



Sales and Market Access Programs: Current Legal Perspectives & Compliance Challenges

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Presenter



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Elements of an Effective Compliance Program

The Department of Health and Human Services Office of the Inspector General (OIG) has identified seven elements of an effective compliance program:

- 1) Implementing written policies and procedures;
- 2) Designating a compliance officer and compliance committee;
- 3) Conducting effective training and education;
- 4) Developing effective lines of communication;
- 5) Conducting internal monitoring and auditing;
- 6) Enforcing standards through well-publicized disciplinary guidelines; and
- 7) Responding promptly to detected problems and undertaking corrective action.

Consequences of Non-Compliance

JUSTICE NEWS

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE

Wednesday, October 9, 2019

Genetic Testing Company and Three Principals Agree to Pay \$42.6 Million to Resolve Kickback and Medical Necessity Claims

The Justice Department announced today that UTC Laboratories Inc. (RenRX) has agreed to pay \$41.6 million, and its three principals, Tarun Jolly M.D., Patrick Ridgeway, and Barry Griffith, have agreed to pay \$1 million to resolve allegations that they violated the False Claims Act by paying kickbacks in exchange for laboratory referrals for pharmacogenetic testing and for furnishing and billing for tests that were not medically necessary. RenRX, a laboratory company headquartered in New Orleans, Louisiana, also agreed to a twenty-five year period of exclusion from participation in any federal health care program.

“The payment of kickbacks in exchange for medical referrals undermines the integrity of our healthcare system. Today’s settlement reflects the Department of Justice’s commitment to ensuring that taxpayer monies are well spent and not wasted on unnecessary medical testing,” said Assistant Attorney General Jody Hunt of the Department of Justice’s Civil Division.

“Healthcare fraud, in any incarnation, hurts patients, honest medical practitioners, and all of the nation’s taxpayers,” said United States Attorney Peter G. Strasser of the Eastern District of Louisiana. “The favorable resolution of this False Claims Act matter illustrates the collaborative efforts and firm commitment by our federal partners to use all available remedies, both civil and criminal, to address signs of waste and abuse by providers in our healthcare markets.”

The government alleged that between 2013 and 2017, UTC and its principals offered and paid remuneration to physicians to induce the ordering of pharmacogenetic tests, purportedly in return for their participation in a clinical trial known as the Diagnosing Adverse Drug Reactions Registry (DART), clinical trial identifier NCT01970709. The government also alleged that UTC and its principals offered and paid remuneration, including sales commissions, to entities and individuals as part of the scheme, and furnished pharmacogenetic tests that were not medically necessary and billed the Medicare program.

“The payment of cash and thinly-disguised referral bribes, as contended by the government, resulted in a more than \$42 million dollar resolution in this case,” said Special Agent in Charge CJ Porter of the Department of Health and Human Services Office of Inspector General (HHS-OIG). “Additionally, my agency barred RenRX from receiving any payments from federal health programs for a full 25 years. Genetic testing scams are becoming all too common. OIG has a genetic testing fraud alert [here](#).”

Consequences of Non-Compliance

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Wednesday, September 1, 2021

Laboratory Owner Pleads Guilty to \$73 Million Medicare Kickback Scheme

A Florida man pleaded guilty yesterday in the Southern District of Florida for his role in a \$73 million conspiracy to defraud Medicare by paying kickbacks to a telemedicine company to arrange for doctors to authorize medically unnecessary genetic testing. The scheme exploited temporary amendments to telehealth restrictions enacted during the COVID-19 pandemic that were intended to ensure access to care for Medicare beneficiaries.

According to court documents, Leonel Palatnik, 42, of Aventura, admitted that, as a co-owner of Panda Conservation Group LLC, he conspired with other co-owners, and with Michael Stein, the owner of 1523 Holdings LLC, to pay kickbacks to Stein in exchange for his work arranging for telemedicine providers to authorize genetic testing orders for Panda's laboratories. Panda's owners and Stein entered into a sham contract for purported IT and consultation services to disguise the true purpose of these payments. 1523 Holdings then exploited temporary amendments to telehealth restrictions enacted during the pandemic by offering telehealth providers access to Medicare beneficiaries for whom they could bill consultations. In exchange, these providers agreed to refer beneficiaries to Panda's laboratories for expensive and medically unnecessary cancer and cardiovascular genetic testing.

Consequences of Non-Compliance

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Monday, April 27, 2020

Testing Laboratory Agrees to Pay Up to \$43 Million to Resolve Allegations of Medically Unnecessary Tests

Genova Diagnostics Inc., a clinical laboratory services company based in Asheville, North Carolina, has agreed to pay up to approximately \$43 million to resolve allegations that it violated the False Claims Act, including claims that it billed for medically unnecessary lab tests, the Department of Justice announced today.

“Government healthcare programs are designed to provide beneficiaries with care that is medically reasonable and necessary,” said Assistant Attorney General Jody Hunt of the Department of Justice’s Civil Division. “Providers of taxpayer-funded federal healthcare services will be held accountable when they knowingly cause false claims to be submitted for services that do not meet this standard of care.”

Enforcement Trends



- Anti Kickback Statue (AKS)/False Claims Act (FCA) cases are a large source of revenue for the federal government.
- Industry-wide DOJ investigations into Financial Assistance Programs (FAPs) ongoing for with subpoenas/CIDs issued to many companies.
- Local U.S. Attorney's Offices & Department of Justice continue to focus on health care fraud matters.
- Like the federal government, privacy payors tend to disfavor FAPs; they believe:
 - FAPs steer patients to unnecessary and/or higher cost services and therapies.
 - FAPs are not effective in addressing systemic impacts

EKRA Overview

- The Eliminating Kickbacks in Recovery Act (EKRA) enacted in 2018 as part of Support Act, which expanded access to opioid addiction treatment
- EKRA generally prohibits recovery facilities, treatment centers and clinical labs from receiving or offering any remuneration to induce patient referrals
- Statutory definition of laboratory applies broadly to all labs and testing covered by private and public health plans
- Minimal federal guidance and case law interpreting EKRA
- Clinical laboratories can take steps to mitigate level of risk in interactions with patients and providers through established policies and best practices

Key Statutory Requirements:

18 U.S.C. § 220



- For lab tests covered by health care plan, EKRA prohibits anyone from knowingly or willfully:
 1. Soliciting or receiving remuneration “in return for referring a patient” to lab; or
 2. Paying or offering remuneration:
 - a. “to induce a referral of an individual” to lab; or
 - b. “in exchange for an individual using the services” of lab
- EKRA is criminal statute allowing for fines up to \$200,000 and imprisonment

EKRA and Compensation for Sales and Marketing Services



- Must be interpreted in concert with existing AKS exceptions and safe harbors
- In particular, EKRA prohibits soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient to a recovery home, clinical treatment facility, or laboratory
- However, EKRA omits the language that exempted from AKS marketing and sales activities performed by employees
- It is possible that the Attorney General will promulgate regulations to clarify the meaning of “referral” under EKRA so that it more clearly applies to marketing and sales agents in the substance abuse field, consistent with its legislative intent

What to Do About Post-EKRA Sales Commissions?

- Employment and personal services safe harbors to AKS:
 - More permissive for employees versus independent contractors
 - AKS personal services safe harbor requires compensation to be aggregate, set in advance, Fair Market Value, unrelated to value or volume of sales
 - In light of the more favorable treatment of employees under the AKS, many laboratory and other marketing and sales arrangements have been structured as employment relationships so that commission-based compensation may be paid in compliance with the AKS.
- EKRA's exception for employees is narrower than the AKS exception and safe harbor for employees:
 - Restricts the ways in which employees can be paid if they are governed by both the AKS and EKRA
 - Employees of a clinical laboratory who historically received commission-based compensation may not comply with EKRA's exception

Recent EKRA Enforcement by DOJ

- In March 2023, DOJ settled federal criminal action against Genotox Laboratories Ltd.
 - Genotox is provider of urine drug, pharmacogenetic, and infectious disease testing
- Case initiated by whistleblower, a former billing manager of lab
- Complaint alleged Genotox paid sales reps and specimen processors (SPs) based on number of tests and revenue they generated
 - DOJ argued payments “designed to induce referrals” of tests in violation of EKRA
 - DOJ also argued SPs performed valuable administrative work for physicians, creating further inducement under EKRA
- In settlement, Genotox paid \$5.9 million and entered 5-year Corporate Integrity Agreement (CIA) with HHS

Setting the Stage:

2014 OIG Supplementary Special Advisory Bulletin



- On May 30, 2014, OIG issued a Supplemental Special Advisory Bulletin (“Supplemental Bulletin”) that expanded on its 2005 guidance and focused on the risks for fraud and abuse posed by patient financial assistance programs operated by independent charities.
- OIG identified three areas of concern with respect to independent charity financial assistance plans.
 - First, a charity FAP with a narrowly defined disease fund may end up primarily or exclusively funding the products of its donors, which could be an unlawful inducement.
 - Second, defining patient eligibility for FAP assistance with reference to the cost of a particular drug/device/service could be evidence of intent to induce the use of that drug/device/service rather than an effort to accurately identify and meaningfully address patient financial need.
 - Third, a charity FAP should not provide donors with information that would permit donors to correlate their donations with the volume of their products supported by the FAP

Immediate Fallout from the OIG Supplementary Bulletin

- The Supplemental Bulletin was followed by an extensive series of OIG Advisory Opinions on PAPs.
- Between October 26, 2015 and January 13, 2016, OIG issued 14 Advisory Opinions, or modifications or terminations of earlier Advisory Opinions.
- Thirteen of these concerned PAPs, including eight modified opinions and the termination of two Advisory Opinions.
- The termination of an Advisory Opinion is an unusual step for OIG to take.
- In their online archive of Advisory Opinions, which dates back to June 1997, there is only one other terminated opinion.

COMPLIANCE AND PATIENT FINANCIAL ASSISTANCE SERVICES: What does the OIG say?



- The Beneficiary Inducements CMP provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program.
- The OIG also may initiate administrative proceedings to exclude such person from Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of the Beneficiary Inducements CMP as including "transfers of items or services for free or for other than fair market value." Section 1128A(i)(6) of the Act contains an exception to the definition of "remuneration" that may apply in the context of the Proposed Arrangement.
- Section 1128A(i)(6)(A) of the Act includes an exception that carves out from the definition of remuneration under the CMP certain waivers of cost-sharing amounts offered to patients in financial need. The exception protects waivers of cost-sharing amounts that are:
 - (i) not offered as part of any advertisement or solicitation;
 - (ii) not routine; and
 - (iii) made following an individual determination of financial need.

<https://oig.hhs.gov/documents/advisory-opinions/1021/AO-22-02.pdf>

Recent OIG Guidance from the Pharma Side/Part D

- There is little recent formal guidance on laboratory patient financial assistance programs.
 - So we look to what guidance there has been in other contexts, such as programs for pharmaceuticals for Part D enrollees.
- “Pharmaceutical manufacturers may sponsor patient assistance programs (PAPs) that provide financial assistance or drug free product (through in-kind product donations) to low income individuals to augment any existing prescription drug coverage.”
<https://www.cms.gov/medicare/coverage/prescription-drug-coverage/patient-assistance-program> issued September 6, 2023

Best Practices and Potential Pitfalls for FAPS

- Be cognizant of the HHS OIG guidance.
- Provide relevant training and supervision of any program.
- Establish specific protocols to govern decision-making for assistance in any form:
 - Prompt pay discounts
 - Payment plans
 - Financial assistance based on federal poverty level
- Promote testing based solely on its quality, performance, and cost-effectiveness.
- Be wary of use of FAP to “prime the pump” of prescriber/patient demand.
- Avoid backing the FAP into an ROI analysis
- Firewall decisions against any actual or perceived influence.
 - Separate the FAP relationship from any sales or marketing activities or personnel.
 - Consider forming a committee to review the program and vet decisions.



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Questions?