CMS Medicare Advantage and Part D Final Rule: Regulatory Compliance Strategies

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Overview

On April 2, 2018, CMS issued a Final Rule (CMS-4182-F) that updates Medicare Advantage (MA) and the Voluntary Prescription Drug Benefit Program (Part D) by promoting innovation, flexibility, and empowering MA and Part D sponsors with new tools to improve quality of care and provide more plan choices for MA and Part D enrollees.

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- Effective date
- June 15, 2018
- Applicability date
 - January 1, 2019
 - Some exceptions are applicable for CY 2020
 - **Regulatory framework**
 - The Bipartisan Budget Act of 2018 (BAA)
 - The Comprehensive Addiction and Recovery Act of 2016 (CARA)
 - The 21st Century Cures Act (CURES Act)

CFRs Impacted by CMS-4182-F The new policy changes and updates to Medicare Advantage and Part D programs represents the biggest changes made to the CFR in the past 10 years. The new policy and updates are reflected in changes to 42 CFR Parts: 405 Federal Health Insurance for the Aged and Disabled 407 Supplementary Medical Insurance (SMI) Enrollment and Entitlement 422 Medicare Advantage Program (Part C) 423 Voluntary Medicare Prescription Drug Benefit Program (Part D) 460 Programs Of All-inclusive Care For The Elderly (PACE) 498 Appeals Procedures that Affect Participation in the Medicare Program and the Medicaid Program CMS states that the final changes will result in an estimated \$295 million in savings a year for the Medicare program in a timeframe of 5 years (2019 through 2023). 4

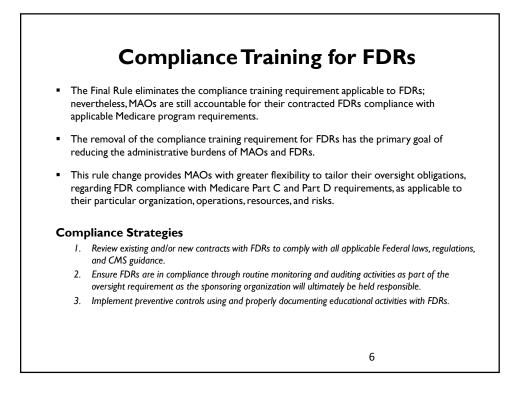
Some Key Provisions of Medicare Parts C and D Policy Changes

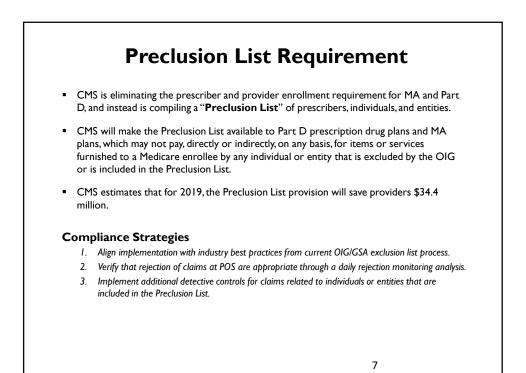
POLICY CHANGES	
Compliance Training for FDRs	Implementation of CARA
Preclusion List Requirement	Any Willing Pharmacy Terms
MA Open Enrollment Period	Timeframes for Payment Appeals
MA Uniformity Requirement	Similar Treatment of Biosimilars as Generic Drugs

Note: This list does not reflect all the policy changes and updates of the CMS-4182-F.

https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheetsitems/2018-04-02.html







Requirement	Summary
MA Open Enrollment Requirement	 New MA open enrollment period (OEP) will take place from January 1st through March 31st annually. Individuals may make a one-time election to go to another MA plan or Original Medicare.
MA Uniformity Requirement	 Beginning in 2020, MA plans may offer 3 forms of supplemental benefits: a. "standard" supplemental benefits offered to all enrollees, b. "targeted" supplemental benefits offered to qualifying enrollees by health status or disease state, and c. "chronic" supplemental benefits offered to the chronically il

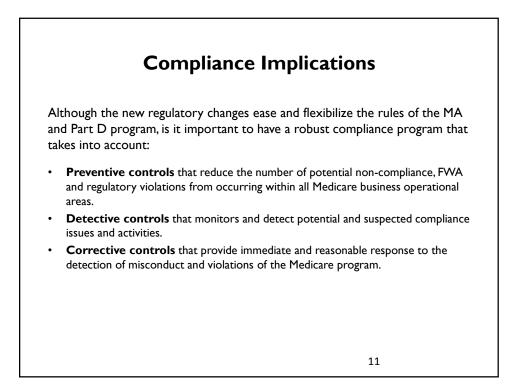
Implementation of CARA Drug Management Programs that limit access to coverage for frequently abused drugs for at-risk beneficiaries; integrated with CMS' existing Overutilization Monitoring System (OMS). Exempted beneficiaries: treated for active cancer-related pain, receiving palliative or end-of-life care, or are in hospice or long-term care. Part D Sponsors will be allowed to limit an at-risk beneficiary's access to frequently abused drugs to a selected prescriber(s) and/or pharmacy(ies) ("lock-in"), and through the use of beneficiary-specific point-ofsale (POS) claim edits, which are already permitted under the current policy. At-risk determinations, which include prescriber and pharmacy lock-in, will be subject to the existing beneficiary appeals process. **Compliance Strategies** 1. Implement preventive controls using and properly documenting educational activities to impacted operational areas and FDRs 2. Develop written P&Ps for case management for the identification of at-risk and/or potentially at-risk beneficiaries including clinical contacts and prescriber verifications. 3. Implement the beneficiary POS claim edits with the PBM along with coordination of pharmacy(ies) lock in and/or prescriber(s) lock-in. 4. Implement additional detective controls for claims related to individuals classified as at-risk beneficiaries. 5. Properly monitor and audit FDRs to ensure compliance with all applicable laws, regulations and sub-regulatory interpretive guidance with respect to CARA.

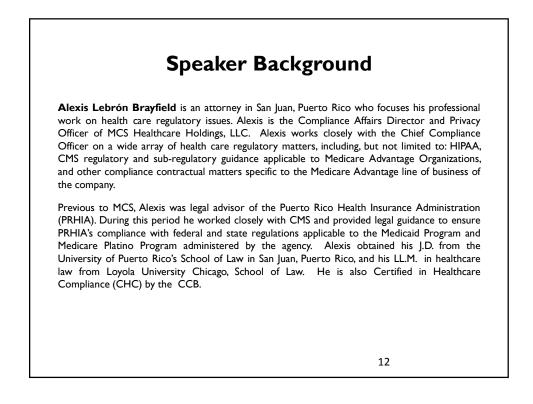
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Requirement	Summary
Timeframes for Payment Appeals	 Changed the maximum timeframe for adjudicating standard Part D enrollee payment appeal requests at the redetermination and independent review entities (IRE) reconsideration levels from 7 calendar days to 14 calendar days.
Any Willing Pharmacy Terms	 Part D plan sponsors are required to contract with any pharmacy that meets the Part D plan sponsor's standard terms and conditions for network participation. Part D plan sponsors must have standard terms and conditions available for requesting pharmacies no later than September 15 of each year and 7 business days of receipt of the request after the September 15th deadline.

- 2. Ensure PBM revise and/or develop new contract models to meet CMS requirements.
- Monitor that the standard terms and conditions are readily available for requesting pharmacies within the new timeframes.
 Properly monitor and audit FDRs to ensure compliance with all applicable laws, regulations and sub-regulatory interpretive guidance with respect to timeframes for payment appeals.

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