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CLIENT ADVISORY

CMS Unveils Draft Guidance for the 2007 Medicare Drug Benefit

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On February 23, 2006, the Centers for Medicare and Medicaid Services (CMS) issued drafts of four documents that will shape the Medicare Part D prescription drug benefit in 2007. The drafts are: the 2007 Formulary Guidelines; the 2007 Transition Guidance; and two 2007 "call letters," one for free-standing Prescription Drug Plans (PDPs), and one for Medicare Advantage (MA) plans and MA-PD plans.

The four drafts are available on the CMS website.[1] CMS will accept comments on the draft formulary guidelines and transition guidance *until March 6*, and will accept comments on the draft call letters *until March 1*. Quick highlights are given below.

DRAFT 2007 FORMULARY GUIDELINES

The draft formulary guidelines for 2007 are generally similar to the current guidelines. Part D formularies currently must include "all or substantially all" of the drugs in six classes (immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics). CMS will continue this requirement in 2007, but invites suggestions on "current managed care strategies that could be implemented within the context of this policy" that would allow plans "to manage these drug classes where appropriate." "All or substantially all" would mean all drugs in these classes available as of April 17, 2006 (when plans must submit proposed 2007 formularies), except: multi-source brands of the identical molecular structure; extended release products, when the immediate-release product is included on the formulary; products that have the same active ingredient; and multiple dosage forms that do not provide a unique route of administration (e.g., tablets and capsules).

[1] www.cms.hhs.gov/PrescriptionDrugCovContra/03_RxContracting_FormularyGuidance.asp#TopOfPage (formulary guidance); www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/TransitionProcess_031605.pdf (transition process); www.cms.hhs.gov/PrescriptionDrugCovContra/01_Overview.asp#TopOfPage (PDP call letter); www.cms.hhs.gov/HealthPlansGenInfo/02_WhatsNew.asp#TopOfPage (MA and MA-PD call letter).

Like the existing guidance, the draft describes the "minimum statutory requirement" as two drugs in each category or class (unless only one drug is available in the category or class), and provides that formularies should normally include at least one drug in each of the USP's "Formulary Key Drug Types" (unless the plan justifies a departure from this benchmark). However, if a Key Drug Type only includes drugs "primarily" covered under Medicare Part B, "it is not CMS' expectation that these Key Drug Types be represented on formularies."

"Specialty tiers" (formulary tiers containing very high cost and unique drugs, which are ineligible for tiering exceptions) would only be approved by CMS if: (1) only one formulary tier is designated a specialty tier; (2) cost-sharing for specialty-tier drugs is limited to 25% (or an actuarially equivalent amount) in the initial coverage period; and (3) the specialty tier only contains drugs that cost over $500/month (as measured by the plan's negotiated prices).

DRAFT 2007 TRANSITION GUIDANCE

Based on its experience with implementing the Part D benefit in 2006, CMS proposes to set minimum standards for plans' transition processes in 2007. For new plan enrollees, a plan generally would be required to refill a prescription for a non-formulary drug (or a formulary drug subject to prior authorization or step therapy requirements) "during the first 90 days of a beneficiary's enrollment" in the plan; during this "90-day" transition period, however, a plan would only be required to "provide a temporary 30 day fill" for the drug.

For new plan enrollees who reside in long-term care (LTC) facilities, the transition period is also 90 days, but plans would have to fill multiple 30-day prescriptions during the transition period (i.e., an LTC resident theoretically could get up to three 30-day fills of a nonformulary drug, or a drug otherwise subject to prior authorization or step therapy requirements, during the 90-day transition). Even after an LTC resident has been enrolled in the plan for 90 days, "the plan must still provide an emergency supply of non-formulary Part D drugs [or formulary drugs subject to utilization management restrictions] while an exception is being processed."

The draft also proposes transition requirements for enrollees who are not new to the plan, but are taking nonformulary medications due to "level of care changes in which a beneficiary is changing from one treatment setting to another" (e.g., beneficiaries discharged from hospitals with a discharge list of medications on the hospital's formulary).

DRAFT 2007 CALL LETTERS FOR PLANS

The draft call letters for PDPs and for MA and MA-PD plans are lengthy documents that cover a range of issues concerning the bidding process for 2007 contracts and the requirements these contracts will contain. Manufacturers should note the new provisions on disclosure of manufacturer rebates to certain parties other than plan sponsors—i.e., PBM subcontractors to plans, and pharmacies (including LTC pharmacies) that are part of plan networks. The proposal for pharmacies to disclose manufacturer rebates to Part D plans stems from concerns about rebates to LTC pharmacies that CMS recently raised, which are reiterated in the call letters. CMS states that plans can assure pharmacies about the confidentiality of this information.

Both letters have a timetable of dates associated with the bidding and contract renewal process. Key dates include April 17, 2006 (formulary submissions due); June 5, 2006 (bid submission deadline); and October 1, 2006 (marketing of CY 2007 benefits begins).

We hope that you find this brief summary helpful. If you would like more information, please feel free to contact your Arnold & Porter attorney or:

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