

Report on Medicare Compliance Volume 29, Number 32. September 14, 2020 Whistleblower: Management 'Joked' About Compliance; Encouraging Internal Reports Is Vital

By Nina Youngstrom

When he was chief compliance officer at Merit Medical Systems, Charles Wolf said compliance wasn't taken seriously—far from it. According to his False Claims Act (FCA) lawsuit, the Utah-based medical device company allegedly paid kickbacks to providers to induce the use of its devices. "Management often openly joked about compliance, coming up with a numeric system to discuss internally how risky, from a compliance standpoint, certain proposals would be. They assessed risk and rated proposed actions on a 'chili pepper' scale of 1–3, in terms of how much 'heartburn' a particular action would give the company in terms of compliance and ethics concerns," his FCA complaint alleged. [1] After four years as its compliance officer, Wolf gave up trying to change the culture at Merit and left in 2015, becoming an external whistleblower instead.

The Department of Justice (DOJ) ultimately intervened in the complaint, and it's expected to announce imminently that Merit has settled the FCA allegations, according to court papers. DOJ will release a complaint in intervention by Sept. 11.

The case is a cautionary tale about encouraging and supporting whistleblowers internally before they take their complaints to the government, said attorney Bob Wade, with Barnes & Thornburg in South Bend, Indiana. "Whistleblowers have negative connotations, but whistleblowers should be encouraged," he said at an Aug. 27 webinar sponsored by Strafford Publications. [2] They should be thanked, "not outed and harassed." Usually whistleblowers are trying to right a wrong, reporting internally to a hotline, supervisors or compliance officers. When whistleblowers are ignored or retaliated against, they may file an FCA lawsuit, but they usually say "they used external reporting as a last resort," said Wade, a former hospital compliance officer.

Having a mechanism to report problems is one of the seven elements of an effective compliance program (eight elements, if you count evaluating the effectiveness of the compliance program). It's the best way to identify potential fraud and abuse (among other problems, such as discrimination) and prevent FCA lawsuits filed by whistleblowers, and the government counts on reporting for corporate self-policing, Wade said. But don't underestimate how difficult it can be for employees. "As a compliance officer, I never thought I would have to have Kleenex sitting near my desk, but when people came to report compliance concerns, emotions ran high," he said. "They were scared and afraid of retaliation."

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