Controversy Looms Over Medicare’s New Policy on ‘Intentional Overfill’ of Injectables

Hospitals Say Curtailed Payments Shouldn’t Apply to Them

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In calendar year 2011, Medicare plans to tighten its reimbursement rules, primarily for injectable and intravenous (IV) drugs. The new policy aims to address the perceived problem of “intentional overfill,” which occurs when a drug manufacturer puts more product into a vial or a container than is required for a single dose. Companies sometimes do this in case part of the drug is lost when a syringe or other applicator is inserted into the vial or if some of the solution sticks to the bottom or side of the vial and can’t be inserted into the syringe.

However, the Centers for Medicare and Medicaid Services (CMS), which issued the final physician payment rule in November, did not specify whether the new policy applies to hospital inpatient and outpatient pharmacies. In its typical mumbo-jumbo of regulatory language, the CMS obliquely noted that its new calendar 2011 Medicare Average Sales Price (ASP) policy affects a physician supplier or any other person that bills for Part B covered drugs that are not paid under a cost or prospective payment system. (Part B coverage includes anticoagulation factors, immunosuppressants, and antineoplastics, as well as some medical devices.)

The agency refused to elaborate on who “any other person” is, whether this means hospital pharmacies, dialysis centers, cancer centers, or any setting other than a physician’s office. The final rule does offer a hint, however. It states that the new ASP payment policy is not restricted to health care professionals who provide drugs to patients “incident to” physicians’ services; this terminology, in the Medicare lexicon, typically means physicians who provide drugs to patients in the office. The CMS says that the “incident to” distinction is irrelevant with regard to its policy for calculating the ASP.

We can thus expect Medicare to crack down on any health care providers who bill for intentional overfill in a vial or package purchased from a drug manufacturer. The problem arises when the “extra” drug becomes usable and is applied to a dose for a second patient.

For example, a hospital could buy 10 vials of a drug whose labeled dosage is 5 mg, with each vial containing 5.5 mL and 0.5 mg of overfill. If the hospital pharmacist harvests the 10 0.5-mg overfill amounts, another dose could be available. In effect, at least theoretically, the pharmacy pays for 10 doses but bills Medicare for 11. Some drugs could be expensive chemotherapy agents.

The U.S. Pharmacopeia, which sets standards for prescription and over-the-counter drugs, recommends up to an additional 0.1 mL (a 10% overfill) for a 1-mL dose vial. The appropriate amount of necessary overfill can vary from product to product, depending on the drug’s viscosity, surface tension, vial size, dose, and other factors. As a result, it is not always clear what is overfill and what is regular fill.

Billing Medicare for overfill extras is definitely fraudulent when physicians buy Part B drugs for administration in the office. It is apparently less clear whether billing for overfill doses is illegal in hospitals. Medicare’s overpayments for overfill has been spotlighted over the years by the Office of the Inspector General. In a 2004 report, for example, the Inspector General noted:1

Three providers reported that they are able to lower actual acquisition costs through the utilization of overfill for Epogen (EPO). According to one respondent, the manufacturer of EPO overfills its vials to guarantee a minimum dosing level for effective use of the product. The overfill ranges from 7 to 14 percent based on type of vials. Another provider reported a similar overfill percentage for paricalcitol [Zemplar].

The American Society of Health System Pharmacists (ASHP) lobbied the CMS not to apply the new policy to hospitals. Justine Coffey, JD, LLM, Director of Federal Regulatory Affairs at ASHP, said in her initial comments to the CMS prior to the final rule:

ASHP is extremely concerned by CMS’s proposal to update its regulations to state that Medicare Average Sales Price (ASP) payment limits are based on the amount of product in the vial or container, as reflected on the FDA-approved label, and that payment for amounts of product in excess of the amount reflected on the FDA-approved label will not be made under Medicare. If CMS updates its regulations in the manner proposed, hospitals will effectively receive lower reimbursement rates for their overhead costs relating to the procurement, preparation, and dispensing of the affected drugs. Additionally, hospitals will need to purchase more drug product from manufacturers.

The American Hospital Association (AHA) sang a similar tune. Rick Pollack, AHA’s Executive Vice President, wrote to Donald Berwick, CMS Administrator:

“Nothing in the CMS’s regulations requires a provider (as opposed to a physician) to have incurred a cost in order to bill for an item or service including a drug.”

Neither Ms. Coffey nor the AHA’s Roslyne Schulman responded to a request for their comments on the final rule. Given the opacity of the language in the final rule, the CMS is probably going to get some challenges from hospitals—maybe legal, maybe legislative.

REFERENCE