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**
  - Bipartisan Budget Act of 2018 (BBA)
  - Comprehensive Addiction and Recovery Act of 2016 (CARA)
  - 21st Century Cures Act (Cures Act)
The new policy changes and updates to Medicare Advantage and Part D programs represent 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:

- 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).

Some Key Provisions of Medicare Parts C and D Policy Changes

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

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. Establish FDRs are in compliance through routine monitoring and auditing activities as part of this oversight requirement as the sponsoring organization is ultimately held responsible.
3. Implement preventive control and properly documenting educational activities with FDRs.
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.

Medicare Parts C and D Policy Changes

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<td>MA Open Enrollment Requirement</td>
<td>New MA open enrollment period (OEP) and 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.</td>
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<td>MA Uniformity Requirement</td>
<td>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.</td>
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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.

Implementation of CARA

- Drug Management Programs that limit access to coverage for frequently abused drugs for at-risk beneficiaries; integrated with OIG’s 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 FDRs for case management for the identification of at-risk enrollees and prescribers.
3. Implement the beneficiary POS claim edits with the PBM along with coordination of pharmacy(s) lock-in and/or prescriber(s) lock-in.
4. Implement additional detective controls for cases 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.
Requirement | Summary
---|---
| 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 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 timelines for payment appeals.

Compliance Implications
Although the new regulatory changes ease and flexibilize the rules of the MA and Part D program, it is 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.

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 Plano 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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Regulatory Compliance Strategies

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