Health Care Law Update

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Ninth Circuit Upholds Laboratory Operator Conviction Under Eliminating Kickbacks in Recovery Act

The U.S. Court of Appeals for the Ninth Circuit in *United States v. Schena* recently interpreted the Eliminating Kickbacks in Recovery Act (EKRA), a 2018 federal law that criminalizes payment to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory ("Covered Provider"), by finding that EKRA applies to payments by Covered Providers to marketing intermediaries who do not actually refer or directly engage with patients. While the federal Anti-Kickback Statute criminalizes kickbacks for medical services reimbursed through Medicare, Medicaid, and other federal health care programs, EKRA was passed to impose a similar prohibition for services provided to patients with private insurance.[1] The purpose of EKRA was to prevent unscrupulous practices in connection with addiction treatment services.

In *Schena*, the defendant operated a medical testing laboratory that focused on selling allergy blood tests, which he marketed as superior to the skin tests typically used by allergy doctors. Each test evaluated 120 allergens, not because this was medically necessary, but because it was the number of tests his laboratory equipment could run. He paid marketing agents a percentage of revenues to pitch his laboratory tests to "naïve" doctors who lacked allergy experience. The marketing agents misleadingly told less sophisticated doctors that the lab's blood testing was "highly accurate" and "far superior" to skin tests. Moreover, the marketers controlled where the blood samples would be sent. The court noted that the financial incentives ensured that these marketers would push the lab's blood tests and not mention skin tests as an option.

The defendant argued that his conduct did not violate EKRA because the incentives were paid only to marketing intermediaries, not to the doctors who made the referrals.

The court, however, rejected the defendant's argument and confirmed that EKRA applies to payments made to marketing intermediaries who interface with those who make referrals, and liability is not limited to those who directly refer patients (such as medical professionals).

The court then considered what it means to "induce a referral" and concluded that percentage-based compensation structures for marketing agents, without more, does not violate EKRA, noting that all marketing efforts are intended to influence the recipient. However, it found that there is an EKRA violation if there is evidence to show *wrongful inducement*, such as, in this case, when the defendant paid marketing agents to unduly influence doctors' referrals through false or fraudulent representations about the lab tests.

The court noted that future cases will be needed to give content to the specific circumstances in which payments to marketing agents constitute a wrongful effort to unduly influence doctors' decisions in violation of EKRA, such as when percentage-based payments are made to marketing agents who are directed to mislead those making referrals about the nature of and need for covered medical services. This opinion is binding only in the Ninth Circuit.

Although the circumstances surrounding wrongful inducement under EKRA remain unsettled, *Schena* provides some practical considerations and takeaways. First, the

Ninth Circuit may look to the Anti-Kickback Statute to interpret EKRA, which can provide guidance for health care organizations when negotiating and entering into marketing contracts. Additionally, percentage-based payments made to marketing agents that do not rise to the level of wrongful inducement are not per se violations of EKRA in the Ninth Circuit. Covered Providers should continue to review and monitor their marketing and referral arrangements and policies to confirm compliance with EKRA.

FOR MORE INFORMATION

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[1] EKRA includes a safe harbor for payments made by an employer to an employee or independent contractor for employment as long as the employee's payment is not determined by or does not vary by (A) the number of individuals referred; (B) the number of tests or procedures performed; or (C) the amount billed to or received from a patient's insurance company. The court noted that the payments to the marketers did vary based on the number of tests or procedures performed, so the safe harbor did not apply.