

CLIENT ALERT

CMS Issues Proposed Regulations Implementing Medicare Part D Drug Benefit and Medicare Advantage Program

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On Monday, July 26, 2004, CMS released proposed regulations implementing the Medicare Part D prescription drug benefit and Medicare Advantage (MA) program authorized under the Medicare Modernization Act of 2003 (MMA), Pub. L. 108-173 (December 8, 2003). The proposed regulations, as well as CMS' press release and a 16 page fact sheet summarizing highlights of the proposed regulations, are available on the [CMS web site](#). In their current form, the regulations are 1,342 and 614 double-spaced pages, respectively. The regulations are to be published in a more manageable format in the *Federal Register* on Tuesday, August 3, 2004. CMS will accept comments on the proposed regulations until October 4, 2004.

Medicare Part D Drug Benefit Regulations. The proposed Part D regulations would be in a new part 423 to Title 42 of the *Code of Federal Regulations*. In recognition of the MMA requirement that MA coordinated care plans offer a Medicare Advantage prescription drug plan (MA-PD) in each service area in which the coordinated care plan operates, the implementing regulations set forth in part 423 are modeled on the parallel provisions of 42 C.F.R. part 422 (governing the Medicare Advantage program).

CMS has filled the proposed regulations with very specific instructions on how to handle some issues and rather vague and highly tentative guidance on a number of others. For example, the regulations include a specific proposal to exclude correctional facilities from PDP and MA-PD service areas, so that incarcerated persons will not be eligible for Part D benefits while in jail and can thus avoid the late enrollment penalty if they choose to enroll in Part D after their release. By contrast, in addressing internal inconsistencies within MMA statutory provisions such as those governing the provision of Part D benefits to dual eligible individuals who are in an MA plan but fail to enroll in a PDP or MA-PD plan, CMS has proposed alternative approaches and seeks comments as to which approach is most appropriate.

Overall, the regulations reflect an appreciation for the complexity of the issues that must be resolved before the Part D benefit is implemented, and a willingness to consider comments from industry representatives and the public at large. Nevertheless, with implementation looming, organizations seeking concrete guidance will likely be disappointed.

Medicare Advantage Regulations. The proposed Medicare Advantage regulations would make substantive changes to 42 C.F.R. part 422 needed to transition from the old Medicare+Choice program to the new Medicare Advantage program and effect changes to the Medicare cost contract provisions set forth in 42 C.F.R. part 417.

Like the proposed Part D regulations, the proposed Medicare Advantage regulations in many instances merely suggest general principles CMS plans to follow instead of proposing a concrete guidelines. For example, in addressing how specialized needs Medicare Advantage plans are to be defined, the regulations state that CMS "will establish quantitative criteria to be able to designate MA plans that disproportionately serve special needs beneficiaries," but do not identify the proposed criteria, other than to refer to one "possible criterion" contemplated and the possibility of others "based on diagnosis data or other administrative data." The proposed regulation expressly declines to define or elaborate upon the MMA's addition of individuals

with “severe or disabling chronic conditions” to the class of special needs beneficiaries, and instead seeks comments on how it might define such conditions. While such lack of specificity presents a valuable opportunity for interested parties to promote their own proposals during the comment period, it could also foreclose the opportunity to respond to specific items once the final regulations are promulgated.

Another approach frequently used in the regulations is to propose several options and invite comment as to which should be adopted in the final regulations. For example, in addressing how plans should handle ESRD costs in their bid submissions for contract year 2006, the regulations set forth three alternatives: (i) having plans exclude costs for ESRD enrollees from their basic A/B bids and paying plans for such enrollees using the MMA rate setting methodology; (ii) having plans exclude costs for ESRD enrollees from their basic A/B bids but directing plans to include such costs in the supplemental portion of the bid in order to determine the appropriate price of supplemental benefits other than Part B premium reductions; and (iii) having plans incorporate costs for ESRD enrollees in the pricing of both basic and supplemental benefits other than Part B reductions. Again, while the solicitation of comments on alternative approaches signals a welcome openness and flexibility on the part of CMS, it offers little guidance to plans trying to prepare for bid submissions which are due in June 2005.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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