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Health Care Regulatory and Legislative Update

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Weekly Health Care Criminal and Civil Fraud Enforcement Round-Up

The following highlights notable health care fraud and abuse news, settlements and enforcement actions from the previous week.

1. **Laboratory Company and Owners Agree to Pay $3.75 Million to Settle False Claims Act Allegations Relating to Inflated Mileage Claims Submitted to Medicare**. On December 13, 2016, the Department of Justice (*"DOJ"*) issued a press release announcing that Texas laboratory company, Elite Lab Services, LLC, along with its owners, agreed to pay the United States $3.75 million to settle False Claims Acts allegations that it billed Medicare for tens of thousands of miles that were never driven by Elite Lab's personnel. The suit was initially filed by an employee-whistleblower under the *qui tam* provisions of the False Claims Act which permit private citizens to bring suits on behalf of the government. The employee whistleblower will receive a 21% share of the government's recovery, a total of $787,500. As a result of this settlement, Elite Lab Services, LLC will be excluded from participating in Medicare for eight years.
2. **South Miami Hospital Agrees to Pay $12 Million to Settle False Claims Act Allegations Relating to Medically Unnecessary Care.** On December 7, 2016, the DOJ issued a press release announcing that non-profit South Miami Hospital has agreed to pay $12 million to settle allegations that it had violated the False Claims Act by submitting false claims to federal health care programs for medically unnecessary studies and other procedures performed by a hospital

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physician (John R. Dylewski, M.D.). The allegations arose from a lawsuit filed by two physician whistleblowers — James A. Burks, M.D., and James D. Davenport, M.D. According to court documents, the physician plaintiffs claimed to have personal knowledge of Dr. Dylewski and South Miami Hospital engaging in a number of unnecessary cardiac procedures, including echocardiograms, electrophysiology studies, head upright tilt tests, and other treatments of arrhythmia by ablation, cryoablation, or implantation of an electronic device, for the sole purpose of increasing the amount of physician and hospital reimbursements paid by Medicare and other federally-funded programs. Under the *qui tam* provisions of the False Claims Act, private citizens can bring suit on behalf of the government for false claims and share in any recovery. Drs. Burks and Davenport will receive approximately $ 2.7 million from the recovery.

3. **Orthopedic Surgery Practice Agrees to Pay $4.48 Million to Settle Claims That It Billed for Services that Were Unreasonable or Not Medically Necessary in Violation of the False Claims Act**. On December 7, 2016, the DOJ issued a press release announcing that Southeast Orthopedic Specialists has agreed to pay the government $4.48 million to settle claims that it billed federal health care programs for services that were not medically necessary or reasonable. The government specifically alleged that the practice received inflated reimbursement by knowingly: (1) certifying that it met "meaningful use" of electronic health record standards when it had not met to those standards, (2) billing for certain claims as "incident to" physician supervision when no physicians were present, (3) billing for certain claims using Modifier 25 signifying that a separate evaluation and management service was performed even when there was no such separate service, (4) billing for certain claims using Modifier 59 signifying that two procedures, rather than one, were billable even when these procedures should have more appropriately been billed as one such procedure, (5) scheduling patients' follow-up operative visits from 12 weeks following surgery to 14 weeks in an effort to bill for a separate visit outside the normal Medicare 90-day Diagnosis-Related Group charge, (6) using and billing for ultrasound-guided injections routinely even in the absence of medical necessity, and (7) billing for certain physical therapy claims using Modifier KX so as to exceed the Medicare cap on physical therapy, despite the absence of medical necessity.

OIG Issues Long-Awaited Final Rule with Revisions to the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements

After a two-year wait, the Office of the Inspector General (*"OIG"*) has issued its final rule (1) amending existing Anti-Kickback Statute (*"AKS"*) safe harbors and adding safe harbors that provide new protections and (2) amending the Civil Monetary Penalty Law (*"CMPL"*) rules by codifying revisions to the definition of "remuneration." The regulations are effective on January 6, 2017.

The AKS prohibits giving or receiving anything of value to induce or reward referrals for items or services covered by the federal health care programs. A violation of the AKS is a felony, and may also result in large fines and penalties. Due to the broad reach of the AKS, Congress created statutory exceptions and the OIG promulgated regulatory safe harbors designed to protect certain activities or business arrangements which are not believed to pose a risk of fraud to the federal health care programs. In its final rule, the OIG modified certain existing safe harbors and added new safe harbors. These changes include new protections for: (1) certain pharmacy cost-sharing waivers for financially needy beneficiaries, (2) waivers of cost-sharing for

emergency ambulance services furnished by State-owned or municipality-owned ambulance services, (3) certain remuneration between Medicare Advantage organizations and federally qualified health centers, (4) discounts by drug manufacturers furnished to beneficiaries under the Medicare Coverage Gap Discount Program and (5) free or discounted local transportation services that meet specified criteria.

The CMPL beneficiary inducement provisions prohibit any person from offering "remuneration" to a Medicare or state health care program beneficiary that the offeror knows is likely to induce such beneficiary to obtain reimbursable items or services from a particular health care provider or supplier. The final rule revises the definition of the "remuneration" to clarify that remuneration does not include (1) coupons, rebates or other retailer reward programs that meet certain criteria, (2) items or services to the financially needy that are reasonably connected to a such person's medical care and that meet certain other criteria, (3) items or services that promote access to care and pose a low risk of harm to patients, and (4) co-payment waivers for first-fill generic drugs.

The OIG acknowledges that it has taken the transition from volume to value-based and patient-centered care into account in this final rule. While the changes will give providers added flexibility in structuring their business arrangements in an evolving health care world, providers should still consult with counsel to determine on a case by case basis whether a new arrangement implicates the AKS or CMPL.

Despite Industry Pushback, FDA Finalizes Policy Regarding Public Notification of "Emerging" Medical Device Safety Issues

A year after proposed guidance was released, the Food and Drug Administration (*"FDA"*) has released final industry guidance explaining the factors the FDA intends to consider in deciding whether to notify the public about "emerging signals" related to medical device safety, and the processes and timelines it intends to follow in issuing and updating the public notification. The FDA states that the guidance is intended to "improve the consistency, transparency, and predictability of the process for notifying the public about emerging signals." Factors the FDA will consider in determining whether to notify the public of a potential medical device safety issue include, but are not limited to, the following:

- Likelihood (probability) of the harmful event(s);
- Magnitude (severity), duration, and reversibility of the harmful event(s);
- Magnitude of the benefit (e.g., the degree to which a given condition, symptom or whether function is improved and whether the device provides life-sustaining or life-saving benefits);
- The quality of the data or information;
- The strength of the evidence of a causal relationship between the use of a device and the adverse event;
- Extent of patient exposure (e.g., how broadly is the device used, the duration of exposure, including whether the device is intended to be permanently implanted);
- Whether there is a disproportionate impact on vulnerable patient populations (e.g., children, pregnant women, elderly, cancer patients, chronically ill patients, at-home/unmonitored patients);

- Potential for preventing, identifying, monitoring or mitigating the risk;
- Availability, risks, and benefits of alternative therapies;
- Potential for patients to not receive treatments they should even in light of the new information;
- Implications for similar or related devices (e.g., multiple models from multiple manufacturers);
- Anticipated time for completion of FDA's assessment of the available information and development of recommendations; and
- Accuracy and availability of information already in the public domain.

The draft guidance was criticized by several device manufacturers, as well as industry advocacy groups which argued that the policy could unfairly prejudice patient and providers again beneficial products. In response, the revised final guidance clarified that emerging signals will not be announced until "credible scientific evidence supports a new causal relationship" between the adverse event and the medical device. The guidance also states that FDA communications will be "clear about what the Agency knows and does not know, as well as whether or not the Agency recommends specific actions and why." The FDA also issued a Medical Device "allegations of regulatory misconduct" reporting page earlier this year, which is available here. Whether the new administration will dedicate resources sufficient to support these medical device safety initiatives is yet to be seen.