

**CMS Rule 4085-F :
Policy and Technical Changes
to the
Medicare Advantage and
Medicare
Prescription Drug Benefit
Programs**

4085-F

- Changes reflect the knowledge and experience gained from implementing and then administering the Medicare Part C and D programs
- Issued on April 6, 2010; appeared in the Federal Register on April 15, 2010
- Changes effective June 7, 2010. Note: Most changes are applicable for 2011 contract year

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This rule includes provisions to:

- Strengthen Sponsor Entrance & Exit Rules,
- Strengthen Beneficiary Protections,
- Provide Plan Offerings with Sufficient Enrollment and Meaningful Differences,
- Improve Payment Rules and Processes,
- Improve Data Collection for Oversight and Quality Assessment,
- Implement New Policy,
- Clarify Various Sponsor Program Participation Requirements; and
- Implement Corrections and Technical Changes

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Strengthen Sponsor Entrance & Exit Rules

- This section contains provisions designed to strengthen CMS' ability to approve for participation, strong applicants for the Part C and D programs and to remove consistently poor performers

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Strengthen Sponsor Entrance & Exit Rules

-- Application Requirements

- Requires Parts C & D Applicants to submit Notice of Intent to Apply
- Clarifies that Applicants must meet all application requirements, not “substantially” all
- New/corrected application materials—not considered past a 10-day “cure” period

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Strengthen Sponsor Entrance & Exit Rules -- Compliance Activities

- Replaces existing Corrective Action Plan (CAP) process to ensure a timely outcome-oriented approach
- Clarifies that outlier analysis may be used when measuring performance
 - CMS will make outlier-based performance standards public as soon as each is sufficiently developed

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Strengthen Sponsor Entrance & Exit Rules -- Compliance Activities

- Requires sponsoring organization to hire an independent auditor to verify deficiencies have been corrected and not likely to recur for sanctioned plans
- Clarifies that CMS may temporarily impose a “test period” for enrollment and marketing activities for certain organizations under sanction

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Strengthen Sponsor Entrance & Exit Rules -- Compliance Activities

- Establishes deemed status for individuals concerning Parts C and D Fraud, Waste and Abuse (FWA) Training. Downstream providers who have met the FWA requirement through enrollment into the Medicare program or DMEPOS are deemed to have met the FWA training and education requirements under Parts C and D
- Modifies each of the seven required elements of the compliance program

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Changes to Strengthen Beneficiary Protections

- This section includes provisions aimed at strengthening beneficiary protections under Parts C and D

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Strengthen Beneficiary Protections

- Requires standardized marketing materials when specified by CMS
 - Promotes compatibility of marketing materials between MAOs and PDPs
 - Ensures easier selection process because plan materials are more understandable to beneficiaries

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Strengthen Beneficiary Protections

- Extends the grace period for members who do not pay their premiums from 1 month to 2 months
- Establishes an out-of-pocket maximum applicable to all MA plans
- Specifies discriminatory cost sharing thresholds for Medicare A and B services. Under Part D, CMS may specify discriminatory cost sharing thresholds for non-defined standard designs

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Strengthen Beneficiary Protections

- Expands the period an LIS-individual may be deemed eligible
- Amends the auto-enrollment and reassignment provisions to explicitly include other LIS-eligibles, consistent with our current practices
- Revises disclosure regulations to permit CMS to require a sponsoring organization to disclose its current compliance and/or performance deficiencies to its existing and potential enrollees

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Strengthen Beneficiary Protections

- Allows the option for continued enrollment in Part D for out-of-area members for up to 12 months
 - Ongoing presence in a service area is unnecessary for certain stand-alone PDPs with a broad network and/or mail order pharmacy options

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Strengthen Beneficiary Protections

- Codifies into regulation drug transition process requirements
 - Part D sponsors must make reasonable efforts to notify prescribers that the affected enrollees' prescription cannot be refilled, either because of utilization management requirements or because the prescribed medication is not on the plan sponsor's formulary

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Strengthen Beneficiary Protections

- Establishes a limitation on coordination of benefits under Part D
- Requires that Part D sponsors account for other payers when reconciling claims adjustments that create overpayments and underpayments
- Makes a number of changes to Parts C and D appeals policy
- Requires Part C plans to report primary payers

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Provide Plan Offerings with Sufficient Enrollment and Meaningful Differences

- This section promotes plan offerings with meaningful differences, and ensures plan viability. Our goal is to encourage robust competition while providing health plan and PDP choices to beneficiaries that do not create confusion

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Provide Plan Offerings with Sufficient Enrollment and Meaningful Differences

- Requires meaningful differences among plans offered by a sponsoring organization in a service area
- Permits CMS to establish a minimum enrollment requirement at the *plan* level, and requires, as part of the renewal/contracting process, that plans meet the enrollment requirement or face termination

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Improve Payment Rules and Processes

- This section addresses several Part C payment rules and processes
- For example, it gives consistency to the term “qualified actuary” between Part C and Part D programs

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Improve Payment Rules and Processes

- Establishes in regulation a two-pronged appeals process for the risk adjustment data validation process. MA organizations will be permitted to appeal medical record review determinations and RADV error calculations

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Improve Data Collection for Oversight and Quality Assessment

- This section addresses both Part C and D provisions in order to improve Part C and D data collection and use for oversight and quality assessment

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Improve Data Collection for Oversight and Quality Assessment

- Requires Medicare Advantage Plans to meet CMS' criteria for chronic care improvement programs and quality improvement projects. Also, addresses using data collected by Quality Improvement Organizations for MA quality improvement and performance assessment purposes

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Improve Data Collection for Oversight and Quality Assessment

- Requires Plans and Sponsors to validate reported data per CMS instruction
- Organizations required to pay for Consumer Assessment of Healthcare Providers and Systems (CAHPS) (600+ enrollees only)
- Allows added elements to PDE record to be used for non-payment purposes

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Implement New Policy

- Continues to protect the current six drug classes of clinical concern
- Establishes that beneficiaries who elect a Medicare Medical Savings Account (MSA) will pay only a pro-rated deductible, if their MSA deposit is pro-rated because they enroll after January 1

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Clarify Various Sponsor Program Participation Requirements

- This section either clarifies existing regulations or contains provisions that implement new requirements consistent with existing policy guidance

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Clarify Various Sponsor Program Participation Requirements

- Part C plans and Part D sponsors may not waive underpaid beneficiary cost sharing—violates uniform benefit provisions
- New 14 calendar day limit to determine and respond to (or pay, if applicable) a reimbursement request under Part D

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Clarify Various Sponsor Program Participation Requirements

- Clarifies an MA organization's obligation to cover services out of the service area
- Clarifies Medication Therapy Management Program Requirements under Part D

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Implement Corrections or Technical Changes

- This section addresses a number of technical changes to the regulations
- For example, it clarifies the definition of *Gross Covered Prescription Drug Cost* to account for *usual and customary charges* at non-network pharmacies

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In total, 76 provisions in the rule

The regulation may be viewed at www.regulations.gov