DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

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TO: Current and Future Medicare Advantage Organizations, Prescription Drug Plan sponsors, Employer/Union Direct Medicare Advantage Organizations and Prescription Drug Plan Sponsors, and Cost Based Plans

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SUBJECT: Effective date of final Medicare Part C and D policy and technical changes regulation

On April 15, 2010, the Centers for Medicare & Medicaid Services (CMS) issued a new regulation (4085-F) providing for a series of policy and technical changes to the Medicare Part C and D programs. That rule appeared in the Federal Register on April 15, 2010 (75 FR 19678). The text of the regulation states that its provisions are effective on June 7, 2010, but goes on to note that because Part C and D programs operate under contracts with CMS that are applicable on a calendar year basis, the provisions will not be applicable prior to January 1, 2011, unless otherwise noted. CMS is issuing this memorandum to provide organizations with direction concerning the timing of the application of certain recently published requirements to the Part C and D program operations.

Activities Performed in Preparation for Contract Year (CY) 2011

Generally, CMS considers all provisions that govern organizations' and CMS' preparation for contract year (CY) 2011 operations to be effective on June 7, 2010. Therefore, organizations should expect that the provisions of the new regulation related to contract qualification applications, formulary submissions, and bid submissions for CY 2011 will be enforced beginning June 7, 2010. CMS provides the following as an illustrative, but not exhaustive, list of provisions that will be applied to Part C and D operations as of that date.

1) Contract Qualification Applications: CMS is currently reviewing applications from organizations seeking new Medicare Part C and D contracts, or to expand the service areas of existing contracts, for CY 2011. On or after June 7, 2010, CMS will issue application determinations based on the regulations in effect on that date, including those adopted by CMS

through the publication of 4085-F. In particular, CMS directs the attention of organizations to the following provisions that will govern the application review and denial appeal process (cite is to the preamble section of 4085-F and incorporates the new regulatory language by reference):

> *Section II.B.2.* – Applicants must demonstrate that they meet all (not substantially all) Part C and D program requirements.
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> *Section II.B.3.* – Clarification of authority to deny applications based on organization's past contract performance.
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> *Section II.B.11* – Clarification of the rules governing the timing and process for an organization to file a request for a hearing on contract determinations.
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> *Section II.B.12.* – Burden of proof, standard of proof, standard of review, and conduct of hearing.
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> *Section II.B.13.* – Requirement for the hearing officer to extend the timeframe of a hearing upon request of either party.
>
> *Section II.B.15.* – Elimination of formal discovery process.

CMS notes that the June 7, 2010 effective date for Section II.B.11, 12, 13, and 15 governs appeals of application denials only because, as noted above, the application process is related to CY 2011 plan operations. Appeals of CMS-initiated contract terminations issued during 2010 have a more direct bearing on CY 2010, rather than CY 2011, operations. Therefore, there is no compelling reason for the new regulations concerning the conduct of appeals as they apply to contract terminations to be made effective prior to January 1, 2011. Prior to that date, the regulations already in effect prior to June 7, 2010 will remain applicable to the conduct of contract termination appeals requested by organizations with contracts terminated by CMS.

2) Bids: CMS will evaluate the Part C and D bids submitted on June 7, 2010, in accordance with the meaningful differences provisions described in Section II.C.1. of 4085-F and the limitations on plan offerings by organizations acquired by or merged with another Medicare contracting organization. Following are additional requirements in 4085-F that MA organizations must abide by when submitting bids for contract year 2011:

> *Section II.B.5* - CMS established at 422.100(f)(4) that all local MA plans (employer and non-employer plans, including HMOs, local PPOs, PFFS plans, and dual SNPs) must establish an annual maximum out-of-pocket (MOOP) limit on total enrollee cost sharing liability for Parts A and B services, the dollar amount of which will be set annually by CMS. In addition, 422.100(f)(5) requires that effective for contract year 2011, local PPO plans are required to have a catastrophic limit inclusive of both in and out-of-network cost sharing for all Parts A and B services, the dollar amount of which also will be set annually by CMS. The MOOP and catastrophic limit amounts for CY 2011 were communicated to MAOs in an April 16, 2010 HPMS memorandum.

Section II.B.6 – CMS established a new requirement at 422.100(f)(6) that MA plan cost sharing for Parts A and B services specified by CMS not exceed levels annually determined by CMS to be discriminatory. In addition, Section 3202 ("Benefit Protection and Simplification") of the Patient Protection and Affordable Care Act specifies that, unless a specified exception applies, the cost sharing charged by MA plans for chemotherapy administration services, renal dialysis services, and skilled nursing care may not exceed the cost sharing for those services under Parts A and B. The Parts A and B cost-sharing thresholds for CY 2011 were communicated to MAOs in an April 16, 2010 HPMS memorandum.

Similarly, under Part D, CMS established a new requirement at 423.104(d)(2) to specify that tiered cost sharing for non-defined standard benefit designs may not exceed levels annually determined by CMS to be discriminatory. CMS issued guidance on this topic in our April 16, 2010 instructions concerning Part D plan benefit package submissions and reviews for contract year 2011.

Section II.B.7 - CMS finalized a prohibition on the establishment of prior notification rules fort PFFS plans, PPO plans (for out-of-network services), and MSA Sections 422.4(a)(1)(v), (a)(2), and (a)(3) were revised accordingly. CMS also finalized prohibition on the offering of point-of-service (POS)-like benefits by PPO plans. Specifically, we revised the definition of POS in sections 422.2 and 422.105(b), (c), and (f) to reflect the policy that only HMOs may offer a POS benefit.

Section II.G.4 - CMS clarified for MAOs that offer plans with a visitor/travel benefit to retain enrollees when they are outside of their service area for 6 to 12 months that they must furnish the complete plan benefit package for those enrollees, including all Parts A and B and supplemental benefits provided in the service area, in the areas where it offers the visitor/traveler benefit. Absent such a visitor/travel benefit, plans must disenroll beneficiaries who are absent from the plans service area for six months. Section 422.74(d)(iii) was revised accordingly.

3) <u>Non-Renewal for Low Enrollment Plans</u>: CMS will evaluate MA plan enrollments prior to bid submissions for the 2011 contract year and non-renew low enrollment plans for contract year 2011 in accordance with the provisions in Section II.C.3 of 4085-F. We provided additional guidance on low enrollment criteria for MAOs for CY 2011 in an April 16, 2010 HPMS memorandum. CMS will be conducting a similar enrollment level analysis of Part D plans as noted in our April 16, 2010 instructions concerning Part D plan benefit package submissions and reviews for contract year 2011.

Effective Date for Other Significant Provisions

1) Risk Adjustment Data Validation (RADV) Appeals Audit: By way of this HPMS notice, CMS is specifying that the RADV appeals provisions finalized in 4085-F are effective and applicable beginning June 7, 2010. We are clarifying this date so that MA organizations are afforded appeal rights at the earliest possible effective date.

2) Compliance Deeming: By way of this HPMS notice, CMS is specifying that the fraud, waste, and abuse training and education deeming provisions (422.503(b)(4)(vi)(C)(2) and 423.504(b)(4)(vi)(C)(3)) finalized in 4085-F and described in Section II.B.5. are applicable beginning June 7, 2010. These provisions will reduce burden on providers, and ultimately sponsors, who have already met fraud, waste, and abuse training requirements through enrollment into the Medicare program or accreditation as a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies supplier.

3) Quality Improvement Program Requirements: CMS finalized the revisions to sections 422.152(a)(1) (a)(2) in Section II.E.1.a of 4085-F to require that MA organizations conduct chronic care improvement programs in patient populations and quality improvement projects in areas identified by CMS. This provision is applicable beginning June 7, 2010.

4) MSA deductible: MSA plan bids submitted for contract year 2011 should consider that the MSA deductible will be pro-rated (consistent with the pro-rating of the deposit that is already occurring) for enrollments that occur during the calendar year, as specified at section 422.103.