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JANUARY REGULATORY UPDATE SUMMARY

This issue of McDermott's *Healthcare Regulatory Check-Up* highlights regulatory activity for January 2024. We discuss several US Department of Health and Human Services (HHS) agency actions, including the new Innovation in Behavioral Health Model (IBH) released by the Centers for Medicare & Medicaid Services (CMS), amendments to New York's Section 1115 Medicaid waiver, new final rules related to prior authorization and conscience rights, and the Food & Drug Administration's (FDA) approval of Florida's drug importation program. We also discuss four favorable Office of Inspector General (OIG) Advisory Opinions and several criminal and civil enforcement actions pertaining to healthcare fraud, including alleged violations under the False Claims Act (FCA), federal Anti-Kickback Statute (AKS) and Physician Self-Referral Law (Stark Law).

NOTABLE REGULATORY DEVELOPMENTS

CMS ANNOUNCED NEW MODEL TO IMPROVE CARE INTEGRATION IN BEHAVIORAL HEALTH

CMS announced a new model to test approaches for integrating physical and behavioral health services as well as addressing health-related social needs of Medicare and Medicaid beneficiaries. The Innovation in Behavioral Health Model (IBH) adopts a "no wrong door" approach, in which interprofessional care teams made up of community-based supports as well as physical and behavioral health providers provide patients access to the full range of available services. The goal of the program is to bridge gaps between historically siloed services necessary for treating certain individuals suffering from mental-health disorders or substance-use disorders.

The program will use a value-based payment model for providers and includes infrastructure payments intended to provide participants with necessary resources and to support increased health IT capacity, functionality and practice transformation. The program will be administered by the CMS Innovation Center and is scheduled to launch in fall 2024. CMS anticipates the program will operate for eight years in up to eight states, and a Notice of Funding Opportunity for the IBH model will be released in spring 2024.

CMS APPROVED AMENDMENT TO NEW YORK'S NEW SECTION 1115 DEMONSTRATION TO IMPROVE PRIMARY CARE, BEHAVIORAL HEALTH AND HEALTH EQUITY

CMS announced its approval of amendments to New York's Medicaid section 1115 demonstrations. Section 1115 demonstrations provide a pathway for CMS to approve innovations. The amendment approved for New York combines a range of actions meant to improve health equity and access to primary care and behavioral-health care across the state. The approved actions include:

- Establishing sustainable base reimbursement rates of safety net hospitals and funding for a value-based reimbursement program
- Supporting initiatives to increase integration of physical- and behavioral-health providers and expand access to health-related social-needs supports such as housing and nutrition
- Expanding access to comprehensive treatment for substance-use disorders
- Creating a loan repayment program for clinicians who commit to working in community-based practices in underserved areas
- Expanding training for under- and unemployed individuals who assist doctors and nurses
- Approving New York's plan to increase and sustain provider payment rates and managed-care payment rates for obstetrics, primary care and behavioral health

CMS and New York will use independent evaluations to monitor the impact and outcomes of the program. The approval is the latest in a series of recent actions taken by CMS and HHS to improve the primary care infrastructure. For more information regarding the approved amendment, read our full article here.

HHS ISSUED NEW NONDISCRIMINATION FINAL RULE TO PROTECT CONSCIENCE RIGHTS

On January 9, 2024, the HHS Office for Civil Rights (OCR) announced a final rule, *Safeguarding the Rights of Conscience as Protected by Federal Statutes*, that strengthens protections against conscience and religious discrimination in healthcare and clarifies the process for enforcing federal conscience objection laws. The final rule, which becomes effective on March 11, 2024, follows the original regulatory framework established in 2011 and a 2019 rulemaking effort by OCR that was held unlawful by three federal district courts and never took full effect. The final rule partially rescinds the content of the 2019 rule and ultimately provides clarity on federal conscience protections, which federal conscience laws are enforced by OCR, how OCR will enforce these laws, and encourages covered entities, including providers and grantees, to voluntarily post a notice of rights regarding conscience laws to ensure compliance and educate the public. For more information on the Final Rule, read our full article here.

FDA AUTHORIZES FLORIDA'S DRUG IMPORTATION PROGRAM

On January 5, 2024, the FDA authorized Florida's drug importation program under a pathway that allows the agency to approve proposals from states and Indian tribes to import certain prescription drugs from Canada, if doing so will significantly reduce costs for consumers without increased risk to public safety. The approval comes nearly four years after Florida first submitted its proposal to the FDA and follows a 2022 lawsuit by the state intended to force the FDA to act on its proposal. A challenge to the program by a pharmaceutical industry group was also thrown out, for lack of standing, by a federal judge in February 2023.

The FDA's authorization of Florida's program is only the first step in allowing the state to import certain prescription drugs from Canada. Among the additional steps required before drugs can be imported, Florida must:

- Submit further drug-specific information for review and approval by the FDA.

- Ensure that the drugs to be imported have been tested for authenticity and compliance with FDA-approved drug specifications and standards.
- Relabel the drugs with FDA-approved labeling.

Florida's program is authorized for two years from the date of the first import shipment, and the state must submit regular quarterly reports to the FDA that include information about the drugs, cost savings, and potential safety and quality issues.

DOJ AND HHS REMINDED STATE MEDICAID ADMINISTRATORS OF COVERAGE OBLIGATIONS FOR LIFE-SAVING HEPATITIS C MEDICATIONS

On January 24, 2024, the US Department of Justice (DOJ) and HHS issued a joint letter to state Medicaid administrators advising them to review their programs to ensure compliance with the Americans with Disabilities Act (ADA). Specifically for beneficiaries who have both Hepatitis C and substance-use disorders (SUD), the ADA requires that Medicaid programs allow such individuals to access direct-acting antivirals, which are life-saving Hepatitis C medications.

The letter emphasized a December 2022 settlement agreement between the DOJ and Alabama's Medicaid Agency that addressed an Alabama Medicaid policy to deny coverage of the Hepatitis C drugs for patients who had consumed alcohol or illicit drugs within six months of starting treatment. After the DOJ initiated an investigation, Alabama ultimately withdrew the policy and entered into the settlement agreement to ensure future Medicaid coverage for such patients.

The DOJ and HHS reminded administrators that both agencies enforce the ADA with respect to state Medicaid programs and that the ADA requires states to provide individuals with disabilities (including SUD) an equal opportunity to participate in and benefit from Medicaid programs.

ILLINOIS ATTORNEY GENERAL RELEASED HEALTHCARE TRANSACTION NOTICE FORM

The Illinois attorney general released its much-anticipated Healthcare Transaction Notice Form, which applies to certain transactions closing after January 30, 2024. Parties must submit this form before undertaking certain defined "covered transactions" that are not otherwise reportable under the Hart-Scott-Rodino (HSR) Act or Illinois Health Facilities and Services Review Board requirements. Parties involved in covered transactions also will be required to comply with related timing restrictions. For more detail, read our full article here.

CMS FINALIZED INOPERABILITY AND PRIOR AUTHORIZATION RULE

On January 17, 2024, CMS issued the CMS Interoperability and Prior Authorization final rule aimed at improving prior authorization processes and enhancing access to interoperable patient data for patients, providers and payers. The final rule applies broadly to a range of payers and federal healthcare programs and, among other things, requires the implementation of certain application programming interfaces (APIs) to improve electronic data exchange, adds a new measure to incentivize adoption of electronic processes to the Merit-based Incentive Payment System (MIPS), and streamlines prior authorization processes to make it easier on providers and increase patient access to care. For more detail on the changes to prior authorization practices, read our full article here.

HHS AND DOJ PROPOSED NEW RULES TO INCREASE HEALTHCARE ACCESSIBILITY FOR PEOPLE WITH DISABILITIES

Both HHS and the DOJ have recently published new proposed rules that update and modernize federal protections for individuals with disabilities. On September 14, 2023, HHS proposed a rule under Section 504 of the Rehabilitation Act of 1973 meant to improve equity and strengthen protections for people with disabilities in programs and activities that receive federal funding or are conducted by a federal agency. More recently, on January 9, 2024, the DOJ's Notice of Proposed Rulemaking under Title II of the ADA focuses on medical diagnostic equipment. The DOJ's proposed rule seeks to increase accessibility by addressing existing barriers through new standards for state and local government entities that provide healthcare services. These proposed rules are part of a concerted effort by the administration of President Joseph Biden to address accessibility and improve equity in healthcare. For more detail, read our full article here.

OIG ADVISORY OPINIONS

OIG ISSUES FAVORABLE ADVISORY OPINION 23-12 REGARDING RETIRING PHYSICIAN HOSPITAL OWNERS

This Advisory Opinion 23-12, posted on January 3, 2024, responds to a request by a hospital operator organized as a limited liability partnership (LLP) and which wholly owns a subsidiary entity that operates a second hospital. The hospital entity, which is owned in part by a medical center and in part by individual physicians, proposed a one-time, voluntary redemption offer to its physician partners who reach age 67. The offer would allow eligible physician partners to redeem their units over a two-year period in three equal increments, provided that any such physician partner will retire from practicing medicine within six months of the first redemption payment.

The repurchase amount would be equal to the fair market value of the physician partner's units as of each repurchase date. In addition, physician partners who accept the redemption offer must execute a document that states that they will not, nor be in a position to, make any referral of patients to the requestor hospitals, or any of their physician partners, as of the earlier of the date they retire or the date upon which they satisfy the partnership agreement's eligibility requirements.

The requestor noted that the units could grow in value over the two-year redemption period, meaning any physician who accepted the redemption offer could receive additional remuneration when compared to the one-time payment (made for redeeming their units upon retirement) that they would otherwise receive under their partnership agreement.

OIG concluded that it would ultimately not impose administrative sanctions on the requesting hospital if the proposed arrangement was undertaken, despite the possibility that the arrangement would generate prohibited remuneration under the AKS if the requisite intent were present, and that no safe harbor applied. Evaluating the arrangement on the totality of the circumstances, OIG centrally came to this conclusion for the following reasons:

- The criteria for the redemption offer are objective and unrelated to the volume or value of referrals or other business generated by the physician partners. The offer is made to all partners reaching age 67, regardless of referrals or business generated for the requesting hospital or the physician partners, reducing the risk of steering or increased costs to federal healthcare programs.

- The remuneration paid is unlikely to result in unfair competition. The arrangement specifically includes a "no-referral certificate" signed by any participating physicians. Although a physician who accepts the offer may continue to refer patients for the six-month period between the first payment under the redemption offer agreement and retirement, this period is necessary to allow such physicians to wind down their practice, and is not likely to cause retiring physicians to change their referral patterns to benefit the requestor or other of their physician partners.

OIG ISSUES TWO FAVORABLE ADVISORY OPINIONS ADDRESSING MEDIGAP PREFERRED HOSPITAL NETWORKS

OIG issued two favorable advisory opinions (AO 23-13 and AO 23-14), also posted on January 3, 2024, responding to a request from a licensed offeror of Medicare Supplemental Health Insurance policies (Medigap Plans) and a preferred hospital organization (PHO). The proposals involve incentivizing the Medigap Plan policyholders to seek inpatient care from a hospital within the PHO's network, including three separate streams of remuneration.

First, under the proposal, each hospital in the PHO's network would provide a discount, applied uniformly to all policyholders for at least one year, on the Medicare Part A inpatient deductible that the Medigap Plan would otherwise cover for a policyholder. The discount would be established in advance pursuant to a written agreement between the PHO and each hospital in its network, and the PHO and Medigap Plan would also separately enter into a written agreement to document the discount. Second, the proposed arrangement involves a $100 premium credit offered by the Medigap Plan to each policyholder for selecting a hospital in the PHO's network for a Medicare Part A-covered inpatient stay, subject to certain frequency limitations. Third, the Medigap Plan would pay the PHO a monthly, fair-market-value, percentage-based administrative fee for establishing the hospital network and for arranging for the hospitals in the PHO network to discount the Medicare Part A inpatient deductible. The PHO would receive a percentage of the total savings that the Medigap Plan would gain from the discounts on policyholders' Medicare Part A inpatient deductibles in a given month.

For the reasons set forth below, the OIG concluded that while all three streams of remuneration would implicate the AKS, and that the premium credit offered by the Medigap Plan to policyholders would also implicate the civil monetary penalty provision prohibiting inducements to beneficiaries at section 1128A(a)(5) of the act (Beneficiary Inducements CMP), OIG would not impose penalties. OIG determined it was unlikely that either the deductible discount or the premium credit would result in overutilization of healthcare items or services or pose a risk of increased costs to federal healthcare programs, because the Medigap Plan has a responsibility for all policyholder costs that its policies cover, and it is in Medigap Plan's financial interest to ensure appropriate utilization and costs. Further, OIG noted that, with respect to the premium credit, (i) patients generally do not control the clinical decision of their admission as an inpatient, and (ii) the premium credit only reduces the amount the policyholder would owe to the Medigap Plan, as opposed to a cash or check payment. OIG concluded that these facts, as certified by the Medigap Plan, made it unlikely that the premium credit would result in overutilization.

OIG also concluded that the discounts on policyholders' Medicare Part A inpatient deductibles offered by hospitals in the PHO network and the Medigap Plan's offer of a premium credit posed minimal potential for patient harm. Both the deductible discount and the premium credit would apply to all policyholders and would not be limited by discriminatory eligibility criteria, and patient choice would not be impacted, since cost-sharing obligations and premiums would not be increased based on a patient's election to seek care at a hospital outside of the PHO network.

OIG determined it was also unlikely that deductible discount or the premium credit would significantly impact competition, highlighting the Medigap Plan's certification that it would not advertise any aspect of the proposal to potential enrollees. OIG found

the risk of inducing policyholders to re-enroll in a Medigap Plan policy in future years to be mitigated by the fact that policyholders receive the premium credit only if they require an inpatient stay during that policy year, which may not occur and is difficult to predict, and if they also selected a hospital in the PHO network for their inpatient care. Further, the PHO certified that it would not advertise the proposed arrangement, and that any Medicare-certified hospital meeting the licensing and other applicable requirements, and which agreed to the discount on behalf of all licensed offerors of Medigap Plan policies that contract with the PHO, would be eligible to join the PHO network, reducing the risk of anti-competition.

Finally, the Medigap Plan and the PHO certified that the PHO's administrative fee would be consistent with fair-market value. In addition, while the proposed administrative-fee arrangement takes into account the volume or value of federal healthcare program business, there is a low risk that the methodology for calculating the administrative fee would drive overutilization or result in increased costs to any federal healthcare program because the fee reflects a percentage of the savings realized by the Medigap Plan, not revenue generated by the hospitals in the PHO network. Further, as noted above, it would be against the financial interest of the Medigap Plan to drive overutilization of inpatient hospital services paid for by Medicare Part A, and the Medigap Plan certified that it would not shift the cost of the PHO's administrative fee to any federal healthcare program. The PHO also certified that it would not advertise the proposed arrangement, thereby limiting the potential for the PHO or the hospitals in its network to influence policyholder referrals to the hospitals in the network and, in turn, the PHO's administrative fee.

OIG ISSUES FAVORABLE ADVISORY OPINION 23-15

This Advisory Opinion, also posted on January 3, 2024, responds to a request from a provider of consulting services to physician practices. The services include practice optimization services such as helping practices uncover workflow issues, as well as data-analytics services, electronic-health-record consulting services, compliance-monitoring services, biannual Medicare Merit-Based Incentive Payment System (MIPS) eligibility checks, annual MIPS-related training, auditing MIPS-related performance measures and assistance with submitting MIPS data.

The requestor's proposed arrangement involved giving its current customers, who recommend the requestor's services to prospective physician-practice customers, a $25 gift card for each recommendation. If the recommendation resulted in the physician-practice customer hiring the requestor, the requestor would give the customer making the recommendation another $50 gift card for that successful recommendation.

OIG ultimately determined that the AKS was not implicated by the proposed arrangement. OIG identified three potential streams of remuneration in the arrangement and concluded that none of the potential remuneration streams generated prohibited remuneration under the AKS, as detailed below:

- *The requestor giving gift cards to physician practice customers who recommend the requestor to potential physician-practice customers*. The gift cards that the requestor would provide to its customers would not be in exchange for the physician practices making referrals of, purchasing, arranging for or recommending services that are federally reimbursable. The proposal specified that none of the services that the requestor provides are, or would be, paid for by a federal healthcare program, and that no items or services were provided outside of the proposed arrangement that may be paid for by a federal healthcare program. Finally, the requestor certified that it does not own or have any investment interest in any other entity that provides any items or services that are paid for by a federal healthcare program.

- *Physician-practice customers' payment to the requestor for consulting services*. Physician-practice customers pay the requestor to provide consulting services to those customers, but the requestor confirmed that it does not recommend to

any customer the purchasing, leasing or ordering of any item or service for which payment may be made under a federal healthcare program.

- Physician-practice customers potentially would receive an opportunity to earn a fee, because of the consulting services, in the form of higher MIPS reimbursements from Medicare. Any remuneration such customers would receive under the arrangement would not be in return for referrals for, the purchase of, or arranging for or recommending the purchase of any item or service for which payment may be made under a federal healthcare program.

This opinion is particularly noteworthy as a rare example of where OIG discusses what services are *not* reimbursed by federal healthcare programs.

NOTABLE CRIMINAL ENFORCEMENT RESOLUTIONS AND ACTIVITIES

COMPANY AGREES TO $4.5 MILLION FORFEITURE FOR DISTRIBUTING MISBRANDED DIETARY SUPPLEMENTS

A Texas-based company pled guilty to distributing misbranded dietary supplements. Pursuant to the plea agreement, the company admitted that it delivered into interstate commerce misbranded dietary supplements, which are a type of food under the federal Food, Drug and Cosmetic Act. The products were marketed as workout supplements but contained ingredients mislabeled as dietary ingredients as well as ingredients not listed on the product label. As part of the plea, the company agreed to forfeit $4.5 million and comply with the terms of a compliance program and certain compliance-reporting requirements.

FLORIDA RESIDENTS SENTENCED FOR $93 MILLION HEALTHCARE FRAUD AND MONEY-LAUNDERING SCHEME

A Florida man and woman were sentenced to prison for more than eight and five years, respectively, for their roles in a wide-ranging conspiracy to defraud Medicare by billing in excess of $93 million for home-health therapy services that were never rendered. The court also ordered forfeiture of fraud proceeds. The residents were also found guilty of conspiring with others to submit false bills to Medicare for three home-health companies located in Michigan. Their co-conspirators recruited individuals from Cuba to sign Medicare-enrollment documents and appear as the owners of the home-health agencies to conceal the identities of those involved in the scheme. The residents and their co-conspirators then used these home-health companies to submit claims for services that were not rendered, using lists of stolen patient identities; they also leveraged various shell companies and bank accounts to launder the Medicare fraud proceeds and converted the proceeds into cash at Miami-area ATMs and check-cashing stores.

FORMER EMPLOYEE OF MEDICAL-DEVICE MANUFACTURER SENTENCED FOR FORGING FDA LETTERS THAT LED TO ILLEGAL SALE OF MEDICAL DEVICES

A federal judge sentenced a Philadelphia-area man to 12 months in prison, followed by supervised release, for his role in distributing medical devices without FDA clearance. According to court documents, the former employee was a regulatory-affairs specialist at a medical-device manufacturer and was responsible for making required submissions to the FDA. In pleading guilty, the former employee admitted that he created two false letters that purported to show that the FDA had granted clearance to sell two different medical devices. As a result, the medical-device manufacturer illegally sold tens of thousands of dollars' worth of medical devices throughout the United States.

FORMER PHARMACY PRESIDENT SENTENCED TO PRISON FOR $32 MILLION HEALTHCARE-KICKBACK SCHEME

A former president of a New Jersey pharmacy business was sentenced to 36 months in prison, followed by three years of supervised release, and ordered to pay $32 million in restitution for his role in a healthcare conspiracy to violate the AKS. The former president and others agreed to engage in a scheme to pay marketing companies to direct prescriptions for expensive medications to the pharmacies and specifically targeted Medicare and TRICARE beneficiaries to do so. The marketing companies pressured beneficiaries into ordering expensive medications over the phone, and then submitted recordings of these calls, together with pre-marked prescription pads for drugs that would yield exorbitant reimbursements, to telemedicine companies. The marketers paid the telemedicine companies kickbacks for every beneficiary referred for a prescription, and the telemedicine companies paid doctors to approve the prescriptions. The marketing companies then directed the prescriptions to the pharmacies, with which they had kickback arrangements. The pharmacies filled the prescriptions, sought reimbursement from the federal healthcare benefit programs, and then paid a portion of each reimbursement to the marketing companies as a kickback.

NOTABLE CIVIL ENFORCEMENT RESOLUTIONS AND ACTIVITIES

RESEARCH HOSPITAL AGREES TO PAY MORE THAN $19.5 MILLION TO RESOLVE LIABILITY RELATING TO SELF-DISCLOSURE OF IMPROPER BILLING FOR CLINICAL-TRIAL COSTS

Following a self-disclosure, a Florida non-profit cancer treatment and research center agreed to pay more than $19.5 million to resolve its civil liability under the FCA for improper claims submitted to federal healthcare programs. The research hospital allegedly billed federal healthcare programs for items and services provided as part of clinical-trial research that should have been billed to non-government trial sponsors. After learning of these issues, the research hospital initiated an independent investigation and compliance review, voluntarily provided the government with a written disclosure of its findings, fully cooperated with the government's subsequent investigation and promptly implemented substantial remedial measures. In connection with the settlement, the US government acknowledged that the research hospital took several significant steps entitling it to credit for cooperation, including its self-disclosure of the activity.

HOSPITAL AND INVESTORS AGREE TO PAY $30.6 MILLION FOR ALLEGED FALSE CLAIMS RELATED TO EXCESSIVE COST-OUTLIER PAYMENTS

A long-term-care hospital based in Newark, New Jersey, agreed to pay more than $18.6 million, plus interest, to resolve alleged FCA violations for claiming excessive cost-outlier payments from the Medicare program. In addition, certain investors in the hospital have agreed to pay $12 million, plus interest, to resolve alleged Federal Debt Collection Procedures Act (FDCPA) violations for the fraudulent transfer of money by the hospital to its investors. The settlement resolved allegations concerning Medicare's supplemental reimbursement for hospitals, known as cost-outlier payments. These payments are made to incentivize hospitals to treat inpatients whose care may be unusually expensive. The hospital had been accused of improperly distorting its cost-outlier payment system by rapidly increasing its charges more than any increase in its costs and far beyond what the hospital had the financial ability to repay once its Medicare cost reports were reconciled to account for these charge increases. The settlement also resolved allegations of FDCPA violations, specifically that the hospital transferred millions of dollars to its investors without receiving equivalent value in return, at a time when the hospital had reason to believe that it would not be able to repay its debts to the Medicare program.

LABORATORY AND ITS OWNER/CEO AGREE TO PAY MORE THAN $13 MILLION TO SETTLE ALLEGATIONS OF KICKBACKS AND UNNECESSARY TESTING

A clinical laboratory in New Jersey and its owner and chief executive officer agreed to pay in excess of $10 million to the US government and nearly $3 million to the State of New Jersey to resolve FCA allegations involving illegal kickbacks and medically unnecessary laboratory testing. The settlement resolves allegations that the company and its owner billed or caused Medicare and Medicaid to be billed for laboratory tests despite paying or knowing of five different types of kickbacks paid to induce referrals to the company for laboratory testing. In addition, the company and its owner allegedly submitted or caused false claims to be submitted to Medicare and Medicaid for laboratory tests that were not reasonable and necessary, not covered because they were identical orders of urine drug-testing panels for all patients within a clinician's practice without individualized decision-making, or not covered because they were improperly duplicative of other claims for the same date of service, the same patient and the same drugs.

HOSPITAL AND HEALTHCARE FACILITY OPERATOR AGREES TO PAY $42.5 MILLION TO RESOLVE HEALTHCARE FRAUD ALLEGATIONS

A Delaware-based hospital and healthcare facility operator agreed to pay $42.5 million to resolve allegations of healthcare fraud arising under the FCA and the Delaware False Claims and Reporting Act. In the complaint, the company's former chief compliance officer alleged that the company had provided illegal remuneration to non-employee neonatologists and surgeons in the form of services from ancillary-support providers to inpatients at the company's hospitals. The lawsuit alleged that the services of the ancillary-support providers impermissibly sought to induce those neonatologists and surgeons to refer their patients to the company's hospitals and created financial relationships between the non-employee providers and the company. As a result, the complaint alleged, the company's claims to government-funded healthcare programs, including Medicare and Medicaid, for the care it provided to the referred patients during their hospitalization violated the AKS and Stark Law.

DURABLE MEDICAL EQUIPMENT COMPANIES TO PAY $2.1 MILLION IN FALSE CLAIMS SETTLEMENT

Four durable medical equipment (DME) companies agreed to pay $2.1 million to resolve allegations that the companies violated the FCA by submitting false claims for payment to the Medicare, TRICARE, Department of Veterans Affairs, and Medicaid programs. The settlement resolved allegations that the DME companies billed federal healthcare programs for used beds sold to the programs as if they were new beds, and that the companies had sold certain hospital beds and pressure-support surfaces to beneficiaries of federal healthcare programs under a miscellaneous code to result in a higher price paid by the government. The settlement also resolved allegations that the DME companies had mischaracterized travel time as DME-repair time, in order to be reimbursed by federal healthcare programs.

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