

CMS Issues Proposed Rule on Medicare Reimbursement for Intentional Overfills

On July 13, 2010, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule that would impact Medicare Part B reimbursement for drugs and biologics. The proposed rule would modify CMS regulations to specify that payment under Medicare is unavailable for the portion of a drug or biologic in a container or vial that exceeds the amount specified on the product's approved label.

Intentional Overfill

Manufacturers will sometimes include small amounts of "overfill" in drug containers as a way to compensate for the portion of the product that may be lost when the drug is administered. In proposing its new rule, CMS observes that when a provider purchases a vial or container of a product from the manufacturer, the provider purchases the amount of the drug as defined by the product's label, not the overfill. Accordingly, CMS describes overfill as "excess, free product."

The Proposed Rule

The proposed rule seeks to make clear that the amount of a drug or biologic that is reimbursable under Medicare is limited to the amount that the provider actually purchases, or the amount on the product's label. Specifically, CMS proposes to modify its regulations so that they clearly indicate the following points:

- Medicare average sales price (ASP) payment limits depend upon the amount of a product in the vial or container as indicated on the product's approved label.
- Payment for portions of a product in excess of the amount indicated on the product's approved label will not be made under Medicare.

Importantly, CMS does not characterize the proposed rule as a change in policy but rather as a clear statement of existing policy. CMS references "longstanding Medicare policy" permitting providers to bill only for those services or supplies that represent expenses to the providers. CMS specifically notes that providers may not bill Medicare for overfill harvested from containers, including overfill amounts pooled from more than one container, because such overfill amounts do not represent a cost to the provider. According to CMS, claims that do not represent a cost to the provider may subject such provider to "scrutiny and follow up action by CMS, its contractors, and OIG."

The deadline for comments to CMS regarding the proposed rule is 5:00 p.m. on August 24, 2010. If you have questions regarding the proposed rule, please contact the Ropes & Gray attorney with whom you regularly work.