FOLEY HOAG LLP

CY 2023 NBPP Proposed Rule

Summary

January 3, 2022

On Dec. 28, 2021, the Department of Health and Human Services published, for public inspection, the CY 2023 Notice of Benefits and Payment Parameters (NBPP) Proposed Rule. Among its many provisions are several proposals affecting prescription drug requirements applicable to issuers offering plans in the Exchanges, including proposals/clarifications relating to adverse tiering and standardized plan options. Below is a summary of those provisions.

Comments are due no later than 5:00 pm on January 27, 2022.

Nondiscrimination Based on Sexual Orientation and Gender Identity (pg. 41) 1

Adverse Tiering Presumptively Discriminatory (pg. 223) 2

Standardized Options (pg. 245) 3

MLR Reporting of Provider Incentive and Bonus Payments (pg. 292).....5

Solicitation of Comments on Health Equity, Climate Health, and Qualified Health Plans (pg. 298) 6

Nondiscrimination Based on Sexual Orientation and Gender Identity (pg. 41)

- **Background**
  - In 2014 rulemaking, HHS prohibited discrimination based on sexual orientation and gender identity.
  - In 2020 rulemaking revising regulations implementing section 1557 of the ACA, HHS also revised certain CMS regulations, including removing sexual orientation and gender identity as a basis of discrimination.
    - The removal of sexual orientation and gender identity in the 2020 rulemaking is subject to ongoing litigation.
    - NOTE: In *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), the Supreme Court held that Title VII of the Civil Rights Act of 1964 includes discrimination on the basis of sexual orientation and gender identity.
  - EO 13988, issued by the Biden Administration on Jan. 20, 2021, instructed HHS (among other agencies) to review existing regulations and consider whether any regulation is inconsistent with the Administration's overarching policy of preventing and combating discrimination on the basis of gender identity and sexual orientation.
- **Proposal/Clarification**
  - HHS proposes to prohibit discrimination on the basis of sexual orientation and gender identity on grounds **independent of section 1557** by amending sections 147.104(e), 155.120(c), 155.220(j), 156.125(b), 156.200(e), and 156.1230(b).
  - HHS is relying on specific statutory authority to support the amended regulations as follows:

- Amendments to 147.104(e) is being supported by section 2702 of the Public Health Service Act (PHSA), as well as section 2792 of the PHSA, which provides HHS with broad rulemaking authority to promulgate regulations as may be necessary or appropriate to carry out the provisions of title 27 of the PHSA. *See* pg. 44.
- Amendments to 155.102(c) are supported by section 1321(a)(1)(A) of the ACA, which authorizes HHS to prohibit States from discriminating in the Exchanges. *See* pg. 144
- Amendments to 155.220(j) are supported by section 1312(e) of the ACA to prohibit discrimination in the group and individual market based on the Secretary's authority to establish procedures for States to permit agents and brokers to enroll consumers in QHPs through FFEs, and section 1312(e) of the ACA, which provides HHS with the authority to establish requirements with respect to the operation of exchanges, the offering of QHPs through such Exchanges, and other requirements the Secretary determines appropriate. *See* pg. 286.
- Amendments to 156.125(b) are supported by section 1302(b) of the ACA, which authorizes HHS to define EHBs to take into account the health care needs of diverse segments of the population. *See* pg. 220.
- Amendments to 156.200(e) is the standard nondiscrimination provision applicable to issuers, which is supported by section 1302(b) of the ACA as described above. *See* pg. 220.
- Amendments to 156.123(b) are supported by sections 1321(a)(1)(A), (B), and (D) of the ACA, which authorizes the Secretary to establish requirements with respect to the operation of Exchanges, the offering of QHPs through such Exchanges, and other requirements as the Secretary determines appropriate.

Adverse Tiering Presumptively Discriminatory (pg. 223)

- **Background**
  - Qualified Health Plans (QHPs) may have different tier structures for prescription drugs that may be based on, among other factors, the cost of the medications.
  - HHS expresses concern regarding "adverse tiering", which occurs when "plans structure the formulary by assigning all or the majority of drugs for certain medical conditions to a high-cost prescription drug tier."
- **Problem/Rationale**
  - Individuals with certain chronic conditions have reported that the majority of their prescription drugs have been designated as specialty drugs and placed in the highest cost tier, including all drugs in the same therapeutic class in some instances.
  - Health benefit designs with "adverse tiering may discriminate based on an individual's present or predicted disability or other health conditions in a manner prohibited by regulations. *See* 45 CFR 156.125(a).
- **Proposal/Clarification**
  - HHS is clarifying that issuer policies which place most or all drugs that treat a specific condition on the highest cost tiers (i.e. adverse tiering) are presumptively discriminatory

and that issuers and PBMs assigning tiers to drugs should weigh cost of drugs on their formulary with clinical guidelines for any such drugs used to treat high-cost chronic health conditions.
        - Such policy will become effective 60 days after publication of the final rule.
    - HHS states that placing all drugs for a high cost chronic condition on the highest formulary tier is presumed to be discriminatory, even when the drugs are costly.
    - Issuers should expect to cover and provide sufficient access to treatment recommendations that have the highest degree of clinical consensus based on available data, such as professional clinical practice guidelines. In other words, issuers should be able to demonstrate that neutral principles were used to assigning drugs to tiers, and that such principles were applied consistently across all types of drugs.
        - *For example, a generic drug requiring no special handling that is inexpensive to obtain might rightly placed on a generic tier or the lowest tier whereas a specialty drug requiring special handling and counseling, and that is also very costly, might be rightly placed on specialty tier that has the highest cost sharing. However, a generic drug or common brand drug that does not require special handling, counseling, or medication management, and is not expensive, should not be placed on a specialty tier just because it is used to treat a condition that is a high-cost chronic condition.* Pg. 235-236.

Standardized Options (pg. 245)

- **Background**
    - In the 2017 Payment Notice, HHS began requiring that issuers offer standardized options similar to the most popular QHPs in the 2015 individual market FFEs at the bronze, silver, and gold metal levels.
    - HHS subsequently update these options in the 2018 Payment Notice to reflect changes in QHP enrollment data in 2016 (to include SBE-FP data) and to account for state cost sharing laws.
    - In the 2019 Payment Notice, however, HHS discontinued standardized options. The discontinuance was challenged in federal court and overturned. HHS indicated that it would resume standardized options by PY 2023.
- **Problem/Rationale**
    - HHS believes that market conditions have changed since the discontinuance of standardized options in 2019, which was intended to maximize innovation during a time when the individual market was considered to be at risk of destabilization.
    - HHS states that the number of the number of counties with a single issuer offering plans through the Exchange has decreased significantly, and the number of plan options that consumers have access to on the Exchanges has increased substantially since standardized options were discontinued in the 2019 Payment Notice, thereby indicating that resuming standardized options can play a "constructive role in enhancing consumer experience, increasing consumer understanding, simplifying the plan selection process, combatting discriminatory benefit designs…and advancing health equity."

- HHS specifically cites the proliferation of plans in the past few years as potentially contributing to choice paralysis in enrollees, and indicates that standardized options could enable consumers to make more meaningful choices.
- HHS responds to comments submitted in response to Part 3 of the 2022 Payment Notice on this issue in pages 253-255.
- HHS discusses the design of the standardized options at page 255-

- **Proposal/Clarification**
  - HHS proposes to require issuers of QHPs through FFEs and SBE-FPs to offer standardized QHP options at every product network type for PY 2023 and beyond.
    - *For example, if an issuer offers a non-standardized gold health maintenance organization (HMO) plan in a particular service area, that issuer must also offer a standardized gold HMO plan in that same service area. HHS does not propose to limit the number of non-standardized QHP options that issuers of QHPs in FFEs and SBE-FPs can offer through the Exchange in PY 2023.*
  - HHS is proposing two sets of standardized options, both of which are detailed in Table 16 (pg. 259) and Table 17 (pg. 260)—key design features include:
    - Proposed standardized options are similar to most popular QHPs based on proportion of consumers enrolled in plans with different cost sharing types for every benefit category in the actuarial value calculator (AVC) at each meta level.
    - Proposed creation of two standardized options is consistent with 2018 Payment Notice that established three sets of options which differed from the first set only to the extent necessary to comply with state cost-sharing laws.
    - The first set of standardized option includes features from second set of standardized options from the 2018 Payment Notice, including cost sharing parity between the primary care visit, speech therapy, and occupational and physical therapy benefit categories**. There are also copays for all prescription drug tiers, including the non-preferred brand and specialty tiers, instead of coinsurance rates.** Finally, the copayment for the mental health/substance use disorder in-network outpatient office visit sub-classification is equal to the least restrictive level for copayments for medical/surgical benefits in the in-network outpatient office visit sub-classification.
    - The second set of standardized options includes all the features of the second set of standardized options from the 2018 Payment Notice, but the feature that distinguishes the first set of standardized options from the second set is that the second **set of standardize options have copays of $150 or less for the specialty drug tiers of standardized options at all metal levels.**
      - This second set of standardized options was established to accommodate relevant specialty tier prescription drug cost sharing laws in Delaware and Louisiana—**HHS proposes that this set of standardized options apply to issuers in only those two specific states.**
  - HHS is <u>NOT</u> requiring:
    - That standardized options be offered for the Indian CSR plan variations as these are already largely standardized.
    - States Exchanges to offer standardized options.

        - FFE and SBE-FP issuers that are already required to offered standardized options under state action taking place on or before January 1, 2020 (such as issuers in Oregon) will be exempt from the standardized options requirements in this proposed rule.
    - HHS solicits comments on:
        - (1) requiring FFE and SBE-FP issuers to offer standardized options at every product network type, metal level, and throughout every service area that they offer non-standardized options;
        - (2) not limiting the number of non-standardized options that issuers can offer through the Exchanges;
        - (3) the feasibility, advantages, and disadvantages of gradually limiting the number of plan options over the course of several PYs;
        - (4) whether standardized options should be differentially displayed on HealthCare.gov as well as the best manner for doing so;
        - (5) whether web-brokers and issuers using the Classic DE and EDE Pathways should remain subject to differential display requirements;
        - (6) the continuation of an exceptions process that allows these entities to deviate from the display of standardized options on HealthCare.Gov;
        - (7) exempting State Exchange issuers from these requirements;
        - (8) whether these plan designs should apply to State Exchanges that do not use the Federal platform and that have not implemented their own standardized
        - (9) exempting FFE and SBE-FP issuers that are subject to existing state standardized options requirements under state action taking place on or before January 1, 2020 from being required to offer the standardized options in this proposal;
        - (10) the methodology used to design these standardized options;
        - (11) if these standardized options are compliant with state cost sharing laws in FFE and SBE-FP states;
        - (12) the cost sharing parameters and plan designs for these standardized options;
        - (13) how these plans can be designed in a way that maximizes the likelihood that plans will be able to comply with MHPAEA;
        - (14) the policy approach for P 2023 and beyond; and (15) having two sets of standardized options (that is, a separate set for Delaware and Louisiana).

MLR Reporting of Provider Incentive and Bonus Payments (pg. 292)

- **Background**
    - Issuers are required to, for MLR purposes, separately report the percentage of total premium revenue (after certain adjustments) expended on reimbursement for clinical services provided to enrollees under such coverage for activities that improve health care quality, and on all other non-claims (administrative) costs.
    - Issuers are required to provide an annual rebate to each enrollee if the issuer's MLR falls below the applicable MLR standard.

- **Problem/Rationale**
    - HHS has noticed that some issuers reporting incentive or bonus payments to providers are not based on quality or performance metrics, but rather, involve transferring excess premium revenue to providers to circumvent MLR rebate requirements and avoid paying MLR rebates when issuers do not meet the applicable MLR standard.
    - Incentive/bonus agreements typically have clinical metrics that msut be met by the provider, rather than the issuer, in order for payment to occur—however, HHS has observed arrangements where the issuer's failure to meet the MLR standard is itself the metric that triggers the payment of a bonus to the provider (i.e. the excess profits are paid to the provider group or hospital system).
    - Such a practice artificially raises the issuer's MLR so that it is close to or meets the applicable MLR standard, which often eliminates the rebate owed to enrollees, regardless of how low enrollees' claims costs are relative to premiums those enrollees pay.
- **Proposal/Clarification**
    - HHS is clarifying that only those provider incentives and bonuses that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting and rebate calculation purposes.
    - Only expenses directly related to activities that improve health care quality may be included as quality improvement activity (QIA) expenses for MLR reporting and rebate calculation purposes.

Solicitation of Comments on Health Equity, Climate Health, and Qualified Health Plans (pg. 298)

- HHS is soliciting comments on, among other things, "what types of utilization reviews could issuers perform of medical or prescription data to better understand the impact of climate change events on their enrollees?"