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Health Care Regulatory and Legislative Update

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Potential Penalties for False Claims Act Violations Continue to Rise

On June 30, 2016, in connection with the November 2015 enactment of the Federal Civil Penalties Inflation Adjustment Act Improvements Act, the Department of Justice (“DOJ”) issued an Interim Final Rule with Request for Comments (Interim Rule) that adjusts for inflation civil monetary penalties, including almost doubling penalties for False Claims Act (“FCA”) violations. The Interim Rule, which went into effect on August 1, 2016, increased the minimum per-claim penalty under the FCA from \$5,500 to \$10,781 and increased the maximum per-claim penalty from \$11,000 to \$21,563. Going forward, the civil penalties authorized under the FCA will increase incrementally annually on August 1st.

On the heels of this dramatic FCA penalty increase, the Office of Inspector General (OIG) for the U.S. Department of Health & Human Services recently announced that it plans to review state false claims laws to determine whether such laws that qualify for a financial incentive under federal law. Pursuant to the Deficit Reduction Act of 2005, states receive a 10% increase in FCA recoveries if the OIG determines that the state’s false claims law, among other things: (1) is “at least as effective” as the federal FCA, and (2) contains a civil penalty amount at least the same as the federal FCA civil penalty. States have a two-year grace period to amend their state false claims laws to reflect the increased federal penalty. In light of the budget challenges facing many states, it is likely that states will choose to increase their state false claims act penalties rather than forgo the federal financial reward incentive. The potential for large

penalties likely will factor into their calculation about whether to challenge or settle FCA allegations.

[Medicaid Fraud Control Unit FY 2015 Annual Report Highlights \\$744M in Criminal and Civil Fraud Recoveries; Civil Settlements, Judgments and Recovery Amount Have Decreased Over 5-Year Period](#)

The Office of Inspector General (“OIG”) has released its Medicaid Fraud Control Units Fiscal Year 2015 Annual Report. The Report compiles data on investigations and prosecutions by the 50 Medicaid Fraud Control Units (“MFCUs”), jointly funded state entities which investigate and prosecute Medicaid provider fraud and patient abuse or neglect under State law. According to the Report, MFCUs attained 1,553 convictions in FY 2015, the highest in the last five years. Seventy-one percent of these convictions involved fraud and nearly one-third were of personal care services (“PCS”) attendants or other home care aids. For the same period, MFCUs reported 731 civil settlements and judgments and \$744M in criminal and civil recoveries. Of the 731 civil settlements and judgments reported, nearly 40 percent involved pharmaceutical manufacturers. The Texas MFCU reported over a quarter (\$210M of \$744M) of the total recoveries reported. New York, Tennessee, California, Florida and Wisconsin, combined accounted for 50 percent of civil recoveries (\$196M of the \$394 in civil recoveries). The Report notes that civil settlements and judgments have decreased modestly over the last 5 years, and civil recovery amounts have decreased significantly. The OIG attributes the decrease in the MFCUs civil settlements, judgements, and recoveries as part of a national trend of declining civil health care fraud complaint settlements, especially those involving large pharmaceutical companies.

[OIG Data Brief Indicating Escalating Medicare Billings for Home Respiratory Ventilators May Result in Targeted Program Integrity Efforts](#)

A recently released OIG Data Brief, *Escalating Medicare Billing for Ventilators Raises Concerns* (OEI-12-15-00370) found that in 2015, Medicare paid 85 times more claims for E0464 ventilators (non-invasive pressure support ventilators) than it did in 2009, leading to rapidly escalating expenditures for this type of device. The OIG concluded that the E0464 ventilator billing trend is being driven primarily by three unnamed national suppliers that have rapidly expanded their market share and that accounted for 54 percent of the nationwide growth in beneficiaries with E0464 ventilator claims from 2012 to 2015. The OIG also concluded that Medicare paid \$25 million for E0464 ventilator claims with indicators of inappropriate billing (e.g., billing for multiple devices, billing for separate accessories, or billing to treat obstructive sleep apnea) and indicated that these claims will be referred to CMS for further review. This OIG Brief will likely result in targeted program integrity efforts in this area, such more frequently Durable Medical Equipment (“DME”) Medicare Administrative Contractors prepayment reviews.

[Comment Period for New Bundled Payment Models Closing October 3rd](#)

On July 25, the Centers for Medicare & Medicaid Services (“CMS”) issued a proposed rule mandating bundled payments models for cardiac care. Under the proposed episode-based payment models, the hospital in which a patient is admitted for care for a heart attack, bypass surgery, or surgical hip/femur

fracture treatment would be accountable for the cost and quality of care provided to Medicare fee-for-service beneficiaries during the inpatient stay and for 90 days after discharge. For the new cardiac bundles, participants would be hospitals in 98 randomly-selected metropolitan statistical areas. Hospitals outside these geographic areas would not participate in the model. There is no application process for hospitals for these models. Recognizing that hospitals will need time to adapt to the new models and establish processes to coordinate care, the proposed rule includes measures to ease the transition, including gradually phasing-in risk.

If implemented, the new bundled payment program would be CMS's second program requiring providers to accept set payments for an episode of care, and signals the agency's continued efforts to shift Medicare reimbursements from quantity to quality. CMS will accept comments on the proposed rule until 5 p.m. on Oct. 3.