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OIG: Too Much Fraud Risk in Plan to Give Drug Free to Hospitals; Price Has Skyrocketed

By Nina Youngstrom

A pharmaceutical manufacturer's plan to give hospitals an expensive drug to treat infants diagnosed with a form of epilepsy—for free—was nixed by the HHS Office of Inspector General because it could implicate the Anti-Kickback Statute. As appealing as the freebie is to help tiny patients while they are in the hospital, OIG essentially saw the proposal as a Trojan horse: Inside the offer is the potential for future purchases of the drug with no benefit to federal health care programs, according to the advisory opinion (AO-18-14), which was posted Nov. 16.

"The advisory opinion is remarkable," says former federal prosecutor Robert Trusiak, an attorney in Buffalo, New York. "The clinical efficacy of the drug is clear and important. Notwithstanding the efficacy, the present absence of federal savings and the real danger of increased costs resulted in an absolute rejection by OIG. Free plus clinical efficacy is no defense to kickbacks."

But it's a hard thing to swallow, he says. "No situation is more vexing to a hospital compliance officer than saying no to free products. It is counterintuitive to refuse free products for hospital patients serving to reduce hospital costs. The hospital finance officer is concerned about the bottom line," Trusiak explains.

The drug company, which was not identified, asked OIG whether it would impose sanctions if it gave free doses of the drug to hospitals to use only with patients diagnosed with the form of epilepsy, which is called "the syndrome" in the advisory opinion, with a dose when they go home. The syndrome occurs within the first two years of life, and the drug company says patients are usually diagnosed in the hospital after extensive testing.

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