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CLIENT ALERT

HHS Broadens Federal Controls Over Private Health Insurance Benefits and Operations

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On November 21, 2014, the Obama administration released two proposed rules[1] affecting health insurance issuers' offering of private health insurance products both inside and outside of the public insurance exchanges ("Exchanges"). Depending on the topic, some of these proposed rules affect the individual, small group, and/or large group markets.

The broadest of the two proposed rules, titled "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016"[2] ("Proposed NBPP Rule"), was released by the Department of Health and Human Services ("HHS"). The Proposed NBPP Rule addresses a range of Affordable Care Act ("ACA") implementation topics, including payment and premium support programs, cost-sharing parameters and reductions, user fees for federally-facilitated exchanges ("FFEs"), minimum essential coverage, essential health benefits ("EHB") requirements, and network adequacy and quality requirements for qualified health plans ("QHPs").

The second proposed rule, titled "Patient Protection and Affordable Care Act; Establishment of the Multi-State Plan ("MSP") Program for the Affordable Insurance Exchanges"[3] ("Proposed MSP Rule"), was issued by the federal Office of Personnel

[1] The Obama administration also released a third rule on November 21, 2014, finalizing previous proposals on the scope of minimum essential coverage and other aspects of the employer provision of health insurance. This third rule was released by the Internal Revenue Service ("IRS") and is titled "Minimum Essential Coverage and Other Rules Regarding the Shared Responsibility Payment for Individuals." *See* http://www.gpo.gov/fdsys/pkg/FR-2014-11-26/pdf/2014-27998.pdf.

[2] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, 79 FR 70674 (Nov. 26, 2014), http://www.gpo.gov/fdsys/pkg/FR-2014-11-26/pdf/2014-27858.pdf.

[3] Patient Protection and Affordable Care Act; Establishment of the Multi-State Plan Program for the Affordable Insurance Exchanges, 79 FR 69802 (Nov. 24, 2014), http://www.gpo.gov/fdsys/pkg/FR-2014-11-24/pdf/2014-27793.pdf.

Management ("OPM"). The Proposed MSP Rule amends MSP standards related to coverage area, benefits, and certain contracting requirements under the ACA's MSP provisions.

Issuers, in particular, should closely review the provisions of these proposed rules in a timely fashion, in order to understand possible regulatory changes that could affect them as they develop their plan offerings for the 2016 benefit year and beyond. The HHS and OPM are each accepting comments on their respective proposed rules through **December 22, 2014**.

PROPOSED NBPP RULE

Premium Stabilization Programs

The Proposed NBPP Rule introduces proposals affecting the three premium stabilization programs, including the Risk Adjustment, Reinsurance, and Risk Corridor Programs.

Risk Adjustment Program. The **Risk Adjustment Program** transfers funds from lower risk, non-grandfathered plans to higher risk, non-grandfathered plans in the individual and small group markets, inside and outside of the Exchanges, to balance risk and maintain market stability. Proposed changes to the Risk Adjustment Program for 2016 include the following:

- Increasing the **risk adjustment user fee** charged to issuers of risk adjustment-covered plans from $0.96 per enrollee in 2015 to **$1.75 per enrollee in 2016** (based on a total cost for HHS to operate the 2016 Risk Adjustment Program of approximately $50 million). The increased user fee amount is due to the increased contract costs to support the risk adjustment data validation process, which will be administered for the first time in 2016.

- Recalibrating the risk adjustment models for 2016 by updating the risk factors to use 2010, 2011, and 2012 Truven Health Analytics MarketScan® data, instead of relying upon the 2010 MarketScan® data, alone.[4] HHS also seeks comments on whether the recalibrated model should be implemented for 2015 as well.

Reinsurance Program. The transitional **Reinsurance Program** was established in each state to help stabilize premiums for coverage in the individual market inside and outside of the Exchanges from 2014 through 2016. The temporary reinsurance fund established through this program will be used to pay a portion of the costs for individuals with very high medical expenses. Proposed changes to the Reinsurance Program for 2016 include the following:

[4] If 2013 MarketScan® data becomes available, HHS would rely upon 2011, 2012, and 2013 MarketScan® data when finalizing the risk factors in the final rule.

- Establishing the **uniform reinsurance contribution rate** of **$27 per enrollee** for the 2016 benefit year. Three components make up the total dollar amount to be collected from contributing entities for each of the 2014, 2015, and 2016 benefit years under the uniform reinsurance contribution rate. The three components include a reinsurance payment pool to be collected from contributing entities ($4 billion in 2016), a required contribution to the U.S. Treasury ($1 billion in 2016), and a collection for administrative expenses ($32 million in 2016).[5]

- Proposing to use any excess contributions for reinsurance payments for the current benefit year by increasing the coinsurance rate for the 2016 benefit year up to 100 percent before rolling over any remaining funds to the next year. HHS seeks comments on whether to expend all reinsurance contributions for 2016 requests or to roll over any excess funds to the 2017 benefit year, since that could help stabilize 2017 premiums.

- Clarifying how to determine if a third-party administrator ("TPA") is under common ownership or control with a self-insured group health plan or its plan sponsor for purposes of determining if such plan is a "contributing entity" to the reinsurance fund for the 2015 and 2016 benefit years. The principles established under section 414(b) and (c) of the Internal Revenue Code for controlled groups will be used in determining whether a TPA is under common ownership or control of the group.

- Amending 45 CFR § 153.400(a)(1)(iii), which currently exempts expatriate health coverage from reinsurance contributions, so that it also exempts, beginning for the 2015 benefit year, any self-insured group health plan with respect to which enrollment is limited to participants who reside outside of their home country for at least six months of the plan year, and any covered dependents.

- Offering contributing entities the option to pay the entire 2014, 2015, or 2016 benefit year contribution in one payment (no later than January 15, 2015, 2016, or 2017, as applicable, or, if such date is not a business day, the next applicable business day) or in two separate payments for the 2014, 2015, or 2016 benefit years (with the first remittance due by January 15, 2015, 2016, and 2017, as applicable, and the second remittance due by November 15, 2015, 2016, or 2017, as applicable).

- Establishing the uniform reinsurance payment parameters for the 2016 benefit year to be established at an **attachment point of $90,000**, a **reinsurance cap of $250,000**, and a **coinsurance rate of 50 percent**.[6] Further, HHS is proposing to lower the 2015 attachment point from $70,000 to $45,000 for the 2015 benefit year.

[5] The uniform reinsurance contribution rate for HHS administrative expenses is proposed to be $0.17 annually per capita. If a state establishes its own reinsurance program, HHS would transfer $0.085 of the per capita administrative fee to the state for the state's administrative expenses incurred in making reinsurance payments.

[6] The attachment point is the threshold at which a claim would be eligible for reinsurance coverage.

Risk Corridor Program. The temporary **Risk Corridor Program** was established to protect against inaccurate rate setting and limit volatility in the individual and small group markets from 2014 through 2016. Proposed changes to the Risk Corridor Program 2016 include the following:

- Clarifying that the risk corridors transitional adjustment for benefit year 2014 applies only with respect to plans under the transitional policy—that is, plans that renew after January 1, 2014, for which HHS and the applicable state are not enforcing market rules.[7] Member-months of enrollees in early renewal plans will not be counted towards the risk corridor's transitional adjustment (that is, unless and until the plan becomes a transitional plan in a transitional state upon renewal in 2014).

- Specifying that any excess collections from the Risk Corridor Program (i.e., if collections received over the course of the three-year program exceed total payments requested over the three years) in the last year of the program would be allocated to plans that have a medical loss ratio ("MLR") of at least 80 percent or more through adjustments in the program's administrative expense definitions (i.e., the profit margin floor and the ceiling for allowable administrative costs).

HHS also proposes to amend 45 CFR § 153.740(a) to extend the safe harbor for noncompliance with the HHS-operated risk adjustment and reinsurance data requirements during the 2015 calendar year if the issuer has made good faith efforts to comply with these requirements. Good faith efforts could include notifying, communicating with, and cooperating with HHS with respect to issues that arise with the establishment and provisioning of the issuers' dedicated distributed data environment.[8] Additionally, HHS clarifies that it may consult and share information about issuers of a risk adjustment-covered plan or a reinsurance-eligible plan with other federal and state regulatory and enforcement entities to the extent that the consultation and information is necessary for HHS to determine whether an enforcement remedy against the issuer of the risk adjustment-covered plan or reinsurance-eligible plan under 45 CFR § 153.740 is appropriate.

Rate Increases: Federal Disclosure and Review Requirements

HHS proposes several changes to the federal rate review program, which reviews the rates charged in the individual and small group market inside and outside of the

[7] On November 14, 2013, the Obama administration announced a transitional policy allowing for certain health insurance coverage in the individual or small group markets renewed for a policy year starting after January 1, 2014, not to be considered out of compliance with specified 2014 market rules. States were encouraged to adopt similar non-enforcement policies. HHS extended the transitional policy on March 5, 2014, allowing issuers to renew transitional policies through policy years beginning on or before October 1, 2016.

[8] The good faith safe harbor does not apply to noncompliance with dedicated distributed data environment standards applicable during 2016, even if the noncompliance in the 2016 calendar year relates to data for the 2015 benefit year.

Exchanges. The changes include modifying the standard for determining when a plan's rate increase is subject to review under the rate review regulations at 45 CFR Part 154. Presently, a rate increase in the individual or small group market is subject to review if it is 10 percent or greater, or meets or exceeds an applicable state-specific threshold. The percent increase is calculated as the average increase *for all enrollees under the product*. HHS proposes that the percent increase be calculated at the *individual plan level within a product*. Therefore, if the average percent increase for any plan within a product exceeds the applicable threshold, the entire product will be subject to review to determine if the increase is reasonable. HHS also proposes to clarify that an issuer must submit a Rate Filing Justification for all products within the issuer's single risk pool when any one of its plans within a product is subject to a rate increase.

Noting the wide variation in state timelines for submission of those rate justifications, HHS proposes a uniform timeline by which an issuer must submit a Rate Filing Justification to HHS by the earlier of (1) the state's date for required filing to the state, or (2) the date specified by the Secretary of the HHS in guidance. HHS seeks comments on its proposal that the guidance will set the date as the end of the QHP application window for the FFE. HHS's interest in this date is assuring that all proposed rate increases in every relevant state market for both QHPs and non-QHPs are filed at a consistent time each year in order to facilitate transparency and consistency and to reduce the opportunity for anticompetitive behavior. States would still be able to impose an earlier rate filing deadline.

For states operating an Effective Rate Review Program, HHS is proposing to set a deadline for those states to publicly post information on proposed rate increases and accept public comment. HHS is seeking comments on its plans in future guidance to set the deadline as 10 days following the receipt of all filings of proposed rate increases. Information on all final rate increases would be posted by the state no later than the first day of the annual open enrollment period. Additionally, states would be required to post at a uniform time all proposed or final rate increases in order to promote fair market competition and make comprehensive information available to the public to support informed choices.

Guaranteed Renewability

HHS proposes to codify its earlier guidance that issuers cannot meet the guaranteed renewability requirement by automatically enrolling a plan sponsor or individual into a product of another issuer that is separately licensed in a state. HHS does note that, if an issuer decides to discontinue all health insurance coverage in a market, then it may be allowed to automatically enroll a plan sponsor or individual into a product of another issuer so long as it is allowed by state law.

HHS also has been examining the effect of the guaranteed renewability provisions of the ACA on various corporate transfers that involve the change of ownership of an issuer, such as through a merger or acquisition. In order to address its concerns about the effect of these transfers, including ensuring the seamless coverage of enrollees and

the ongoing operational success of HHS-administered programs, HHS is seeking comments on various proposals related to ownership transfers, including whether automatic enrollment in the acquiring-issuer's products should be allowed, and what protections enrollees should have when their coverage is transferred to another issuer. HHS is also proposing that issuers of QHPs, a plan subject to risk corridors, or a risk adjustment-covered plan be required to notify HHS of any change of ownership on either the date that the transaction occurs or within 30 days of the transaction becoming effective, whichever is later. HHS is seeking comments as to whether any additional requirements are necessary when there is an ownership transfer.

Enrollment and Payment of First Month's Premium

HHS is asking for comment on three significant changes with respect to eligibility for and (re)enrollment into QHPs offered in the FFE. First, HHS is proposing to revise the open enrollment period, starting with 2016, to run from October 1 through December 15 of the year prior to the related benefit year. Second, HHS is proposing to require in the FFE that enrollees pay their first month's premium in order to effectuate enrollment, and to allow state-based Exchanges to apply this same requirements. Third, HHS is also proposing changes to the provisions on Special Election Periods ("SEPs"), including creation of an SEP for certain individuals in states that did not expand their Medicaid programs under the ACA, and on the re-enrollment process.

Annual Enrollment Period. HHS has proposed to set the annual enrollment period for benefit years beginning on or after January 1, 2016, to begin on October 1 and extend through December 15 of the calendar year preceding the benefit year. This enrollment period would apply to non-grandfathered policies in the individual market that are sold inside and outside of the Exchanges. HHS notes that while the proposed enrollment period is shorter than in previous years, it will help reduce enrollee confusion due to the enrollment period no longer spanning two years. Issuers would also have more time to make any necessary changes and process enrollments prior to the start of the benefit year.

Payment of First Month's Premium. Payment of the first month's premium is significant in that it finalizes a person's enrollment into a plan and qualifies him or her for a three-month grace period of coverage should he or she fail to make future premium payments. Concerns were raised after the 2014 open enrollment period on the Exchanges due to the large numbers of people who failed to pay their initial premiums.[9] Issuers used varying cutoff dates for when initial premiums had to be submitted in order to effectuate coverage. In the Proposed NBPP Rule, HHS states that it is considering implementing a standard policy for setting deadlines for payment of the first month's premium and is seeking comments as to which of the proposed premium payment deadlines give issuers the time needed to send an invoice and allow for timely payment by the enrollee.

[9] Robert Pear, One-Fifth of New Enrollees Under Health Care Law Fail to Pay First Premium, New York Times, Feb. 13, 2014, http://www.nytimes.com/2014/02/14/us/politics/one-in-5-buyers-of-insurance-under-new-law-did-not-pay-premiums-on-time.html?_r=0.

Special Election Periods. Along with changes to several existing SEPs,[10] HHS proposes to create several new SEPs to address a number of special circumstances. The new SEPs would allow for off-cycle enrollment in the following situations and events:

- a court order (such as a child support or custody order);
- the death of an enrollee or any dependents;
- the loss of dependent status through divorce, legal separation, or death;
- enrollment in non-calendar year plans when coverage ends in 2014;
- errors or misrepresentations by the Exchange or any of its employees causing enrollment or non-enrollment in a QHP; and
- changes in household income that make an individual eligible for advance payments of the premium tax credit in non-Medicaid expansion states.

HHS also has proposed eliminating the existing special enrollment period granted when there are errors or misconduct on the part of non-Exchange entities, instead providing the Exchange with the ability to take appropriate action to correct the misconduct.

Re-Enrollment. With respect to re-enrollment, HHS is asking for comment on a proposal to enable enrollees to choose a default re-enrollment process at the time of their initial enrollment. Indicating that this would not apply to the FFE until the 2017 enrollment period, HHS describes the proposed process as providing the option of default "re-enrollment hierarchies" through which the individual could elect for the following year to default into a lower-cost plan, triggered by either an increase in the cost of the current plan of a particular threshold amount (e.g., 5 or 10 percent) or an increase relative to the cost of other similar plans. The enrollee would retain the ability to actively choose to enroll in a different plan than that defined in the agreed to re-enrollment hierarchy. State-based Exchanges would have the option of applying this process for the 2016 enrollment period.

Termination of Coverage. HHS proposes several changes to the rules governing termination of coverage, allowing enrollees to cancel their coverage so long as appropriate notice is provided and allowed under a state's "free look" cancellation laws, if applicable. Retroactive cancellations also are addressed, with HHS proposing

[10] HHS also has proposed changes to existing special enrollment periods, such as a change to one of the options for coverage effective dates in the case of a birth, adoption, placement for adoption, or placement in foster care. Instead of consumers selecting one of these event dates or the first of the month following the event to begin coverage, HHS has proposed changing this requirement to either the event date or the regular coverage effective date. Another proposed change, effective January 1, 2016, would allow consumers advanced access to the special enrollment period when a qualified individual or enrollee gains access to new QHPs due to a permanent move.

appropriate actions that Exchanges must take to refund premiums, user fees, cost-sharing reductions, and premium tax credits. HHS also is proposing to require that Exchanges establish a process for a third party to report the death of an enrollee.

Required Contribution Percentage

Under the ACA's individual mandate, most individuals must sign up for health insurance coverage or pay a penalty. However, individuals who lack access to "affordable" minimum essential coverage are exempt from such penalties. Coverage is considered affordable if the amount for the lowest-cost, self-only coverage does not exceed 8 percent of household income for 2014, adjusted annually by the amount of the premium adjustment percentage (discussed below at page 16). HHS announced in this proposed rule that the required contribution percentage for 2016 will be 8.3 percent.

Small Business Health Options Program ("SHOP")

HHS proposes to modify the definition and application of a "group participation rate" standard, the minimum percentage of all individual eligible employees of an employer that must be enrolled to participate in the SHOP, so that, if a SHOP elects to establish a minimum participation rate, it would have to be a single, uniform rate that applies to all groups and issuers in the SHOP.

Instead of a rate based on employee participation in any one QHP or issuer's products, the rate would have to be based on the rate of participation in minimum essential coverage, such as a SHOP or other group health plan, governmental coverage, or coverage sold in the individual market. HHS seeks comment on whether this change should be applied beyond the SHOP to the entire small group market to create uniformity and prevent "gaming by issuers through their use of non-standard definitions for other acceptable coverage."

In order to minimize the reported burden on small employers of administering continuation of coverage under applicable laws such as COBRA and enrolling employees in the SHOP, each of which may have separate timelines for the collection of premiums, HHS proposes that a SHOP may enter into an agreement to assist an employer by billing and collecting continuation of coverage premiums directly from the employee, rather than the employer.

HHS is proposing numerous amendments and updates to clarify effective dates of coverage for SHOPs and seeks comments on any conforming amendments that may be required. This includes making clear that a newly qualified employee becomes eligible for an enrollment period beginning on the first day of employment, regardless of whether the employee is subject to a waiting period, and establishing a minimum 30-day enrollment period for those newly qualified employees.

Regarding termination of coverage, the rule proposes to clarify that, in the FF-SHOP, termination of coverage based on non-payment of premiums would be effective on the

last day of the month for which the SHOP received full payment. A qualified employer whose coverage was terminated for non-payment of premiums could only be reinstated once per calendar year. Responsibility for issuing certain enrollee notifications of termination of coverage would shift from the issuers to the SHOP. Also, such notifications would go to dependents of qualified enrollees in addition to the enrollees themselves and would have to be sent within 24 or 48 hours, depending upon the method of communication.

HHS proposes that, if a SHOP certifies QHPs on a calendar-year basis, the certification must be in effect for the duration of any employer's plan year that begins in the calendar year for which the plan was certified. This is designed to address the issue where groups enrolled in the SHOP might have coverage that does not end on a calendar year (due to the ability of being able to enroll at the beginning of any month), yet the QHPs may only offer coverage until the end of the calendar year of its certification.

FFE User Fee for 2016 Benefit Year

The ACA[11] and other federal laws[12] permit Exchanges to charge assessments or user fees to participating health insurance issuers, or otherwise generate funds to support their operations. HHS proposes setting a 2016 user fee rate of 3.5 percent for all participating FFE issuers, the same rate applied for 2015. HHS is seeking an exception from the OMB policy that user fees charged be sufficient to cover the costs to the federal government of providing the service. Instead, HHS seeks to continue to the 3.5 percent rate to ensure FFE operation can support the overall goals of the ACA.

State Selection of the Benchmark Plan

The Proposed NBPP Rule includes several changes to the benchmark requirements, including an attempt to address the controversial issue of defining "habilitative services" and proposing enhanced coverage of prescription drugs. In addressing the broader issue of how EHB will be defined in future years, HHS appears to have taken the least controversial path by extending the application of current state benchmarks through the 2016 benefit year, allowing states to choose from among updated versions of the 10 largely state-specific plan options described in current regulations.[13]

[11] ACA Section 1311(d)(5)(A), as implemented at 45 CFR 156.50.
[12] *See* 31 U.S.C. 9701.
[13] These 10 options include the following: the largest health plan by enrollment in any of the three largest small group insurance products by enrollment in the state's small group market; any of the largest three employee health benefit plan options by enrollment offered to the state's employees; any of the largest three national Federal Employees Health Benefits Program ("FEHBP") plan options by aggregate enrollment that is offered to all health-benefits-eligible federal employees; or the coverage plan with the largest insured commercial non-Medicaid enrollment offered by a health maintenance organization operating in the state. 45 CFR 156.100(a). States that failed to select a benchmark option were "defaulted" to the "largest plan by enrollment in the largest product by enrollment in the State's small group market." 45 CFR 156.100(c).

In previous guidance, HHS stated that its initial EHB approach, allowing state-by-state selection of an EHB benchmark as well as state-level EHB enforcement, would apply for a transitional period, during the 2014 and 2015 benefit years, "in order to directly reflect current market offerings and limit market disruption in the first years of the Exchanges," and that it "intend[ed] to revisit the policy for subsequent years."[14] Commenters to this proposal encouraged HHS to use the 2014-2015 transitional years to collect data to annually update EHB and/or to adopt a comprehensive federal EHB standard, starting with the 2016 benefit year.[15] HHS responded that it was "reviewing all options."[16] The newly proposed EHB benchmark approach differs little from the earlier approach, but it does allow states to choose anew from among the 2014 configurations of the 10 provided plan options.

Habilitative Services

When defining EHB under the original final rule, HHS employed a transitional approach that provided flexibility to the states, reasoning that habilitative benefits were "not well defined in the current commercial market."[17] Specifically, the final rule provided that, if the state's benchmark plan did not include habilitative services, the state had the option of defining the habilitative services to be covered by their benchmark plan. If the state chose not to define habilitative services in this context, the issuer was permitted to define such benefits. In the Proposed NBPP Rule, and where not otherwise covered by the benchmark plan, HHS has maintained some level of flexibility by continuing to allow the state to define these services. However, where the state chooses not to define the missing services, HHS would no longer allow the issuer to use its own definition. Rather, where neither the selected benchmark plan nor the state defines such services, HHS now proposes to employ a standard definition of "habilitative services" to mean "health care services that help a person keep, learn, or improve skills and functioning for daily living." Such services would need to be provided in a manner "no less favorable than" for rehabilitative services.[18]

Prescription Drug Benefits

The information in this section would apply to issuers in the small group and individual health insurance markets, both inside and outside of the Exchanges. In order to address a number of challenges associated with its initial approach to prescription drug benefits under EHB, HHS proposes and asks for comment on several significant

[14] Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation; 77 FR, 70644, 70649 (Nov. 26, 2012), http://www.gpo.gov/fdsys/pkg/FR-2012-11-26/pdf/2012-28362.pdf.
[15] Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 78 FR 12834, 12841 (Feb. 25, 2013), http://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.
[16] *Id*. at 12842.
[17] Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation; Final Rule, 78 FR 12834, 12844 (Feb. 25, 2013), http://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.
[18] Proposed 45 CFR 156.115(a)(5).

regulatory changes to the prescription drug requirements and provides an alternative approach for discussion. For example, HHS proposes to replace the drug count standard with the requirement that plans create a pharmacy and therapeutics ("P&T") committee that follows a number of standards to ensure that the plan's formulary covers a sufficient number and type of prescription drugs. This is the approach used under the Medicare Prescription Drug Program ("Medicare Part D"), as well as by the National Association of Insurance Commissioners ("NAIC") and other stakeholders, to ensure the adequacy of a plan's formulary.[19] This proposed approach would be effective with the 2017 benefit year.

The proposed P&T committee provisions specify standards on membership, meetings, and establishment and development of a formulary drug list. Specifically, HHS proposes that the members of the P&T committee represent a sufficient number of clinical specialties to adequately represent the needs of enrollees, include consist of a majority of physicians, pharmacists, and other practicing health care professionals, and meet certain conflict of interest standards.

HHS also provides as a possible concurrent change or altogether alternative to the use of the P&T committee to replace its reliance on the United States Pharmacopeia ("USP") as the reference resource for defining categories and classes with a standard based on the American Hospital Formulary Service ("AHFS"). HHS states in the preamble to the Proposed NBPP Rule that because "the AHFS system is more gradual and has more classifications than the USP system," it believes that using the AHFS system "would better ensure that a broader distribution of drugs would be required to be covered to the meet the drug count standard."

HHS also proposes changes to the requirement that an issuer provide a standard and expedited exceptions process to request review of a decision to cover a non-formulary drug. Specifically, HHS proposes that an issuer must provide a decision under the standard exceptions process no later than 72 hours after plan receipt of the request and a decision on an expedited request within 24 hours of the request for review. The Proposed NBPP Rule would further require that a coverage decision arising from the exceptions process would require coverage of the non-formulary drug for the duration of the prescription, including refills, and clarifies that the excepted drug would be considered EHB for all purposes, including that cost sharing for such drug would count towards the annual limitation on cost sharing. In addition, HHS proposes to require that issuers arrange for review by an independent party in cases where coverage of a non-formulary drug is denied under the exceptions process. The independent review entity would be subject to the same decision timeline as the plan was required to meet for the underlying process through which coverage was initially denied (72 hours for standard or 24 hours for expedited).

[19] *See* Social Security Act (SSA) § 1860D–4(b)(3)(G), codified at 42 CFR § 423.120(b), 42 CFR § 423.272(b)(2), for Medicare Part D P&T committee requirements. NAIC includes P&T committee provisions in its Model Act titled "Health Carriers Prescription Drug Benefit Management Model Act" (July 2003), http://www.naic.org/store/free/MDL-22.pdf.

The Proposed NBPP Rule further includes a new transparency requirement, providing that a plan must "publish an up-to-date, accurate, and complete list of all covered drugs on its formulary drug list, including any tiering structure that it has adopted and any restrictions on the manner in which a drug can be obtained."[20] This information must be easily accessible to all stakeholders as well as the general public via the plan's public website. HHS is requesting comment on the proposed requirements generally, as well as on the specific questions of whether cost sharing or other information should be included in the information required to be released and whether issuers should be required to make their formulary information available in a specified machine-readable format or provide it to HHS in a standardized format to enable third parties or HHS to provide additional mechanisms for the public to access and compare plan formulary information.

Also addressed in the Proposed NBPP Rule is the extent to which an issuer may rely on mail-order pharmacy services to provide access to prescription drug benefits under EHB. HHS notes that mail order may not be viable or appropriate in all circumstances. To address this concern, HHS proposes to require that enrollees must generally be able to access their prescriptions through "brick and mortar" pharmacies, although issuers would be able to charge higher cost sharing for prescriptions accessed at retail pharmacies, rather than through mail order. That higher cost sharing, however, would count towards an enrollee's annual limitation on out-of-pocket costs. The proposed amendments to the prescription drug provisions would allow issuers to limit access for drugs for which (1) the FDA has restricted distribution to certain facilities or practitioners, or (2) appropriate dispensing of the drug requires extraordinary special handling, provider coordination, or patient education that cannot be met by a retail pharmacy.

While not included as a regulatory proposal, HHS encourages issuers to adopt a 30-day transition policy to enable enrollees switching into the issuer's plans to work through prior authorization requirements or to familiarize themselves with the new formulary or exceptions process. The suggested transition policy would allow for temporary coverage of non-formulary drugs without requiring the new enrollee to use the exceptions process or coverage of a formulary drug without meeting applicable prior authorization or step therapy. Issuers should pay close attention to this recommendation, as HHS notes that it is considering whether a transition provision should be added to the EHB prescription drug requirements.

Prohibition on Discrimination Under EHB Requirements

While HHS did not propose changes to the EHB nondiscrimination provisions, it uses the preamble to the of the Proposed NBPP Rule to caution issuers and states on a number of practices that it believes would be discriminatory under this provision. First, HHS notes that the application of age limits to benefits that have been found to be clinically effective at all ages would be considered discriminatory under EHB non-discrimination provisions. An example given is where a plan attempts to limits access to

[20] 79 FR 70721.

hearing aids to those aged six or under, which would be discriminatory as hearing aids may also be medically necessary for those over age six. Second, HHS emphasizes that placement of all or most drugs for a specific condition on the highest cost tiers would effectively discriminate against, or discourage the enrollment of, individuals who have those particular conditions. This latter example appears to speak directly to the circumstances raised in a discrimination complaint filed with the HHS Office for Civil Rights ("OCR") regarding four QHPs offered in the Florida Exchange, which placed all or most HIV-AIDS drugs on the highest costs tiers.[21]

Cost-Sharing Requirements

HHS proposes several clarifications to the regulatory cost-sharing requirements. First, HHS proposes to clarify that the annual limitation on cost sharing applies to the benefit year when that differs from the calendar year, and the limitation amount that applies is specific to the calendar year in which the plan begins. Second, HHS further proposes to clarify in regulation that the annual limitation on cost sharing for self-only coverage applies to all individuals, whether covered by a self-only plan or by one that is other than self-only (e.g., family). In other words, an individual should never be required to pay more than the out-of-pocket cost-sharing limit for individuals, even when covered under a family plan. Lastly, HHS proposes to revise the regulation on cost-sharing limits to clarify that issuers may count out-of-network cost-sharing amounts towards the annual limitation on cost sharing, but are not required to do so.

Minimum Value

In response to the controversy that arose upon reports of employers' offering minimum value plans that exclude hospital benefits and/or include only limited coverage of physician services, HHS proposes to amend the existing minimum value regulations to reflect the policy expressed in recently issued guidance, that such "skinny plans" will not be considered to meet minimum value.[22] Specifically, HHS proposes to amend its regulations to provide that an "employer-sponsored plan provides minimum value (MV) only if the percentage of the total allowed costs of benefits provided under the plan is greater than or equal to 60 percent **and** the benefits under the plan include substantial coverage of inpatient hospital services and physician services."[23]

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[21] *See* AIDS Institute and NHeLP Administrative Complaint dated May 29, 2014, http://www.healthlaw.org/issues/disability-rights/HHS-HIV-Complaint#.VBY3Qlaaq2w. The OCR has not yet rendered a decision on this complaint, though the Florida Office of Insurance Regulation reached a settlement with one of the plans whereby the plan agreed to reduce the out-of-pocket costs that patients in Florida must pay for HIV drugs. See FOIR Consent Order, Case No. 162232-14-CO, Nov. 6, 2014, http://www.floir.com/siteDocuments/Cigna162232-14-CO.pdf. A second plan stated that it made changes to the structure of its 2015 drug benefit structure to spread its covered HIV drugs across several tiers, including the cheaper generic tiers. Cigna Agrees to Reduce H.I.V. Drug Costs for Some Florida Patients, New York Times, Nov. 7, 2014, http://nyti.ms/1AAQSXp.

[22] See http://www.irs.gov/pub/irs-drop/n-14-69.pdf, issued on Nov. 4, 2014, by the Departments of HHS and Treasury.

[23] Proposed 45 CFR 156.145.

An employee or covered dependent who is offered coverage under an eligible employer-sponsored plan that is affordable and meets minimum value requirements may not receive premium tax credit assistance for coverage in a QHP.[24] If the employer plan does not provide minimum value and the employee or covered dependent receives a premium tax credit for QHP coverage, the employer is subject to penalties under the Internal Revenue Code.[25] HHS specifically requests comments with respect to determining whether a plan has offered ''substantial'' benefits.[26]

Transparency in Coverage

Current regulations on transparency in coverage at 45 CFR 156.220 require QHPs to report on a variety of information, including claims payment policies and practices; periodic financial disclosures; data on enrollment, disenrollment, denied claims, and rating practices; and data on cost sharing and payments for out-of-network coverage. HHS anticipates that this information will be collected and displayed beginning in 2016.[27] HHS does not propose revisions to these requirements, although it does request comments "on the form and manner of data collection that will be most useful to consumers selecting a QHP in an Exchange." HHS specifically asks for input on the following: the data elements to be collected; the format to be used; the schedule for submission; submission mechanisms; ways to minimize duplication with information already required by HHS, states, or other entities (e.g., accreditation entities); how to display the collected information; and whether state-based Exchanges should follow the same display requirements.[28]

Network Adequacy Standards

HHS proposes several amendments to the QHP requirements on network adequacy to clarify application of these provisions, facilitate enrollee transition to a new plan, and strengthen provider directory requirements. Specifically, the proposed amendments would clarify that the network adequacy provisions apply only to those QHPs that use a provider network and that the network only includes providers that are contracted with the issuer. In other words, an issuer cannot rely on the availability of out-of-network providers to meet network adequacy requirements.

To strengthen provider directory requirements and enhance transparency, HHS proposes to amend the regulations to require QHP issuers to publish a current, accurate, and complete provider directory, including provider location, contact information, specialty, medical group, and any institutional affiliations, as well as information on which providers are accepting new patients. This information would need to be easily accessible and updated at least once a month. HHS also requests comments on the possibility of requiring issuers to make this information publicly

[24] Internal Revenue Code Section 36B.
[25] Internal Revenue Code, Section 4980H.
[26] 79 FR 70725.
[27] *Id.* at 70726.
[28] *Id.*

available in a format to enable third parties to create resources that aggregate information on different plans or in a manner through which the agency itself could provide a standardized template of information.[29]

Given recent controversy around QHPs having narrow provider networks,[30] it is not surprising that HHS states in the preamble to the Proposed NBPP Rule that it "continues to take great interest in ensuring strong network access." However, the proposed rule includes no further amendments to strengthen network requirements, indicating that, for the 2016 benefit year, HHS will continue to apply the "reasonable access standard" described in sub-regulatory guidance.[31] Rather, HHS states that it will await the results of efforts by NAIC to develop model rules on network adequacy before proposing significant changes to its policy approach in this area.[32]

Essential Community Providers

HHS proposes extensive revisions to section 156.235 with the intent to "strengthen" essential community provider ("ECP") requirements. The proposed revisions add detail to the regulation to, among other things, expand the types of providers with which issuers could contract to meet ECP standards, establish Exchange authority to set an annual baseline percentage of available ECP providers with which QHP issuers must contract, revise the requirements with respect to offering contracts in good faith to the available Indian and ECP providers, and allow the Exchanges to accept an alternate justification from applicants that fail to meet the set baseline percentage.

Health Plan Applications and Notices

HHS has proposed extending the requirement that QHPs provide applications and notices to enrollees in plain language and in a form accessible to those with limited language proficiency or disabilities to include all forms and notices that are critical for obtaining health insurance coverage or access to health care services. HHS has stated that these proposed requirements would not apply to marketing materials.

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[29] *Id.*

[30] *See*, e.g., David Blumenthal, M.D., Reflecting on Health Reform—Narrow Networks: Boon or Bane?, Feb. 24, 2014, http://www.commonwealthfund.org/publications/blog/2014/feb/narrows-networks-boon-or-bane.

[31] Specifically, CMS states that it will assess "reasonable access" by "identify[ing] networks that fail to provide access without unreasonable delay as required by 45 CFR 156.230(a)(2)," focusing "most closely on those areas which have historically raised network adequacy concerns." These areas may include: Hospital systems; Mental health providers; Oncology providers; and Primary care providers." 2015 Letter to Issuers in the Federally-facilitated Marketplaces, March 14, 2014, http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2015-final-issuer-letter-3-14-2014.pdf.

[32] The NAIC is developing a model rule on network adequacy, which currently is in draft form subject to comment. *See* http://www.naic.org/documents/committees_b_rftf_namr_sg_exposure_draft_proposed_revisions_mcpna_model_act.pdf. The subcommittee developing this model rule is accepting comments through January 12, 2015.

Segregation of Funds for Abortion Services

The ACA prohibits the use of federal funds to pay for abortion services, except in limited circumstances. Issuers of QHPs can elect to cover abortion services in states where such coverage is allowed, but these issuers must ensure that no premium tax credit or cost-sharing reduction funds are used to pay claims for abortion services. In the Proposed NBPP Rule, HHS provides guidance for issuers trying to comply with these requirements to segregate funds for abortion services. HHS states that an issuer can send a single invoice that separately itemizes the premium amount for abortion services, send a separate monthly bill for these services or a notice at the time of enrollment that the monthly invoice will include a separate charge for such services, and specify the charge. Once an issuer receives the premium payment, it must deposit the abortion-related funds of the premium in a separate allocation account.

Premium Adjustment Percentage

The premium adjustment percentage is an amount calculated annually by HHS to set the increase in three parameters required under the ACA:

> [T]he maximum annual limitation on cost sharing (defined at § 156.130(a)), the required contribution percentage by individuals for minimum essential health coverage the Secretary may use to determine eligibility for hardship exemptions under section 5000A of the Code, and the assessable payment amounts under section 4980H(a) and (b) of the Code (finalized at 26 CFR 54.4980H in the "Shared Responsibility for Employers Regarding Health Coverage" . . .).[33]

The premium adjustment percentage reflects the HHS Office of the Actuary's calculation of the difference between the average per enrollee employer-sponsored insurance ("ESI") premium for 2015 and the average per enrollee ESI premium for 2013. Based on a proposed premium adjustment percentage of 8.316047520 percent for 2016, HHS proposes to set the 2016 out-of-pocket cost-sharing limit at $6,850 for self-only coverage and $13,700 for other than self-only coverage.

Enforcement Remedies for FFEs

HHS is proposing to extend its good faith compliance standard through the end of calendar year 2015. HHS implemented this policy in 2014 to forgo imposing sanctions on QHP issuers for violations of Exchange requirements if that issuer has made good faith efforts to comply. This policy was intended to allow issues to become familiar with Exchange requirements and encourage issuers to work with HHS on compliance questions.

Further, as demonstrated in 2014, HHS reserves the power to suppress a QHP from any avenue of enrolling consumers through an FFE when determined necessary to

[33] 79 FR 70729.

support the protection of consumers' interest. HHS now proposes a formal definition of "suppression" and an enumeration of bases for suppression of a QHP. The bases include (1) intent to withdraw from the FFE, (2) the FFE possesses incorrect data about the QHP, (3) the QHP is in the process of decertification, (4) the QHP is subject to pending state regulatory or enforcement action, (5) a state department of insurance has imposed enrollment caps, or (6) upon notification of a compliance violation by OPM in the case of a multistate plan.

Quality Standard: Quality Improvement Strategy

Starting with plans offered on the 2016 FFEs and state-based Exchanges, issuers will be required to implement and report on a quality improvement strategy ("QIS"). The ACA requires a QIS to include a payment structure to provide increased reimbursement or other market-based incentives to improve health outcomes, reduce hospital readmissions, improve patient safety, and reduce medical errors. HHS has proposed that only issuers that have been participating in an Exchange for at least two years be required to implement and report on a QIS. Issuers will also be required to submit an implementation plan, as well as annually submit data to demonstrate compliance with the standards for a QIS. HHS states that it will establish QIS standards that use market-based incentives for QHPs offered through the Exchanges that align with the National Quality Strategy, the HHS Quality Strategy, and other federal, state, and private sector initiatives.

Treatment of Cost-Sharing Reductions in MLR Calculation

HHS proposes to specify that cost-sharing reduction payments should be deducted from incurred claims under the MLR program just as they are deducted from allowable costs under the Risk Corridor Program. HHS further proposes that federal and state employment taxes should not be excluded from premium in MLR and rebate calculations. Finally, group policy holders of non-federal governmental plans will be required to use the subscribers' portion of the rebate for the subscribers' benefit within three months of receipt of the rebate.

PROPOSED MSP RULE

Section 1334 of the ACA established the MSP Program, which allows a health insurance issuer or group of issuers to contract with the OPM to offer at least two MSP options on each of the Exchanges. The goal of the MSP Program is to foster competition in the individual and small group health insurance markets by providing at least two high-quality options in each state. The MSP Program final rule was published March 11, 2013. The recently issued Proposed MSP Rule proposes to amend certain standards related to coverage area, benefits, and contracting provisions. In the Proposed MSP Rule, OPM notes challenges with expansion of the MSP Program, including limited participation of MSP issuers on the SHOPs and difficulty providing consistent coverage. The proposed changes and the items on which OPM seeks

comment indicate a willingness to create flexibility in the MSP Program to attract issuers and to assist existing MSP issuers with further expansion.

The MSP Program is a creation of the ACA but recalls past attempts to offer comprehensive coverage and competition. The Medicare Modernization Act of 2003 created regional preferred provider organization ("PPO") networks with the goal of offering comprehensive coverage to beneficiaries in rural areas. There was great enthusiasm for introducing regional PPOs as competition to traditional Medicare health maintenance organizations ("HMOs"), but the program never quite produced results. The participating PPOs were low in number and could not compete, given low enrollment and the challenges of operating in rural, CMS-defined regions to which they were assigned. It remains to be seen whether OPM will have more success as it attempts to refine the MSP Program.

Service Area Coverage

The final MSP rule established standards for phased-in participation of an MSP within a state and in the SHOPs. In order to contract with OPM, an issuer has to agree to phased coverage expansion in states. To address challenges faced with such expansion, OPM seeks comment on how it may expand participation in the MSP Program. To foster statewide coverage, OPM proposes to delete the requirement that an MSP issuer submit a plan to become statewide. Instead, OPM proposes that the issuer work with OPM to assess the issuer's ability to do so. Additionally, OPM notes very limited MSP SHOP options and solicits comments on when MSP issuers should be required to participate in the SHOPs.

Benefits

MSP issuers must offer a uniform package of benefits within a state, and such benefits must be substantially similar to a certain benchmark plan, such as a state's EHB-benchmark plan. OPM proposes to allow more flexibility in the selection of benefits by allowing an MSP issuer to make benchmark selections on a state-by-state basis, with allowance for multiple MSP options in a given state. OPM requests comment on whether this increased flexibility would encourage participation while balancing ease of consumer understanding. OPM also proposes to, and seeks comment on, the feasibility of substituting an OPM-selected benchmark plan prescription drug formulary for the EHB-benchmark plan formulary to address confusion about the MSP drug formulary standards.

Network Adequacy

To ensure network adequacy, OPM proposes to require that an MSP issuer comply with any additional standards related to provider directories set by HHS QHP issuers. (See section above titled "Network Adequacy Standards").

User Fees

OPM clarifies that it will begin collecting user fees, as it is authorized to do under the MSP Program, as early as plan year 2015. However, OPM is seeking comments about how to collect and use such fees.

Contracting

As issuers will contract with OPM under the MSP Program, OPM has established contract performance requirements. The requirements by which an issuer will be judged, as listed in the final rule, were not meant to be exhaustive and OPM clarifies in the preamble to the Proposed MSP Rule that it will consider an issuer's specific facts and circumstances when determining contractual compliance. OPM further clarifies that it may withdraw certification of an MSP option for noncompliance.

Under the ACA, OPM is required to contract with at least one MSP issuer that excludes coverage of abortion services, except in special circumstances. OPM proposes to require MSP issuers to disclose either coverage or exclusion of such benefits before a consumer enrolls. OPM may review and approve these notices.

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CMS and OPM will be accepting comments on their respective proposals until 5 p.m. (EST) on December 22, 2014. We encourage all stakeholders to provide public comment to CMS and/or OPM regarding these proposals. Comments should address considerations in this proposal, discuss significant challenges related to implementation, and provide detailed suggestions based on experience with similar requirements. Epstein Becker Green is available to assist with drafting and submitting comments to the proposed rules.

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This Client Alert was authored by **Helaine I. Fingold, Philo D. Hall,** *and* **Lesley R. Yeung**. *For additional information about the issues discussed in this Client Alert or if stakeholders need assistance with drafting and submitting comments to the proposed rules, please contact one of the authors of this Client Alert or the Epstein Becker Green attorney who regularly handles your legal matters.*

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