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Billing for drug overfill: New compliance risk or old prohibition?

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Drug overfill is the amount of a drug formulation included in the vial of an injectable drug in excess of the quantity indicated on the label. A certain amount of overfill is included as part of the manufacturing process in order to compensate for the waste space volume located in many of the syringes or injectable devices that are used to administer these medications. Including a small amount of overfill in a drug vial ensures that the labeled dose can be prop-

erly withdrawn from the vial and administered to the patient.

Prior to last year, the Centers for Medicare and Medicaid Services (CMS) had never publicly commented on whether providers were permitted to bill for drug overfill. That all changed in 2010, however, when CMS published a rule that made revisions to the Physician Fee Schedule and other Medicare Part B payment policies.¹ In that rule, for the first time, CMS commented directly on the subject of drug overfill and whether overfill may be billed to Medicare. CMS stated that overfill is not reimbursable and that providers who bill for it could find themselves the subject of regulatory scrutiny or even prosecution. Was CMS's comment a logical application of existing Medicare billing rules, or an extension of those rules that created a new and previously unknown compliance risk?

In the new rule, CMS first reviewed how it computes drug reimbursement rates based on average sales price (ASP) and how the ASP formula had changed over time, most recently with the

enactment of the Medicare, Medicaid and SCHIP Extension Act in 2007. CMS then explained that overfill is not included in ASP calculations, because it is not part of the drug purchase price and does not represent a cost incurred by the provider. CMS rejected the notion that overfill should be considered an "in-kind" discount that reduces the price of the drug, or that the purchase price of the drug encompasses overfill.² Accordingly, CMS concluded that overfill is not reimbursable by Medicare:

. . . [W]e have become aware of situations where manufacturers, by design, include a small amount of "intentional overfill" in containers of drugs. We understand that this "intentional overfill" is intended to compensate for loss of product when a dose is prepared and administered properly. For instance, a hypothetical drug is intended to be delivered at a 0.5 mg dose that must be drawn into a syringe from a vial labeled for single use only. The vial is labeled to contain 0.5 mg of product but actually contains 1.5mg of product. The additional 1.0 mg of product is included, by design, and is intended to be available to the provider so as to ensure a full 0.5 mg dose is administered to the patient.

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Our ASP payment calculations are based on data reported to us by manufacturers. This data includes the “volume per item”. . . In order to accurately calculate Medicare ASP payment limits under section 1847A of the [Social Security] Act, we interpret “the amount in one item” to be the amount of product in the vial or other container as indicated on the FDA approved label.

It has been longstanding Medicare policy that in order to meet the general requirements for coverage under the “incident to” provision, services or supplies should represent an expense incurred by the physician or entity billing for the services or supplies (See MedicareBenefit Policy Manual (Publication 100-02), Chapter 15, Sections 50.3, 60.1.A). Such physicians’ services and supplies include drugs and biologicals under section 1861(s)(2)(A) of the Act. In accordance with this policy, providers may only bill for the amount of drug product actually purchased and that the cost of the product must represent an expense to the physician.

We further understand that when a provider purchases a vial or container of product, the provider is purchasing an amount of drug defined by the product packaging or label. Any excess product (that is, overfill) is

provided without charge to the provider. In accordance with our current policy as explained above, providers may not bill Medicare for overfill harvested from single use containers, including overfill amounts pooled from more than one container, because that overfill does not represent a cost to the provider. Claims for drugs and biologicals that do not represent a cost to the provider are not reimbursable, and providers who submit such claims may be subject to scrutiny and follow up action by CMS, its contractors, and OIG.

Because such overfill is currently not included in the calculation of payment limits under the methodology in section 1847A of the Act and does not represent an incurred cost to a provider, we proposed to update our regulations at 42 CFR part 414 Subpart K to clearly state that Medicare ASP payment limits are based on the amount of product in the vial or container as reflected on the FDA-approved label. We also proposed to update our regulations at Subpart J to clearly state that payment for amounts of free product, or product in excess of the amount reflected on the FDA-approved label, will not be made under Medicare.³ (Emphasis added)

CMS’s comments drew support in some quarters, and opposition

in others. Some contended that the rule imposed a “new” restriction that would limit provider utilization of overfill in a clinical setting, notwithstanding that CMS had long been aware of overfill utilization practices and had expressed no concerns about them. CMS responded by reiterating that it has been “longstanding Medicare policy” that any drugs, services, and supplies billed by a provider to Medicare must represent an actual expense in order to be reimbursable. CMS also distinguished between overfill utilization and overfill billing, commenting that its policy was not intended to regulate overfill utilization in clinical practice as a cost-saving measure, but merely to clarify that drug overfill is not considered by CMS in setting drug reimbursement rates and is not reimbursable under Medicare billing rules: “The intent of this proposal is merely to clarify that the Medicare ASP payment limit is based on the amount of drug conspicuously indicated on the FDA label, and that no payment will be made for any intentional overfill included as free drug for the proper preparation of a single therapeutic dose.”⁴ CMS further stated that its position on overfill applies to any provider in any setting, provided that the drug is being reimbursed under ASP-based payment limits.⁵

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The issue of whether CMS's comments on drug overfill represent a "new" rule, or reflect (as CMS indicated) "longstanding Medicare policy" is not an academic one. For starters, a new rule cannot be applied retroactively and would permit providers to conform their conduct to a new regulatory landscape. There is no such leeway with a "longstanding" policy, which could potentially bring years of prior non-conforming conduct under regulatory scrutiny.

Further, several whistleblower cases have been initiated under the False Claims Act (FCA) that include overfill-related allegations based on past conduct. Indeed, it is quite possible that CMS's comments on overfill were, at least partly, a reaction to these lawsuits.

There is a lawsuit pending in Massachusetts, *United States ex rel Westmoreland v. Amgen, Inc. et al*⁶ that alleges that Amgen sales personnel marketed drug overfill contained in vials of the anemia drug Aranesp as a kickback to providers to induce orders of the drug, in violation of the Anti-kickback Statute, rendering resulting Aranesp claims "false" under the FCA. The relator charged that Amgen urged providers to file false Medicare claims for Aranesp overfill that they received at no cost, and that this extra reimbursement was an illegal kickback. The *Westmoreland* lawsuit, which

targeted the drug suppliers and not the providers, predicates the "falsity" of the Aranesp reimbursement claims on an anti-kickback theory, and not on the ground that the providers submitting the claims did not incur costs for the overfill doses for which they sought reimbursement.

Two other lawsuits brought under the FCA (one pending in Georgia and the other in Texas) do include such specific allegations, related to the anemia drug Epogen, which is used heavily in the dialysis setting.⁷ In both lawsuits, the relators allege that dialysis provider DaVita defrauded the Medicare program by submitting claims for Epogen overfill that it had received at no cost.

Interestingly, the federal government has not intervened in any of these cases, despite CMS's recent public comments on drug overfill as being non-reimbursable. Rulings from two district courts in the *Westmoreland* and *Woodard* lawsuits appear to support the argument that overfill billing is not only actionable under the FCA, but also that such a claim arises from a longstanding prohibition against billing Medicare for free goods.

Last year, prior to publication of the final CMS rule referenced above, Judge William Young denied a defense motion to dismiss the

complaint in the *Westmoreland* case. Rejecting the defense argument suggesting that Medicare permits overfill billing and thus advising others of that alleged circumstance cannot constitute an illegal kickback, Judge Young noted:

*The Defendants' argument that Medicare reimburses for excess overfill—dosages that do not represent an expense to the provider—appears flawed. . . . Relator points to the Medicare Reimbursement Policy Manual (the "Manual"), which states that "the cost of the drug ... [for which reimbursement is sought] must represent an expense to the physician." . . . Relator also cites to a Medicare Proposed Rule which appears to clarify the just-mentioned policy, stating that "[a]ny excess, free product (that is, overfill) is provided without charge to the provider. In accordance with our policy, providers may not bill Medicare for overfill harvested from containers." . . . A plain reading of the Manual suggests that because providers do not pay for excess overfill, it is not reimbursable by Medicare. The Defendants have not pointed to any regulation directly to the contrary.*⁸ (Emphasis added)

Subsequently, in May 2011, Judge Marcia Crone provided a

more detailed analysis in denying DaVita's motion to dismiss the relator's overfill claim in the *Woodard* lawsuit. Concluding that the relator there stated a valid claim under the FCA by alleging that DaVita billed for overfill it had received free of charge, Judge Crone wrote:

Medicare regulations dictate that reimbursable costs are costs "actually incurred." 42 U.S.C. §§ 1395x(v), 1395rr(b)(2)(B). Further, the Medicare Program Integrity Manual identifies "billing Medicare for costs not incurred" as a common form of fraud. Medicare Program Integrity Manual, Chapter 4, § 4.2.1. As previously discussed, the complaint details a purported scheme by DaVita to extract and administer overfill, which it received free of cost, and to bill the government for that administration. . . . Here, Woodard alleges that DaVita submitted claims to the government that incorrectly described the goods provided, i.e., the claims represented overfill as an expense to DaVita when, in fact, the corporation had not paid for the drug. This alleges a factually false claim and, therefore, no certification by DaVita is required.

Accordingly, Woodard's overfill allegations regarding DaVita's submission of bills for captured

*overfill are sufficient to state an FCA claim.*⁹ (Emphasis added)

Judge Crone acknowledged that the CMS rule discussing overfill, which became effective in January 2011, could not be applied retroactively, but noted that the relator's overfill claim was based on an established and pre-existing rule prohibiting providers from billing Medicare for costs not incurred. Judge Crone also rejected DaVita's argument that the government had condoned overfill billing merely because it had been aware of overfill utilization practices by some dialysis providers, as reflected in government audit reports analyzing Medicare reimbursement rates for Epogen.¹⁰ Like CMS, Judge Crone distinguished between drug utilization and drug billing, commenting that government knowledge of the former practice "stop[s] far short of authorizing the practice" of billing overfill.¹¹

Judge Crone's ruling, together with the comments of Judge Young in the *Westmoreland* case, would seem to support CMS's view that overfill is not reimbursable under pre-existing rules that require providers to incur an actual cost as a legal prerequisite to Medicare reimbursement. On this view, overfill is just another type of free product for which providers may not earn a profit by charging Medicare, making

the prohibition against overfill billing a new application of an old rule, analogous to prohibiting providers from billing Medicare for an innovative new type of medical treatment that was never rendered.

The immediate effect of these court rulings and CMS's recent comments on overfill, including its warning that "providers who submit such claims may be subject to scrutiny and follow up action by CMS, its contractors, and OIG," remains to be seen. Might there be a new, broad federal enforcement initiative in the offing, based on the practice of overfill billing? Only time will tell, but this much is clear: Some amount of drug overfill is common to all injectable medications as part of the manufacturing process, and anemia drugs are not the only costly medications for which there might be an incentive for certain providers to collect, utilize, and bill the extra doses that overfill can be harvested to create. Chemotherapy drugs, for example, are very expensive, and potentially could likewise be subject to overfill utilization and billing as well. Indeed, before the CMS rule became final, opposition to the overfill provision came from, among others, multiple organizations representing the interests of

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oncologists, with those organizations arguing that the CMS position was misguided and that oncologists should be allowed to use and bill for overfill.¹² There are many other injectable drugs that carry a similar risk.

What all this adds up to is a very real and worrisome compliance risk for institutional and individual providers who may have billed for drug overfill in the past and/or may be doing so today, despite the recent CMS pronouncement. This risk is not limited to Medicare and other public health insurance programs. It is probably fair to say that private health insurers are no more likely than Medicare to reimburse for drug doses that they believe do not represent an actual cost to the provider.

All providers should immediately examine their drug utilization and billing procedures with this in mind, and implement any changes that may be needed to bring themselves into compliance with the government's recently expressed view on overfill billing. Whether and how quickly providers amend non-compliant billing practices in reaction to the CMS warning on overfill could well make a critical difference in how they are perceived by regulators, should they one day wake up to find themselves in the proverbial crosshairs of a government enforcement action. ■

1. See Federal Register, Volume 75, Number 228 (42 CFR Parts 405, 409, 410, 411, 413, 414, 415, and 424) (November 29, 2010) (Effective date, January 1, 2011).
2. Federal Register, Volume 75, Number 228, at p. 73468.
3. Federal Register, Volume 75, Number 228, pp. 73466-73467
4. Id. at p. 73467
5. Id. at p. 73469
6. Civil Action No. 06-10972
7. *United States ex rel. Woodard v. Davita, Inc.*, (1:05-cv-00227-MAC) (E.D. Tex.) and *United States ex rel. Vainer et al. v. Davita, Inc. et al.* (1:07-cv-02509-CAP) (N.D. Ga.)
8. *United States ex rel. Westmoreland v. Amgen, Inc. et al.*, 738 F. Supp. 2d 267, 274 n.11 (D. Mass. 2010)
9. Slip Op. at pp. 12-13
10. Department of Health & Human Services, Office of Inspector General: "Medicare Reimbursement for Existing End-Stage Renal Disease Drugs." May 2004, pp. 8-9; and Department of Health & Human Services, Office of Inspector General: "Review of Epogen Reimbursement." November 1997, pp. 1, 5.
11. Slip Op. at p. 14 n.6
12. See, e.g., Letter to CMS from the Community Oncology Alliance, dated August 24, 2010, opposing CMS position on overfill; Letter to CMS from the Association of Community Cancer Centers, dated August 24, 2010, opposing CMS position on overfill; Letter from U.S. Oncology, Inc., dated August 24, 2010, opposing CMS position on overfill.



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