

reconsideration, and ultimately an ALJ hearing on the assessed overpayment.

Throughout the appeals process, the appellant argued that it was without fault in causing the overpayment because it relied on instructions in the Federal Register and "sought clarification from CMS when it became aware that two different payment methods had been published." Exh. 1 at 558. The Qualified Independent Contractor (QIC) affirmed the determination of the WIC that the provider had been overpaid. The QIC decided that code J2505 "is defined as one unit does of 6 milligrams," therefore, in billing six units, the provider was billing for "36 milligrams, of Pegfilgrastim per claim" and that it would be "far outside the standards of medical practice to administer 36 milligrams of Pegfilgrastim to a patient on one day." Exh. 1.1 at 546. The appellant requested an ALJ hearing.

The QIC subsequently participated in the ALJ hearing, and submitted a post-hearing brief. The QIC asserted that, notwithstanding the typographical error in the Federal Register notice of January 6, 2004, which was later corrected, the provider was on notice of the correct billing unit for Pegfilgrastim from other sources; in particular, the provider was on notice via the definition of the code in the HCPCS codebook and previous CMS transmittals in 2002. Exh. 24.

The ALJ found that "the correct manner for which to bill Pegfilgrastim is to use HCPC J2505, which represents an injection of the drug, per 6 mg. single dose vial. Appellant submitted a different billing, which resulted in an overpayment to Appellant." Dec. at 9. The ALJ further found that "Appellant did not know, and could not reasonably be expected to know that it improperly billed for Pegfilgrastim" and decided that "no recovery or adjustment will be made" for the non-covered charges. Dec. at 10, 11.

CMS referred the ALJ's decision to the Council for own motion review, asserting that the ALJ erred in finding that recovery of the overpayment was waived. Exh. MAC-1.

EVALUATION OF THE EVIDENCE

The Council limits its review of the ALJ's decision to those exceptions raised by CMS. 42 C.F.R. § 405.1110(c)(1).¹ The Council

¹ The Council notes that the record does not incorporate the file before the QIC, but only the request for hearing and those documents entered subsequently. (The appellant's attachments to the request for hearing appear to constitute a

adopts the ALJ's description of the facts and recitation of the applicable authorities, and we adopt the ALJ's finding that the appellant was overpaid for the Pegfilgrastim administered to the listed beneficiaries.

The ALJ did not make a finding as to the amount in controversy, which was in dispute. The final overpayment letter, dated March 14, 2006, informed the provider that the amount of the overpayment was \$1,452,041.60. Exh. 1.4.B. The appellant argues that the "only detailed findings of the total amount of overpayments were the findings by the WIC, i.e., \$1,328,924.09," and that neither the WIC nor the QIC "has offered any proof to substantiate a different number." Exh. 23 at 945. At the ALJ hearing, the QIC representatives said that they had no direct knowledge of the reason for the difference in the two amounts or the method of computation by the WIC. The Council notes that there are two tables in the record that appear to be lists of the billed and paid amounts. Exh. 1.4.B,C. The table at Exhibit 1.4.C. indicates that the total overpayment is \$1,328,924.09. The table at Exhibit 1.4.B does not include totals, and the total overpayment cannot be independently determined from the amounts listed there. When notifying a provider of postpayment review results, the contractor must include:

- * The findings for each claim in the sample, including a specific explanation of why any services were determined to be non-covered, or incorrectly coded; a list of all individual claims including the actual amounts determined to be noncovered, the specific reason for noncoverage, the amounts denied, the amounts which will not be recovered from the provider or supplier, under/overpayment amounts and the §§1879 and 1870 determinations made for each specific claim;

. . .

- * Total overpayment amounts for which the provider or supplier is responsible.

procedural history of the appeal, including copies of the overpayment notices, the redetermination, and the reconsideration decision.) The QIC, First Coast Service Options, participated at the ALJ hearing, and another CMS contractor (Q2 Administrators) referred the case to the Council on behalf of CMS. Neither raised the issue that the record below the ALJ was not incorporated into the record before the ALJ. The QIC did not object to any of the documents entered into the record by the ALJ or submit its case file, and Q2 Administrators did not submit the QIC case file when it referred the case to the Council. The appellant-provider stipulated before the ALJ that record appeared to be complete. Exh. 14, p.1. Therefore, the Council accepts the record as it is currently constructed.

Medicare Program Integrity Manual (Pub.100-08), Ch. 3, § 3.6.5 (Rev. 135, Issued: 01-06-06, Effective: 02-06-06). Given that none of the involved contractors clarified the basis for the amount of overpayment for the appellant, the ALJ or the Council, the Council finds that the amount of overpayment is \$1,328,924.09.

Finally, for the reasons set forth below, the Council hereby reverses the ALJ's findings and conclusions of law concerning waiver of the overpayment.

Section 1870(b) of the Social Security Act ("the Act") allows the waiver of recovery of an overpayment to a provider of services or supplier whenever that provider or supplier is "without fault" in incurring the overpayment. The Medicare Financial Management Manual (MFMM) describes when a provider may be considered without fault in causing an overpayment, for purposes of waiver of liability under section 1870(b). The manual provides:

The [contractor] considers a provider without fault, if it exercised reasonable care in billing for, and accepting, the payment; i.e.,

- It made full disclosure of all material facts; and
- On the basis of the information available to it, including, but not limited to, the Medicare instructions and regulations, it had a reasonable basis for assuming that the payment was correct, or, if it had reason to question the payment; it promptly brought the question to the [contractor's] attention.

MFMM (Pub. 100-06), chap. 3, § 90.

The ALJ found that the appellant "did not know, and could not reasonably be expected to know that it improperly billed for Pegfilgrastim, given that the Federal Register provided two conflicting means of submitting claims. Therefore, Appellant was without fault with respect to the overpayment." Dec. at 10. The ALJ noted that he did "not want to create a windfall in favor of the hospital and penalize CMS." However, he concluded that, "in viewing the matter against the standard set forth in section 1870(c) of the Act, the undersigned finds that to rule otherwise would create an inequity and shock the conscience." *Id.* Accordingly, he decided that "no recovery or adjustment will be made" for the overpayment. Dec. at 11.

In his decision, the ALJ referred to section 1870(c) - in particular, the provision that the overpayment may be waived when recovery would be "against equity and good conscience." However, section 1870(c) allows for waiver of recovery "with respect to an individual," not a provider of services. As described above, the authority for waiver of recovery against a provider is section 1870(b). Section 1870(b) does not include an equity standard in determining whether recovery against a provider may be waived.

Accordingly, the Council finds that the ALJ erred in deciding against recovery of the overpayment pursuant to section 1870(c) and under an equity standard. We further find, after reviewing the record and the arguments of the appellant and CMS, that the appellant was not without fault in causing the overpayment.

HCPCS code J2505 is defined as "Injection, Pegfilgrastim, 6 mg." HCPCS 2004 Codebook. Calendar-year 2004 payment rates for "pass-through" drugs like Pegfilgrastim in the outpatient prospective payment system (OPPS) were established in the interim final rule published on January 6, 2004. See Medicare Program: Hospital Outpatient Prospective Payment System; Payment Reform for Calendar Year 2004, 69 Fed. Reg. 819 (January 6, 2004).

The provider argues, through its representative, that it relied on Addendum A of the interim final rule in billing for Pegfilgrastim in one milligram units during the period at issue. Exh. 23. The table in Addendum A, labeled "List of Ambulatory Payment Classifications (APCS) With Status Indicators, Relative," lists Pegfilgrastim "per 1 mg" as APC 9119, with a reimbursement of \$2,596. Payment Reform for CY 2004, 69 Fed. Reg at 843. This was apparently a typographical error. CMS subsequently issued Transmittal 132 (CR 3154) on March 30, 2004, which stated that the billing unit in the "new description" of Pegfilgrastim was "6 mg." Exh. MAC-1 at 3.

The provider asserts that CMS never "issued a correction indicating that the language [in the interim final rule] was in error," and that CMS did not issue guidance for correct billing of Pegfilgrastim until 2006. Exh. 23 at 948. However, in the same interim final rule, Table 3C, entitled "Pass-Through Drugs Paid As Sole Source Drugs At 88% of AWP," lists code J2505 as "Injection, Peglfilgrastim, *per 6 mg single dose vial*", paid at the rate of \$2,596. Payment Reform for CY 2004, 69 Fed. Reg. at 827 (emphasis added). Thus, the interim final rule was at best confusing and inconclusive about the billing unit for Pegfilgrastim. Moreover, CMS corrected its error in Addendum A by issuing a transmittal in

March, 2004, less than three months after the inadvertent error was published. Yet the provider did not change its billing practices or seek clarification until September 2005. Finally, as the agency points out in the referral memorandum, the HCPCS code definition for this period did not change in 2004. Thus, the provider had ample authority to question the information in Addendum A.²

The provider points to CMS Transmittal 949 (CR 4380), issued on May 12, 2006, in which CMS acknowledges that "many of the providers billing multiple units of J2505 were consistently billing 6 units per date of service, indicating that 36 mg of Pegfilgrastim were given." Exh. 23 at 931, 947. The provider argues that CMS acknowledged the confusion, and that the transmittal consequently advised contractors not to "search history to identify overpayments for J2505." Exh. 23 at 947. Therefore, the provider asserts, "the proposed recoupment in this proceeding thus conflicts with Change Request 4380."

The actual statement in Transmittal 949 is: "Contractors shall not search history to identify overpayments for J2505, *but shall adjust any claims brought to their attention.*" Exh. 23 at 930 (emphasis added). The provider admits that it requested guidance from CMS regarding Medicare billing for Pegfilgrastim, and in fact submitted a list of claims to the contractor for review. Exh. 22.³ Therefore, the contractor was not acting in contravention of CMS policy when it reviewed the claims and issued the overpayment letter.

The provider has asserted that another ongoing Medicare payment issue masked the overpayment it received in 2004; thus, it did not become aware of the overpayment until 2005. Exh. 1.2 (FN 2), 22. Moreover, the delay in identifying the overpayment "masked the Hospital's actual financial crisis and led to the decision to delay conversion to [critical access hospital] status." Exh. 1.2. The overpayment should be waived because "the claimed overpayments for [Pegfilgrastim] were less than the additional revenue which the

² The proposed rule concerning OPPS payment reform, published in August, 2003, listed APC 9119 as billed per one milligram, but paid at a rate of \$467.09. Medicare Program: Hospital Outpatient Prospective Payment System; Payment Reform for Calendar Year 2004; Proposed Rule, 68 Fed. Reg. 47966, 48029 (August 12, 2003). Thus, the increase in the payment rate to \$2,596 *per milligram* in the interim final rule should also have alerted the provider that the information in Addendum A was suspect.

³ While the claim list is not attached to the copy of the letter at Exh. 22, the appellant's Stipulated Facts acknowledges that "the claims included in the audit included substantially the same claims as identified by the hospital on its September 6, 2005 letter to CMS." Exh. 20 at 911.

Hospital would have received from Medicare had the Hospital become a CAH." Exh. 23 at 945.

The Council does not find these arguments persuasive. As described above, there was sufficient notice at the time the provider billed and received payment for Pegfilgrastim to identify the overpayments received. The provider cannot be held without fault because its internal accounting procedures masked the overpayments received. Moreover, the Medicare Financial Management Manual lists examples of situations in which the provider is liable for an overpayment it received. These situations include an "error in calculation by the [fiscal intermediary] or carrier in calculating reimbursement;" and "error by the provider in calculating charges." MFMM chap. 3, §90.1.D. Thus, errors in calculation do not lead to a conclusion that the provider had a reasonable basis for assuming the payment was correct, when the provider had other reason to know that it was not.

Accordingly, the Council finds that the provider did not have a reasonable basis for assuming that the payments it received for Pegfilgrastim from January 1, 2005, to May 31, 2005, were correct. Therefore, recovery of the overpayment is not waived under section 1870(b) of the Act.

DECISION

It is the decision of the Medicare Appeals Council that the provider has been overpaid in the amount of \$1,328,924.09, for Pegfilgrastim provided to the listed beneficiaries from January 1, 2004, to May 31, 2005, and that the provider was not without fault in causing this overpayment. The provider is liable for the overpayment.

MEDICARE APPEALS COUNCIL

/s/ Gilde Morrisson
Administrative Appeals Judge

/s/ Constance B. Tobias, Chair
Departmental Appeals Board

Date: December 3, 2007