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

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Alexis Lebrón Brayfield, Esq., LLM, CHC

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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.

- **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)

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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).

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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-sheets-items/2018-04-02.html

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Compliance Training for FDRs

- The Final Rule eliminates the compliance training requirement applicable to FDRs; nevertheless, MAOs are still accountable for their contracted FDRs compliance with applicable Medicare program requirements.
- The removal of the compliance training requirement for FDRs has the primary goal of reducing the administrative burdens of MAOs and FDRs.
- This rule change provides MAOs with greater flexibility to tailor their oversight obligations, regarding FDR compliance with Medicare Part C and Part D requirements, as applicable to their particular organization, operations, resources, and risks.

Compliance Strategies

1. *Review existing and/or new contracts with FDRs to comply with all applicable Federal laws, regulations, and CMS guidance.*
2. *Ensure FDRs are in compliance through routine monitoring and auditing activities as part of the oversight requirement as the sponsoring organization will ultimately be held responsible.*
3. *Implement preventive controls using and properly documenting educational activities with FDRs.*

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Preclusion List Requirement

- CMS is eliminating the prescriber and provider enrollment requirement for MA and Part D, and instead is compiling a "**Preclusion List**" of prescribers, individuals, and entities.
- CMS will make the Preclusion List available to Part D prescription drug plans and MA plans, which may not pay, directly or indirectly, on any basis, for items or services furnished to a Medicare enrollee by any individual or entity that is excluded by the OIG or is included in the Preclusion List.
- CMS estimates that for 2019, the Preclusion List provision will save providers $34.4 million.

Compliance Strategies

1. *Align implementation with industry best practices from current OIG/GSA exclusion list process.*
2. *Verify that rejection of claims at POS are appropriate through a daily rejection monitoring analysis.*
3. *Implement additional detective controls for claims related to individuals or entities that are included in the Preclusion List.*

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Medicare Parts C and D Policy Changes

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 ill.

Compliance Strategy

1. *Align implementation according to new timeframes and rules.*
2. *Implement preventive controls using and properly documenting educational activities to impacted operational areas.*
3. *Establish policy and procedures consistent with the new regulations.*

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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-of-sale (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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Medicare Part D Policy Changes

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.

Compliance Strategy

1. *Update and establish a process, policy and/or procedure to communicate and provide training to employees on the new requirements.*
2. *Ensure PBM revise and/or develop new contract models to meet CMS requirements.*
3. *Monitor that the standard terms and conditions are readily available for requesting pharmacies within the new timeframes.*
4. *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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Compliance Implications

Although the new regulatory changes ease and flexibilize the rules of the MA and Part D program, is it important to have a robust compliance program that takes into account:

- **Preventive controls** that reduce the number of potential non-compliance, FWA and regulatory violations from occurring within all Medicare business operational areas.
- **Detective controls** that monitors and detect potential and suspected compliance issues and activities.
- **Corrective controls** that provide immediate and reasonable response to the detection of misconduct and violations of the Medicare program.

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Speaker Background

Alexis Lebrón Brayfield is an attorney in San Juan, Puerto Rico who focuses his professional work on health care regulatory issues. Alexis is the Compliance Affairs Director and Privacy Officer of MCS Healthcare Holdings, LLC. Alexis works closely with the Chief Compliance Officer on a wide array of health care regulatory matters, including, but not limited to: HIPAA, CMS regulatory and sub-regulatory guidance applicable to Medicare Advantage Organizations, and other compliance contractual matters specific to the Medicare Advantage line of business of the company.

Previous to MCS, Alexis was legal advisor of the Puerto Rico Health Insurance Administration (PRHIA). During this period he worked closely with CMS and provided legal guidance to ensure PRHIA's compliance with federal and state regulations applicable to the Medicaid Program and Medicare Platino Program administered by the agency. Alexis obtained his J.D. from the University of Puerto Rico's School of Law in San Juan, Puerto Rico, and his LL.M. in healthcare law from Loyola University Chicago, School of Law. He is also Certified in Healthcare Compliance (CHC) by the CCB.

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Alexis Lebrón Brayfield, Esq., LLM, CHC
Compliance Affairs Director & Privacy Officer
MCS Healthcare
Alexis.Lebron2@medicalcardsystem.com
t: .787.758.2500 ext. 2694