

# The Future of the Stark Law is Clouded by Uncertainty

Insights

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On September 12, 2024, a federal court order from the Southern District of West Virginia confirmed the uncertainty that clouds the future of the Stark Law. See [\*United States ex rel. Kyer v. Thomas Health System, Inc., 2024 WL 4165082 \(Sept. 12, 2024\)\*](#).

In this case, a relator filed a *qui tam* action arguing that the defendant's violation of the Stark Law and accompanying regulations gave rise to False Claims Act (FCA) liability. The judge ruled that liability cannot be determined without subjecting the applicable Stark provisions to a thorough judicial review under *Loper Bright Enterprises v. Raimondo*, this year's U.S. Supreme Court decision that reversed *Chevron*, establishing that federal agency regulations are not entitled to deference and ambiguous statutes must instead be interpreted by federal courts, *de novo* (see our prior write up on the decision [here](#)). The judge has ordered the parties to brief the issue.

This federal court order confirms the uncertainty that has clouded the Stark Law since the *Loper Bright* decision came out earlier this year. As the district court explains, the Stark Law statutory framework is relatively skeletal and its application to many common situations is ambiguous. An extensive, complex set of regulations, which has evolved for more than 30 years, help to flesh out the areas of uncertainty and provide guidance on the Stark Law to the healthcare field. In the wake of *Loper Bright*, as this order clarifies, providers cannot necessarily assume that the Stark Law regulations govern conduct in situations where the application of the statute alone, without the regulatory gloss, is ambiguous.

The uncertainty created under the Stark Law in the wake of *Loper Bright* is potentially a double-edged sword. If a provider has done (or wishes to do something) that contravenes the statute as interpreted or implemented by regulations, but which might be permissible under an alternative interpretation of the statute, then this uncertainty might be viewed as creating latitude for the provider's course of action. However, a provider that is planning to move ahead with a carefully crafted course of action in reliance on a CMS regulatory exception that has an uncertain statutory basis (e.g., a value-based arrangement), arguably might face the risk that if a judge decides that the regulation is invalid, it might leave the provider potentially unprotected from the Stark Law's prohibitions and penalties.

Until more clarity emerges, cautious providers may want to consider how their arrangements would be evaluated under the statute itself, and not rely solely on the regulations. Ironically, this may mean that Stark Law compliance efforts could be coming back around to where they began 30 years ago, with providers struggling to comply with the Stark Law, but without clear regulatory guidance,

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and with a statute that leaves many questions unanswered.

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