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CLIENT ALERT

CMS Proposes Modest Increases to Medicare Advantage and Part D Plan Payment Rates Accompanied by Significant Revisions to Risk Adjustment Methodologies and Employer/Union-Only Group Welfare Plan Bids

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The Advance Notice ("Advance Notice") of Methodological Changes for Calendar Year ("CY") 2017 for Medicare Advantage ("MA") Capitation Rates, Part C and Part D Payment Policies and 2017 Call Letter was released by the Centers for Medicare & Medicaid Services ("CMS") on February 19, 2016.[1] The Advance Notice describes proposed payment and risk adjustment methodology changes for MA and Medicare prescription drug benefit ("Part D") plans. It also includes CMS's preliminary estimates of factors that will affect 2017 payments for MA and Part D plans and the Part D and retiree drug program benefit parameters for 2017. The draft Call Letter outlines policy modifications and other considerations for MA and Part D plan sponsors preparing bids for the 2017 contract year.

While the Advance Notice may be initially welcomed, thanks to the modest proposed increase in plan payments and the lack of any proposal to limit in-home health assessments, CMS's proposed updates to the risk adjustment and quality bonus measure models will have varying positive or negative effects on MA and Part D plans, depending on the make-up of the plans' enrollees. Further, CMS is proposing to lower payments to employer/union-only group welfare plans ("EGWPs") to be more in line with payments to non-EGWPs.

A wide range of stakeholders are impacted by these proposals, including MA and Part D plan sponsors, pharmacy benefit managers, pharmacies, drug manufacturers, and the vendors that provide services and products to this segment of the health care industry. Stakeholders may comment on the Advance Notice and draft Call Letter by 6:00 p.m. ET on March 4, 2016. Please visit the Medicare Advantage Announcements and Documents

[1] Centers for Medicare & Medicaid Services, Advance Notice of Methodological Changes for Calendar Year (CY) 2017 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2017 Call Letter, February 19, 2016, available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2017.pdf.

webpage[2] for more information on how to submit comments. If you would like to discuss submitting comments, please contact one of the authors of this Client Alert or the Epstein Becker Green attorney who regularly handles your legal matters. Final payment rates and the final Call Letter will be released on April 4, 2016.

PROVISIONS AFFECTING MA PAYMENTS

Estimated 1.05 Percent MA Plan Payment Increase

The Advance Notice projects a 3 percent increase in county benchmarks. This rate increase will be offset by 0.8 percent reduction due to the final year of the six-year phase-in of the new methodology for MA benchmarks established in the Affordable Care Act ("ACA"). CMS further estimates that the payments to MA plans will be additionally reduced by 0.95 percent due to changes in risk adjustment methodology, with a 0.1 percent increase due to increased Star Ratings. CMS estimates the total change in payments (before coding changes) to be an increase of 1.35 percent. CMS will continue to calculate the pre-ACA MA Growth Percentage in order to determine the county-level benchmark cap. In total, CMS projects a national average payment increase of 3.55 percent after accounting for coding trends, which CMS estimates will increase payments by 2.2 percent over the 1.35 percent increase.

Epstein Becker Green projects that MA plans could realize an approximate 1.55 percent increase in MA plan payments over 2016 levels when all factors impacting payment rates (benchmark calculations and risk adjustment changes) are considered. Our estimates differ from CMS because we believe that there will be a further decrease to MA plan payments after CMS rebases the county rates. This is because the change in the risk model may shift funding from counties that have large MA enrollment to counties that do not have the same level of MA penetration. We also differ from CMS as to the 2.2 percent increase in payments in one year attributable to coding trends. We believe that the coding trend will be approximately 0.5 percent due to the implementation of ICD-10 codes and the further reliance on the Encounter Data submission process to calculate risk scores.

These average national estimates project a nominal increase in payments. We caution that certain MA plans in some counties may be subject to payment reductions due to the phase-in and their patient mix, leading to premium increases and benefit cuts in certain areas.

The following are some of the main factors impacting MA plan payments from CMS:

- **Fee-for-Service ("FFS") Growth Percentage:** The current estimate of the Aged/Disabled FFS United States per capita cost ("USPCC"), which will be used for the county portion of the benchmark, is 3 percent.

- **MA Growth Percentage:** The sole reason for calculating the MA Growth Percentage is its use in determining benchmark caps. CMS announces that the estimated change in the national per capita MA Growth Percentage is 2.92 percent, approximately 0.66 percent lower than anticipated. This reflects an underlying trend

[2] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents-Items/2017Advance.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending.

change of 2.68 percent and required adjustments to estimates for prior years. The lower MA Growth Percentage compared to the FFS Growth Percentage means that there may be more counties in 2017 that are capped than in 2016. There is no way to calculate this impact at this time because the county benchmarks will be rebased for 2017.

- **Proposed Statutory Minimum Coding Adjustment:** CMS has increased the adjustment factor for MA coding pattern differences to 5.66 percent in 2017 from 5.41 percent, the lowest increase possible under the Medicare law.

- **Preliminary Normalization Factors:** Consistent with prior years, CMS proposes to use a "quadratic functional form" to risk scores from 2012 to 2015 in order to reflect more recent changes in population trends when calculating FFS normalization. The new normalization factor for 2017 is approximately 0.1 percent higher than the 2016 factor, which causes a corresponding decrease in payment.

- **Encounter Data:** Continuing the transition to Encounter Data-based risk scores, CMS proposes a blended risk score calculation for 2017. The blend will be equally weighted between one risk score calculated using diagnoses from the Risk Adjustment Processing System ("RAPS") and FFS, and another risk score calculated using diagnoses submitted through the Encounter Data System ("EDS"). In 2016, RAPS and FFS diagnoses were weighted at 90 percent in the blended calculation. CMS did not estimate an impact for this change, but we believe that it could be a significant decrease to MA payment and further believe that it will certainly impact MA plans' ability to increase risk scores anywhere near CMS's projection of 2.2 percent.

Risk Adjustment Model and Vulnerable Populations

For several years, stakeholders have raised concerns with CMS over the inability of the MA and Part D programs to adequately account for the true expenses of covering vulnerable populations. Many MA and Part D plan sponsors believe that the current program disadvantages plans with enrollment of a disproportionate number of enrollees from vulnerable populations, including enrollees with lower socioeconomic status ("SES"), those eligible for the Medicare low-income subsidy ("LIS"), those dually eligible for Medicare and Medicaid ("dual eligibles"), and the disabled, all of whom are more likely to have complex conditions and comorbidities. Many plan sponsors believe that the Star Ratings system and quality bonus eligibility are structured in a way that leads to lower scores for plans with disproportionate numbers of enrollees from these vulnerable populations.

In response to these concerns, CMS issued Health Plan Management System ("HPMS") memoranda in 2015 previewing revisions to the CMS-HCC risk adjustment model and Star Ratings.[3] CMS finalizes its Star Ratings recommendations in the draft Call Letter (discussed below), but the Advance Notice makes clear that CMS intends to primarily account for vulnerable populations through updates to the risk adjustment model.

[3] *See* "Proposed Changes to the CMS-HCC Risk Adjustment Model for Payment Year 2017" (Oct. 28, 2015); "Request for Comments: Enhancements to the Star Ratings for 2017 and Beyond" (Nov. 12, 2105).

The Advance Notice proposes a CMS-HCC risk adjustment model with a separate community model segment for each of six subgroups of eligibility: non-dual aged, non-dual disabled, full benefit dual aged, full benefit dual disabled, partial benefit dual aged, and partial benefit dual disabled. CMS tested several models to better predict actual costs of these various subgroups of enrollees.

CMS's analysis projects that its new model will be more accurate than the 2014 model that CMS characterizes as having over-predicted the costs of non-dual and partial benefit dual aged and disabled subgroups, and under-predicting full benefit dual aged and disabled subgroups. The impact on individual MA plans will vary based on how these vulnerable populations groups are represented among enrollees. Sponsors with MA plans that have high numbers of partial benefit dual eligibles will have to consider the impact of this proposed reduction on the aged and disabled dual-eligible enrollees who may have their coinsurance paid for but not their other cost sharing for Part B services.

CMS notes that it is declining to implement this new model in a budget-neutral manner.

Employer/Union-Only Group Welfare Plans

EGWPs are MA plans that do not compete in the open market but are offered instead through negotiated arrangements between the MA plan and employers and/or union groups to exclusively serve their members. In 2015, EGWPs accounted for three million MA beneficiaries. CMS has previously expressed concern over the competitiveness of bids submitted by plan sponsors for EGWPs. Specifically, CMS has found that the projected average risk scores for EGWP members are lower than for individual market plan MA enrollees, but the average EGWP bids are higher than those for individual market MA plans. Therefore, the Advance Notice proposes to waive the bidding requirements for all EGWPs and to use individual market non-EGWP bids to establish Part C county-level payment amounts for EGWPs. CMS did not estimate how much this change would lower MA payments. We believe the reduction will not affect the national average payments but will materially impact payments to EGWPs.

PROVISIONS AFFECTING PART D PAYMENT

Changes to Part D Risk Adjustment Model

CMS proposes to update the RxHCC risk adjustment model used to adjust direct subsidy payments for Part D benefits. Last year, CMS calibrated the model using 2012 diagnosis data and 2013 expenditure data. The exception last year was CMS's use of 2014 Hepatitis C treatment expenditure data in order to account for the cost of new treatment regimens that have recently become available. CMS anticipated the need to apply a downward adjustment for the chronic Hepatitis C coefficient for 2017.

CMS now expresses continued uncertainty about the pattern of chronic Hepatitis C prevalence and expenditures among Medicare beneficiaries. As such, CMS is proposing not to apply a downward adjustment to the coefficient for 2017.

Annual Update to Part D Benefit Parameters

CMS is required by the Medicare law to update the parameters annually for the defined standard Part D prescription drug benefit. These updated parameters are to be indexed to the percentage increase in the average per capita total Part D drug expenses for Medicare beneficiaries. Specifically, the annual percentage increase is the "average expenditures for Part D drugs in the United States for Part D eligible individuals . . . for the 12 month period ending July of the previous year."[4]

The benefit parameters reflect an 11.75 percent increase in Part D average per capita drug expenses projected through July 2016, almost the same amount projected last year. The actuarial value and cost of the Part D benefit increases commensurate with increases in drug expenses, and the Part D benefit covers a constant share of beneficiary drug expense.

The revised 2017 parameters are as follows:

	2016	2017
Deductible	$360	$400
Initial Coverage Limit	$3,310	$3,700
Out-of-Pocket Threshold	$4,850	$4,950
Total Drug Spending Out-of-Pocket Threshold for Those Ineligible for Coverage Gap Discount	$7,062.50	$7,425
Estimated Total Drug Spending Out-of-Pocket Threshold for Those Eligible for Coverage Gap Discount	$7,515.22	$8,071.16
Minimum Co-Pay in Catastrophic Portion of Benefit		
• Generic/Preferred Source Drug	$2.95	$3.30
• All Other Drugs	$7.40	$8.25
Retiree Drug Subsidy		
• Cost Threshold	$360	$400
• Cost Limit	$7,400	$8,250

Part D Premiums May Experience a Significant Increase

While the increases in the benefit thresholds are similar to last year's increases (11.76 percent for 2016), unlike last year, the preliminary normalization factor for the RxHCC model is increasing relative to the prior year. For the 2016 plan year, CMS announced that premiums were projected to be relatively flat even after the 11.76 percent increase in the threshold. We believe that the lower normalization factor in 2016 (0.939 percent) relative to

[4] Social Security Act § 1860D-2(b)(6).

the previous year (0.961 percent in 2015) mitigated against the increased threshold amounts to keep premiums flat. For the 2017 plan year, the opposite effect is likely as the projected normalization factor increase (0.996 percent) is rising relative to the prior year (0.939 percent in 2016) and may increase premiums even more.

DRAFT CALL LETTER POLICIES

The policies contained in the draft 2017 Call Letter are largely restatements of issues that CMS has outlined elsewhere. CMS reiterates its intent to non-renew consistently low-performing plans, announces annual proposed changes to the MA/Part D Star Ratings measures, seeks comment on its proposed interim approach to address the SES and disability status of plan enrollees through Star Ratings, and identifies issues on which it will focus enforcement efforts.

Non-Renewal of Plans with Low Star Ratings for Three Consecutive Years

CMS again uses the draft Call Letter to restate its authority to non-renew the contracts of plans that have failed to receive a rating of three stars or better on their MA or Part D performance for three consecutive years. CMS deferred exercising this authority at the end of the 2015 contract year but now affirms its intent to pursue non-renewal at the end of the 2016 contract year.[5] CMS states that, in February of 2016, it will send non-renewal notices, effective December 31, 2016, to all plans that have failed to achieve three stars in either the MA or Part D areas for three consecutive years.

This non-renewal timeline will be an annual occurrence, with affected plans receiving non-renewal notices each February for non-renewal at the end of the contract year based on that year's Star Ratings, as released the previous October. Affected beneficiaries will be notified in March of their current plans' non-renewal and informed that they will need to choose a new plan during the next annual election period. Additionally, CMS will not calculate or publish Star Ratings for the non-renewed contracts during the year in which the plan receives the non-renewal notice "so terminated contracts should not expect there to be an opportunity for CMS to reverse its determination based on the contract's improved Star Rating performance during its last year of operation."

Adjustments to Star Ratings for Socioeconomic and Disability Status

Within the draft Call Letter, CMS proposes interim analytic adjustments to address the impact of SES and disability enrollment on Star Ratings while it builds a long-term policy "that appropriately addresses the . . . two distinct aspects of the [SES] and/or disability issue - quality and payment." This continues CMS's ongoing efforts since 2014 to address concerns from stakeholders that a plan's enrollment of disproportionate numbers of dual-eligible enrollees, those who receive the LIS, or those with disabilities, disadvantages the plan's eligibility to earn from CMS bonus payments under the current Star Ratings system. CMS assessed two options for these interim analytic adjustments: (1) a Categorical Adjustment Index ("CAI") factor and (2) Indirect Standardization ("IS").

[5] See the September 8, 2014, HPMS memorandum, "Suspension of Termination of Low Performing Icon (LPI) Plans for 2015."

Ultimately, CMS is proposing use of the CAI factor to be "added to or subtracted from a contract's Overall and/or Summary Star Rating to adjust for the average within-contract disparity." The factor varies by a contract's percentage of LIS/dual-eligible and disabled beneficiaries. The CAI factor works like a case-mix adjuster for contract performance scores for LIS/dual-eligible and disabled status. Medicare Advantage – Prescription Drug contracts would have up to three adjustments: one for their overall Star Rating and one each for their Part C and Part D summary rating. Part D plans would have one adjustment for their Part D summary rating. Plan sponsors will have access through HPMS to review simulations of how each methodology would affect their own contract-level data.

CMS projects that CAI adjustments will lead to "modest negative adjustments" for plans with lower percentages of dual/disabled enrollees and "larger positive adjustments" for plans with higher percentages of LIS/dual-eligible and disabled enrollees.

CMS has undertaken further research to assess the impact on Star Ratings from plan's LIS/dual-eligible and disabled enrollees. CMS also is reviewing research by other entities, such as the Medicare Payment Advisory Commission and the National Quality Forum, and has requested that measure developers, such as the National Committee for Quality Assurance and the Pharmacy Quality Alliance, examine their measures to determine if they need to be respecified due to the impact of the enrollee's SES and/or disability status. CMS also is awaiting the results of a congressionally required report on the impact of SES on quality measures, resource use, and other measures for individuals in the Medicare program.[6]

Other Provisions Related to Star Ratings

Enhancements, Removals, and New Measures: CMS proposes several new measures for contract year 2017 Star Ratings. These would appear as display measures for 2017 and include measures of the following: Timely Receipt of Case Files for Appeals (Part D) and Timely Effectuation of Appeals (Part D), Medication Reconciliation Post Discharge (Part C), Hospitalizations for Potentially Preventable Complications (Part C), Statin Therapy for Patients with Cardiovascular Disease (Part C), Asthma Measures (Part C), and Statin Use in Persons with Diabetes (Part D). Revisions to the following measures are proposed: Colorectal Cancer Screening (Part C), Fall Risk Management (Part C), Pneumococcal Vaccination Status for Older Adults (Part C Display), Medication Adherence for Hypertension (RAS Antagonists) (Part D), Medicare Plan Finder Price Accuracy (Part D), and Drug-Drug Interactions (Part D Display).

CMS also proposes changes in the methodology for calculating the Part C and D improvement measures, the Appeals Timeliness/Reviewing Appeals Decisions measures (Part C) and Appeals Upheld measure (Part D), and the Medication Therapy Management ("MTM") Program Completion Rate for Comprehensive Medication Reviews measure (Part D). CMS proposes removing two measures from the 2017 Star Ratings: Improving Bladder Control (Part C) and High Risk Medication (Part D).

[6] The IMPACT Act (P.L. 113-185) instructs the Department of Health and Human Services' Office of the Assistant Secretary for Planning and Evaluation ("ASPE") to conduct a study that examines the effect of individuals' SES on quality measures, resource use, and other measures for individuals under the Medicare program. ASPE must report its findings to Congress by October 2016.

Other measures under consideration for 2018 include the following: Care Coordination (Part C), Depression (Part C), Appropriate Pain Management (Part C), Use of Opioids from Multiple Providers or at High Dosage in Persons without Cancer (Part D), and Antipsychotic Use in Persons with Dementia (Part D).

Data Integrity: CMS references its recent efforts to ensure the integrity of the data on which the Star Ratings are based but also notes that the agency "continue[s] to identify new vulnerabilities where inaccurate or biased data could exist." In addition, CMS states its intent to "safeguard against the Star Ratings Program creating perverse incentives for sponsors." It is particularly concerned with the soon-to-be-piloted audit protocol for MTM programs. Specifically, inappropriate practices by Part D sponsors, such as restricting eligibility to MTM programs or encouraging beneficiary opt-outs, could compromise related data in ways that would not be identified through the data validation process. Accordingly, CMS states that it "may perform additional audits or reviews to ensure the validity of data for specific contracts" in order to further ensure "rigorous validation of Star Ratings data" and lower the risk of rewarding contracts with "falsely high ratings."

Impact of Value-Based Insurance Design ("VBID") and MTM Model Tests: A number of stakeholders have expressed concern that MA plans participating in the VBID and MTM model tests will enjoy an improvement in quality that would increase their Star Ratings as compared to those ratings of MA plans ineligible to participate in these programs. CMS states that it will closely monitor performance trends in these programs to determine if changes are needed. The agency is considering excluding some of the participants in the VBID model test when calculating measure-level cut points. CMS is requesting comment on how to address the possible impact of MTM model test participation on the measure of the MTM Program Completion Rate for Comprehensive Medication Reviews. Possibilities mentioned include elimination of this measure for Part D contracts with model-participating plans, establishment of different cut points for model participants, or to case-mix adjust scores when determining cut points.

Earlier Release of Program Audit Protocols

CMS states that it will now release the final audit protocols for the following contract year by the end of each July. This is in response to plan sponsor requests for earlier receipt of the annual audit protocols in order to allow additional time for plans to prepare for audits and to implement any required changes.

The early release of the yearly protocols will prevent CMS from incorporating plan sponsor feedback into the next year's version. For example, feedback on the 2016 protocols will be incorporated into the 2018 protocols. This new release timeframe will specifically impact CMS's ability to fully implement the 2016 pilot MTM and Provider Network Adequacy protocols on the previously stated schedule. Accordingly, CMS is proposing to extend the pilot period for these protocols into 2017.

Parts C & D Enforcement

Methodology for Calculating Civil Money Penalties ("CMPs"): CMS intends to release guidance by 2017 describing its interpretation of the applicable CMP rules that affect how

CMS determines CMP amounts and how certain deficiencies are factored into a CMP. CMS will accept comments on this material prior to finalizing.

Increased Enforcement Actions Against Part D Auto-Forwards: Part D plan sponsors are required to meet specific timeframes for making coverage determinations and redeterminations and notifying enrollees of their decisions. Failure to provide timely notification requires that the case be auto-forwarded to the Part D Independent Review Entity. CMS notes that any auto-forwarding represents a failure to comply with CMS requirements. However, CMS is concerned with what it calls a "significant and sustained" volume of auto-forward rates over the past few years. CMS states that it is putting Part D plan sponsors on notice that, for the 2017 contract year, it will "continue to increase the level and severity of the compliance and enforcement actions imposed on plans that substantially fail to comply with adjudication requirements for coverage determinations and redeterminations" and that it may impose CMPs on plan sponsors that significantly fail to meet these requirements.

Enforcement Based on Findings from the One-Third Financial Audits: CMS is required to annually audit the financial records of at least one-third of Part C and D plan sponsors. Findings from such audits require sponsors to implement corrective action plans. However, CMS notes that findings with adverse beneficiary impact "warrant further enforcement actions." CMS is notifying plan sponsors that, starting with the one-third financial audits conducted in 2017 (based on contract year 2015), the agency will consider taking enforcement actions based on findings of noncompliance under the financial audits.

Other Part C Issues

Provider Directories: CMS expresses continued concern regarding the accuracy of sponsors' provider directories, noting that it will "continue to aggressively identify and pursue instances of non-compliance." Such deficiencies will be identified through a range of available oversight methods, including a currently operating contractor-supported comprehensive process for monitoring provider directory accuracy. CMS further states that the data collected through its monitoring efforts could "drive additional reviews of network adequacy, as well as future monitoring and/or audit-based activities." Moreover, CMS emphasizes its intent to pursue compliance and/or enforcement actions for identified non-compliance in this area.

CMS further states that, currently, among MA, qualified health plans, and Medicaid managed care, MA has the least prescriptive provider directory requirements. Harmonizing provider directory requirements across these three programs is an ultimate goal for CMS. In advance of any future rulemaking, CMS urges sponsors to incorporate the following provider directory elements: machine readable content, provider medical group, provider institutional affiliation, non-English languages spoken by provider, provider website address; and accessibility for people with physical disabilities. CMS also suggests that sponsors incorporate a "warm transfer" policy to their customer call centers, directly connecting enrollees to the provider's office.

Other Part D Issues

Formulary Submissions: CMS announces several important changes. CMS will add a new quantity limits column to the Formulary Reference File ("FRF"), though not for formulary validation purposes. An Out-of-Pocket Cost ("OOPC") model tool is scheduled for release in April to assist sponsors in satisfying total beneficiary cost and meaningful difference requirements. The OOPC model tool will not be updated as additional FRFs are released by CMS. CMS will offer a summer formulary update, but this will be limited to new summer FRF drugs and negative brand drug changes.

Prior Authorization ("PA") in Transition: CMS clarifies that the use of PA edits during enrollee plan transition is appropriate. The agency also encourages sponsors to limit PA grandfathering and conduct robust retrospective reviews to control drug use for non-medically accepted indications.

Potential Rulemaking on Clinical Decision-Making: CMS is contemplating rulemaking to improve clinical decision-making in Part D coverage determinations. Specifically, extension of adjudication timeframes may be permitted in certain circumstances where delays might occur. Criteria for extensions would favor the best interest of the enrollee and would be available in only limited circumstances. CMS is soliciting comments on this proposal and its potential consequences.

Access to Preferred Cost-Sharing Pharmacies: CMS announces that access to preferred cost-sharing pharmacies ("PCSP") has improved since policies were implemented in the 2016 Call Letter. Therefore, CMS is continuing these policies to better address low access to PCSPs with the expectation that plans will continue to self-assess against outlier thresholds. Lower-access plans are required to make marketing disclosures accordingly.

Benefit Parameters and Specialty Tiers: CMS sets forth proposed benefit design parameters for non-defined standard plans, including adjustments to the minimum meaningful difference requirement and specialty tier thresholds. For 2017, CMS has added a non-preferred drug tier option with details forthcoming. Sponsors must choose either a non-preferred drug tier or non-preferred brand tier. To maximize beneficiary benefit, CMS encourages the use of coinsurance in the non-preferred tier rather than copays and will conduct outlier tests for the latter. CMS will continue to scrutinize expected cost-sharing amounts and disallow low or $0 cost-sharing incentives unless also offered in retail networks.

To ensure that enrollees who are reliant on higher-cost drugs are not discouraged from enrollment, CMS will only approve specialty drug tiers with formularies and benefit designs meeting cost-sharing standards. In return, CMS will shield sponsors and not require them to increase bids and Part D premiums to reflect costs associated with tier exceptions. CMS is increasing the specialty tier eligibility cost threshold from $600 to $670 for 2017.

To remedy lagging generic use, CMS encourages sponsors to consider first dollar generic coverage and other methods to drive generic use in Part D.

Part D EGWPs: CMS clarifies that all Part D rules apply to EGWPs, unless explicitly waived or modified by CMS. The agency has specifically waived full bid submission requirements

for Part D sponsors of EGWPs. EGWPs are required to meet deductible and actuarial equivalence requirements. EGWPs need not submit separate formulary variations for each plan but cannot provide a formulary benefit lesser than the base formulary. CMS also clarifies that negative changes to formularies require the agency's approval.

Opioid Overutilization: CMS updates its opioid and acetaminophen overutilization policy, including continued monitoring overutilization at the contract level and the addition of a related patient safety metric. Additionally, CMS requests comments on its proposed changes, including parameters for formulary-level cumulative morphine equivalent dose point of sale ("POS") edits. Finally, CMS acknowledges the public health challenges with opioid addiction, emphasizing that benefit designs that restrict access or feature methadone as the sole preferred opioid analgesic will not be approved.

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