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# Medicare Advantage and Part D Benefit Final Rule

## OVERVIEW

On April 2nd, the Centers for Medicare and Medicaid Services issued a final rule that will implement significant regulatory changes for Medicare Advantage (MA) and Prescription Drug Benefit (Part D) plans, beginning in 2019. The rule generally eases reporting requirements, updates the Medicare Star Rating methodology, removes the meaningful difference requirement, redefines marketing materials, and addresses drug management. CMS estimates that the rule will result in $295 million in net savings per year for Medicare between 2019 and 2023. Selected major provisions are described below.

The rule is available here.

## MA AND PART D PROVISIONS

### Meaningful Difference Requirement

Under current law, insurers may submit bids for multiple MA or Part D plans in the same service area as long as those plans are deemed substantially different according to CMS' meaningful difference standards. Under the final rule, the meaningful difference requirement will be fully eliminated for MA plans and partially eliminated for Part D plans in 2019. The requirement will not apply among two enhanced Part D plans, but Part D sponsors will still be required to ensure that enhanced plans are meaningfully different from basic plans.

### Marketing Requirements

CMS currently defines marketing materials for MA and Part D plans as those that: promote the plan organization, inform beneficiaries that they may enroll in a plan offered by that organization, explain plan benefits, and explain how Medicare services are covered by a MA or Part D plan. The final rule will distinguish "communications" from "marketing" and will define marketing as the use of materials or activities that are intended to encourage enrollment. Such materials and activities will be subject to more stringent requirements, while other communication will be subject to less oversight.

The rule also requires that unsolicited marketing and mailing marketing materials be prohibited during the MA open enrollment period (OEP). A plan may offer educational or marketing materials to individuals who proactively reach out to that plan about the OEP.

### Medical Loss Ratio (MLR)

MA and Part D plans are currently required to report their MLRs and are subject to penalties if their MLR is below 85 percent. To better align Medicare MLR reporting requirements with commercial MLR requirements, the final rule will only require MA and Part D plans to report the adjusted MLR percentage and remittance amount. Plans will still be required to submit supporting documentation for their MLR calculation if the validity of their MLR were to come under review. These eased reporting requirements will take effect in 2019 when plans submit their data from contract year 2018.

The rule will also allow expenditures for fraud reduction activities and Medication Therapy Management to be included in the MLR numerator as Quality Improvement Activities, which will have the effect of increasing the profitability of some plans with MLRs at or near 85%.

### Star Ratings

CMS is finalizing several changes to MA and Part D Star Ratings, including the implementation of scaled reductions for incomplete data reporting on some measures and a new methodology that accounts for contract consolidations:

- *Scaled Reductions* – Under current regulations, plans that are identified as having significant data incompleteness issues on the two appeals measures may have their ratings on these measures reduced to One Star. The final rule will implement scaled reductions, ranging from a one-star to a four-star reduction, based on the degree of missing data.
- *Contract Consolidations* – The final rule requires that when two plans are consolidating, the Star Rating for the surviving plan will reflect the weighted average of the scores received by both the surviving plan and the consumed plan for two years following the consolidation. Under the proposed rule, this change would have taken effect in the 2019 performance period for 2021 Star Ratings. Due to provisions of the Bipartisan Budget Act, the new methodology will apply to contract consolidations approved on or after January 1, 2019 and will be reflected in 2020 Star Ratings.

### Preclusion List

MA and Part D benefits are currently covered if they are ordered or prescribed by a provider who is enrolled in or has validly opted-out of Medicare. Beginning in 2019, CMS will distribute a preclusion list containing prescribers and providers who are not eligible to participate in Medicare for various reasons. Plans will be required to deny any claims from individuals on the list. CMS did not finalize a provision that would have required that beneficiaries who request reimbursement for a drug that was prescribed by a provider on the preclusion list be offered a 90-day provisional supply. The final rule allows plans 30 days to intake the preclusion data and an additional 60-day beneficiary notification period, during which time claims will not begin to be denied.

The preclusion list will also apply to Programs of All-Inclusive Care for the Elderly (PACE).

### Electronic Delivery of Documents

The final rule will allow plans to electronically deliver benefit documents, such as Evidence of Coverage (EOC) and the Annual Notice of Change (ANOC), but plans will be required to comply with beneficiary preferences for hardcopy materials. The rule will also separate the delivery of the EOC from the ANOC, requiring that beneficiaries receive the ANOC as a stand-alone document 15 days before the annual OEP and pushing back the EOC delivery to the first day of the OEP.

## MA-SPECIFIC PROVISIONS

### Uniformity Requirements

MA plans have historically been required to satisfy uniformity requirements by offering all enrollees access to the same benefits at the same level of cost sharing. The final rule will allow plans to create benefit packages for groups of individuals with specific health statuses, as long as the cost sharing and supplemental benefits are

appropriate for the specific disease conditions. The uniformity requirement will be satisfied as long as all similarly situated individuals are being treated uniformly. MA plans will still be prohibited from denying, limiting, or conditioning coverage based on health status.

## Enrollment

As directed by the 21st Century Cures Act, the rule will eliminate the existing MA disenrollment period (MADP) and replace it with a new MA OEP in 2019. During the MADP, which currently runs from January 1st through February 14th each year, individuals may disenroll from MA and enroll in traditional Medicare and Part D. During the fall OEP, which runs from October 15th to December 7th each year, individuals can change from traditional Medicare to MA, MA to traditional Medicare, switch MA plans, and enroll/disenroll from Part D.

The new MA OEP, which will run between January 1st and March 31st, will allow individuals enrolled in MA and newly MA-eligible individuals to make a one-time election into another MA plan, traditional Medicare, or change Part D coverage. Individuals newly eligible for Medicare Part A and B could enroll in MA during the fall OEP and then make a one-time election to switch MA plans during the immediately following MA OEP. In subsequent years they will make changes only during the MA OEP.

The rule also finalizes changes to the default and passive enrollment processes:

- *Default Enrollment* - Subject to state approval, the rule will allow Medicaid managed care enrollees who are newly eligible for Medicare to be defaulted into an authorized Dual Eligible Special Seeds Plan (D-SNP) or Fully Integrated Dual Eligible-SNP (FIDE-SNP) that is offered by the same parent organization as the Medicaid managed care plan. The plan will be required to notify the individual of the default enrollment and the individual will have the opportunity to opt out. Eligible D-SNPs and FIDE-SNPs must have at least a Three-Star Rating, unless the plan is new or a low enrollment contract.
- *Passive Enrollment* – Currently, passive enrollment is restricted to situations in which an MA contract is immediately terminated or when CMS determines that enrollment in a plan poses potential harm to the beneficiary. Subject to state approval, the rule will allow passive enrollment for full-benefit dually eligible beneficiaries from a non-renewing integrated D-SNP into another highly integrated D-SNP. The D-SNP receiving passive enrollees will have to meet continuity of care standards and operate as a FIDE-SNP or a highly-integrated D-SNP that has at least a Three-Star Rating. Individuals who are passively enrolled will be offered a three-month special election period (SEP) to enroll in different Medicare coverage.

## Maximum Out-of-Pocket (MOOP) and Cost Sharing Limits

CMS currently sets MOOP and cost sharing limits based on Medicare fee-for-service (FFS) data. The final rule does not change this methodology, but notes that changes to MOOP limits, incentives for plans to lower MOOP limits, and new cost sharing standards (including greater flexibility for MA plans using voluntarily lower MOOP limits), will be implemented as early as 2020.

## PART D-SPECIFIC PROVISIONS

### Drug Management Program for At-Risk Beneficiaries

As directed by the Comprehensive Addiction and Recovery Act, the final rule will allow Part D plans to implement drug management programs that are integrated with CMS' Overutilization Monitoring System. The rule will enable plans to prevent specific at-risk beneficiaries from misusing drugs by engaging in case management and limiting access to selected prescribers and/or pharmacies and enforcing point-of-sale safety edits. Beneficiaries who are being treated for active cancer-related pain or are receiving palliative, end of life care, hospice, or long-term care will be exempt from drug management program restrictions.

Part D plans that intend to limit access of a frequently abused drug to an at-risk beneficiary will be required to provide written notices to that beneficiary notifying them of their status and right to redetermination.

### Cost Sharing for Low Income Subsidy (LIS) Beneficiaries

Under current Part D regulations, biosimilar products do not meet CMS' definition of a generic drug and are subject to higher maximum co-payments for LIS-eligible individuals. CMS finalized its proposal to treat biosimilar and interchangeable biological products as generics solely for purposes of cost-sharing for LIS beneficiaries.

### SEP for Dual and Other LIS-Eligible Beneficiaries

The final rule will limit Part D SEPs for dual-eligible and LIS beneficiaries to once per calendar quarter for the first nine months of the year. For the last quarter of the year, beneficiaries may use the Annual Election Period to make an election for January 1 of the following year. Time-limited exceptions will be made following a CMS or state-initiated enrollment or a change in an individual's LIS or Medicaid status.

### Tiering Exceptions

Part D beneficiaries are entitled to request an exception to the plan's tiered cost-sharing structure for prescription drugs that are medically necessary. It has become standard practice for Part D plans to consider any tier that is labeled "generic" to be exempt from tiering exceptions, even if that tier also contains brand name drugs. Under the final rule plans will be prohibited from excluding generic drug tiers from tiering exceptions. Plans will, however, be able to limit tiering exceptions for brand name and biological products to the lowest applicable cost sharing associated with preferred brand name and biological product alternatives.

### Point-of-Sale Rebates and Price Concessions

The proposed rule solicited comment on the potential application of manufacturer rebates and pharmacy price concessions to pharmaceuticals at the point-of-sale. CMS is not implementing any point-of-sale rebates or price concession requirements at this time, but will continue to consider proposals for future rulemaking.

Prior to issuance of the final rule, insurers UnitedHealthcare and Aetna recently announced that they will apply point-of-sale rebates to their fully insured commercial group members.