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Legal Alert

CMS Redesigns the Medicare Part D Prescription Drug Program Beginning in 2025

As a result of the changes to Medicare Part D under §11201 of the Inflation Reduction Act of 2022, on April 1, 2024, CMS released **Final Redesign Program Instructions** ("Final Program Instructions") for the Medicare Part D prescription drug program, which are effective starting in 2025.

The Final Program Instructions reflect a newly defined standard Part D benefit design through several changes or enhancements to the Part D program beginning in 2025. Of those changes or enhancements, the modification most likely to significantly impact the "creditability" of many group health plans next year is the annual out-of-pocket maximum threshold, which is reduced from $8,000 in 2024 to $2,000 in 2025. Many group health plans, particularly high deductible health plans, will not be able to meet this threshold, which may result in the coverage offered by impacted employers to be non-creditable.

As explained more fully below, employers are not required to offer creditable prescription drug benefits, and there is no penalty for employers who do not. The impact is only to Medicare-eligible employees or their eligible dependents who are not offered creditable coverage and who do not enroll in Medicare Part D when they are initially eligible for benefits.

Background on Medicare Part D Requirements for Employers

Medicare Part D requirements for employers are limited to reporting obligations. Specifically, the Medicare Modernization Act (MMA) requires plan sponsors (e.g., employers) to notify Medicare-eligible participants whether their prescription drug coverage is creditable coverage, which means that the coverage is expected to pay on average as much as the standard Medicare prescription drug coverage. There are generally two disclosure requirements:

1. **Report to CMS:** Group health plan sponsors must provide an annual report/disclosure of prescription drug coverage that contains certain, specified information that the group health plan submits to CMS annually (as well as at any time the plan's prescription drug coverage terminates and/or ceases to be creditable). The annual disclosure is required to be filed electronically with CMS within 60 days after the start of each plan year; and
2. **Report to Individuals:** Group health plan sponsors must also provide an annual notice to participants containing certain, specified information that indicates whether their coverage is creditable or non-creditable, which must be provided (a) before October 15 each year, (b) before the effective date of coverage for Part D eligible employees enrolling in the employer's group health plan, (c) when/if the employer terminates prescription drug coverage, (d) if the employer's coverage later becomes non-creditable or vice versa, and/or (e) at the request of an individual. Many employers provide the creditable coverage notice with the plan's open enrollment materials each year to satisfy the requirements to provide the notice before the Medicare Part D annual coordinated election period and within the 12 months before any individual's Medicare Part D Initial Enrollment Period.

As defined in the Medicare Part D regulations, coverage is considered creditable if the actuarial value of the coverage equals or exceeds the actuarial value of standard Medicare prescription drug coverage. In general, only drugs covered by Part D are taken into account in determining actuarial value.

The purpose of the individual disclosure notice is to inform Medicare beneficiaries of whether or not the employer's drug coverage is "as good as" the Medicare Part D prescription drug coverage. This serves an important function because employees who do not enroll in Medicare during their first open enrollment period must pay a late enrollment penalty of 1% per month if they go 63 days without "creditable coverage" and then subsequently enroll in Medicare Part D. However, individuals who have creditable coverage through their employer's health plan may opt to stay in that plan in lieu of participating in Medicare Part D. Those individuals would not be subject to late enrollment penalties.

Only employers that contract with a prescription drug plan ("PDP") through Medicare, or that contract with Medicare to become a PDP, are exempt from this notice requirement. This means that an individual disclosure notice is required regardless of whether the employer's coverage is primary or secondary to Medicare and regardless of whether the employer's coverage is fully insured or self-funded.

CMS provides **model notices** that plans can use for disclosure to individuals.

What is Creditable Coverage?

Under the MMA, coverage is considered creditable when the actuarial value (i.e., the expected amount of paid claims) of the employer's prescription drug coverage equals or exceeds the actuarial value of standard prescription drug coverage under Medicare Part D.

This is true regardless of whether it is the employee or the employer who pays for the coverage. If a plan has multiple benefit options, the actuarial test must be performed separately for each option.

How is Creditable Coverage Determined?

Per CMS guidance, there are two methods: the "simplified method" and the actuarial equivalence determination or "gross value" test. A plan can be creditable based on plan design using the "simplified determination", which is a safe harbor that may be used, but the requirements for the safe harbor vary depending on whether the plan is "integrated" (i.e., whether prescription drug benefits are integrated with other types of benefits, such as medical, dental or vision) or whether drug coverage is offered on a stand-alone basis.

A PLAN IS "INTEGRATED" WHEN THE PRESCRIPTION DRUG BENEFITS ARE COMBINED WITH OTHER COVERAGE OFFERED BY THE EMPLOYER (E.G., MEDICAL, DENTAL OR VISION) AND THE PLAN CONTAINS ALL OF THE FOLLOWING PROVISIONS:

- A combined plan-year deductible for all benefits under the plan;
- A combined annual benefit maximum for all benefits under the plan; and/or
- A combined lifetime benefit maximum for all benefits under the plan.

TO BE CREDITABLE, AN INTEGRATED PLAN MUST MEET THE FOLLOWING CRITERIA:

- The coverage is designed to pay, on average, at least 60% of participants' prescription drug expenses;
- The coverage covers both brand and generic prescriptions;
- The plan provides reasonable access to retail providers and, optionally, to mail order coverage; and
- The plan satisfies three additional standards:
  - It has no more than a $250 deductible per year (as indexed);
  - It has no annual benefit maximum or an annual maximum of at least $25,000; and
  - It has a lifetime combined benefit maximum of at least $1 million.

TO BE CREDITABLE, A NON-INTEGRATED PLAN MUST:

- Provide coverage for brand-name and generic prescriptions;
- Provide reasonable access to retail providers;
- Be designed to pay on average at least 60% of participants' prescription drug expenses; and
- Satisfy one of the following standards:
  - The prescription drug coverage either has no annual benefit maximum or has a maximum annual benefit of at least $25,000; or
  - The prescription drug coverage has an actuarial expectation that the amount payable by the plan will be at least $2,000 annually per Medicare-eligible individual.

If the employer is not applying for the MMA's retiree drug subsidy and its plan meets the applicable requirements set forth above, an actuarial certification of equivalence is not necessary. If the employer does not meet the applicable requirements set forth above, however, an actuarial certification may be required to prove creditable coverage. An actuarial determination measures whether the plan's expected prescription drug claims are, on average, at least as much as the expected claims under the standard Medicare prescription drug benefit. Thus, any changes in the plan from year-to-year, such as increases in the plan's deductible or other cost sharing requirements, could impact whether the plan remains creditable or non-creditable.

The Impact of the Redesign of the Program on Group Health Plans

In 2024, the following are the parameters for prescription drug benefit coverage under Medicare Part D:

- Deductible: $545;
- Initial coverage limit: $5,030;
- Out-of-pocket (OOP) threshold: $8,000;
- Total covered Part D spending at the OOP expense threshold for beneficiaries who are not eligible for the coverage gap discount program: $11,477.39; and
- Estimated total covered Part D spending at the OOP expense threshold for beneficiaries who are eligible for the coverage gap discount program: $12,447.11.

The Final Program Instructions lower the annual out-of-pocket threshold from $8,000 in 2024 to $2,000 in 2025. This significant reduction is likely to impact a number of employer- sponsored health plans starting with their 2025 plan year, particularly high deductible health plans, which typically have much higher deductibles.

Moreover, while CMS initially considered eliminating the simplified determination safe harbor for 2025, the Final Program Instructions allow group health plans to continue using the simplified determination safe harbor to determine whether coverage is creditable; however, CMS intends to re-evaluate its continued use beyond 2025 or will establish a revised simplified method to be used in 2026 and beyond.

Penalties for Noncompliance

Neither the law nor the regulations provide mechanisms for CMS to enforce penalties against employers that fail to comply with the Part D notice requirements; however, failure to comply could result in employee relations issues.

Moreover, the U.S. Department of Labor takes the view that ERISA plan fiduciaries must administer their plans to comply with both ERISA and other federal laws. An employer risks violating ERISA's fiduciary duties if it misrepresents its plan's creditable status to participants or fails to make a good faith effort to determine whether coverage is creditable.

Conclusion

While employers are not required to offer creditable coverage to individuals, employers are required to communicate to Medicare-eligible individuals and CMS whether the coverage offered is creditable. Because of the significant changes beginning in 2025, communication to impacted individuals will be crucial so that they understand whether or not their coverage will be creditable for their 2025 plan year and can decide whether to enroll in Part D if or when they are eligible.

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*STATISTICS ACCURATE AS OF DECEMBER 31, 2023.

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