

SPAN Parent Advocacy Network & Family Voices-New Jersey comments on the Department of Health and Human Services, Centers for Medicare and Medicaid Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations

December 14, 2020

Thank you for the opportunity to comment on the Centers for Medicare/Medicaid (CMS) Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters. The SPAN Parent Advocacy Network (SPAN) is NJ's federally designated Parent Training and Information Center, Family-to-Family Health Information Center, and RSA Transition Parent Information and Training Center. We are the NJ State Affiliate Organization (SAO) of Family Voices, the NJ State Organization of the Federation of Families for Children's Mental Health, and the NJ affiliate of Parent-to-Parent USA. We also house a Military Family 360 Support program. Our comments today are based on our over 30 years of work supporting diverse families in advocacy on behalf of their children as well as in systems improvement activities across the Maternal and Child Health priority areas.

**SUMMARY:**

We understand that the proposed rule covers payment parameters, risk adjustment, cost-sharing, exchange user fees, special enrollment periods; Navigator standards; direct enrollment entities, appeals processes, medical loss ratio program, and acceptance of payments by issuers.

I. Executive Summary

We acknowledge these changes involve amending payment parameters, risk adjustment models in the adult and child models, adding severity, multi-year state risk adjustment transfer reductions of up to 3 years, lowering exchange user fees, raising the annual limit on cost sharing, new special enrollment periods, revising the collection of certain prescription drug data from QHP issuers new direct enrollment option, and State Innovation Waivers under section 1332 of the PPACA.

II. Background

A. Legislative and Regulatory Overview

We appreciate the background information and have commented on many of these.

B. Stakeholder Consultation and Input

We appreciate the opportunity to provide input.

C. Structure of Proposed Rule

We understand that the proposal will make technical and conforming amendments regarding limited and special enrollment periods and procedural changes to the requirements for administrative appeals of CMPs. This would include recalibrating the HHS risk adjustment, and

a two-stage specification in the adult and child models, including severity. We also understand that the definition of direct enrollment technology provider will be changed. **We appreciate** the flexibility for special enrollments including changing to a QHP of a lower metal level and understand that there will be requirements to verify eligibility for at least 75 percent of special enrollments for consumers newly enrolling in Exchange coverage. We further understand that a methodology was proposed for analyzing the impact of preliminary values of the reduced annual maximum limitations. Lastly, we understand that the proposal would establish the definition of prescription drug rebates and other price concessions that issuers must deduct. Our comments in these areas appear below.

### III. Provisions of the Proposed HHS Notice of Benefit and Payment Parameters for 2022

#### A. Part 147 – Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

##### 1. Guaranteed Availability of Coverage (§ 147.104)

We understand that SEPs apply to nongrandfathered plans. **We appreciate** that SEPs apply to those who didn't receive timely notice of a triggering event. **We support** that SEPs apply if “their enrollment or non-enrollment in a QHP is unintentional, inadvertent, or erroneous and is the result of the error, misrepresentation, misconduct, or inaction of an officer, employee, or agent of the Exchange or HHS, its instrumentalities, or a non-Exchange entity providing enrollment assistance or conducting enrollment activities.”

#### B. Section Part 150 – CMS Enforcement in Group and Individual Markets

##### 1. Technical Corrections

We acknowledge that this proposal removes references to “HIPAA” and replaces them with “PHS Act” for clarification.

##### 2. Administrative Hearings

**We support** the proposal to “remove requirements to file submissions in triplicate and instead require electronic filing.” **We also support** the “option of video conferencing as a form of administrative hearing.”

#### C. Part 153 – Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment

Because HHS “did not receive any requests from states to operate risk adjustment for the 2022 benefit year...HHS will operate risk adjustment in every state.” **We support** continuing “a pricing adjustment related to the Hepatitis C drugs.” **We also support** streamlining to “allow states to submit multi-year requests for reductions to transfer calculations under the state payment transfer formula.” **We support** the clarification and expansion of the conflict of interest standards.

##### 1. HHS Risk Adjustment (§ 153.320)

We understand that [T]the HHS risk adjustment models predict plan liability for an average enrollee.

##### a. Updates to Data Used for Risk Adjustment Model Recalibration

**We seek clarification** on the reasoning and implications of “rather than using 2017, 2018 and 2019 enrollee-level EDGE data, we propose to use the 2016, 2017, and 2018 enrollee-level EDGE data.” This would appear to increase inaccuracy as 2019 data would include COVID-19.

#### b. Risk Adjustment Model Updates

We understand that “[B]eginning with the 2022 benefit year, we are proposing two modeling updates to the risk adjustment models.”

##### (1) Changes to the model specifications

We understand that regarding “the two-stage specification, we explored calibrating the adult and child models in two stages: in the first-stage estimation, the model coefficients would be estimated using the current model specifications; and in the second stage, we would re-estimate the model weighted by the reciprocal of the predicted values of relative expenditures from the first step estimation.” *We seek clarification* on the second stage only.

*We are deeply concerned* about “the addition of severe and transplant indicators interacted with HCC counts...Table 3 lists the HCCs that were selected for the severity and transplant indicators.” This appears to be a discriminatory practice.

#### c. Changes to the Enrollment Duration Factors

*We were pleased* to find that “partial year enrollees without HCCs do not have PMPM expenditures that are significantly different compared to full year” for consistency purposes. We understand that comment is being sought on whether “we should implement these model changes starting with the 2022 benefit year, whether we should delay implementation.” *We would suggest* delaying due to the pandemic and associated costs to consumers.

#### d. Pricing Adjustment for the Hepatitis C Drugs

Although we understand that the proposed rule will “continue applying the market pricing adjustment to the plan liability associated with Hepatitis C drugs that has been in place beginning with the 2020 benefit year final risk adjustment models. We continue to believe this market pricing adjustment is necessary to account for the significant pricing changes...” *we are concerned and agree with CMS* that “we also continue to be cognizant that issuers might seek to influence provider prescribing patterns if a drug claim can trigger a large increase in an enrollee’s risk score that is higher than the actual plan liability of the drug claim...”

#### e. List of Factors to be Employed in the Risk Adjustment Models (§ 153.320)

*We seek more details* on the “proposed 2022 benefit year risk adjustment model factors resulting from the equally weighted (averaged) blended factors from separately solved models using the 2016, 2017, and 2018 enrollee-level EDGE data, including all of the proposed model changes detailed above.” as this is unclear.

#### **TABLE 1: Proposed Adult Risk Adjustment Model Factors for 2022 Benefit Year**

*We are concerned* with the gender difference in pricing.

#### **Diagnosis Factors [Table 1]**

*We are deeply concerned* that this list is extremely comprehensive and will adversely affect those with preexisting conditions.

#### f. Cost-Sharing Reduction Adjustments

**We are concerned** with the proposal “to continue including an adjustment for the receipt of CSRs in the risk adjustment models to account for increased plan liability due to increased utilization of health care services” as there should not be a deterrent for appropriate healthcare access and this is a risk the plans take.

g. Model Performance Statistics

We acknowledge that this will be used to “evaluate risk adjustment model performance” but seek more information on blending “the coefficients from separately solved models based on the 2016, 2017, and 2018 benefit years’ enrollee-level EDGE data, we are publishing the R-squared statistic...” as this is unclear.

h. Calculation of Plan Average Premium and State Average Premium Requirements for Extending Future Premium Credits (§ 153.320)

**We agree** with “temporary policies of relaxed enforcement” due to consumers having to “struggle to pay premiums because of illness or loss of incomes or revenue resulting from the COVID-19...”

2. Overview of the HHS Risk Adjustment Methodology (§ 153.320)

**We agree** with continuing “to use the HHS state payment transfer formula that was finalized in the 2021 Payment Notice” and support that the “state payment transfer formula for the 2022 benefit year is unchanged from what was finalized for the previous benefit year.”

3. State Flexibility Requests (§ 153.320(d))

We understand that “[I]n the 2019 Payment Notice, we provided states the flexibility to request a reduction to the otherwise applicable risk adjustment state transfers calculated by HHS under the state payment transfer formula...”

a. Requests to Reduce Risk Adjustment Transfers for the 2022 Benefit Year

We acknowledge that “[F]or the 2022 benefit year, HHS received a request to reduce risk adjustment state transfers for the Alabama individual and small group markets by 50 percent.”

b. Multi-Year State Flexibility Requests

We understand that this proposal will “allow states to request a reduction to otherwise applicable risk adjustment state transfers calculated under the HHS-operated risk adjustment methodology for up to 3 years, beginning with the 2023 benefit year.” We acknowledge that HHS will have “authority to approve a shorter duration than that requested by the state if the supporting evidence...” **We agree** with the proposal that “beginning for the 2023 benefit year, all multi-year reduction requests would be published in the annual HHS notice of benefit and payment parameters.” This will increase transparency and help identify systemic issues.

4. Audits and Compliance Reviews of Issuers of Reinsurance-eligible Plans (§ 153.410(d)) and Audits and Compliance Reviews of Issuers of Risk Adjustment Covered Plans (§ 153.620(c))

a. Audits and Compliance Reviews of Issuers of Reinsurance-eligible Plans (§ 153.410(d))

We understand that “HHS encountered significant challenges that impeded its ability to efficiently administer and complete the audits. More specifically, HHS experienced difficulties receiving requested audit data and materials in a timely fashion...obtaining data from these

issuers in a format that was usable by HHS.” *We agree* with additional audit requirements, compliance, and consequences. This would include additional oversight by HHS. *We agree* that “if an issuer fails to comply...HHS would notify the issuer that HHS may recoup any payments identified as not adequately substantiated...”

b. Audits and Compliance Reviews of Issuers of Risk Adjustment Covered Plans (§ 153.620(c))

We understand that “HHS intends to begin audits of issuers of risk adjustment covered plans to ensure the proper payment of high cost risk pool payments and confirm compliance with applicable requirements.”

5. EDGE Discrepancy Materiality Threshold

We understand that “an issuer of a risk adjustment covered plan must provide to HHS, through their EDGE server, access to enrollee-level plan enrollment data, enrollee claims data, and enrollee encounter data as specified by HHS for a benefit year.” This will help identify systemic issues.

6. Risk Adjustment User Fee for 2022 Benefit Year (§ 153.610(f))

As stated previously, no states have chosen to do risk adjustment so “HHS will be operating the risk adjustment program in every state and the District of Columbia.”

7. Risk Adjustment Data Validation Requirements when HHS Operates Risk Adjustment (HHS-RADV) (§ 153.630)

We understand that to “ensure the integrity of the HHS-operated risk adjustment program, HHS conducts risk adjustment data validation (HHS-RADV).

a. Exemptions from HHS-RADV (§ 153.630(g))

We understand that the proposal will “codify the previously established exemption for issuers who only offer small-group carryover coverage in the state during the benefit year being audited at new proposed § 153.630(g)(4)...We also propose to codify the previously established exemption for issuers who are the sole issuer in a state market risk pool during the benefit year that is being audited...” We acknowledge that “[T]hese exemptions do not introduce new policies; instead, the proposed amendments to §153.630(g) are simply to codify these previously established exemptions in regulation.”

b. IVA Requirements (§ 153.630(b)(3))

*We agree* that to ensure the “[E]ntity is reasonably free of conflicts, the IVA Entity must also not have or previously have had a role in establishing any relevant internal controls of the issuer related to risk adjustment or serve in any capacity as an advisor to the issuer regarding the IVA.”

c. HHS-RADV Administrative Appeals

*We agree* that “only those issuers who have insufficient pairwise agreement between the IVA and second validation audit will receive a Second Validation Audit.”

d. Timeline for Collection of HHS-RADV Payments and Charges

We understand that “[I]n the 2020 Payment Notice, we finalized an updated timeline for the publication, collection, and distribution of HHS-RADV adjustments to transfers. This timeline allowed issuers to report HHS-RADV adjustments in a later MLR reporting year and to consider, in accordance with any guidance from the state DOIs, these adjustments in rate setting during a later benefit year.” We further understand that “[B]eginning with 2019 benefit year HHS-RADV, we propose to revert to the previous schedule for the collection of HHS-RADV charges and disbursement of payments.”

e. Second Validation Audit and Error Rate Discrepancy Reporting Windows

We understand that this rule proposes to “shorten the window to confirm the findings of the SVA (if applicable) or the calculation of the risk score error rate.” Previously issuers had 30 days.

8. Risk Adjustment Data Reporting Requirements for Future Premium Credits (§ 153.710)

As stated above, “HHS issued an interim final rule on COVID-19 wherein we set forth risk adjustment reporting requirements for issuers offering temporary premium credits in the 2020 benefit year to align with the relaxed enforcement policy announced in guidance. For the 2021 benefit year and beyond, we propose to permanently adopt these risk adjustment reporting requirements for all health insurance issuers in the individual and small group markets.”

D. Part 155 – Exchange Establishment Standards and Other Related Standards under the Affordable Care Act

1. Definitions (§ 155.20)

a. Definitions of QHP Issuer Direct Enrollment Technology Provider and Agent or Broker Direct Enrollment Technology Provider

We understand the proposal will “add a definition of QHP issuer direct enrollment technology provider, which we propose to mean a business entity that provides technology services or provides access to an information technology platform to QHP issuers to facilitate participation in direct enrollment.”

b. Definition of Exchanges

**We agree** with the definition of exchanges as “State Exchanges, also called State-based Exchanges (SBEs); Federally-facilitated Exchanges (FFE); State-based Exchanges on the Federal platform (SBE-FPs); and the new proposed Direct Enrollment (DE) Exchanges (FFE-DEs, SBE-FP-DEs, or SBE-DEs).”

2. Consumer Assistance Tools and Programs of an Exchange (§ 155.205)

**We agree** with the technical change to “replace all references in § 155.205(c) to ‘an agent or broker subject to § 155.220(c)(3)(i)’ with the term ‘web-broker.’” However, **we disagree** with allowing “QHP issuers and web-brokers participating in the FFE EDE program additional time to come into compliance with the website content translation requirements.” In order to be operating on the exchange, issuers and brokers must be accessible to all.

3. Navigator Program Standards (§ 155.210)

**We disagree** with the proposal with “allowing, but not requiring, Navigators and CACs in FFEs and SBE-FPs to use web-broker non-Exchange websites to assist consumers with applying for insurance affordability programs and QHP enrollment under certain circumstances and to the

extent permitted by state law.” There is already confusion on the part of consumers regarding exchanges and brokers/Navigators/Assisters.

#### 4. Ability of States to Permit Agents and Brokers to Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs (§ 155.220)

##### a. Navigator and Certified Application Counselor Use of Web-broker Websites

Here again *we disagree* with the proposal to “permit, but not require, assisters in FFEs and SBE-FPs to use webbroker non-Exchange websites to assist consumers with QHP selection and enrollment, provided the non-Exchange website meets certain conditions.” There should be “no wrong door access” through exchanges.

##### b. QHP Information Display on Web-broker Websites

We seek clarification on the proposal to “provide flexibility to web-brokers regarding the information they are required to display on their non-Exchange websites for QHPs”.

##### c. Web-broker Operational Readiness Review Requirements

We seek additional details on the proposal to “clarify the operational readiness requirements applicable to web-brokers.”

#### 5. Standards for Direct Enrollment Entities and for Third Parties to Perform Audits of Direct Enrollment Entities (§ 155.221)

##### a. Direct Enrollment Entity Plan Display Requirements

We understand that “the web-broker or QHP issuer must display and market QHPs offered through the Exchange, individual health insurance coverage as defined in § 144.103 offered outside the Exchange (including QHPs and non-QHPs).” We would recommend that non-QHPs be identifiable to consumers.

##### b. Direct Enrollment Entity Operational Readiness Review Requirements

We seek additional clarification on “additional detail on the operational readiness requirements for direct enrollment entities” similar to web brokers.

##### c. FFE, SBE-FP, and State Exchange Direct Enrollment Options

We understand that “CMS has taken a number of actions to reduce the burden on states in establishing State Exchanges.”

##### (1) Federally-Facilitated Exchange Direct Enrollment (FFE-DE) and State Exchange on the Federal Platform Direct Enrollment (SBE-FP-DE) Options

We agree with the proposal of “an option for any FFE or SBE-FP state to request the use of direct enrollment as the enrollment avenue through which individual market consumers and qualified individuals.” However, *we would suggest* support services for consumers as needed.

##### (2) State Exchange Direct Enrollment Option (SBE-DE)

We agree that “a State Exchange that does not rely on the federal eligibility and enrollment platform can also elect the Exchange Direct Enrollment option.”

#### 6. Certified Applications Counselors (§ 155.225)

We agree with the proposal “to allow, but not require, certified application counselors to assist consumers with applying for eligibility for insurance affordability programs and QHP enrollment through web-broker websites under certain circumstances.”

7. Verification Process Related to Eligibility for Insurance Affordability Programs (§ 155.320)

We appreciate that HHS “not perform random sampling as required by paragraph (d)(4) and will extend this nonenforcement posture from plan year 2021 through plan year 2022.”

8. Special Enrollment Periods (§ 155.420)

a. Exchange Enrollees Newly Ineligible for APTC

We **strongly support** the proposal to “allow current Exchange enrollees and their dependents to enroll in a new QHP of a lower metal level<sup>153</sup> if they qualify for a special enrollment period due to becoming newly ineligible for APTC.”

b. Special Enrollment Periods – Untimely Notice of Triggering Event

We **strongly agree** with the proposal “to allow a qualified individual, enrollee, or dependent who did not receive timely notice of a triggering event and was otherwise reasonably unaware that a triggering event occurred to select a new plan within 60 days of the date that he or she knew...”

c. Cessation of Employer Contributions to COBRA as Special Enrollment Period Trigger

We understand that the “Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA)<sup>159</sup> (Pub. L. 99-272, April 7, 1986) provides for a temporary continuation of group health coverage following, among other circumstances, employees’ separation from an employer, for reasons other than gross misconduct, in instances where such separation would otherwise cause termination of coverage.” We **agree** that discontinuation of COBRA is a triggering event warranting special enrollment.

d. Special Enrollment Period Verification

We **support** the proposal to “require that Exchanges conduct special enrollment period verification for at least 75 percent of new enrollments.”

9. Required Contribution Percentage (§ 155.605(d)(2))

We **strongly disagree** with the “increase of about 6.4 percent over the 2021 premium adjustment percentage (1.4409174688÷1.3542376277).” This should not be done during a pandemic when families are struggling economically and having difficulties accessing health care.

10. Excluding the Special Enrollment Period Trigger in § 155.420(d)(1)(v) from Applying to SHOP Plans (§ 155.726)

We understand that “Special enrollment periods due to cessation of employer contributions to COBRA continuation coverage are generally not available in the group insurance market. Therefore, in order to maintain consistency between SHOP and the rest of the group insurance market, we propose to amend § 155.726(c)(2)(i) to exclude the special enrollment period trigger in proposed paragraph § 155.420(d)(1)(v) from applying to SHOP plans.”

E. Part 156 – Health Insurance Issuer Standards under the Affordable Care Act, Including

## Standards Related to Exchanges

### 1. User Fee Rates for the 2022 Benefit Year (§ 156.50)

#### a. FFE and SBE-FP User Fee Rates for the 2022 Benefit Year (§ 156.50(c))

We understand that “[A]s in benefit years 2014 through 2021, issuers seeking to participate in an FFE in the 2022 benefit year will receive two special benefits not available to the general public: (1) the certification of their plans as QHPs; and (2) the ability to sell health insurance coverage through an FFE to individuals determined eligible for enrollment in a QHP.”

#### b. FFE-DE and SBE-FP-DE User Fee Rates for the 2023 Benefit Year (§ 156.50(c)(3))

**We agree** with the proposal to “charge issuers offering QHPs through an FFE-DE or SBE-FP-DE a user fee rate calculated based on the proportion of FFE user fee eligible costs incurred by HHS that are associated with implementation and operation of the FFE-DE or SBE-FP-DE.”

#### c. State User Fee Collection Administration (§ 156.50(c)(2))

We understand that HHS proposes “to eliminate the state user fee collection flexibility.”

#### d. Eligibility for User Fee Adjustments for Issuers Participating through SBE-FPs (§ 156.50(d))

**We agree** with the proposal “to amend § 156.50(d) to clarify that issuers participating through SBE-FPs are eligible to receive adjustments to their federal user fee amounts that reflect the value of contraceptive claims they have reimbursed to third-party administrators (TPAs) that have provided contraceptive coverage on behalf of an eligible employer.”

#### e. Request for Comments on Alternatives to Exchange User Fees (§ 156.50)

We understand the HHS recognizes “the concerns with the Exchange user fee, we are considering and seek comment on both the appropriateness of an alternative revenue source and the type of an alternate revenue source to ensure Exchanges can cover the costs of the Exchange in an effective, appropriate, and fair manner.” We have no suggestions at this time.

### 2. State Selection of EHB-Benchmark Plan for Plan Years Beginning on or after January 1, 2020 (§ 156.111)

#### a. Annual Reporting of State-Required Benefits

**We strongly agree** with the requirement of states “to annually notify HHS in a form and manner specified by HHS ...of any state-required benefits applicable to QHPs in the individual and/or small group market that are considered to be “in addition to EHB” in accordance with § 155.170(a)(3).”

#### b. States’ EHB-Benchmark Plan Options

We understand that the proposal will be “May 6, 2022, as the deadline for states to notify HHS that they wish to permit between-category substitution for the 2023 plan year. States wishing to make such an election must do so via the EHB Plan Management Community.”

### 3. Premium Adjustment Percentage (§156.130)(e)

We understand that HHS proposes “the 2022 benefit year annual premium adjustment percentage using the most recent estimates and projections of per enrollee premiums for private health insurance.”

a. Maximum Annual Limitation on Cost Sharing for Plan Year 2022

**We strongly oppose** the proposal to increase the maximum annual limitation on cost sharing for the 2022 benefit year based on the proposed value calculated.” This should not be done in the midst of a pandemic.

b. Reduced Maximum Annual Limitation on Cost Sharing (§ 156.130)

We understand the HHS proposes “for the 2022 benefit year and beyond, unless changed through notice-and comment rulemaking, to use the reductions in the maximum annual limitation on cost sharing for cost-sharing plan variations determined by the methodology.”

c. Publication of the Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage (§ 156.130)

Here again **we disagree** with the proposal of “reductions to the maximum annual limitation on cost sharing as well as the methodology” during COVID-19.

4. Network Adequacy Standards (§ 156.230)

We understand that the rule proposes to “codify this longstanding interpretation at paragraph (f) to provide that a plan that does not vary benefits based on whether the issuer has a network participation agreement with the provider that furnishes the covered services does not comply with the network adequacy standards at paragraphs (a) through (e) in order to be certified as a QHP. This proposal would simply clarify existing QHP requirements and would not change or add any additional QHP certification requirement.”

5. Termination of Coverage or Enrollment for Qualified Individuals (§ 156.270)

We appreciate that there is no proposal of “any changes to § 156.270(b)(1) beyond what we finalized in the 2021 Payment Notice.”

6. Prescription Drug Distribution and Cost Reporting by QHP Issuers (§ 156.295)

We understand that this proposal will “codify in regulation the statutory requirement that PBMs that are under contract with an issuer of one or more QHPs report the data required by section 1150A of the Act.”

b. Reporting of Data by Pharmacy Type

Section 1150A(b)(1) of the Act requires the Secretary to collect certain QHP prescription

We understand that to “reduce the burden of this collection, we propose to revise § 156.295(a)(1) to remove the requirement to report the data described at section 1150A(b)(1) of the Act by pharmacy type.”

7. Oversight of the Administration of the Advance Payments of the Premium Tax Credit, Cost-sharing Reductions, and User Fee Programs (§ 156.480)

a. Application of Requirements to Issuers in State Exchanges and SBE-FPs

As stated previously, **we support** HHS “expanding the audit authority.”

b. Audits and Compliance Reviews of APTC, CSRs, and User Fees (§ 156.480(c))

As stated above *we also support* the “amendments to § 156.480(c) to expand the oversight tools available to HHS beyond traditional audits.”

8. Subpart I—Enforcement Remedies in Federally-Facilitated Exchanges; Available remedies; Scope. (§ 156.800)

*We agree* that “HHS can collaborate with State Exchanges, SBE-FPs, and state authorities to proactively address non-compliance.” *We would suggest* provision of technical assistance when needed, and corrective action if necessary.

9. Bases and Process for Imposing Civil Money Penalties in Federally-facilitated Exchanges (§ 156.805)

As stated above, *we agree* with the proposal to “amend § 156.805 to more clearly reflect HHS’s authority to impose CMPs due to non-compliance.”

10. Subpart J – Administrative Review of QHP Issuer Sanctions (§§ 156.901, 156.927, 156.931, 156.947)

*We agree* with the technical change of “the title to subpart J, removing the reference to “in Federally-Facilitated Exchanges” to make clear it applies to QHPs participating in any Exchange type.” *We agree* also to “remove requirements to file submissions in triplicate and instead require electronic...”

11. Quality Rating System (§ 156.1120) and Enrollee Satisfaction Survey System (§ 156.1125)

*We strongly agree* with the proposal to “make the full QHP Enrollee Survey results publicly available in an annual Public Use File (PUF)” to increase transparency and consumer satisfaction.

12. Dispute of HHS Payment and Collections Reports (§ 156.1210)

*We agree* that “this proposed flexibility does not reduce an issuer’s obligation to make a good faith effort to identify and promptly report discrepancies within the 90-day reporting window established under § 156.1210(a).”

13. Payment and Collection Processes (§ 156.1215)

*We agree* with the proposal to “eliminate state user fee collection flexibility that HHS had previously offered to states in 2017 Payment Notice, and propose to conforming amendments to remove the reference to “State” governments from paragraph (b).”

14. Administrative Appeals (§ 156.1220)

*We agree* with the addition of “‘if applicable’ when discussing an issuer’s ability to appeal the findings.” *We also agree* with the amendment to “clarify that the 30-calendar day timeframe to file a request for reconsideration of second validation audit findings (if applicable).”

15. Enrollment process for qualified individuals (§ 156.1240)

**We agree** with the proposal to streamline to allow “issuers offering individual market QHPs to accept payments of premiums that are received directly from an individual coverage HRA or QSEHRA that are made on behalf of an enrollee who is covered by the individual coverage HRA or QSEHRA.”

#### F. Part 158 – Issuer Use of Premium Revenue: Reporting and Rebate Requirements

##### 1. Definitions (§ 158.103)

**We agree** with establishing “the definition of prescription drug rebates and other price concessions that are deducted from incurred claims for MLR reporting and rebate calculation purposes” as this will enhance clarity.

##### 2. Premium Revenue (§ 158.130)

**We agree** that “issuers must account for temporary premium credits provided to enrollees during a declared PHE as reductions in earned premium for the applicable MLR reporting years, consistent with any technical guidance.”

##### 3. Rebating Premium if the Applicable Medical Loss Ratio Standard is Not Met (§ 158.240)

**We agree** with the proposal to “allow issuers to prepay a portion or all of their estimated rebates to enrollees for any MLR reporting year regardless of the form in which they are paid.”

##### 4. Form of Rebate (§ 158.241)

**We further agree**, “to allow issuers to provide rebates in the form of a premium credit prior to the date that the rules currently provide...”

#### G. Part 184 – Pharmacy Benefit Manager Standards under the Affordable Care Act

##### 1. Prescription Drug Distribution and Cost Reporting by Pharmacy Benefit Managers (§§ 184.10 and 184.50)

We understand that this will “codify in regulation the statutory requirement that PBMs under contract with QHP issuers report the data described at section 1150A(b) of the Act to the Secretary and to each QHP for which the PBM administers the prescription drug benefit.”

#### IV. Provisions of the Proposed Rule for State Innovation Waivers

##### A. 31 CFR Part 33 and 45 CFR Part 155 – State Innovation Waivers

##### 1. Section 1332 Application Procedures (31 CFR 33.108 and 45 CFR 155.1308), Monitoring and Compliance (31 CFR 33.120 and 45 CFR 155.1320), and Periodic Evaluation Requirements (31 CFR 33.128 and 45 CFR 155.1328)

##### Section 1332 of the PPACA

**We strongly agree** “to provide certainty to states that the requirements and expectations of the section 1332 program will not change abruptly, or without notice to states and the public and an opportunity to comment, during a period in which states are doing the work to prepare a section 1332 waiver proposal that would satisfy the statutory guardrails or during a state’s approved waiver period.”

#### V. Collection of Information Requirements

##### A. Wage Estimates

##### B. ICRs Regarding State Flexibility for Risk Adjustment

- C. ICRs Regarding Submission of Adjusted Premium Amounts for Risk Adjustment
- D. ICRs Regarding Direct Enrollment Agents and Brokers
- E. ICRs Regarding Prescription Drug Distribution and Cost Reporting by QHP Issuers and PBMs
- F. ICRs Regarding Medical Loss Ratio
- G. ICRs Regarding State Innovation Waivers
- H. ICRs Regarding Special Enrollment Period Verification (§ 155.420) State Exchanges
- I. Summary of Annual Burden Estimates for Proposed Requirements  
*We agree* with the estimates and have no further comments in this area.

#### J. Submission of PRA-related Comments

We understand that a copy of this proposed rule has been submitted to OMB for its review.

#### I. Response to Comments

We understand not to expect a response due to the large number of public comments.

### VII. Regulatory Impact Analysis

#### A. Statement of Need

We understand that this rule covers risk adjustment program, premium adjustment percentage, exchange user fees, special enrollment periods; Navigator program standards, direct Enrollment, administrative appeals, medical loss ratio, reporting of certain prescription drug Information, new direct enrollment, and State Innovation Waivers.

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#### B. Overall Impact

We understand that HHS “has concluded that this rule is likely to have economic impacts of \$100 million or more in at least one year, and therefore, meets the definition of ‘significant rule’ under Executive Order 12866.”

#### C. Impact Estimates of the Payment Notice Provisions and Accounting Table

*We agree* with the estimates and have no further comments on this issue.

#### D. Regulatory Alternatives Considered

Although we appreciate the documentation of alternatives considered, *we would strongly recommend* no changes, or only those that benefit consumers during the pandemic.

#### E. Regulatory Flexibility Act

We understand that the “Secretary has determined that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals.”

#### F. Unfunded Mandates

We understand that “[A]lthough we have not been able to quantify all costs, we expect the combined impact on state, local, or Tribal governments and the private sector to be below the threshold.”

#### G. Federalism

We understand that “this regulation has federalism implications due to potential direct effects on the distribution of power and responsibilities among the state and federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets.”

#### H. Congressional Review Act

We understand that this proposed rule has “been transmitted to the Congress and the Comptroller for review.”

#### I. Reducing Regulation and Controlling Regulatory Costs

We understand that “new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.”

Thank you again for the opportunity to provide input on the CMS 2022 payment parameters, pharmacy benefits, and 1332 waivers.

Sincerely,



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***To empower families and inform and involve professionals and other individuals interested in the healthy development and education of children, to enable all children to become fully participating and contributing members of our communities and society.***