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CLIENT ALERT

CMS Continues to Strengthen Federal-Level Requirements for Qualified Health Plans

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December 2015

On December 2, 2015, the Centers for Medicare & Medicaid Services ("CMS") released a proposed rule titled "Patient Protection and Affordable Care Act; CMS Notice of Benefit and Payment Parameters for 2017" ("Proposed Rule")[1] containing proposals to create regulatory standards for a new health insurance exchange ("Exchange") model. The Proposed Rule also provides new network adequacy requirements and changes to requirements relating to, among other things, (i) qualified health plan ("QHP") standards; (ii) cost sharing; (iii) medical loss ratio ("MLR") requirements; (iv) the rate review program; and (v) the risk adjustment, reinsurance, and risk corridors programs. These proposals would continue to strengthen the federal requirements imposed on QHPs and, in some circumstances, compel states to strengthen their standards as well or defer to federal rules. CMS will be accepting comments on the Proposed Rule until **5:00 p.m. (EST) on December 21, 2015.**

This Client Alert addresses the proposals that CMS advances in the Proposed Rule. Stakeholders should closely review the Proposed Rule to fully assess its potential impact and ensure that they submit comments to either support or express alternative suggestions to CMS's proposals.

New Exchange Model: The State-Based Exchange on the Federal Platform

CMS has proposed recognizing a new Exchange model known as the "state-based Exchange on the federal platform" ("SBE-FP") to address the current states that are employing this approach and to prepare for possible future ones. SBE-FPs are state-based Exchanges that use the federal Exchange online platform to perform certain tasks, such as eligibility and enrollment functions. Four states—Hawaii, Nevada, New Mexico, and Oregon—currently use this new model. Under this model, a state, through its SBE-FP, would remain responsible for plan management and consumer support

[1] 80 Fed. Reg. 75488 (Dec. 2, 2015), *available at* http://www.gpo.gov/fdsys/pkg/FR-2015-12-02/pdf/2015-29884.pdf.

functions. States wishing to operate a SBE-FP would enter into a federal platform agreement with CMS that outlines what federal Exchange services the state-based Exchange will rely on and the user fee that CMS will collect from issuers on the SBE-FP for the federal services provided.

Standardized Plan Options

The 2017 plan year would bring standardized plan options to the individual market Exchanges under the Proposed Rule. This would be to help consumers when assessing the many and varied plan options offered on the Exchanges. However, CMS is considering ways to highlight standardized options available on the Exchanges so that they are easier for consumers to identify, including distinguishing them from non-standardized plans. CMS has proposed six standard option plan designs: a bronze plan, a gold plan, a standard silver plan, and three silver plan options at the 73 percent, 87 percent, and 94 percent actuarial levels, which would align with the three actuarial levels for cost-sharing reduction plans. The general features of the standardized options include:

- four-tier drug formularies (generic, preferred brand, non-preferred brand, and specialty drug tiers), and issuers would be permitted to offer additional lower-cost tiers, if desired;
- no more than one in-network provider tier;
- certain deductible-exempt services, such as primary care, specialist visits (at the silver and gold plan levels), and generic drugs;
- preference for copayments over coinsurance; and
- standard deductibles: $6,650 for a bronze plan; $3,500 for a standard silver plan; $1,250 for a gold plan; and a range of $250 to $3,000 for the silver plan options with varying percentage actuarial levels.

An issuer would be able to offer multiple standardized options within a service area so long as they were meaningfully different, and CMS is seeking comments as to whether it should limit the number of non-standardized options that an issuer may offer through an Exchange in future years.

Meaningful Difference

CMS proposes to modify the meaningful difference standards currently applicable to QHPs on the federal Exchanges. First, CMS proposes to remove health savings account eligibility as an option for meeting the meaningful difference standard since this criterion overlaps with the cost-sharing criterion (i.e., a plan that meets the meaningful difference standard for health savings account eligibility also meets the standard under the cost-sharing criterion). In addition, CMS proposes removing the individual coverage

or enrollment group coverage criteria, noting that no self-only coverage plans were reviewed for meaningful difference in 2015, and none are currently offered for 2016.

Selective Contracting

During the first few years of Exchange operations, CMS utilized an "open market" approach in certifying QHPs. So long as a QHP met the minimum certification criteria, it was allowed to be offered on the Exchange. CMS has indicated an interest in moving away from the open-market approach. Under Section 1311(e)(1)(B) of the Affordable Care Act, the Exchange is authorized to certify a plan as a QHP if it meets minimum certification criteria and the Exchange has determined that allowing the offering of the health plan is "in the interests of qualified individuals and employers." Application of the "interest" standard would require that QHPs "should provide quality coverage to consumers to meet the Affordable Care Act's goals."

CMS proposes to rely on that standard to deny certification of QHPs that meet minimum QHP certification standards but are not ultimately in the interests of qualified individuals and qualified employers due to questions as to the integrity of the plans. Reasons for which a plan may be denied certification under this standard could include an issuer's "material non-compliance with applicable requirements, financial insolvency, or data errors related to QHP applications and data submissions." Also considered could be past performance with respect to oversight identified through compliance reviews and consumer complaints. In exercising this authority, CMS would use a "measured approach," including the consideration of market competition. CMS requests comments on this proposal in general, though the agency anticipates seeking more specific comments in the future. Comments should include the factors that CMS should consider in assessing whether the offering of a QHP would be in the interest of consumers and employers.

Network Adequacy Standards

CMS has indicated its intention to develop network adequacy standards through guidance issuances over the past several years.[2] These discussions referenced the possible use of time and distance or other measures and expressed a desire to collaborate with the states and review the work of the National Association of Insurance Commissioners ("NAIC") in updating its model network adequacy law. The NAIC's revised model law was not quite finalized when CMS released the Proposed Rule, which includes its own network adequacy standards. CMS acknowledged the significant work of the NAIC and stated that it will continue to monitor and consider the NAIC's final recommendations in CMS's rulemaking process regarding network adequacy.

[2] See 2015 Letter to Issuers in the Federally-facilitated Marketplaces, Chapter 2, Section 3, March 14, 2014, *available at* https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2015-final-issuer-letter-3-14-2014.pdf; CMS FINAL 2016 Letter to Issuers in the Federally-facilitated Marketplaces, Chapter 2, Section 3, Network Adequacy, Feb. 20, 2015, *available at* https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2016-Letter-to-Issuers-2-20-2015-R.pdf.

Under the Proposed Rule, in states under a federally facilitated Exchange ("FFE"), CMS proposes to rely on state reviews for network adequacy, provided that a state uses "an acceptable quantifiable metric." CMS anticipates providing, in each Annual Letter to Issuers, a list of metrics from which a state can select that will at least include time and distance and minimum provider covered ratios for specialties with the highest utilization within the state.

In FFE states that do not review for network adequacy or decline to select quantifiable metrics, FFE plans would be reviewed by CMS under a federal default standard. Beginning in 2017, CMS anticipates that it will evaluate QHP issuer networks based on the numbers and types of providers and their general geographic location. CMS specifically proposes calculating county-level time and distance standards, possibly similar to those used in Medicare Advantage, with a focus on high-utilization specialties. QHPs that cannot meet the given standards would be allowed to submit a justification to explain any variances. These justifications would be reviewed to determine whether the variance is reasonable based on the given circumstances—for example, provider availability or local patterns of care.

CMS states that its intent in establishing default standards is not to "prohibit certification of plans with narrow networks or otherwise impede innovation in plan design," but, rather, to set a network adequacy "floor" and enhance network transparency for consumers. To that end, CMS is considering developing ratings for QHP network coverage and making them available to consumers through HealthCare.gov. Networks would be rated in three categories according to time and distance standards and based on provider information submitted by QHP issuers.

CMS indicates that it is carefully considering and seeks comments on other network standards for FFEs, including state, accrediting entity, and other federal health program standards. The agency also seeks comments regarding wait time variation among provider types, whether issuers should be required to survey providers to determine sufficient acceptance of new patients, transparency requirements for selecting and tiering providers in FFE QHPs, and the application of network adequacy requirements to stand-alone dental plans. Finally, CMS welcomes comments on additional data sources, calculation methods, and provider types to be considered for rating plans.

Notification and Continuity of Care When Providers Are Terminated

CMS proposes to require QHPs in an FFE to provide written notice of a terminated provider 30 days (or as soon as practicable) before the effective date of the termination to all enrollees who are patients seen on a regular basis by that provider or receive primary care from the terminated provider. This notice would be required regardless of whether the termination is with or without cause or due to a contract non-renewal. The Proposed Rule would also allow continuity of care for enrollees under "active treatment" by providers terminated without cause, allowing an enrollee to continue with the provider at in-network cost-sharing rates until the treatment is complete or for 90 days, whichever is shorter. "Active treatment" would include (i) an ongoing course of treatment for a life-threatening condition, (ii) an ongoing course of treatment for a serious acute

condition, (iii) the second or third trimester of pregnancy, or (iv) an ongoing course of treatment where the provider attests that discontinuing care would worsen the condition or interfere with anticipated outcomes.

CMS seeks comments on (i) whether different notification timeframes should apply depending on provider types; (ii) the definitions of "regular basis" and "active treatment"; and (iii) whether individual state notification standards, NAIC-defined standards, or those from federal programs (such as Medicaid or Medicare Advantage) should apply.

Cost-Sharing Protections and "Surprise Billing"

"Surprise billing" describes the situation when an enrollee seeks care from an in-network provider but, during treatment, unknowingly receives services from non-participating physicians or other practitioners who may bill the enrollee directly for amounts above the QHP's allowable payment. CMS proposes providing cost-sharing protection for enrollees who make reasonable efforts to stay in-network but unknowingly receive care from non-participating providers.

The Proposed Rule would require QHPs to count toward maximum out-of-pocket ("MOOP") limits any cost sharing paid for essential health benefits ("EHBs") provided in an in-network setting but by out-of-network providers. Alternatively, the QHP could provide advance written notice to the enrollee of the possibility that he or she may be subject to additional costs, including balance billing charges, for EHBs provided by an out-of-network provider in an in-network setting, where allowed by state law.

CMS seeks comments on this proposal, including whether it should instead require issuers to provide to enrollees customized information, such as available in-network providers.

Medical Loss Ratio

CMS proposes to amend the reporting requirements for incurred claims for the MLR calculation. Currently, insurers must meet specified targets for the amount of premiums spent on medical claims and activities related to quality of care relative to administrative expenses. Part of the medical claims calculation includes the amount of estimated unpaid claim reserves. The Proposed Rule would amend the definition of "medical loss ratio" to provide that unpaid claim reserves be reported at a six-month (as opposed to the current three-month) run-out period. Under the Proposed Rule, incurred claims would be calculated as of June 30 instead of March 31 of the year following the reporting year to reduce the amount of estimation required, improve accuracy, and ultimately increase rebate payments from issuers to consumers.

Additionally, CMS seeks comment on whether to modify the treatment of an insurer's investments in fraud prevention activities for purposes of MLR calculations. CMS is considering amending the MLR regulation to permit the counting of such investments as expenses attributable to incurred claims rather than to administrative expenses for purposes of the ratio calculation. Attributing fraud prevention activities to claims

expenses and not administrative expenses would be a notable shift, as these activities are traditionally considered administrative in nature.

Rate Review

Beginning in 2017, CMS proposes to subject issuers in the individual and small-group markets to rate review if their average increase in rates exceeds 10 percent or a specific threshold as proposed by an individual state and approved by the Secretary of Health and Human Services. In an effort to increase transparency of the rate review program, CMS proposes to collect and publicize a Unified Rate Review Template from all issuers offering single risk pool coverage in the individual and small-group market. The data collection and disclosure would include not only rate increases, both above and below the currently required 10 percent level, but also proposed rate decreases or unchanged rates, as well as rates for new plans. CMS seeks comment on this proposal.

Rating Areas

Each state has great flexibility to establish rating areas that issuers in the state must use as part of setting rates. Rating areas must be based on counties, zip codes, or metropolitan and non-metropolitan statistical areas. In the Proposed Rule, CMS notes that it has observed wide variation in the size of rating areas among the various states, a circumstance that could lead to pockets of smaller rating areas with higher-risk groups. While these smaller, high-risk pockets may compromise the risk-spreading objective of health care reform, CMS acknowledges the uniqueness of each state's needs and the need for a certain level of state autonomy in this area. Given the perhaps competing interests, CMS seeks comment on whether it should require more uniformity in the size of rating areas or establish a minimum size for rating areas. Further, CMS seeks comment on how it could improve uniformity and sufficient size for risk pooling to balance the need for risk spreading with the unique needs of each state. Finally, CMS notes the inconsistency that may occur between an issuer's rating area and the service area of some of its network-based plans. To that end, CMS seeks comment on whether and how to make these two areas more consistent.

The Three R's: Risk Adjustment, Reinsurance, and Risk Corridors

CMS proposes various changes to the risk adjustment, reinsurance, and risk corridors in 2017. These changes include, in addition to the topics discussed below, clarification of data submission and reporting requirements for these programs as well as clarification of a guaranty fund's ability to participate in these programs.

Risk Adjustment

Risk adjustment factors reflect enrollee health risk and the costs of a given disease relative to average spending. Last year, CMS recalibrated the risk adjustment models for 2016 by using 2011, 2012, and 2013 claims data from the Truven Health Analytics 2010 MarketScan® Commercial Claims and Encounters database ("MarketScan") to develop updated risk factors. For 2017, CMS proposes to use the 2012, 2013, and 2014

claims data, when the 2014 MarketScan data become available. CMS would publish and finalize the updated factors in the final rule.

CMS proposes to incorporate preventive services into the simulation of plan liability in the recalibration of the risk adjustment models for 2017, using procedure and diagnosis codes, prescription drug therapeutic classes, and enrollee age and sex. This incorporation of preventive services will more accurately compensate risk adjustment-covered plans with enrollees who use preventive services. CMS is also evaluating how to incorporate prescription drug data in the federally certified risk adjustment methodology that CMS uses when it operates risk adjustment. CMS expects that prescription drug data could be utilized in the risk adjustment methodology to supplement diagnostic data by using the prescription drug data as a severity indicator, or as a proxy for diagnoses in cases where diagnostic data are likely to be incomplete. CMS seeks comment on effective methods of incorporating prescription drug data in future recalibrations. Other aspects of the risk adjustment methodology that CMS seeks comment on include whether there are better methods of accurately compensating for new treatments for high-cost conditions and modeling the severity of these conditions for high-cost enrollees, and ways to make the methodology more predictive for partial-year enrollees.

If a state is not approved to operate, or chooses to forgo operating, its own risk adjustment program, CMS will operate risk adjustment on the state's behalf. CMS's operation of risk adjustment on behalf of states is funded through a risk adjustment user fee. The total cost for CMS to operate the risk adjustment program on behalf of states for 2017 will be approximately $52 million, and the risk adjustment user fee is estimated to be $1.80 per enrollee per year (up from $1.75 in 2016).

Reinsurance

If any reinsurance contribution amounts remain after calculating reinsurance payments for the 2016 benefit year (including after CMS would increase the coinsurance rate to 100 percent for the 2016 benefit year), CMS proposes to lower the 2016 attachment point of $90,000 to pay out any remaining contribution amounts for the 2016 benefit year. The final attachment point and coinsurance rate for the 2016 benefit year will be calculated based on total available reinsurance collections and accepted reinsurance payment requests.

CMS has the authority to audit a contributing entity to assess compliance with the reinsurance program requirements. The proposed regulations at 45 C.F.R. 153.405(i) would amend the audit provision for the reinsurance program to clarify that this authority also extends to third parties that assist contributing entities with their obligations under this program. This would include third-party administrators, administrative services-only contractors, or other third parties that complete any part of the reinsurance contribution submission process on behalf of contributing entities, assist contributing entities with compliance with the requirements for the transitional reinsurance program, provide contributing entities with their annual enrollment counts, or maintain records to

substantiate the annual enrollment counts (even if the third party does not submit the annual enrollment count to CMS).

Risk Corridors

CMS suggests several changes to the risk corridors program for 2015 and 2016. CMS proposes that, for 2015 risk corridors and MLR reporting, if an issuer reported a certified estimate of 2014 cost-sharing reductions on its 2014 MLR and Risk Corridors Annual Reporting Form that is lower than the actual cost-sharing reductions provided, CMS would make an adjustment to the issuer's 2015 risk corridors payment or charge amount in order to address the impact of the inaccurate reporting on the risk corridors and MLR calculations for the 2014 benefit year. CMS also proposes that the issuer must adjust the cost-sharing reduction amounts that it reports for the 2015 MLR and risk corridors reporting cycle by any difference between 2014 reported and actual cost-sharing reduction amounts.

For the 2015 and later benefit years, CMS proposes that the issuer must true up claims liabilities and reserves used to determine the allowable costs reported for the risk corridors program for the preceding benefit year to reflect the actual claims payments made through June 30 of the year following the benefit year. CMS seeks comment on the most appropriate way to true up estimates of unpaid claims for 2016 (e.g., by providing for a 2017 payment or charge calculated with the 2018 MLR, providing for a simplified true-up process, requiring that the 2016 estimate be based on actual 2014 and 2015 amounts, or providing for no true-up at all in the final year).

Impact of Sequestration

Both the transitional reinsurance program and the permanent risk adjustment program are subject to the fiscal year ("FY") 2016 sequestration (beginning on October 1, 2015). The reinsurance program will be sequestered at a rate of 6.8 percent for payments made from FY 2016 resources (i.e., funds collected during FY 2016). CMS will sequester risk adjustment payments made using FY 2016 resources in all states in which CMS operates risk adjustment at a rate of 7.0 percent. If Congress does not enact deficit-reduction provisions that replace sequestration, these programs will be sequestered in future FYs, and any sequestered funding will become available in the FY following that in which it was sequestered (e.g., funds that are sequestered in FY 2016 from the reinsurance and risk adjustment programs will become available for payment to issuers in FY 2017 without further Congressional action).

Good Faith Safe Harbor

CMS is permitted to impose civil money penalties ("CMPs") upon issuers of risk adjustment covered plans and reinsurance-eligible plans for failure to adhere to certain standards relating to their dedicated distributed data environments. CMS previously applied a "good faith" test to an issuer's efforts to comply with these standards when determining whether to impose CMPs for noncompliance in 2014 and 2015.

Starting in 2016 and beyond, CMPs may be imposed if an issuer of a risk adjustment covered plan or reinsurance-eligible plan fails to establish a dedicated distributed data environment in a timeframe and manner specified by CMS; fails to provide CMS with access to the required data in such environment; fails to adhere to the reinsurance data submission requirements; or fails to adhere to the risk adjustment data submission and data storage requirements, even if the issuer has made good faith efforts to comply with these requirements.

Conclusion

CMS's Proposed Rule seeks to continue to expand federal control over the private health insurance market. Stakeholders should closely review CMS's proposals and provide comments by **5:00 p.m. (EST) on December 21, 2015,** on significant challenges related to the proposals' implementation as well as detailed suggestions based on experience with similar requirements.

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This Client Alert was authored by **Helaine I. Fingold, Lesley R. Yeung, Richard H. Hughes IV, M. Brian Hall IV,** *and* **Meghan F. Weinberg.** *For additional information about the issues discussed in this Client Alert, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

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