■ Grim Provider and Supplier Gross Margins of 1.8%-3.7% if CMS-1670-P Is Finalized As Proposed

Physicians that purchase drugs, administer to patients, and bill Medicare (“buy-and-bill”) are reimbursed at 106% of the average sales price (ASP). ASP is net of discounts such as volume, prompt pay, and cash discounts; free goods contingent on purchase requirements; chargebacks; and rebates other than those paid under the Medicaid drug rebate program. However, ASP includes wholesaler prompt pay discounts that are not passed on to purchasers, reducing Part B reimbursement by about 1.5%.^{1,2}

Since Congress mandated the sequester in 2012, Part B reimbursement has been 104.3% of ASP.³ On March 8, 2016, the Centers for Medicare & Medicaid Services (CMS) announced CMS-1670-P, a proposed rule to “test new models to improve how Medicare Part B pays for prescription drugs and supports physicians and other clinicians in delivering higher quality care.”⁴ As proposed, providers and suppliers of Part B drugs selected for a particular demonstration would be required to participate over the 5-year test period. Historically, private sector payers tend to follow CMS’s lead. These changes could irreversibly change medical oncology practice, with no assurance of reduced Part B expenditures.

Because “almost 80% of oncology practice Medicare fee-for-service revenue is from Part B drugs,”⁵ I performed an oncology-focused analysis of the proposed rule. Posted at the resources tab of the EB Rubinstein Associates website are topline results of the analysis of a CY 2014 Part B claims data file posted to the CMS website.^{6,7}

The analysis uses ASPs and Healthcare Common Procedure Coding System (HCPCS) quantities per HCPCS unit effective April 2016.⁸ It examines all-generic and mixed-generic/brand first-line cancer chemotherapy regimens recommended in National Comprehensive Cancer Network (NCCN) guidelines for non-small cell lung cancer, breast cancer, and colon cancer.⁹ To provide a “whole patient” perspective, drugs used to prevent emesis and neutropenia—common chemotherapy side effects—are included. Average dose modeled is as calculated per the CMS CY 2014 data file, not as recommended in NCCN guidelines.

The model calculates provider and supplier gross margins at 104.3% of ASP, at the proposed reimbursement of 102.5% of ASP plus \$16.80 per drug per day and at the sequester reimbursement of 1.0086% of ASP plus \$16.53 per drug per day. Model results are grim. For chemotherapy regimens that include brand and generic products plus supportive care drugs, gross margins range from 1.8%-3.3%. For generic-only chemotherapy regimens, gross margins are slightly higher: 2.3%-3.7%.

Results assume acquisition at ASP, which may not be possible for smaller community oncology practices, due to lack of leverage, nor for specialty pharmacies considered in the retail “class of trade.” Gross margins would be reduced if providers and pharmacies are unable to acquire expensive drugs at ASP.

Given proposed Part B reimbursement, impact of the sequester, and impact of wholesalers’ prompt pay discount, smaller community oncology practices may find that in-office infusions are not financially feasible. Might they refer patients to hospital-affiliated 340B clinics,¹⁰ which, according to MedPAC’s March 2016 Report to the Congress,¹¹ are able to acquire drugs at an average of 34% below ASP?

Alternatively, might community medical oncology practices refer patients to infusion suites? But if so, can pharmacies remain whole at the net reimbursement, particularly if they cannot acquire single source brand products at ASP? Might they be willing to accept low gross margins or even small losses to gain patient access? What of the impact of 6-month delays in ASP updates after a price increase, potential copay bad debt, and delayed cash flow? Can pharmacies that are smaller, less diversified, and with fewer resources compete?

CMS invites comments to CMS-1670-P, which must be received no later than May 9, 2016. The proposed rule is published in the Federal Register: <https://www.gpo.gov/fdsys/pkg/FR-2016-03-11/pdf/2016-05459.pdf>.

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