CMS Releases Key Proposals for the 2016 Qualified Health Plan Application Process

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Stakeholders received insight on the Obama administration's expected approach to the certification and oversight of qualified health plans ("QHPs") on December 19, 2014, with the release by the Centers for Medicare & Medicaid Services ("CMS") of its Draft 2016 Letter to Issuers in the Federally-facilitated Marketplaces ("Draft Letter"). This annual release comes more than a month before than the release of the 2015 version of this document. CMS is accepting comments on the Draft Letter through **January 12, 2015**.

While the Draft Letter largely mirrors the provisions of its 2015 predecessor,[1] or restates proposals from the proposed 2016 Notice of Benefit and Payment Parameters ("2016 Payment Notice"),[2] CMS does propose several significant changes for the 2016 application cycle. These changes include the use of an earlier timeline for application submission, review, and approval, as well as a more extensive review of benefit offerings for compliance with non-discrimination requirements.[3]

The Draft Letter speaks specifically to issuers seeking to offer QHPs in the individual and small group markets through the Federally-facilitated Marketplaces ("FFMs"). However, this proposed guidance should also be closely reviewed by issuers seeking to offer coverage in State-based Marketplaces and outside the Marketplaces for insight into CMS's perspective on market-wide provisions discussed in the context of QHPs.

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[1] CMS, 2015 Letter to Issuers in the Federally-facilitated Marketplaces, March 14, 2014, *available at* http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2015-final-issuer-letter-3-14-2014.pdf.

[2] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016; Proposed Rule, 79 Fed. Reg. 70674, November 26, 2014, *available at* http://www.gpo.gov/fdsys/pkg/FR-2014-11-26/pdf/2014-27858.pdf.

[3] CMS, Draft 2016 Letter to Issuers in the Federally-facilitated Marketplaces, December 19, 2014, *available at* http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2016DraftLettertoIssuers12-19-2014.pdf (hereinafter "Draft Letter").

QHP Application and Certification Process

In the Draft Letter, CMS proposes to require earlier submission, review, and approval of applications for certification to offer QHPs and stand-alone dental plans ("SADPs") in the FFMs. QHP applicants would submit certification applications between March 16 and April 15, 2015, rather than during the late May to late June timeframe followed for the 2015 application cycle.[4]

CMS's cautions applicants to be sure to fully and accurately complete and file application materials so as not to require making "significant changes" to QHP applications after the final data submission deadline. In past years, as CMS points out, the majority of issuers requesting to make significant changes after the final data submission deadline were due to "data inaccuracies and/or the incompleteness of an application." CMS noted that the need to request significant changes at that point in the application process "calls into question an issuer's ability to submit a valid QHP application" and indicated that, starting with the 2016 application process, those requesting to make significant changes after the final data submission deadline "may be at risk for non-certification or compliance action."[5]

Recertification for 2016

Issuers seeking to renew benefit year 2015 QHPs for offering in the FFMs will need to reapply during the upcoming application cycle. To be eligible for recertification for plan years beginning in 2016, a QHP or SADP certified by an FFM must be the same "plan" as the plan that was certified for plan years beginning in 2015.[6] CMS states that it anticipates using the amended definition of "plan" from Section 144.103 of the 2016 Payment Notice proposed rule, if it is finalized as proposed. The same definition of "plan" also will apply to reenrollment of current enrollees into the same plan, pursuant to Section 155.335(j). CMS intends to use this standard (45 C.F.R. 144.104) to determine whether an SADP is eligible for recertification.

The Draft Letter does not state whether a plan already being offered is guaranteed to be renewed under the market-wide guaranteed renewability requirement.

Plan ID Crosswalk. For the 2015 application cycle, CMS developed and released a Plan ID Crosswalk Template for issuers to complete and submit to CMS. For the FFMs, this template enabled issuers to crosswalk their 2014 QHP plan ID and service area combinations (e.g., Plan ID and County combinations) to a 2015 QHP plan ID. CMS states that this data will facilitate enrollment transactions from CMS to the issuer in mid-December 2014 for those individual market enrollees who have not actively selected to

[4] For states performing plan management functions, CMS defers to the states to set QHP application submission timeframes. However, the proposed schedule for these states to transfer data to CMS relating to QHP applicants has also been moved up by approximately two months; thus, these states will also need to impose an earlier submission deadline than was used for 2015.

[5] Draft Letter, *supra* note 3 at 13.

[6] "Plan" is defined in 45 C.F.R. 144.103 as health insurance coverage of a health insurance issuer under which the financing and delivery of medical care (including items and services paid for as medical care) are provided, in whole or in part, through a defined set of providers under contract with the issuer.

switch to a different QHP during open enrollment. CMS expects to implement a similar approach for automatic re-enrollment from 2015 to 2016 for QHPs in the FFMs. In addition, CMS expects that the Federally-facilitated Small Business Health Options Programs ("FF-SHOPs") will support automatic reenrollment for plan years beginning in 2016. CMS also expects that issuers will submit the template to a CMS email address, in the same manner as was required for the 2015 plan year.

The Draft Letter notes that SADPs, as excepted benefits, are not subject to the guaranteed renewability standards specified at 45 C.F.R. 147.106. However, as CMS has stated in previous guidance, CMS again aims to apply the hierarchy set forth at 45 C.F.R. 155.335(j) and the business rules established for the 2016 Plan ID Crosswalk Template to SADPs in order to support automatic re-enrollment for plan years beginning in 2016.

CMS will conduct an overall data integrity review of submitted Plan ID Crosswalk data. This will include, but not be limited to, an evaluation for compliance with 45 C.F.R. 155.335(j) and with the final rule on Annual Eligibility Redeterminations for Marketplace Participation and Insurance Affordability Programs.[7] This will also include a review for consistency with submitted Service Area and Plans and Benefits Template data for both the 2015 and 2016 plan years.

QHP and SADP Certification Standards

CMS proposals with respect to the review of QHP and SADP 2016 certification applications generally mirror the review approach for 2015 applications, with the exception of prescription drug benefit requirements and assessing compliance with QHP non-discrimination provisions.

Essential Health Benefits ("EHB") Discriminatory Benefit Design. CMS put forth no new policies regarding EHB discriminatory benefit design but, rather, repeats the concerns that CMS first expressed in the preamble to its proposed 2016 Payment Notice, published on November 26, 2014. Specifically, CMS restates its concern over plans' application of improper age limits for benefit eligibility where enrollees of all ages could benefit from an item or service. CMS also repeats its caution that issuers "avoid discouraging enrollment of individuals with chronic health needs," including by failing to include multiple versions of a drug treatment regimen (e.g., single table or extended release, in addition to a multi-tablet regimen) where individuals "would benefit from such therapeutic options."

Next, the U.S. Department of Health and Human Services ("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. Also restated is CMS's position that placement on the highest cost tiers of most or all drugs that treat a specific condition would discriminate or discourage enrollment by those individuals who have such "chronic conditions."

[7] 79 Fed. Reg. 52995, *available at* http://www.gpo.gov/fdsys/pkg/FR-2014-09-05/pdf/2014-21178.pdf.

QHP Discriminatory Benefit Design. CMS's proposed approach to assessing QHP discriminatory benefit design departs from its 2015 approach in one significant way. Both the 2015 review and the proposed 2016 review compared plan out-of-pocket cost estimates to identify outliers and reviewed plan explanations and exclusions for discriminatory features that are "not based on clinically indicated, reasonable medical management practices." However, while the 2015 approach compared cost sharing for certain specific benefits, the proposed 2016 approach would look at estimated out-of-pocket costs across multiple benefit categories that are associated with treatment for specific medical conditions, including bipolar disorder, diabetes, HIV, rheumatoid arthritis, and schizophrenia.

Prescription Drugs. CMS's discussion of its proposed review of plans' prescription drug coverage restates its proposals in the 2016 Payment Notice. Also referenced is CMS's intent to review plans' prescription drug benefit design to ensure non-discrimination, through identifying outliers in requiring prior authorization and/or step therapy requirements for an unusually large number of drugs in a particular United States Pharmacopeia ("USP") category and class, as it did when reviewing applications for 2015.

CMS also proposes to subject QHPs' prescription drug coverage to a new "clinical appropriateness" review to assess whether the proposed benefit package offers "a sufficient number and type of drugs needed to effectively treat" four specific medical conditions—bipolar disorder, diabetes, rheumatoid arthritis, and schizophrenia—and "are not restricting access through lack of coverage and inappropriate use of utilization management techniques."

QHP Performance and Oversight

CMS is proposing expanded guidance regarding performance and oversight issues, reflecting a clear intent to increase compliance monitoring and enforcement activities, especially with respect to oversight of brokers and agents. Many of the requirements discussed in the Draft Letter are already set forth in regulations, although additional requirements are proposed, as discussed below.

Issuer Compliance Monitoring. For 2014, CMS provided that it would monitor QHP issuers for compliance, but that it would not seek to impose civil money penalties or decertify QHPs that are not in compliance with the applicable requirements where issuers had demonstrated good faith efforts to comply with those requirements. CMS has proposed to extend this good faith policy through the 2015 calendar year. Such "good faith efforts" include the development of "effective internal monitoring programs to identify, report, and correct compliance violations in [issuers'] operations," as well as "internal policies and procedures for coordinating with CMS to correct those violations when notified." Failure to develop a work plan to correct a violation or failure to act upon a developed work plan would be inconsistent with "good faith."

Issuer Compliance Reviews. For 2014, CMS used a risk-based process, based on compliance monitoring and performance data, to select issuers for standard compliance

reviews. For 2016, CMS proposes to use a similar approach. Specifically, CMS proposes to continue relying on a risk-based approach that looks to compliance monitoring (e.g., complaint data) and available performance data to select issuers for standard compliance reviews as well as to target issuers for ad hoc reviews. Where an issuer is selected for review based on a specific issue of potential non-compliance, CMS may limit its review to that specific area of concern and/or may conduct the compliance review on an expedited basis, depending on the potential magnitude of harm to consumers.

In addition, the proposed guidance specifies that audits may be either desk reviews or on-site reviews and that CMS may request all relevant documentation. Finally, CMS intends to share the results of the audits with the relevant state regulators.

Oversight of Agents and Brokers. CMS is proposing significant new specific requirements related to oversight of agents and brokers. The proposed requirements include a broad requirement that the issuer is responsible for ensuring that all activities conducted on its behalf by affiliated agents and brokers comply with applicable state and federal standards, including those related to privacy and security, conflicts of interest, marketing, and continuing education. This requirement would appear to mandate a much more stringent oversight program than the ones currently maintained by most issuers.

FF-SHOPs

The operational and technical guidance in the Draft Letter generally applies to QHPs in both the individual market and the FF-SHOP. The Draft Letter also proposes additional requirements specific to the FF-SHOPs for plan years beginning on or after January 1, 2016, as described below.

Availability of SADPs. Beginning as early as the 2016 plan year, employers offering coverage through the FF-SHOPs will be able to offer dental coverage without also having to offer medical coverage. Where an employee enrolls in both medical and dental coverage offered by his or her employer, the employee's dependents may enroll in either the medical or dental coverage selected by the employee, or in both. An employee's dependents are only eligible to enroll in the coverage selected by the employee.

Employer Group Size in the FF-SHOPs. QHPs and SADPs will be available through the 2016 FF-SHOPs to small employers. Under the Affordable Care Act[8] and its implementing regulations,[9] a "small employer" is defined as an employer that employed an average of at least one but not more than 100 full-time-equivalent employees ("FTEs") during the preceding calendar year and that employs at least one employee on the first day of the plan year. The law and regulations, however, allowed states to use a phased-in approach to defining "small employers." Specifically, and through plan years

[8] ACA section 1304(b)(3).
[9] 45 C.F.R. 155.20.

beginning before January 1, 2016, states may define a "small employer" as an employer with between one and 50 FTEs. Accordingly, beginning with plan years starting on January 1, 2016, or later, that definition is no longer in effect.

In a related action, CMS implemented a transitional relief policy for non-grandfathered coverage in the small group and individual health insurance markets that would otherwise be cancelled or considered out of compliance with certain market reforms.[10] States could choose to adopt this transitional relief policy for large businesses that currently purchase insurance in the large group market but that, as of January 1, 2016, will be redefined as small employers purchasing insurance in the group market.[11] Through the Draft Letter, CMS seeks comments on how the transitional relief policy should affect the operation of the FF-SHOPs in 2016.

Renewals. CMS expects that FF-SHOPs will support automatic re-enrollment for plan years beginning in 2016. Further, CMS anticipates that all renewals of FF-SHOP participation and all renewals of health and dental coverage offered through the FF-SHOPs in 2016 will be handled by employers and employees online at HealthCare.gov, including those employers and employees working with an agent or broker.

The FF-SHOPs must allow an employer to continue its participation in the FF-SHOP for plan years beginning in 2016 if the following conditions are met: (1) the employer received a determination of eligibility from an FF-SHOP in a prior year and has continued participating in that FF-SHOP since that time; (2) the employer had 100 or fewer full-time-equivalent employees when the group began participating in FF-SHOPs, but added employees after the group began participating and now has more than 100 full-time-equivalent employees; and (3) the employer continues to meet all other requirements for participating in an FF-SHOP.

Employers renewing participation will have an annual election period during which they can renew or change the FF-SHOP coverage offered to employees, beginning when rate and plan information becomes available for the quarter in which coverage would end.

Employee Choice. In 2016, all qualified employers will have a choice of two methods to make QHPs available to qualified employees through the FF-SHOPs: (1) they can offer employees a choice of all QHPs at a single level of coverage (bronze, silver, gold, or platinum), or (2) they can offer employees a single QHP. Employers will also have the option to make available either (1) all SADPs at a single level of coverage (high or low), or (2) a single SADP. This replaces a transitional policy for plan years beginning in 2015 that allowed states to request that the FF-SHOPs provide employers only with the

[10] CMS, Insurance Standards Bulletin Series – Extension of Transitional Policy through October 1, 2016, March 5, 2014, *available at* http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/transition-to-compliant-policies-03-06-2015.pdf.

[11] *Id*. at 2 (under the transitional relief policy, large businesses have the option of renewing their current policies through policy years beginning on or before October 1, 2016, without their policies being considered out of compliance with provisions that apply to the small group market but not to the large group market).

option to offer a single plan, rather than providing employers with the option to offer employee choice.

FF-SHOP Plan Premiums. CMS anticipates that the capacity to calculate and display premiums based on an average enrollee premium amount will be available in the FF-SHOPs in 2016.

Issuers must communicate to CMS whether they will make available plans with premiums based on average enrollee premium amounts at the time of initial enrollment. When qualified employers choose to offer their employees a single plan option (rather than offering employees a choice of plans at a specified level of coverage), they will also be able to decide whether to pay premiums using a per-member methodology or one based on average enrollee premium amounts. The total premium charged for a given family composition under an average enrollee premium amount methodology is based on the sum of the average enrollee premium amount for each covered family member age 21 and older and the average enrollee premium amount for each covered family member under age 21, as applicable (taking into account no more than three covered children under age 21).

Consumer Support and Related Issues

Consumer Case Tracking and Resolution. As mentioned in the 2015 Letter to Issuers, CMS expects issuers to resolve all cases in a timely and accurate manner to ensure that consumers receive the highest level of service and to meet QHP issuer participation standards as outlined at 45 C.F.R. 156.200. The 2016 Draft Letter details the types of cases that CMS may forward to QHP Issuers. These include, but are not limited to, cases relating to cancellations/terminations, proper application of the advance payments of the premium tax credit, and adjustments of effective dates based on special enrollment periods or enrollment errors.

In all cases, CMS expects QHP issuers operating in the FFMs to conduct appropriate research using all of the tools and systems available to them, including, but not limited to, 834 transactions and pre-audit files. Additionally, CMS expects QHP issuers operating in the FFMs to contact consumers, as appropriate, to conduct their investigations and research in order to ensure that issuers are using the most recent information available from the consumer.

The Draft Letter also noted the availability of CMS Regional Office staff to provide QHP issuers with technical assistance on casework matters beyond QHP issuers' control to resolve.

Meaningful Access. The Draft Letter largely summarizes existing requirements and guidance for QHP issuers in the FFMs (including SADP issuers) to ensure meaningful access by limited-English proficient speakers and by individuals with disabilities, though it discusses several changes to certain issuer obligations in this area that were included in the proposed 2016 Payment Notice.

CMS proposed in the 2016 Payment Notice that a QHP issuer's existing obligation to provide oral interpretation services include making available telephonic interpretation services in at least 150 languages. CMS also proposed requiring QHP issuers to provide all information that is critical for obtaining health insurance coverage or access to health care services through the QHP to qualified individuals, applicants, qualified employers, qualified employees, and enrollees in a manner consistent with 45 C.F.R. 155.205(c), meaning that all such information would need to be made available in the 150 proposed languages and accessible to disabled individuals. All such requirements would apply to QHP issuers operating in the FFMs.

The Draft Letter also restates CMS's proposal in the 2016 Payment Notice to add as a category of documents to which QHP issuers would be required to ensure meaningful access "any document the issuer is required by state or federal law to provide to a qualified individual, applicant, qualified employer, qualified employee, or enrollee (for example, the summary of benefits and coverage required under 45 C.F.R. 147.200)."[12]

In addition, the Draft Letter omits from the meaningful access requirements one category of documents that was included in the 2015 Letter to Issuers—QHP ratings information. Accordingly, QHP issuers would no longer need to provide translated versions of this information or alternate access for disabled individuals.

Summary of Benefits and Coverage ("SBC"). The content of this section applies to all QHP issuers in the FFMs, including states performing plan management functions, although it does not apply to SADPs.

As mentioned in the previous 2015 Letter to Issuers, issuers must fully comply with the requirement to "provide an SBC in the form, and in accordance with the instructions for completing the SBC, that are specified by the Secretary in guidance."[13] CMS clarifies in the Draft Letter that CMS expects all URL links on the SBC to be easily accessible to consumers, including shoppers, and link directly to the information referenced on the SBC. For example, the link for obtaining information on prescription drug coverage in the SBC should directly link to the formulary for the benefit package reflected on the SBC.

In the proposed 2016 Payment Notice, CMS proposed to amend regulations to require QHP issuers to provide SBCs representing plan variations to ensure that consumers have access to SBCs that accurately represent cost-sharing responsibilities for all coverage options. If this amendment is finalized as proposed, QHP issuers will be required to create separate SBCs for each plan variation and therefore will not be allowed to combine information on multiple plan variations in one SBC.

Transparency in Coverage Reporting. This section outlines CMS's transparency reporting requirements for all issuers of QHPs in the FFMs, including SADPs, and

[12] Draft Letter, *supra* note 3 at 56.
[13] 45 C.F.R. 147.200(a)(3).

explains CMS's intent to require QHP issuers in the FFMs to comply with transparency requirements beginning in 2016.

As mentioned in last year's final 2015 Letter to Issuers, issuers seeking certification of a health plan as a QHP must make accurate and timely disclosures of certain information to the appropriate Marketplace, the Secretary of HHS, and the state insurance commissioner, and make such information available to the public. CMS anticipates enforcing the transparency requirements beginning in 2016 as, at that time, a full year of claims data will be available. CMS solicited comments through the proposed 2016 Payment Notice to inform future technical guidance on the implementation of the transparency in coverage reporting requirements, including what information must be provided and the timing of submissions. CMS also sought comments on the manner in which the Marketplaces and QHP issuers should publicly display the collected information.

CMS plans to release additional guidance when the transparency in coverage data submission and public display requirements have been finalized.

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Comments on the Draft Letter are due to CMS by January 12, 2015.

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