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Stark Law Update

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STARK LAW UPDATE

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I. Regulatory Developments

A. Increased Stark Penalties.

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Act) requires federal agencies to make cost-of-living adjustments to civil monetary penalty (CMP) amounts based on increases in the Consumer Price Index (CPI). On September 6, 2016, HHS issued its interim final rule (IFR) updating its CMP regulations for all agencies within HHS. (81 Fed. Reg. 61537). Under the Act, agencies are required to make a "catch-up" adjustment, which is the difference between the CPI of the calendar year in which the penalties were last adjusted and the CPI for the current year. However, the "catch up" adjustments are capped at 150% of the current penalty amount. The IFR sets forth the initial "catch-up" adjustment for CMPs as well as any necessary technical conforming changes to the language of the various regulations affected by the IFR. Going forward, the CMP amounts will be adjusted without notice and comment rulemaking each January based on changes in the CPI. The penalty for submitting or causing to be submitted claims in violation of the Stark Law was increased from $15,000 per claim to $23,863.

The adjusted civil penalty amounts are applicable only to civil penalties assessed after August 1, 2016, whose associated violations occurred after November 2, 2015. Violations occurring on or before November 2, 2015 and assessments made before August 1, 2016, will continue to be subject to the civil monetary penalty amounts set forth in the existing regulations or as set forth by statute if the amount has not yet been adjusted by regulation.

II. Case Law Developments / False Claims Act Settlements

A. Lexington Medical Center[1]

On July 20, 2016, Lexington Medical Center (LMC), located in West Columbia, South Carolina, agreed to pay $17 million to settle allegations that it violated the Stark Law and the False Claims Act by purchasing physician practices for access

[1] *United States ex rel. David H. Hammett, M.D. v. Lexington County Health Services District d/b/a Lexington Medical Center*, Case No. 3:14-cv-03653-CMC.

to referrals. LMC is a political subdivision of the State of South Carolina and operates clinics and a medical center. The plaintiff, a former LMC neurologist, alleged that LMC: (1) bought access to patients through the acquisition of physician practices with 28 physicians; (2) paid these physicians commercially unreasonable compensation in exchange for their practices and their employment at LMC; (3) imposed a de facto mandate that required, and closely tracked, referrals to LMC to ensure the hospital received DHS referrals; and (4) punished physicians who refused to refer to LMC. LMC acquired the practice that employed the plaintiff in 2011. As part of the acquisition, the plaintiff contended that LMC entered into physician employment agreements with physicians with generous compensation provisions to reward physicians for anticipated ancillary referrals. Once part of LMC, the plaintiff alleged that LMC held meetings with the physicians to discuss declines in the number of imaging referrals. In July 2013, LMC terminated the plaintiff allegedly because he refused to send all imaging referrals to LMC. In addition to the plaintiff's group, the settlement involved similar allegations related to four other physician groups.

B. University Behavioral Health

On February 9, 2017, University Behavioral Health of El Paso, LLC, a private psychiatric hospital, agreed to pay $860,000 to settle allegations that it violated the False Claims Act and Stark Law by paying a physician under a professional services agreement. The professional services agreement, which involved payments over an approximate three year period, was entered into by a prior owner of the facility and terminated after acquisition. The allegations included payments in excess of fair market value and payment for services not furnished.

III. Proposed Updates to the Self-referral Disclosure Protocol (SRDP). On May 6, 2016, CMS issued a Federal Register notice seeking public comments on updates to the SRDP. 81 Fed. Reg. 27450. In the notice, CMS sought to revise the currently approved information collection request (ICR). Under the current ICR, a party must provide a financial analysis of overpayments arising from actual or potential violations based on a 4-year lookback period. However, on February 12, 2016, CMS published the final overpayment rule on the reporting and returning of overpayments. *See* 81 Fed. Reg. 7654 (Feb. 12 2016). The final overpayment rule established a 6-year lookback period for reporting and returning overpayments. CMS is proposing to revise the ICR for the SRDP to reflect the 6-year lookback period established by the final overpayment rule. The 6-year lookback period would apply only to submissions to the SRDP received on or after March 14, 2016, the effective date of the final overpayment rule. Parties submitting self-disclosures to the SRDP before March 14, 2016, would only provide a financial analysis of potential overpayments based on a 4-year lookback period. Additionally, CMS introduced a required form for SRDP submissions, aiming to streamline and simplify the SRDP process. Comments were due by July 5, 2016.

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