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Via: www.regulations.gov

October 28, 2011

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: **CMS-9975-P**
P.O. Box 8010
Baltimore, Maryland 21244-8010

Re: CMS-9975-P: Patient Protection and Affordable Care Act: Standards Related to Reinsurance, Risk Corridors and Risk Adjustment

Dear Sir or Madam:

Consumers Union, the advocacy division of nonprofit Consumer Reports[1], submits these comments on the July 11, 2011 proposed regulation on "standards relating to reinsurance, risk corridors and risk adjustment." Our comments address selected portions of the proposed regulation solely related to **risk adjustment**. We believe that getting risk adjustment "right" is perhaps the most critical step required under the Affordable Care Act to level the playing field among plans in the individual and small group markets, to fully realize the benefit of eliminating medical underwriting, and to ameliorate adverse selection. Our comments that follow specifically focus on creating the right conditions for a successful risk adjustment system that is viewed as credible both by plans and the public, avoids conflicts of interest, and ensures that the ACA's requirement for single, statewide risk pools is accomplished in each state.

Part 153 – Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment under the Affordable Care Act

Subpart B – State Notice of Insurance Benefits and Payment Parameters

§ 153.100 Establishment of State insurance benefits and payment parameters

[1] Consumer Reports is the world's largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, website, and other publications. Its advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and in the marketplace.

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§153.100(a) General requirement

We strongly support the requirement that a State operating an Exchange publish an annual notice to disseminate information to health insurers and other stakeholders including consumers about the specific parameters the State will use in its reinsurance and risk adjustment programs. The State should indicate in its notice an explanation of why it is choosing to use these specific parameters instead of using those specified for reinsurance and risk adjustment programs included in the annual Federal notice of benefit and payment parameters.

§ 153.110 Standards for the State Notice

§153.110(b) Risk adjustment content

We support the requirement that the State notice indicates the rationale for why the State is modifying a Federal risk adjustment parameter, so that stakeholders can determine whether such modified parameters are warranted.

The proposed wording at §153.110(b), however, should be clarified. As noted in the preamble to §153.310 and in our comments below, section 1343(a) of the Affordable Care Act clearly requires that for purposes of risk adjustment, risk pools are required to be aggregated at the State level. States do not have any discretion in this matter and cannot opt to establish other risk pools for purposes of risk adjustment that are not statewide. As a result, the proposed rules should strike any reference to "establishment of risk pools." Moreover, proposed §153.320 clearly distinguishes between a Federally-certified risk adjustment methodology and the risk adjustment model used in conjunction with that methodology. This proposed rules should be amended accordingly. Finally, there is no federal methodology for risk adjustment data validation, though as we note in our comments to §153.350(a) and (b) below, we recommend that HHS determine the manner in which States shall conduct such audits. The proposed rules should be modified accordingly.

Specific Recommendation: Amend §153.110(b) as follows.

"(b) *Risk adjustment content.* If a State operating an Exchange intends to modify a Federal risk adjustment parameter, the State notice must provide a detailed description of and rationale for any modifications including:
(1) The methodology for determining average actuarial risk~~, including the establishment of risk pools and the Federally-certified~~ and the risk adjustment model specified in §153.320; and
(2) ~~The r~~Risk adjustment data validation ~~methodology~~ set forth in §153.350."

Subpart D – State Standards for the Risk Adjustment Program

§ 153.300 Definitions

As our comments above and to §153.310 below note, we agree that section 1343(a) of the Affordable Care Act clearly requires that for purposes of risk adjustment, risk pools are required to be aggregated at the State level, including those enrolled in catastrophic plans. The definition of risk pool included in proposed §153.300, however, does not specifically require that risk is to be aggregated across the State. The regulations should be amended accordingly.

Specific Recommendation: Amend §153.300 as follows:

"…*Risk pool* means the State population across which risk is distributed in risk adjustment."

§ 153.310 Risk adjustment administration

General comments

As noted above, we agree with the statement in the preamble that section 1343(a) of the Affordable Care Act clearly requires that for purposes of risk adjustment, risk pools subject to risk adjustment are required to be aggregated at the State level even if a State decides to utilize regional Exchanges.

Statewide risk pools should also include any catastrophic plans offered in the individual market, pursuant to section 1302(e) of the ACA. The draft HHS white paper on "Risk Adjustment Methodology Issues" dated Sept. 12, 2011 discusses an option under which catastrophic plans would be excluded from the risk pools subject to risk adjustment and placed in a separate risk adjustment pool. We see no statutory basis for this. Furthermore, taking catastrophic plans out of the rest of the statewide risk adjustment system would defeat the purpose of risk pooling: to ensure a broad mix of risk profiles. Catastrophic plans tend to attract younger, healthier consumers and thus balance out the older, higher risk population. Thus, we oppose exclusion of catastrophic plan enrollees from the state risk pool subject to risk adjustment.

We agree that States should provide HHS with a summary report of risk adjustment activities for each benefit year in the year following the calendar year in the report, and support that such report include the average actuarial risk score for each plan, corresponding charges or payments, and any additional information HHS deems necessary to support risk adjustment methodology determinations. The report should also include information on risk score and cost trends, including evidence of upcoding, as discussed in our comments to §153.350, as well as error rates determined under the most recently completed risk adjustment data validation audits under §153.350. The report should also permit States to make recommendations on how HHS could refine or recalibrate the system to address these trends. The report should also note when charges did not equal payments, and how charges or payments were adjusted to ensure risk adjustment budget neutrality. Finally, the regulation should make clear that States shall make such reports publicly available.

§153.310(a) Risk adjustment administration

We agree with the proposed rules that any State electing to establish an Exchange is eligible to establish a risk adjustment program but that HHS would operate risk adjustment if the State does not establish an Exchange or does not elect to administer risk adjustment even if it elects to establish an Exchange.

If HHS operates an Exchange in a State, it is critical that risk adjustment is administered on a timely and accurate basis and that Exchange QHPs are not subjected to adverse selection relative to plans offered in the outside market. Requiring HHS to administer risk adjustment in a State that does not elect to establish an Exchange would help ensure that risk adjustment is appropriately mitigating the risk of adverse selection against the Exchange operated by HHS.

§153.310(b) Entities eligible to carry out risk adjustment activities

We agree that a State may elect to have an entity other than the Exchange perform the risk adjustment functions in the State. Some states may wish to have a state agency or other public entity other than the Exchange perform its risk adjustment functions, for example. Others may choose to set up a new entity. However, we do not agree that meeting the standards set forth in proposed §155.110 of the Exchange regulation for serving as an *Exchange* is also sufficient to qualify an entity to perform the state's risk adjustment role.

Proposed §155.110 of the Exchange regulation would allow the state Medicaid agency, but does not appear to permit state insurance regulatory bodies, to perform the risk adjustment function. In addition, its conflict of interest standards appear to allow representatives of health insurers to serve on the entity's governing board. Any decisions related to risk adjustment would produce inherent conflicts of interest, because such decisions would directly affect whether insurers are eligible for risk adjustment payments or are required to pay risk adjustment charges, and the amount of such payments or charges. We, therefore, strongly oppose persons or entities with financial interests related to insurers from serving in any risk adjustment decisionmaking process.

Moreover, there is no specific requirement in the proposed rule at §155.110 that requires consumer representation. Decisions regarding risk adjustment are likely to be dominated by insurers and actuaries due to the tremendous stake these parties have in the outcome and due to the topic's technical nature. Just as has proven true in rate review, another technical topic, the participation of consumers and consumer groups is critical to balance out the expected dominance of insurer interests. Consumer representation on the governing board of any entity administering risk adjustment, on related stakeholder groups, and on advisory bodies is essential to provide for a fair balance of interests. This is particularly important because the success—or not-- of risk adjustment will have a direct effect on the affordability of premiums in the individual and small-group markets and on whether the Exchanges are viable over the long-term.

There is also no requirement in the proposed rules at §155.110 that the highly complex and detailed policy decision-making associated with administration of risk adjustment be fully transparent. <u>All</u> decisions should be made in the open — the proposed rules at §155.110 only require that public governing board meetings be held regularly — and all major risk adjustment decisions by a State including rules, guidance, and technical specifications should be subject to public notice and comment to ensure adequate consumer input.

§153.310(c) Timeframes

We agree that risk adjustment should commence with the 2014 benefit year. While section 1343 of the Affordable Care Act does not explicitly require risk adjustment to start in 2014, it was the clear intent of Congress that risk adjustment, like reinsurance and risk corridors, was to begin in 2014 when the major insurance market reforms and the Exchanges first take effect, in order to mitigate the risk of early adverse selection in the individual and small-group markets inside and outside the Exchanges, and among plans within the Exchanges. The success of the Exchanges will depend upon a strong, well executed risk adjustment component.

§ 153.320 Federally-certified risk adjustment methodology

General comments

We suggest that HHS establish a standard risk adjustment methodology that every state would be required to use. States should, however, be given the flexibility to tailor that standard methodology and related standards for their state markets, subject to federal approval. This would provide overall national uniformity and produce comparable results. A uniform methodology also means that States would not have to dedicate scarce resources to developing their own risk assessment tools or purchasing a proprietary system, and data collection elements would be standardized. In addition, a uniform methodology would provide for economies of scale and reduce the administrative burden for insurers in planning for the new system and in collecting and transmitting the data needed to do risk adjustment across states. This would be particularly important since the models will likely need to be modified as more data become available; a single uniform methodology would be easier to refine over time.

The proposed rules and the preamble appear to imply that risk adjustment will be done initially on a retrospective basis and a retrospective system may be used indefinitely. While it may be necessary and appropriate to temporarily use retrospective adjustment because of the lack of data about the newly insured population and the more generalized uncertainty about how risks will be initially distributed, the proposed rules should leave leeway for transition to a prospective system like the one used in the Medicare Advantage risk adjustment system.

Such a prospective system would mean that the adjustment would be based on recent past data (demographic, diagnosis, and perhaps prescription drug and lab data) to estimate health status for the coming plan year. It facilitates competition among insurers by reducing the barriers to market entry for new insurers because they would be assured in advance of higher payments of specified amounts if they attract a higher-risk population. A prospective system may also be more likely to encourage cost-efficiency by plans. We acknowledge, however, that the transition to a prospective system will largely depend on the speed with which data for risk adjustment reported by insurers during the 2014 plan year can analyzed by HHS to design an effective and accurate prospective system and have it tested.

The preamble seeks comments on how risk adjustment methodologies should adjust for differences in premium rating rules across States. We agree that it is critical to account for premium rating variation to ensure that risk adjustment does not inappropriately adjust for actuarial risk that insurers already have been allowed to incorporate into their premium rates. Without accounting for these differences, risk adjustment would result in "double counting" under which certain insurers would receive larger payments (or be required to pay lower charges) than they otherwise would. The methodology developed by HHS (and any alternative State methodology) should clearly explain how the methodology will account for those differences and how States can adapt the HHS methodology to their specific premium rating rules.

The proposed rules do not address how States (or HHS, on behalf of a State) can finance the administrative costs of operating the risk adjustment system on an ongoing basis, although the Exchange Planning and Establishment Grants can be used by States to set up risk adjustment and for financing its operating costs through the end of 2014. The proposed rules should make clear that States could finance operating costs by increasing the charges to insurers with lower-than-average

risk, just like States can collect additional reinsurance contributions to provide funding for reinsurance administrative costs under §153.220(b)(3)(ii). Financing risk adjustment operating costs in this manner would also encourage insurers to report data on a timely basis and otherwise cooperate so that the process works as efficiently as possible. Another alternative approach that the proposed rules could permit would be to fund risk adjustment administrative costs out of assessments on insurers — operating inside and outside the Exchanges — on top of those that could be levied by states to finance Exchange operations. Such an approach would help to spread the costs for the risk adjustment authority more widely across all insurers that operate in the State.

The preamble seeks comment on how to address the situation when charges do not equal payments (either charges exceed payments, or payments exceed charges). We believe that in the situation when charges exceed payments, excess plan charges should be placed in a reserve account, explicitly protected from capture for General Fund expenditures by states. That would ensure that all necessary risk adjustment payments can be covered by the charges in a given year. This would be particularly important in the early years of the risk adjustment program. Over time, a portion of the excess charges could be returned to insurers (with that percentage growing over time, as the system becomes more predictable and it is less likely that charges will significantly exceed payments).

§153.320(a) General requirement

In developing its Federally-certified risk adjustment methodology, HHS should use standardized computer software. Ideally, it should be public and not proprietary and should be made available through an HHS website so that it is readily accessible to insurers and State entities using the system to administer risk adjustment in the State. Insurers need to be able to calculate their own plan scores and expected charges/payments for purposes of developing premiums for their plan offerings.

§ 153.330 State alternative risk adjustment methodology

§153.330(a) State request for alternative risk adjustment methodology

The preamble indicates that the standard of review for HHS in assessing State requests to substitute an alternative risk adjustment methodology is whether the methodology would offer "similar or better performance in that State than the Federally-certified risk adjustment methodology" developed by HHS or another State methodology that has already received federal approval. Yet the proposed rules do not include this rigorous standard or explain how the State is to demonstrate that it meets this standard through the information it is required to submit under proposed §153.330(a). We agree that no State methodology should be certified unless a State can demonstrate that it will do as well or better than the system developed by HHS. The proposed rule, however, should be modified to specifically require that the State do so.

The proposed rules also do not specify that applications by States should be standardized to streamline the HHS evaluation process and allow stakeholders to more easily assess the merits of a State application. In addition, the State should be required to make any applications to use an alternative methodology publicly available for notice and comment before submission. Such state applications should be made available to the public on a website administered by HHS, along with the HHS decision related to the application.

Specific Recommendation: Amend §153.330(a) as follows and renumber accordingly:

"(a) *State request for alternative methodology certification.*
(1) The State request to HHS for the certification of an alternative adjustment model must be submitted in a manner determined by HHS and must include:
(i) A description of how the request incorporated stakeholder input through a public notice and comment process prior to submission;
…
(E) Calibration methodology and frequency of calibration; ~~and~~
(F) Statistical performance metrics, as specified by HHS; ~~and~~
(G) Funding for administrative expenses related to the risk adjustment program; and
(H) Other information required by HHS.
…
(2) The request must demonstrate how the methodology will produce similar or better results than the methodology developed by HHS under §153.320(a)(1) ~~include~~ including the extent to which the methodology:…"

§153.330(b) State renewal of alternative methodology

We strongly support the requirement that States that operate an alternative methodology must renew HHS certification whenever changes occur, including at the time of recalibration. Changes could reduce the effectiveness and accuracy of the risk adjustment system, which would violate the requirement that the alternative methodology produces similar or better performance than the methodology developed by HHS.

§ 153.340 Data collection under risk adjustment

§153.340(a) Data collection requirements

We strongly support the "intermediate" data collection approach set forth under the proposed rules by which issuers submit raw claims and encounter data to the State (or HHS, in States where it is operating the risk adjustment system), subject to the privacy safeguards described below. That will ensure accuracy, transparency and credibility for the system among insurers.

We oppose a "distributed" approach under which issuers would calculate their own risk scores and submit them to the State (or HHS) without providing access to the underlying raw claims and encounter data. This would make the risk adjustment system excessively vulnerable to errors committed by issuers, particularly those that are not already experienced with risk adjustment in Medicare. A distributed approach would also make it far more difficult for States (and HHS) to identify errors in risk score calculations or upcoding trends on a timely basis and instead require reliance on the use of retrospective audits, which under §153.350 would not be completed for as much as three years after the end of the applicable plan year. It would also make the system more easily subject to fraud and abuse if some issuers deliberately skewed their risk scores in order to lower the contributions they would be charged or increase the payments they would receive. This would undermine the system's credibility among insurers, especially in its early years, and could lead to higher premiums in the individual and small group markets inside and outside the Exchanges and discourage insurer participation as Exchange QHPs, both of which could threaten the long-term viability of the Exchanges.

While some insurers may argue that a fully distributed system is necessary to protect enrollees' privacy, we disagree. The proposed rules, under §153.340(b), require that States use identifiable information for only certain purposes, implement security standards that provide administrative, physical and technical safeguards for the individually identifiable information, and establish privacy standards. Moreover, identifiable risk adjustment data for millions of Medicare beneficiaries is already being used and protected in Medicare Advantage and Medicare Part D. We urge that the proposed rule make clear that risk adjustment data must be encrypted when it is submitted and when it is stored. In addition, HHS should make clear that the costs of encryption and other de-identifying security processes are eligible expenses under Exchange Planning and Establishment Grants. In addition, the regulation should make clear that states, or HHS on behalf of the state, shall not re-identify or allows others to re-identify the de-identified data. With these conditions, the benefits of the proposed intermediate approach more than outweigh the privacy concerns, so long as States and HHS fully comply with the privacy requirements of §153.340(b) and our suggested amendments to 153.340(d).

We also support requiring federal standards for the risk adjustment data (and the standardized formatting of such data) that insurers will be required to report. That will make it easier to calculate risk scores on a timely basis, identify reporting errors, and verify such data within a State and to compare the effectiveness and accuracy of risk adjustment across States (including across States with different risk adjustment methodologies). In addition, as with States adopting the Federally-certified methodology, standard data reporting and formatting requirements would provide for economies of scale and reduce the administrative burden for insurers in planning for the new system and in collecting and transmitting the data needed to do risk adjustment across States (if they are offering individual or small group coverage in multiple States).

§ 153.340(c) Exception for States with all payer claims databases

We support HHS' encouragement of States to establish all payers claim databases (APCDs), so long as they too have adequate patient privacy protection standards. Such databases would be invaluable for a variety of purposes, including facilitating initiatives to improve patient safety and the quality of health care furnished in the individual and small group markets. Nevertheless, the proposed rules do not appear to clearly ensure that States with APCDs seeking an exemption to the federal data collection standards actually demonstrate that such databases could be effectively used in conjunction with a Federally-certified risk adjustment methodology (and/or a State alternative risk adjustment methodology that qualifies for certification). Nor do they appear to require that States demonstrate how such data could meet a variety of required purposes including helping HHS refine its risk adjustment methodology, or support a variety of other critical functions including those related to Exchanges.

The proposed rules should be modified to require that a State with an all payers claim database can only qualify for an exemption if it can demonstrate that such a database can meet all relevant data requirements, including the privacy protections in paragraph (d). In addition, to encourage states that cannot meet the January 1, 2013 deadline to forge ahead with creating APCDs, we suggest amending the proposed regulation to allow them to apply for an exception as well once their APCD has been established pursuant to the standards in paragraph (d).

Specific Recommendation: Amend §153.340(c) as follows:

"(c) *Exception for States with all payer claims databases.* Any State with an all payer claims database that is operational on or before January 1, 2013 may request an exception from the data collection minimum standards in paragraph (b) of this section by submitting~~: (1) T~~technical specifications for the all payers claims database including data formats~~; (2)~~ and demonstrating how it will make ~~P~~proposed system modifications to meet the data collection requirements of a Federally-certified risk adjustment methodology ~~and~~ ,support all necessary risk adjustment activities~~; (3) Proposed system modifications to~~ and meet requirements set forth in paragraph (d) of this section and other Exchange-related activities. States with all payer claims databases operational after January 1, 2013 may also apply for an exception at such time and subject to the same criteria.

§ 153.340(d) Uses of risk adjustment data

We support requiring that States (and HHS, in States where it is operating the risk adjustment system) make certain de-identified, encrypted claims and encounter data collected under risk adjustment available to support other activities, including recalibrating Federally-certified risk adjustment models and auditing reinsurance claims. As noted, such data will be critical in making timely, periodic refinements to the Federally-certified risk adjustment model and for correcting upcoding of diagnoses. Such refinements, based on this data, would improve risk adjustment's accuracy and its ability to limit adverse selection in the individual and small-group markets inside and outside the Exchanges. These modifications will be especially important in the first few years, as new information becomes available for incorporation into the models and weights need to be recalibrated. Ensuring protection of individual patients' identity is critical, of course. Thus, we urge that the regulation explicitly state that claims and encounter data used for risk adjustment will be de-identified and encrypted to provide maximum privacy protection for consumers.

The proposed rules should also clarify that states (and HHS, in states where it is operating an Exchange and/or a risk adjustment system) have the authority to use data collected under risk adjustment to enforce other critical Exchange requirements and insurance market reforms. For example, the data could be used to compare the demographic and diagnostic information submitted by insurers for purposes of risk adjustment to the data submitted by insurers for purposes of rate reviews under 45 CFR Part 154, or to help determine whether insurers are complying with the single risk pool requirement across all of their plans offered inside and outside the exchange under section 1312(c) of the Affordable Care Act. The data could also be used in Exchanges' consideration of QHP premium rate increase justifications under §155.1020. Insurers may argue that their premium rate increases were necessary because of past (and anticipated) changes in their risk pool (for which they were not being fully compensated under risk adjustment or risk corridors). Risk adjustment data could be used to evaluate such claims.

In order to be certified as an Exchange QHP, section 1311(c)(1)(A) of the Affordable Care Act requires insurers to demonstrate that they are not employing marketing practices or benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs. Risk adjustment data will help ensure more effective enforcement of this requirement. States can carefully monitor changes in the relative health of enrollees in a plan over time using risk adjustment data to see if a plan's marketing practices or benefit design changes have produced favorable selection over time by deterring enrollment by those in poorer health.

Specific Recommendation: Amend §153.340(d) as follows:

"(d) *Uses of risk adjustment data.*
(1) The State, or HHS on behalf of the State, must make relevant claims and encounter data collected under risk adjustment activities available to support claims-related activities as follows:
(~~1~~a) Provide HHS with de-identified, encrypted claims and encounter data for use in recalibrating Federally-certified risk adjustment models;
(~~2~~b) Provide HHS with summarized claims cost for use in verifying risk corridor submissions; ~~and~~
(~~3~~c) Provide the reinsurance entity with summarized claims and encounter data from reinsurance-eligible plans for payment verification purposes and individual-level from reinsurance-eligible plans for audit purposes~~;~~ and
(d) Provide HHS with de-identified, encrypted claims and encounter data for use for other purposes as determined by HHS.
(2) The State, or HHS on behalf of the State, may use relevant de-identified, encrypted claims and encounter data collected under risk adjustment activities for other enforcement and verification purposes."

§ 153.350 Risk adjustment data validation standards

§ 153.350(a) General requirement

We strongly support the requirement that insurers be subject to risk adjustment data validation audits on an annual basis. We agree that such a process is essential to the establishment of a credible risk adjustment system for insurers and thus would make it more likely that risk adjustment has a positive effect on premium reduction. Such audits will allow the States and HHS to identify reporting errors by insurers and coding trends among insurers that together could skew risk score calculations, and therefore undermine the accuracy of the risk adjustment methodology.

We understand that under Medicare Advantage, "upcoding" has been a persistent issue. The experience with upcoding in the Medicare Advantage program demonstrates the important role data validation can play in ensuring that plans submit accurate data and that risk scores are accurately calculated. In the individual and small-group insurance markets, in which risk adjustment will affect the redistribution of funds among private plans, upcoding and coding errors would undermine the effectiveness of the risk adjustment system by skewing payments so some plans are overcompensated for their risks while others are significantly undercompensated. As a result, risk adjustment validation is a necessary component of the ACA's risk adjustment system.

The proposed rules, however, do not specify how a State would validate a statistically valid sample of risk adjustment data. HHS should establish a standard risk adjustment data validation approach for States to use. In addition, while the preamble notes that these audits will be required of every insurer offering a risk adjustment covered plan every year, the proposed rules do not clearly require annual audits. The rules should specify that States must audit plans every year. It also would be helpful, especially in the first few years, for HHS to directly conduct random audits of issuers across States on a periodic basis. Such a "look back" audit function would help ensure that the annual audits are working as intended, and would identify ongoing patterns of upcoding or coding errors across States and among insurers.

The proposed rules also do not address the need for penalties for plans with error rates consistently exceeding those found for other plans in a State. While such plans would be subject to revised actuarial risk calculations and charge/payment adjustments, as discussed further below, HHS should consider whether such plans would be subject to interim prospective adjustments (prior to a validation being finalized) where there is an ongoing pattern of excessive error rates. Such plans also could be required to institute a corrective action plan to bring their error rates into line with other comparable plans in the State. Other penalties would also be appropriate for a pattern of errors, falsification of risk adjustment data, and for non-compliance with other standards, see comment on section 153.620 below, and we urge HHS to clarify such penalties and who would be responsible for enforcing them—the state risk adjustment entity or other state regulator, or HHS.

Specific Recommendation: Amend §153.350(a) as follows:

"(a) *General requirement*. The State, or HHS on behalf of the State, must annually validate a statistically valid sample of risk adjustment data from each issuer that offers at least one risk adjustment covered plan in that State in a given year, in a manner determined by HHS."

§ 153.350(b) Use of data validation to adjust risk

As noted, risk adjustment data validation audits are a key tool to ensure the accuracy of the risk adjustment system. It is, therefore, logical and essential that States (or HHS on behalf of the State) appropriately act on the results of the data validation audits by adjusting the average actuarial risk for each plan based on the error rate found in the validation audits. The proposed rules merely authorize a State (or HHS) to adjust the calculation of the average actuarial risk but do not require the State (or HHS) to actually do so. Such an adjustment should be mandatory and we recommend that the proposed rules be amended accordingly.

Specific Recommendation: Amend §153.350(b) as follows:

"(b) *Use of data validation to adjust risk*. The State, or HHS on behalf of the State, ~~may~~ shall adjust the average actuarial risk calculated in §153.310 for all risk adjustment covered plans offered by an issuer based on the risk score error determined in the data validation conducted pursuant to paragraph (a) of this section."

§ 153.350(c) Adjustment to charges and payments

Similarly, the proposed rules only authorize a State (or HHS) to take the adjusted risk scores into account, but does not require the State (or HHS) to make the appropriate adjustment to the risk adjustment charges or payments to an insurer based on those adjusted risk scores resulting from the error rates determined in the data validation audits. Such an adjustment should be mandatory and we recommend that the proposed rules be amended accordingly.

Specific Recommendation: Amend §153.350(c) as follows:

(c) Adjustment to charges and payments. The State, or HHS on behalf of the State, ~~may~~ shall adjust charges and payments to all risk adjustment covered plan issuers based on the adjustments calculated in paragraph (b) of this section.

§ 153.350(d) Appeals

The proposed rules appropriately require the State to provide an administrative process for insurers to appeal data validation findings, but do not specify the process to be used including the timing of appeals and their resolution, the scope of the appeal, and the criteria to be used in assessing the merits of appeals. HHS should specify a uniform appeals process that is to be used by states, allowing state variances or modifications only if they can achieve comparable results from a modified appeals approach.

In all cases, HHS should also ensure that the scope of such appeals is limited. For example, insurers should not be able to challenge the error rate calculation methodology itself, but could challenge alleged calculation errors using such methodology made by the State or HHS. Insurers also should not be permitted to substitute data used in the sample. Because the results of the audits are critical in ensuring the accuracy of the risk adjustment system, it is critical that the appeals process be designed to limit the ability of insurers to game the appeals process and unduly delay any required adjustments to their actuarial risk or charges/payments based on the data validation findings.

Specific Recommendation: Amend §153.350(d) as follows:

(d) Appeals. The State, or HHS on behalf of the State, must provide an administrative process to appeal data validation findings in a manner determined by HHS."

Subpart G – Health Insurance Issuer Standards Related to the Risk Adjustment Program

§ 153.610 Risk adjustment issuer requirements

§ 153.610(a) Data submission

We strongly support the requirement that all issuers that offer risk adjustment covered plans must submit all required, underlying risk adjustment data. Such data is necessary for the success of the risk adjustment system to mitigate adverse selection. We also support the required submission of other data, including methods for setting rates, which can be used, for example, to assess whether the risk adjustment methodology is appropriately accounting for a State's premium rating rules, whether risk adjustment should be based on average state premiums or actual plan premiums, and to help enforce other Exchange requirements and insurance market reforms, including the requirements that insurers pool risk across all plans statewide inside and outside the Exchange.

We finally note that the Affordable Care Act is clear that insurer participation in the risk adjustment program is mandatory. Section 1343 of the Affordable Care Act requires each State to assess a charge on non-grandfathered health plans and health insurance issuers providing coverage in the individual or small group market within the State with less than average actuarial risk and to provide a payment to such health plans and issuers with greater than average actuarial risk. Nothing in section 1343 can be reasonably interpreted to allow insurer participation to be voluntary. Moreover, mandatory participation is essential for the success of risk adjustment across the States.

§ 153.610(b) Issuer contracts

It is reasonable to permit insurers to require that contracting providers give them complete and accurate risk adjustment data and subject providers to financial penalties for failure to submit complete, timely or accurate data. Such contractual obligations would help ensure that the data that insurers submit to the State or HHS is as accurate as possible. As noted in our comments to §153.620, it is also critical that insurers be subject to an array of penalties for failure to comply with various risk adjustment standards.

§ 153.610(c) Assessment of charges

The proposed rules do not specify a timeframe for when insurers with a net balance of charges must remit payments to the State or HHS. The preamble indicates that insurers will be given 30 days to make the required payments. That seems reasonable. The proposed rules should be amended to indicate that payments must be made within a timeframe to be determined by HHS. As noted in our comments to §153.620, it is also likely necessary to establish penalties for insurers who fail to make the required payments on a timely basis.

Specific Recommendation: Amend §153.610(c) as follows:

"(c) *Assessment of charges.* ~~After charges and payments for all risk adjustment covered plans have been calculated, i~~Issuers that offer risk adjustment covered plans determined to have a net balance of risk adjustment charges payable will be notified by the State, or by HHS on behalf of the State, for those net charges and must remit those risk adjustment charges to the State, or to HHS on behalf of the State, within a required timeframe determined by HHS."

§ 153.620 Compliance with risk adjustment standards

General comments

The proposed rules do not address what penalties would be applied by a State, or HHS acting on behalf of a State, in the event an insurer fails to submit the required risk adjustment data, provide the requested data to support risk adjustment data validation audits, or comply with other requirements related to risk adjustment operations. HHS should establish an array of sanctions that can be imposed by a State or HHS on insurers that do not comply with risk adjustment standards. For example, insurers consistently failing to comply with risk adjustment data requirements or failing to make required payments when they incur a net balance of charges could no longer be eligible to be certified as a QHP and would be thus barred from offering coverage through the Exchange. Insurers could also be charged additional penalty risk adjustment charges (or have their risk adjustment payments reduced) for patterns of non-compliance. In addition, a State, or HHS acting on behalf of a State, may find such behavior to warrant separate financial penalties significant enough to be considered beyond the "cost of doing business" as a deterrent to future non-compliance by the offending insurer and others.

§ 153.620(a) Issuer support of data validation

We support the requirement that all issuers that offer risk adjustment covered plans must make available all data requested to support the risk adjustment data validation audits required under §153.350. Mandatory participation is essential to ensure that the data validation is effective and can be used to make the needed risk score calculation and charge/payment adjustments to ensure an accurate risk adjustment system in a State.

Very truly yours,

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