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CMS Proposes to Treat Drug Vial "Overfills" As Suspect Free Goods

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CMS's annual summer tome, the proposed Physician Fee Schedule published this year on July 13, 2010, contains a significant new proposal that if adopted would affect the physicians, hospitals outpatient departments and others that bill for drugs and biologics under Medicare Part B. The regulation would target the common pharmaceutical practice of collecting and billing for the "overfill." An overfill is the small quantity of medication that pharmaceutical manufacturers include in drug vials to help assure that appropriate doses of the drug can be withdrawn from the vial for administration, and in pharmacy practice is generally understood to be necessary to account for product loss when a liquid drug is prepared and administered appropriately.

The government has alleged that certain manufacturers deliberately included excess amounts of overfill as a marketing ploy. In particular, in an October 2009 False Claims Act case brought in the District of Massachusetts, New York, 13 other states and the District of Columbia, it was alleged that Amgen and others provided kickbacks in the form of overfills to doctors and clinics, although there is no allegation in the case that providers billing for the administered "overfill" was improper. A number of hospitals have received subpoenas related to the investigation.

CMS Proposal

The CMS proposal (found at 75 FR 40040 at 40155 and 40259) would amend 42 CFR Section 414.904 to prohibit billing for "overfill" in product purchases. The proposed revised Section 414.904(a) states:

> (i) CMS calculates an average sales price payment limit based on the amount of product included in a vial or other container as reflected on the FDA-approved label.
>
> (ii) Additional product contained in the vial or other container does not represent a cost to providers and is not incorporated into the ASP payment limit.

(iii) No payment shall be made for amounts of product in excess of that reflected on the FDA-approved label.

Half Truths and Questionable Policy

CMS justifies the proposal by arguing that, "additional product contained in the vial or container does not represent a cost to providers and is not incorporated in the ASP payment limit." This is half true. While in an excess overfill context, the amount in excess of the fill amount is not in fact incorporated into the ASP payment limit -- a defect perhaps in that process -- it simply has no relationship to the costs of obtaining the product by a hospital. ASP controls Medicare reimbursement. It does not impact the price actually paid by the hospital. Indeed, these pharmaceutical companies could have offered additional supply for the same price without implicating the ASP. The issue, of course, is that the pharmaceutical companies failed to disclose the additional amount of product that they were providing to the hospitals in their ASP calculation. In other words, instead of policing the ASP requirement by, for example, prohibiting overfill in excess of a certain small amount, CMS proposes simply to prohibit the hospitals from billing for it.

The consequence is that hospital costs for drug therapy for Medicare patients will be higher and pharmaceutical companies' profits will be greater. Medicare costs will be the same. It is hard to see this as good policy. Indeed, the ramifications extend far beyond this particular context, and theoretically would apply to any effort by providers to determine more efficient ways of providing care that are not somehow part of the cost basis for Medicare reimbursement.

Moreover, the implications of the proposed regulation are more immediate. In the Preamble discussion of the proposed regulation, CMS noted that under existing law, "free" goods may not be billed to Medicare. Since the "overfill" as stated by and apparently in the mind of CMS is a "free" good, they conclude, "providers who submit such claims may be subject to scrutiny and follow-up action by CMS, its contractors, and the OIG."[1] Thus, any current billing for overfill is deemed suspect. This may present a significant issue.

Next Steps

The proposed CMS prohibition for collecting and billing for “overfill” would seem to effectively be a windfall for pharmaceutical companies and will result in an unnecessary additional expense for hospitals and other providers that may have collected and used such “overfill” in the past. Comments for the proposal are due by 5:00pm August 24, 2010. Providers should both individually and through their associations aggressively address these proposed regulations.

[1] At least one Medicare contractor has suggested that providers using and then billing for “free” pooled overfill amounts are violating Medicare requirements by billing for free goods for which they have incurred no expense.

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