

NEW ALL-PAYOR KICKBACK STATUTE AFFECTS ARRANGEMENTS RELATED TO CLINICAL LABORATORIES, RECOVERY HOMES AND CLINICAL TREATMENT FACILITIES

On October 24, 2018, Congress enacted a new law titled the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA") as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 ("SUPPORT Act"). The SUPPORT Act is a comprehensive law that seeks to combat the opioid epidemic and comprises multiple provisions affecting the health care industry.

EKRA, Section 8122 of the SUPPORT Act, establishes criminal sanctions (up to \$200,000 fine and 10 years imprisonment) for kickbacks with respect to services covered by any type of health care benefit program in or affecting interstate or foreign commerce. The statute specifically prohibits kickbacks related to the solicitation or receipt of remuneration for any referrals to recovery homes, clinical treatment facilities or laboratories. EKRA further criminalizes the payment or offer of remuneration to induce a referral to or in exchange for an individual using the services of such providers.

Importantly, EKRA is an all-payor statute directed towards services covered by a "health care benefit program" and therefore applies to services payable by both a federal health care program and a commercial insurer. EKRA also applies to programs in or affecting interstate or foreign commerce.

The statute incorporates several exceptions of note:

1. Discounts to providers or other entities if properly disclosed and reflected in the provider's or entity's costs or charges;
2. Medicare coverage gap drug discounts;
3. Payments to employees and independent contractors and requires that compensation **not** be determined by or vary with:
 - a. The number of individuals referred to an entity;
 - b. The number of tests or procedures performed; or
 - c. The amount billed or received from the health care benefit program.
4. Arrangements that meet the Anti-Kickback Statute Safe Harbor for Personal Services and Management Contracts;
5. Waivers or discounts of certain coinsurance or copayments by a health care benefit program (must be in good faith and not routine);
6. Transfers to Federally Qualified Health Centers under the Anti-Kickback Statute Safe Harbor;
7. Remuneration made pursuant to approved Alternative Payment Models; or
8. Other payments, remuneration, discounts or reductions as determined by the Attorney General in regulation in consultation with the Secretary of Health and Human Services.

The EKRA exceptions appear noteworthy regarding payments to employees and independent contractors by not expressly exempting various forms of incentive-based compensation permissible under the Anti-Kickback Statute, such as sales commissions payable to bona fide employees, payments made to group purchasing organizations ("GPOs") or group practices. The statute contains a strict three-prong exception that appears to prohibit any type of volume-based form of payment arrangement with sales personnel or other contractor entities.

Further, although part of the SUPPORT Act, EKRA's broad language also appears to permit federal monitoring of payment arrangements for any laboratory services payable by a commercial insurer or federal health care program, regardless of their relation to substance abuse treatment. Health care entities across the continuum must therefore review their sales compensation arrangements, GPO arrangements and

all other arrangements related to recovery homes, treatment facilities or laboratories to ensure compliance with the relevant exceptions.

Clarifications will likely be necessary to determine the breadth of the prohibition on incentive-based compensation and its interplay with permissible arrangements under the Anti-Kickback Statute. Stay tuned for more in-depth analyses as Hall Render continues to monitor any developments that may arise in relation to EKRA.

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