participates in the network. For both the hospital and facility fees as well as the fees of the colorectal surgeon, the health plan can predetermine (or at least make a good faith estimate) of the total anticipated costs of the procedure and therefore the patient's cost-sharing responsibilities. However, the patient may – unbeknownst to them – be sedated by an anesthesiologist who does not participate in their insurance network or find that an assistant surgeon who is also out-of-network aided in the surgery. The anesthesiologist and assistant surgeon will then bill the patient for amounts far above what those specialists would have been paid as part of a market-based negotiated rate with a health plan. If the patient has out-of-network benefits, the plan will pay its share of the bill, but without knowing how much these hospital-based providers will charge – indeed not even knowing who would be interacting with the patient – the plan would be unable to identify the member patient's likely financial responsibility.

The issue of surprise medical bills is one that continues to garner significant attention from both Congress and the Administration and we are actively working for a federal solution to reduce these financial burdens on patients. In December, AHIP joined with nine organizations representing consumers, businesses, and insurance providers to promote four principles for needed federal legislation to protect consumers from surprise medical bills.[24] Until plans have

[24] Consumers, Businesses, and Insurance Providers Come Together to Protect Americans from Surprise Medical Bills, December 10, 2018. Press release and principles available at: https://www.ahip.org/health-care-leaders-unite-to-protect-patients-against-surprise-medical-bills/

certainty that out-of-network providers would be paid a rate they could know in advance, this sort of pre-procedure disclosure of cost-sharing would not be feasible.

C. Promotion of HDHPs and HSAs

Visibility on Healthcare.gov

The Department seeks comment on ways to promote the offering and take-up of high deductible health plans (HDHPs) associated with Health Savings Accounts (HSAs) and ways to increase the visibility of HSAs on healthcare.gov and their adoption generally.

Recommendation:

- **We support the Department's efforts to encourage uptake of high deductible health plans eligible for an HSA, when it is appropriate for the consumer's health and financial needs, and to make it easier for consumers to understand when HSA eligible plans are available.** In AHIP's comments in response to the 2019 Proposed Payment Notice, we provided feedback on ways the Department could encourage uptake of HDHP plans in the individual and small group markets. Specifically, we discussed the importance of making HSA-eligible plans more visible to consumers. The first step in increased utilization is better education of consumers and increased visibility of available plan options. Healthcare.gov already has a flag for HSA-eligible plans and allows consumers to filter search criteria to view these plans. To make these search features actionable, additional education—through text, graphic, or video explainers embedded in the shopping experience; assister and agent/broker training; and marketing materials—could help consumers better understand the pros and cons of HDHPs to determine if such a plan would meet their needs.

Addressing Different Out of Pocket Limits

For 2014, the ACA section 1302 (and PHSA section 2707(b)) maximum out-of-pocket amount limit (the ACA MOOP) was tied to the maximum out-of-pocket limit for HSA-compatible HDHPs under Code section 223(c)(2)(A)(ii) (the HSA MOOP). Beginning in 2015, the ACA MOOP was indexed based on the percentage by which the average per capita premium for health insurance coverage in the US for the preceding calendar year exceeds such average per capita premium for 2013. The HSA MOOP, however, was indexed based on the cost of living adjustment, which is the percentage by which the CPI for the preceding calendar year exceeds the CPI for 1992. The result of this difference was that the ACA MOOP has been increasing at a higher rate than the HSA MOOP, which means that HSA-compatible HDHPs had to apply the lower HSA MOOP to comply with both rules. To compound this issue, the Tax Cuts and Jobs Act generally revised the HSA MOOP indexing for 2018 and later to CPI-U rather than CPI and adjusted the base year. CPI-U is expected to grow at a slower rate than CPI. No similar change was made to the ACA MOOP indexing, and thus, the difference between the ACA MOOP and HSA MOOP will be greater each year.

Due to these different indexing factors for the ACA MOOP and the HSA MOOP, many HSA compatible Bronze plans are no longer able to meet the 60-percent AV required for Bronze plans (primarily in states that have not allowed for the plus-2, minus-4 flexibility) when using the lower HSA MOOP. Without some relief by HHS, to remain a Bronze plan, many plans will have to increase their MOOP to the ACA MOOP, which means that they will no longer be HSA-compatible. Contrary to the Administration's intention, this would result in a decrease in the offering and adoption of HSA-compatible HDHPs.

Recommendation:

- **We recommend the Department provide relief for HSA-compatible plans intending to be bronze plans to meet the actuarial value (AV) requirement for bronze plans.** HHS should resolve the unintended result for 2021 and beyond through a modification to the AV calculator to ensure that this AV issue does not prevent insurers from continuing to offer, or beginning to offer, HSA-compatible Bronze plans. To achieve this, HHS should consider accepting an adjusted MOOP amount in the AV calculator that differs from the actual plan MOOP, for plans that are intended to be HSA-compatible. Additionally, for the 2020 plan year, HHS should provide transitional relief for plans that only exceed Bronze-level AV because they use the HSA MOOP limit by deeming those plans to be Bronze level, despite the de minimis variation from the 60-percent AV. Under the statute, the Secretary retains flexibility to "develop guidelines to provide for a de minimis variation in the actuarial valuations used in determining the level of coverage of a plan to account for differences in actuarial estimates."[25] Here, although the de minimis variation in AV (likely less than 2-percent) would not reflect variations in actuarial estimates, it would reflect differences in estimates made by Congress in establishing the index rates for the ACA and HSA limits. It would also promote the offering and adoption of HSA-compatible HDHPs to give consumers an effective and tax-advantageous method to manage their health care expenditures.

VIII. Other Exchange Establishment Standards (Part 155)

A. Navigator program standards (§155.210)

Certain post-enrollment assistance activities—including filing eligibility appeals, applying for exemptions, premium tax credit reconciliation, providing basic concepts and rights related to health care coverage, and referrals to tax preparers and tax resources—were required beginning plan year 2018. HHS now proposes these post-enrollment assistance activities would be optional, effective upon the awarding of the 2019 navigator grants. HHS proposes to streamline navigator training requirements, including eliminating requirements related to post-enrollment activities.

[25] ACA §1302(d)(3)

Recommendation:

- **We encourage HHS to continue to allow navigators to perform post-enrollment assistance activities and including these topics in navigator training.** Post-enrollment assistance—including filing eligibility appeals, applying for exemptions, assisting with premium tax credit reconciliation, providing basic concepts and rights related to healthcare coverage, and referrals to tax preparers and tax resources—help consumers navigate complex concepts and meet obligations related to coverage and subsidies. Consumers would otherwise contact issuer or exchange call centers for assistance with these topics. We support continuing to allow navigators to optionally provide assistance on post-enrollment activities. While this assistance would no longer be a required navigator function, we recommend HHS continue to make training and resources available on these topics so navigators that continue to provide post-enrollment assistance provide accurate information to consumers.

B. Requirements for agents, brokers, and issuers participating in direct enrollment (§§155.220 and 155.221)

To reflect the expansion of enhanced direct enrollment (DE), HHS proposes several changes to formalize the definitions and standards for "web brokers" and "direct enrollment technology partners." HHS consolidates and streamlines the requirements for all agents, brokers, web brokers, and issuers conducting direct enrollment, including requirements for display and marketing of QHPs and non-QHPs in the direct enrollment shopping experience. Specifically, that DE entities must display QHPs and non-QHPs on separate web pages, include a prominent disclaimer to help distinguish between QHPs and non-QHPs and identify subsidy-eligible products, and must separate marketing and display of non-QHP and off-exchange products from the exchange eligibility application and QHP selection process.

Recommendation:

- **We support the proposed changes to standards for direct enrollment entities, the majority of which streamline existing standards or codify sub-regulatory guidance. In particular, we support the requirements for direct enrollment entities to separately sell, display, and market QHPs offered through the exchange and off-exchange plans or non-QHPs.** We agree QHPs and non-QHPs should be segregated during the shopping process and support limitations on marketing non-QHPs during the QHP eligibility application and plan selection process. Allowing marketing or side-by-side display of QHPs and non-QHPs, such as short term plans that do not provide comprehensive coverage and are not eligible for subsidies, could provide a confusing shopping experience as the two types of coverage cannot be compared apples-to-apples. Requiring segregation of QHPs and non-QHPs would mitigate consumer confusion and ensure consumers who seek to enroll in exchange coverage through a direct enrollment website have the QHP shopping experience they expected.

C. Special enrollment periods (§155.420)

The Department proposes a new special enrollment period (SEP) for consumers who are enrolled in individual market coverage off-exchange who become newly eligible for APTC due to a decrease in income. HHS proposes the SEP would only be available to consumers, and their dependents, who had minimum essential coverage (MEC), as described in 26 CFR 1.5000A-1(b) for at least one day in the 60 days prior to the change in income. The consumer would be required to provide evidence of both a change (decrease) in household income and prior MEC. The FFE would use existing pre-enrollment verification processes to confirm eligibility.

Recommendations:

- **We support the proposed SEP to allow consumers who are enrolled in MEC off-exchange to enroll in exchange coverage with APTC when they become newly eligible for subsidies due to a decrease in income.** In the past, we have advocated for a narrow set of SEPs to promote robust participation in the exchanges and a more stable risk pool. However, we acknowledge there are certain scenarios in which an SEP is appropriate to allow qualified individuals to enroll in exchange coverage to access subsidies that make coverage more affordable. For example, consumers who are not currently eligible for premium tax credits may have faced higher premiums in 2018 and 2019 due to silver loading. Some states took steps to address this for the 2018 plan year by allowing issuers to offer QHPs off-exchange that do not include this load. CMS guidance encouraged the offering of unloaded silver level plans off-exchange, both in states that have a silver load and broad load approach.[26] Consumers who enroll in off-exchange coverage to avoid higher premiums due to silver loading should be permitted to enroll in exchange coverage with APTC if they experience a decrease in income that makes them eligible for subsidies.

- **The proposed SEP should be limited to consumers currently enrolled in MEC to promote a stable individual market risk pool.** This SEP should be limited to consumers who are enrolled in comprehensive coverage who become eligible for subsidies. We recommend HHS finalize as proposed the requirement that eligible individuals had MEC, as described in 26 CFR 1.5000A-1(b), for at least one day in the 60 days prior to the change in income. A stable risk pool depends on consumers enrolling in comprehensive coverage for the full benefit year. Thus, the proposed SEP should be limited to consumers enrolled in comprehensive coverage who become newly eligible for subsidies. It should not be available to consumers who enroll in alternate forms of less-comprehensive coverage. We support this SEP based on the existing definition of MEC.

[26] CCIIO. Offering of plans that are not QHPs without "silver loading." August 3, 2018. https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Offering-plans-not-QHPs-without-CSR-loading.pdf

IX. Other Health Insurance Issuer Standards (Part 156)

A. FFE and SBE-FP user fee rates for the 2020 benefit year (§156.50)

For the 2020 benefit year, HHS proposes to lower the user fee for issuers participating in the FFE and SBE-FPs. HHS proposes to reduce the user fee for FFE issuers to 3.0 percent (from 3.5 percent for the 2014 to 2019 benefit years) and the user fee for SBE-FP to 2.5 percent (down from 3.0 percent for the 2019 benefit year). These reductions are based on HHS' estimates of higher premiums and lower enrollment for the 2020 benefit year.

Recommendations:

We support the proposed reduction in user fee for issuers participating in FFEs and SBE-FPs for the 2020 plan year. The user fee for issuers participating in the FFE and SBE-FPs, calculated as a percent of premiums, is collected to support to support administrative functions of the exchanges. As the administrative functions of the exchange evolve, it is appropriate to lower issuer user fee payments. At the same time, the amount of user fees collected has increased as premiums increased due to the need to reflect the cost of cost-sharing reduction benefits. In recent years, the Department has reduced consumer marketing, outreach, and education for open enrollment, and issuers have correspondingly increased their efforts and investment in consumer outreach. With the increased emphasis on direct enrollment, issuers are taking on more administrative and consumer support functions. As the administrative functions performed by the exchange are scaled back, we recommend HHS redirect user fee payments to re-invest in marketing, outreach, and education for future open enrollment periods.

- **We continue to encourage transparency into FFE and SBE-FP user fee spending.** To date, there has been little transparency into the collection or use of federal user fees. We recommend the Department issue a report on the use of the user fee for recent plan years and continue to do so annually. Such reporting should be used to determine the appropriate user fee amount for future plan years as federal expenditures to support exchange functions evolve. Specifically, we recommend the Department increase its investment in marketing, outreach, and education for annual open enrollment in healthcare.gov states.

B. State selection of EHB benchmark plan for plan years beginning on or after January 1, 2020 and Provision of EHB (§§156.111 and 156.115)

In the 2019 Payment Notice, the Department created three new options for states to modify or select a new essential health benefit (EHB) benchmark plan. HHS also proposed to allow states to permit issuers to substitute benefits between EHB categories. For future plan years, HHS proposes that states must submit required documents for selection of a new EHB benchmark plan or notify HHS that it will allow issuers to substitute benefits between categories:

- By May 6, 2019 for the 2021 plan year

- By May 8, 2020 for the 2022 plan year

Recommendation:

- **We support the proposed deadlines for state selection of the EHB benchmark plan and encourage HHS to develop best practices for states to seek stakeholder input.** Prior to adopting EHB benchmark plan changes, states should undertake a rigorous process to review the effectiveness of or gaps in the existing benchmark plan, identify evidence-based solutions, and seek stakeholder input. We recommend HHS issue guidance to states on best practices for this process, including minimum stakeholder notification and input timelines. It is critical that issuers and other stakeholders have sufficient time to review the proposed benchmark plan changes, submit feedback prior to the state's notification of HHS and have sufficient time to make the necessary changes to their plan designs and premium rates. Seeking stakeholder input early in the benchmark development process will promote adoption of benchmark benefits that balance evidence-based benefits with affordability for consumers.

C. Prohibition on discrimination (§156.125)

In the preamble to the proposed rule HHS encourages issuers to take every opportunity to address the opioid epidemic and notes that Medication-Assisted-Treatment (MAT) for opioid addiction has been proven effective in treating opioid disorders. HHS provides clarification on their interpretation of how two rules apply to MAT treatment for opioid addition: §156.125, which prohibits discrimination based on health condition, among other factors; and §146.136 implementing the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA).

Issuers recognize the far-reaching impact of the opioid crisis and are working to provide access to evidence-based treatment and recovery services for patients in need and their families. Health plans are committed to providing access to MAT to help a person address their substance use disorder, along with services such as counseling, peer support services, and community-based support groups. In fact, HHS acknowledges that the majority of QHPs in the FFE and SBE-FPs, (95 percent), included coverage of all four MAT drugs for the 2018 plan year.

HHS lists four specific MAT drugs for which clinical evidence is available: buprenorphine, naltrexone, methadone, and buprenorphine in combination with naloxone. We acknowledge the usefulness of these specific drugs and note that health insurers need the flexibility to apply reasonable medical management to ensure that MAT treatments are evidence-based and safe, consistent with how plans management to other drug classes. We also caution against coverage requirements that dictate the specific dispensing mechanism, particularly when it has not been shown to contribute to safety or effectiveness but may increase costs.

Additionally, a key challenge to providing access to MAT is the widely recognized and very serious shortage of behavioral health clinicians and clinicians trained and qualified to administer

MAT. Health plans are undertaking efforts to help reduce the effects of this shortage - including providing additional training and support for clinicians offering MAT and leveraging technology such as telehealth. But broader stakeholder involvement is critical to more fully address the shortage. Access to methadone, for example, as a treatment for opioid use disorder (OUD), must be provided through a SAMHSA-certified Opioid Treatment Program (OTP). Streamlining the certification process for new OTPs may be a way to help increase MAT capacity. This may be particularly important given that CMS is in the process of implementing a new Medicare benefit category for OUD treatment services furnished by OTPs under Part B.

Recommendations:

- **Provide clarification in the final rule that issuers are not precluded from applying reasonable medical management techniques to MAT as long as those techniques comply with §156.125 and §146.136.**

- **To increase MAT capacity, we encourage HHS to explore ways to streamline SAMHSA's credentialing of new OTPs to increase capacity and access to MAT services.**

D. Requirement to offer "Mirror QHPs" (§156.280)
Beginning with plan year 2020, QHP issuers that provide coverage of non-Hyde abortion services would be required to also offer at least one "mirror QHP" that omits coverage of non-Hyde abortion services in each service area in which it offers QHP coverage through the exchange. The "mirror QHP" would cover identical benefits, excluding non-Hyde abortion coverage. The issuer would have the flexibility to determine the metal level at which the "mirror QHP" is offered. This requirement would not apply in states that require coverage of non-Hyde services in all plans.

HHS seeks comments on the extent to which allowing QHP issuers to determine at which metal level the mirror plan is offered may inhibit access to these plans, as well as ways exchanges and DE partner websites can differentiate the display of "mirror QHPs."

Recommendations:

- **We strongly oppose requiring issuers that cover non-Hyde abortion services to offer a "mirror QHP" that does not offer such coverage as it would create new administrative burdens for issuers and additional complexity for consumers.** While HHS proposes issuers would only be required to offer at least one mirror QHP, issuers would incur a broad range of costs to support offering just one additional plan. The issuer must develop the benefit structure and pricing, submit separate filings, and conduct separate reporting. In addition, issuers and exchanges would need to modify decision support tools, update marketing materials, revise consumer education (e.g., plan

information and shopping tools) and customer service supports to differentiate mirror plans, respond to consumer questions during plan selection, and provide enrollment and post-enrollment support for this new type of plan. In the recent Program Integrity proposed rule, HHS proposed burdensome new requirements for issuers to separately bill and collect premium payments for coverage of non-Hyde services. In tandem, the two rules would create significant new administrative costs for issuers related to coverage of non-Hyde services. While the proposed requirement for mirror QHPs would only apply in states that do not ban or require coverage of those services, issuers who voluntarily cover non-Hyde services should not be penalized for offering comprehensive coverage. Issuers are best positioned to evaluate the coverage needs of consumers in the markets they serve and should have the flexibility to determine what plans are offered.

- **We do not recommend additional requirements for differential display of QHPs that cover non-Hyde services.** Healthcare.gov already has an option to allow consumers to view plans that cover non-Hyde abortion coverage. Additional labels, filters, or other identifiers for plans that cover these services are not necessary. Plan documents and the SBC, which are made available to consumers prior to enrollment already include information regarding coverage or exclusions for non-Hyde services. Plan shopping tools, customer service resources, and other consumer assistance supports should encourage consumers to review the entire package of benefits and enroll in comprehensive coverage that will meet all their health and financial needs, rather than emphasizing one single covered benefit.

- **While we oppose a requirement for mirror QHPs, if finalized, we recommend the effective date be delayed to 2021 in the FFE and SBEs have the flexibility to determine whether to require mirror plans.** We anticipate the final Payment Notice will be published at earliest, in early Spring. At that time, issuers will be in the end stages of finalizing product offerings and premiums for the 2020 plan year. It would be extremely difficult for QHP issuers to develop, price, and complete filings for mirror QHPs by state and federal deadlines. If finalized, we recommend this requirement be delayed until the 2021 plan year so issuers have adequate time to create these additional QHPs. Further, we recommend SBEs have the flexibility to determine whether to require mirror QHPs. SBEs have authority to develop and oversee QHP requirements appropriate for their market. HHS should continue to defer to states, providing state exchanges the flexibility to determine whether to require mirror QHPs. HHS and states should defer to issuers to evaluate the coverage needs of consumers in their marketplaces and provide issuers flexibility to determine which plans would be mirrored.