



CMA WEEKLY ALERT – January 12, 2006

WHO'S ENFORCING PART D REQUIREMENTS?

Many Medicare beneficiaries are not getting the prescription drugs they need during the initial transition to Part D. On January 6, the Centers for Medicare & Medicaid Services (CMS) wrote to “All Part D Sponsors,” reminding them of “transition policy requirements that must be upheld” and the need to ensure that beneficiaries get prescription drugs without delay, denial, or undue burden.

CMS' letter reports that some customer service representatives are not aware of their plan's transition policies and, as a result, are incorrectly informing beneficiaries that they can get access to non-formulary drugs only by filing for an exception. CMS expresses particular concern that some plans have not provided their network pharmacies with appropriate instructions during the initial transition period. It has received numerous complaints identifying prior authorization and step edit requirements that prevent beneficiaries from getting immediate access to prescription drugs. CMS reminds Part D sponsors either to resolve prior authorization or step edit requirements at point-of-sale, generally by suppressing these edits during the transition period, or to provide beneficiaries with a temporary supply of formulary and non-formulary drugs.

CMS identifies transition issues for long-term care residents, stressing again that prior authorization and step edits “should not prevent an enrollee in an LTC setting from receiving their initial medications.” In addition, discussing the intersection of Medicare Parts B and D, CMS notes that some drugs related to durable medical equipment (and excluded from Part B coverage for long-term care residents) may now be covered under Part D for residents. Infusable and injectable drugs administered by the facility may also be covered under Part D.

The January 6 memorandum by Gary Bailey, Deputy Director of CMS' Center for Beneficiary Choices, to “All Part D Sponsors” alerts plans about these initial transition problems and how to correct them. CMS can do more. It has authority to enforce the requirements of Part D.

CMS has authority (but is not required) to impose sanctions against plans for various kinds of noncompliance with program requirements, including failure “substantially to provide, to a Part D plan enrollee, medically necessary services that the organization is required to provide (under law or under the contract) to a Part D plan enrollee, and that failure adversely affects (or is substantially likely to adversely affect) the enrollee.” 42 C.F.R. §423.752(a)(1). Misrepresentation or falsification of information furnished to an individual is also sanctionable. *Id.* §423.752(a)(5).

Permissive sanctions include civil money penalties, ranging from \$10,000 to \$100,000; suspension of enrollment of Medicare beneficiaries; suspension of Medicare payments to Part D sponsors; and suspension of plan marketing activities. *Id.* §423.750(a)(1)-(4). Before imposing

any of these sanctions, CMS must give the Part D sponsor written notice and an opportunity to respond. *Id.* §423.756. It also must notify the Office of Inspector General, which has authority to impose civil money penalties in addition to, or instead of, those imposed by CMS. *Id.* §423.756(f)(2).

CMS declined commenters' request to provide a methodology for determining when to impose specific remedies, intentionally retaining discretion to impose one or more sanctions as appropriate. 70 Fed. Reg. 4193, 4366 (Jan. 28, 2005) (preamble to final regulations). Although it does not intend to disclose the compliance status of Part D plans, plans' corrective action plans are subject to disclosure under the Freedom of Information Act. *Id.* 70 Fed. Reg., 4377.

While CMS is unlikely to impose any remedies during the early stages of Part D, its January 6 memorandum clearly puts plans on notice that "delaying or denying the filling of initial prescriptions for new enrollees at point-of-sale because of prior authorization/step edit requirements is not consistent with the intent of CMS' transition policy."

Advocates should continue to provide information to CMS and other policy makers about Part D implementation problems. If plans fail to correct these problems, advocates should insist that CMS take action to enforce its requirements.

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