

Report on Medicare Compliance Volume 32, Number 37. October 16, 2023 Another Court Raises Bar for Connecting Kickbacks to False Claims

By Nina Youngstrom

A new federal court decision continues to chip away at the conventional wisdom that kickbacks taint claims submitted to federal health care programs and, by definition, violate the False Claims Act (FCA). The Sept. 27 decision from the U.S. District Court for the District of Massachusetts supported the “but-for” causation standard, which requires the U.S. Department of Justice (DOJ) to prove that kickbacks directly cause the submission of false claims—in other words, without an inducement from a hospital or pharmaceutical manufacturer, for example, the physician wouldn’t have referred the patient to that hospital or ordered that manufacturer’s drug.^[1] But-for causation is a harder standard for DOJ and whistleblowers to satisfy than proximate causation.

The court decision, from Chief Judge F. Dennis Saylor IV, sides with other decisions on but-for causation from the U.S. Court of Appeals for the Sixth and Eighth circuits.

The new ruling came down in the summary judgment phase of a case filed against Regeneron Pharmaceuticals Inc. DOJ alleges Regeneron’s contributions to a patient assistance foundation—which subsidizes patient copays for its drug, Eylea—were kickbacks to physicians to prescribe it, which caused more Medicare claim submissions in violation of the FCA.

“The tide is turning,” said Brenna Jenny, former CMS chief legal officer. “This has been a huge issue for DOJ and relators. They’re starting to lose control over what had been a largely assumed but never rigorously tested conclusion at the district court level.” There are major implications in terms of establishing liability and calculating damages, said Jenny, with Sidley Austin LLP in Washington, D.C. But some of the language in the chief judge’s decision “could be interpreted as watering down the but-for causation standard he said needed to be applied.”

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