

## CMS Finalizes Policy and Technical Changes to the Medicare Advantage and Part D Programs for CY 2019

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The Centers for Medicare and Medicaid Services (“CMS”) issued on April 2, 2018, an [advanced copy of the final rule](#) titled “Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program” (“Final Rule”). This Final Rule will be published in the [April 16, 2018 issue](#) of the Federal Register.

This Final Rule implements provisions of the proposed rule that CMS released titled “Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program” (“Proposed Rule”), which was published in the Federal Register on November 28, 2017.

Upon review of over 1,600 comments, CMS finalized many of the provisions as proposed or with minor revisions, deferred addressing some proposals until a later date, or opted not to finalize some provisions as proposed in the Proposed Rule.

We have summarized major provisions of the Proposed Rule in a [three part Client Alert](#) which EBG published earlier this year. For the provisions summarized in our Client Alert, the following chart reflects CMS’s actions in the Final Rule:

Provision	CMS Action
<b>Part 1 Client Alert: Negotiated Prices</b>	
Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale	Not Finalized

CMS is not finalizing any proposal at this time. Any requirements would be addressed through future rulemaking.

## **Part 2 Client Alert: Beneficiary Cost, Access, and Protection**

Part D Tiering Exceptions	Finalized as proposed
Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes	Finalized with minor revisions
Treatment of Follow-On Biological Products as Generics for Non-Low Income Subsidy ("LIS") Catastrophic and LIS Cost Sharing	Not Finalized

CMS is not finalizing its proposed revision to the definition of generic drug. Instead, CMS is finalizing a different approach by modifying language at 42 CFR 423.782(a)(2)(iii)(A) and § 423.782(b)(2), to achieve the same desired goal of setting the copay amounts for biosimilars and interchangeable products to those for generics.

"Any Willing Pharmacy" Standard Terms and Conditions and Better Definitions of Pharmacy Types	Finalized with minor revisions
Elimination of Meaningful Difference Requirement	Finalized as proposed
Medicare Medical Loss Ratio	Finalized with minor revisions

## **Part 3 Client Alert: Implementation of Comprehensive Addiction and Recovery Act of 2016 ("CARA")**

Drug Management Program for At-Risk Beneficiaries-	
1. Identification of "At-Risk Beneficiaries"	Finalized with minor revisions
2. Requirements of Drug Management Programs:	
• Written policies and procedures	Finalized with minor revisions
• Case management/clinical contact/prescriber verification	Finalized with minor revisions
• Limitations on Access to Coverage for Frequently Abused Drugs	Finalized with minor revisions
• Requirements for Limiting Access to Coverage for Frequently Abused Drugs	Finalized with minor revisions
• Beneficiary Notices	Finalized with minor revisions
• Provisions Specific to Limitations on Access to Coverage of Frequently Abused Drugs to Selected Pharmacies and Prescribers	Finalized with minor revisions
• Drug Management Program Appeals	Finalized with minor revisions
• Termination of a Beneficiary's Potential At-Risk or At-Risk Status	Finalized with minor revisions
• Data Disclosure and Sharing of Information for Subsequent Sponsor Enrollments	Finalized with minor revisions
Special Enrollment Period Limitations for At-Risk Dually-Eligible or Low-Income Subsidy-Eligible Beneficiaries	Finalized with minor revisions
Part D Opioid Drug Utilization Review Policy and Overutilization Monitoring System	Finalized as proposed[1]

The Final Rule will be effective for Medicare Advantage and Part D plans for the 2019 contract year.

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[1] Additional policies for plan year 2019 related to opioid drug utilization review controls were included in the Final Call Letter issued on April 2, 2018, *available at* <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf>.

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