BAKER DONELSON

LOOKING BACK AT 2024

KEY HEALTH CARE REGULATORY LEGAL DEVELOPMENTS IN FRAUD AND ABUSE, COMPLIANCE, AND ENFORCEMENT

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INTRODUCTION

The health care regulatory space realized significant regulatory and enforcement developments in 2024 that are influencing how providers and industry stakeholders approach various compliance measures and enforcement priorities in 2025. In light of these developments, health care providers and industry stakeholders continue to find ways to improve care delivery and patient access to care and services while maintaining compliance with federal fraud and abuse laws.

Updates to the 60-Day Overpayment Regulations for Medicare Parts A, B, C, and D Affecting How Overpayments are "Identified" and the Time Frame for Investigation and Quantification

The Centers for Medicare and Medicaid Services (CMS) finalized changes to the 60-day Rule in the Calendar Year 2025 Physician Fee Schedule Final Rule to state that a person has "identified" an overpayment when the person "knowingly receives or retains an overpayment." The term "knowingly" is assigned the meaning set forth in the FCA at 31 U.S.C. § 3729(b)(1)(A). Under this new definition, the provider or supplier must have actual knowledge of the existence of the overpayment or act in reckless disregard or deliberate ignorance of the overpayment to trigger the 60-day timeframe to report and return the overpayment to avoid False Claims Act (FCA) liability.

The Final Rule appropriately aligns the obligations of the overpayment regulation with the FCA scienter standard. In making this modification, CMS also removed the so-called "reasonable diligence standard," which stated that a person was deemed to have "identified" an overpayment when the person either determined or should have determined "through the exercise of reasonable diligence" that it received an overpayment and "quantified the amount of the overpayment."

Based on CMS's commentary in the Final Rule, suppliers and providers should no longer expect flexibility to extend their investigation of an identified overpayment beyond the stated regulatory timeframe, even when there are extraordinary circumstances. The provisions as finalized codify a brightline outer boundary of no more than 240 days to investigate and return overpayments (including additional related overpayments) once they are identified. This inflexible approach creates new challenges, particularly in the context of complex quantifications and investigations of related overpayments. Providers and suppliers should work with legal counsel to ensure that necessary changes are made to internal processes to take into account the Final Rule's implications for overpayment identification and investigations.

Notable Settlements and Enforcement Actions

In 2024, many types of health care entities entered into settlement agreements with the federal government to resolve claims related to health care fraud and abuse. According to the DOJ, 979 qui tam suits were filed in 2024, more than 2023 and breaking the 2013 all-time record. The DOJ reported $2.9 billion in the FCA settlement and judgments, with health care fraud settlements accounting for approximately $1.67 billion of that total. We highlight a few of these settlements below.

Hospital Resolves Claims That Contractual Arrangements With Physicians at Chemotherapy Infusion Center Were Kickbacks

On March 12, 2024, the United States attorney for the Eastern District of New York announced a settlement agreement with New York-Presbyterian/Brooklyn Methodist Hospital in which the hospital agreed to pay $17.3 million to resolve allegations of an illegal kickback scheme. The hospital was alleged to have made payments pursuant to a contractual agreement that linked the compensation the physicians received to the number of referrals the physicians made to the hospital's chemotherapy infusion center. Physicians at the infusion center were also alleged to have failed to adequately supervise chemotherapy services.

Texas Medical Center Institutions Resolve Claims Related to Concurrent Billing Claims

On June 24, 2024, the United States attorney for the Southern District of Texas announced a settlement with Baylor St. Luke's Medical Center, Baylor College of Medicine, and Surgical Associates of Texas P.A. to pay $15 million to resolve claims that they billed for concurrent heart surgeries in violation of applicable Medicare regulations. Physicians of the hospital were alleged to have engaged in a practice of regularly running multiple operating rooms at once, delegating important aspects of complex heart surgeries to unqualified medical residents, and falsely attesting that the surgeons were physically present for the entire operation in violation of the teaching physician regulations.

Health Care Agencies Resolve False Claims Act related to Unpaid Wages and Benefits to Aids

On September 30, 2024, the United States attorney for the Eastern District of New York announced settlement agreements between Edison Home Health Care of New York LLC, Preferred Home Health Care of New York, the United States, and the State of New York resolving allegations that the home health care service entities violated the federal FCA and the New York FCA by falsely claiming that they paid their home care aides the minimum wages required under New York law. The entities agreed to pay $3.9 million to the United States and $5.85 million to the State of New York to resolve the federal and state false claims. The entities also agreed to pay $7.5 million to current and former aides to resolve compensation claims under the New York Wage Parity Act. This settlement is particularly interesting because it involves wage payment, not items or services directly billed to federal health care programs. It reinforces that when providers submit claims for payment, they are certifying, both expressly and impliedly, that they are in compliance with all applicable laws and regulations relevant to the submission of those claims.

Precision Toxicology Resolves Allegations of Medically Unnecessary Urine Testing Illegal Payments to Physicians

On October 2, 2024, the Department of Justice announced a settlement agreement with Precision Toxicology resolving allegations of violating the FCA by billing Medicare, Medicaid, and other federal health care programs for unnecessary urine drug tests and providing free items to physicians in exchange for referrals. The settlement covers claims from January 1, 2013, to December 31, 2022, and includes a five-year Corporate Integrity Agreement with the Department of Health and Human Services (HHS) Office of Inspector General (OIG). Precision Toxicology also agreed to pay $27 million. The allegations, brought by whistleblowers under the qui tam provision of the FCA, also involved the promotion of "custom profiles" that led to excessive testing without individualized patient assessments. This settlement demonstrates the government's heightened scrutiny of various lab arrangements and enforcement action in this space. This settlement further demonstrates the bidirectional liability that can arise when physicians order lab testing that is not medically necessary and the potential liability imposed on the performing laboratory as a result.

Compound Ingredient Supplier Resolves Allegations of False and Inflated Average Wholesale Prices for Ingredients Used in Compounded Prescriptions

On November 1, 2024, Medisca Inc., a compound ingredient supplier, entered into a settlement agreement and agreed to pay $21.75 million to resolve allegations of inflating the average wholesale prices (AWPs) for two ingredients used in compounded prescriptions, leading to false claims submitted to federal health care programs. The scheme involved reporting AWPs significantly higher than the actual cost, creating substantial profit margins for pharmacies using these ingredients. The settlement addressed claims that Medisca's actions caused inflated reimbursements from programs like TRICARE and the Department of Labor's Office of Workers' Compensation Programs. The whistleblower received over $3.4 million from the settlement proceeds.

Notable Advisory Opinions

In 2024, the HHS Office of Inspector General issued thirteen advisory opinions about the application of certain fraud and abuse enforcement authorities to the requesting party's (Requestor's) existing or proposed business arrangements. We highlight a few of these opinions below, each focusing on different arrangements.

Advisory Opinion 24-02

The OIG posted a favorable Advisory Opinion 24-02 on April 11, 2024. In this Advisory Opinion, the Requestor was a non-profit organization that provided financial support through the form of specific disease funds to patients with rare medical conditions. Each disease fund had a single pharmaceutical manufacturer donor that manufactured or marketed a drug to treat the associated disease. Patients who applied for enrollment in a disease fund were accepted on a first-come, first-served basis, based on medical and financial eligibility. The disease funds were open to all patients, including federal health care program enrollees.

Despite implicating the Anti-Kickback Statute (AKS), the OIG concluded that it would not impose sanctions because: (i) the disease funds vary in the proportion of funds spent to purchase the drugs of the fund donors; (ii) the arrangement includes various safeguards to mitigate risk (e.g., the disease funds are based on established disease states; relief is awarded without regard to the treatment regimen prescribed for a particular patient; there are limitations on sharing information with donors; and the arrangement incorporated a financial eligibility process); and (iii) the disease funds help financially needy patients obtain treatments that they otherwise may not be able to afford.

Of note, the Advisory Opinion is only in effect until January 1, 2027, two years after the implementation of the $2,000 out-of-pocket cap on Medicare Part D cost-sharing obligations. Thus, the OIG would not impose sanctions during this period.

Advisory Opinion 24-03

The OIG posted a favorable Advisory Opinion 24-03 on June 17, 2024. In this Advisory Opinion, the Requestor manufactured a gene therapy product for the treatment of severe genetic diseases administered at treatment centers selected by the Requestor. The product had the potential for significant side effects and required careful monitoring of the patients. The arrangement involved the Requestor offering to eligible patients – including federal health care program beneficiaries – and their caregivers' travel expenses (as applicable), lodging, and reimbursement for other authorized expenses related to transportation and meals.

The OIG determined that although the arrangement implicated the AKS, the arrangement presented a low risk of fraud and abuse because: (i) the arrangement removed a barrier to accessing medically necessary care; (ii) the arrangement facilitated compliance with the applicable drug label instructions by permitting the patients to remain at the treatment centers for monitoring; (iii) the product at issue was a one-time, potentially curative treatment, that likely would not lead to additional referrals; and (iv) the arrangement includes additional safeguards that mitigate the risk of fraud and abuse (e.g., the Requestor would not require physicians or treatment centers to prescribe its product exclusively; the Requestor would not cover expenses that may be paid by another source; the Requestor would not use its offer of the arrangement as a marketing tool to drive product selection, utilization, or referrals).

The OIG also determined that the Beneficiary Inducements Statute is also implicated, but the "promotes access to care" exception is satisfied because: (i) the arrangement improves the beneficiaries' ability to obtain items and services payable by Medicare or Medicaid; and (ii) there is a low risk of harm to Medicare and Medicaid beneficiaries and programs. As such, the OIG concluded that it would not impose sanctions on the Requestor under the AKS, and the arrangement did not generate prohibited remuneration under the Beneficiary Inducements Statute.

Advisory Opinion 24-04

On January 20, 2024, the OIG posted the favorable Advisory Opinion 24-04. In this Advisory Opinion, the Requestor was a corporate affiliate of a pharmaceutical manufacturer that developed a drug to treat an ultra-rare immunodeficiency condition. The drug was a one-time, potentially curative treatment for the condition and the only treatment option of its kind available. Only one treatment center could administer the drug. The Requestor sold the drug to this treatment center.

The arrangement involved the following: (i) a program whereby the Requestor would refund, waive, or delay the treatment center's requirement to pay for the drug in the event of a denial or delay in a patient's insurance reimbursement; and (ii) a program whereby the Requestor would discount the price of the drug in the event that the wholesale acquisition cost of the drug at the time of delivery was lower than the price specified when the treatment center entered into a pricing agreement with the patient's insurer.

The OIG explained that though the refund program implicated the AKS, the risk of fraud and abuse was low as: (i) the refund program was limited in scope because, if triggered, it would only occur once per patient; (ii) the design of the program reduced the risk that the refund program would result in interference with clinical decision-making or overutilization because the drug was a one-time, potentially curative treatment, that was the only treatment option available for a very rare condition; (iii) it was in the treatment's financial interest to administer the drug only in circumstances that satisfied the requirements for insurance coverage because otherwise the refund program would not apply; and (iv) the refund program was unlikely to increase costs inappropriately to federal health care programs because it provided the opportunity for patients with an expensive, rare disease to be potentially cured.

The OIG also explained that the refund program did not generate prohibited remuneration under the Beneficiary Inducements Statute because the refund program did not make it likely that patients would select the treatment center as their provider of choice for the drug. On the contrary, patients did not have any choice regarding their provider, because the treatment center was the only location where they could obtain the drug.

Advisory Opinion 24-07

On August 23, 2024, the OIG posted the favorable Advisory Opinion 24-07. In this Advisory Opinion, the Requestor was a non-profit grant-making organization that proposed operating a patient assistance program (PAP) that would fully subsidize diabetes drug cost-sharing obligations for low-income Medicare enrollees who lived in a specific rural service area. The Requestor certified that eligibility for the PAP was based on financial need and that the PAP had not knowingly solicited or received any donations from any pharmaceutical manufacturer, distributor, pharmacy, or any related entity. Enrolled participants in the PAP could obtain the drugs either: (i) at a "participating pharmacy" where the participant would receive the drugs without having to pay any out-of-pocket expenses; or (ii) at a "non-participating pharmacy" where the participant would have to pay the pharmacy for the drugs, submit a claim for reimbursement to the PAP, and then wait to have the claim reimbursed. The participating pharmacies were all independently owned and were determined based on geographic location, familiarity with Medicare Part D, administrative infrastructure, compliance history, and ability to adequately serve the participant population.

The OIG determined that the arrangement implicated the AKS because it would induce participants to purchase diabetes drugs that are covered by Medicare Part D. The OIG concluded that the cost-sharing subsidies present a low risk of fraud and abuse for purposes of the AKS because: (i) the cost-sharing subsidies would not function as a conduit for payments by a pharmaceutical manufacturer, distributor, pharmacy, or related entity to patients; (ii) the arrangement would subsidize all diabetes drugs, not drugs made by a specific manufacturer; and (iii) eligibility in the PAP would be determined on a good faith evaluation of financial need.

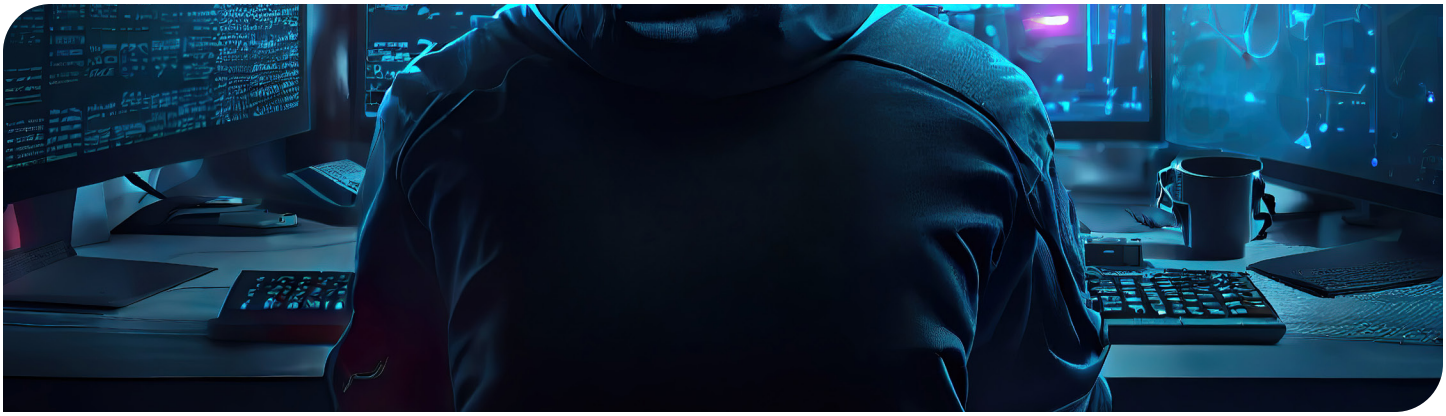
With respect to the aspect of the arrangement that would arguably steer participants to participating pharmacies by allowing their patients to avoid out-of-pocket expenses altogether, the OIG concluded that this presented a low risk of fraud and abuse for purposes of the AKS because: (i) other convenience factors (e.g., location, availability) were likely to influence a patient's choice of pharmacy; (ii) the Requestor selected the participating pharmacies using objective criteria; (iii) the ultimate dollar value of the cost-sharing subsidies would not differ based on the pharmacy selected by a participant; and (iv) enabling participants to avoid upfront out of pocket costs would be unlikely to interfere with clinical decision, result in overutilization, or otherwise increase costs to federal health care programs.

The OIG also determined that the cost-sharing subsidies would not implicate the Beneficiary Inducements CMP because the subsidies would not influence a participant to receive services from a particular pharmacy. With respect to the "participating pharmacy" part of this arrangement, the OIG explained that it would not impose sanctions under the Beneficiary Inducements CMP for the same reasons discussed in the AKS section above.

Advisory Opinion 24-09

On November 25, 2024, the OIG posted the favorable Advisory Opinion 24-09. In this Advisory Opinion, the Requestor was a municipal corporation that provided EMS services to county residents. The Requestor proposed an arrangement whereby the Requestor would waive the cost-sharing requirements for "treatment in place" EMS services provided to patients in response to 911 calls that did not result in ambulance transport.

The OIG explained that, though the arrangement would implicate the AKS and the Beneficiary Inducement CMP, the arrangement presented a low risk of fraud and abuse because: (i) The Requestor certified that it would uniformly apply its cost-sharing waiver policy for all individuals who received treatment in place services regardless of payor; (ii) there was limited risk of the arrangement inappropriately increasing costs to federal health care programs because neither Medicare Part B nor the applicable state's Medicaid program covered treatment in place services; (iii) to the extent that a federal health care program covers treatment in place services, such services could lower costs to federal health care programs by providing treatment to patients without transporting them to a hospital; and (iv) the cost-sharing waivers would not meaningfully affect a patient's decision to use the Requestor for emergency services because other factors likely would be more important (e.g., location, availability of EMS units, and decisions by the 911 dispatcher).



OIG Consumer Alert Involving Remote Patient Monitoring

The OIG issued a Consumer Alert concerning potential fraud schemes involving Remote Patient Monitoring (RPM). On September 19, 2024, the OIG issued a report titled "Additional Oversight of Remote Patient Monitoring in Medicare is Needed." The purpose of the report was to notify consumers that the use of RPM has the potential to expand the Medicare population.

Thus, the OIG seeks to better understand how RPM is being used, including which patients are receiving it and for what conditions. The OIG found that:

- the use of RPM greatly increased from 2019 to 2022;
- approximately 43 percent of Medicare beneficiaries who received RPM did not receive all three components of it which raised concerns that RPM was not being used appropriately;
- OIG and CMS raised concerns about fraud and abuse related to RPM; and
- Medicare lacks sufficient key information for appropriate oversight for RPM which prohibits CMS from identifying whether the requirements for RPM are met.

As a result, the OIG recommended that CMS implement the following measures to increase oversight of RPM:

- Implement additional safeguards to ensure that RPM is used and billed appropriately in Medicare;
- Require that RPM be ordered and that information about the ordering provider be included on claims and encounter data for RPM;
- Develop methods to identify what health data are being monitored;
- Conduct provider education about the billing of RPM; and
- Identify and Monitor companies that bill for RPM.

CMS concurred that it would consider all recommendations. Because of the increased use of RPM to effectively monitor and manage certain medical conditions, providers must understand the requirements to bill for RPM so that they may comply with those requirements. In addition, because RPM services continue to expand through changes to the Medicare Physician Fee Schedule, increased scrutiny over RPM will continue.

Enhancing Compliance in Nursing Facilities: OIG's New Guidance

The OIG issued new Nursing Facility Industry Segment-Specific Compliance Program Guidance (the Nursing Facility ICPG) for nursing facilities and skilled nursing facilities on November 20, 2024. Factors that motivated the Nursing Facility ICPG include long-standing challenges around staffing, infection control, emergency preparedness, employee background checks, reporting of adverse events experienced by residents, inappropriate use of medications, and other compliance and quality issues.

The Nursing Facility ICPG is the first industry-specific guidance published since the 2023 General Compliance Program Guidance (the GCPG), which provides more general guidance to the entire health care compliance community. The Nursing Facility ICPG, together with the GCPG, serves as the OIG's updated and centralized source of voluntary compliance program guidance for nursing facilities. This is the first update to the OIG's nursing facility guidance since 2008.

The Nursing Facility ICPG identifies the following key compliance issues for nursing facilities: (i) Quality of Care and Quality of Life; (ii) Medicare and Medicaid Billing Requirements; (iii) Federal Anti-Kickback Statute; (iv) Other Risk Areas; and (v) Other Compliance, Quality, and Resident Safety Considerations.

Although the Nursing Facility ICPG is considered voluntary, it will likely be considered the minimum standard for nursing facility compliance programs going forward. Nursing facilities' compliance teams should review and reference the Nursing Facility ICPG when assessing whether their current program conforms with the OIG's expectations. While the Nursing Facility ICPG speaks directly to owners and operators of nursing facilities, it also provides guidance to hospitals and contractors that work with nursing facilities and their patients.

The updated guidelines reflect the growing commitment by the government to use fraud allegations as a means of addressing what it perceives as sub-quality or worthless care. This guidance may serve to enable later arguments to soften some relatively high legal thresholds for "worthless services" cases in the various Circuits as well as help bolster Escobar-type certification legal theories under the FCA Act by memorializing agency guidance and understanding, as well as putting owners and operators on notice of such informal interpretation.

OIG FAQ Process

The OIG previously expanded its informal FAQ Process as part of its Modernization Initiative. The FAQs have increased to address additional topics and to provide an alternative to the OIG advisory opinion process. The OIG continues to update its FAQs; thus, providers and industry stakeholders can continually monitor the range of topics covered including the applicability of the Beneficiary Inducement CMPL and AKS to certain arrangements. Providers and stakeholders interested in utilizing the FAQ process are instructed to submit their inquiries to OIGComplianceSuggestions@oig.hhs.gov. The FAQs are considered informal guidance. Therefore, providers and stakeholders must be mindful of this when relying on any guidance issued through this process. Additionally, unlike the advisory opinion process, FAQs cannot be withdrawn once submitted.

Key Takeaways

The recent guidance and enforcement action serve as a resource for providers and other industry stakeholders seeking to navigate the evolving regulatory landscape. By maintaining a culture of compliance and staying abreast of various changes, health care providers and industry stakeholders can work to further mitigate risk.

Should you have any questions regarding this report, please contact one of our trusted advisors listed below, or any member of the Baker Donelson Health Law team.

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