

Report on Medicare Compliance Volume 30, Number 11. March 22, 2021 Provider Wins \$2M Appeal at ALJ Over Modifier 25, Random Sample

By Nina Youngstrom

A cancer center has won its appeal of \$2 million in Medicare claim denials in a case about modifier 25 and the extrapolation of an overpayment. Problems with the random sample underlying the extrapolation helped win the day, according to the March 2 decision by an administrative law judge (ALJ).

"It's a big win for the oncology group," said its attorney, Myla Reizen, with K&L Gates in Miami, Florida. The ALJ decision reinforces the fact that providers may bill for chemotherapy administration services and evaluation and management (E/M) services provided to patients on the same day, with modifier 25, as long as certain criteria are met, she said. "Documentation is key," she noted. The decision also shows how extrapolation may be challenged, although there are limits built into the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003.

Medicare doesn't pay physicians or other providers for E/M services (e.g., 99213-99215) performed on the same patient on the same day as a procedure unless the E/M services are significant and separately identifiable. When services are significant and separately identifiable, providers append modifier 25 and receive additional reimbursement. Misunderstanding and/or misuse of the modifier has made it a top billing compliance risk area. Modifier 25 has been at the heart of several False Claims Act and civil monetary penalty (CMP) settlements and is the focus of a CMS comparative billing report. For example, Memorial Hermann Health System in Houston agreed to pay \$6.4 million to settle a CMP case^[1] about claims that included codes for the history and physical and modifier 25.

According to the ALJ decision, however, the cancer center was on solid ground in its use of modifier 25. The decision grew out of an audit by a zone program integrity contractor (ZPIC). The cancer center, which preferred not to be identified, appealed the denials and received partly favorable decisions at redetermination and reconsideration. The unfavorable findings were appealed to the ALJ.

"There is sufficient evidence to support Medicare coverage for the E/M services, hydration therapy, injection provided to all the beneficiaries. The services provided were medically reasonable and necessary... Therefore, the appellant is entitled to reimbursement under Medicare Part B," the ALJ stated. Also, she said, "the ZPIC did not use a random sample," and therefore, any extrapolation of that sample is invalid under the *Medicare Program Integrity Manual* (ch. 8. § 8.4.2).^[2]

For example, a patient with breast cancer presented at her doctor's office for a follow-up. She previously had a mastectomy and several years of chemotherapy, but the cancer recurred and she started treatment with a new drug. The physician reviewed the findings and impressions, which were breast cancer metastatic to bones.

In the decision, the ALJ noted the beneficiary received the chemotherapy on the same day as E/M services "because she required monthly disease assessments due to her disease progression." When the patient was at the doctor's office, she was evaluated for bone pain and a urinary tract infection that was treated with antibiotics. Her medications were reviewed for drug interactions with the chemo. The ALJ concluded the evaluations were for

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conditions that were separately identifiable from the chemotherapy administered. As a result, modifier 25 was properly appended to the claim.

ALJ Agreed Sample Wasn't Statistically Valid

The cancer center also took issue with the ZPIC's sampling and extrapolation. Although the ALJ ultimately voided the extrapolation, its reasoning was complicated.

The MMA only allows extrapolation of overpayments based on statistical sampling when there's "a determination of sustained or high level of payment error, or documentation that educational intervention has failed to correct the payment error," according to the *Medicare Program Integrity Manual*.

The ZPIC had reopened its initial findings and said it found good cause for a statistical sampling. "Based on the alleged high level of payment error in the sample, the ZPIC determined it was also entitled to use extrapolation," the decision said. But the ALJ noted that was outside her purview because the MMA states "by law, the determination that a sustained or high level of payment error exists is not subject to administrative or judicial review," as the manual explained.

The validity of the sample was another story. According to the expert used by the cancer center for the statistical sampling and extrapolation, a sample was not selected "in a statistically valid random fashion, making proper extrapolation impossible." The ALJ agreed, saying the ZPIC didn't use consistent formulas for estimation and extrapolation. As a result, the sample wasn't statistically valid.

The ALJ noted that "at the redetermination stage, the Contractor sent the Appellant inaccurate and contradictory information including numerous redetermination notes and correction letters. The number or errors that were made at the early stages of this appeal call into question the accuracy and validity of the overpayment amount. There is clear evidence that the Contractors' sampling and extrapolation methodology is fatally flawed. Beyond the obvious due process issues created by the incomplete record, and beyond the many Contractor calculation errors already identified during this appeal process, the actual statistical validity of the sample as drawn and conducted demonstrates actual errors in the methodology that affect the overpayment amount."

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<u>1</u> Nina Youngstrom, "Health System Pays \$6.4M to Settle Case On Pre-Surgery H&Ps; The CoP Is Not Billable," *Report on Medicare Compliance* 28, no. 41 (November 18, 2019), <u>https://bit.ly/30SlvIY</u>. <u>2</u> CMS, "Chapter 8 – Administrative Actions and Sanctions and Statistical Sampling for Overpayment Estimation," *Medicare Program Integrity Manual*, Pub. 100–08, revised October 9, 2020, <u>https://go.cms.gov/32woneV</u>.

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