Government Enforcement in the Clinical Laboratory Space

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The Statutes & Regulations

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The Stark Law

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- AKA the "physician self-referral law"
- **The Rule:** If physician (or immediate family member) has financial relationship with entity (e.g. lab), physician may **not** make referral to entity for designated health service ("DHS") and entity may **not** submit claims for such services
- Applies to Medicare and Medicaid
- Strict liability (no intent required)
- Can lead to FCA liability, CMPs, exclusion

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- **"Designated Health Services" =** Lab services, therapy services, radiology/imaging, DME, prosthetics & orthotics, home health services, outpatient Rx drugs, inpatient & outpatient hospital services

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The Stark Law

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- What qualifies as a **"financial relationship"** under Stark?
  - Any **ownership or investment interest**;
  - Any **compensation arrangement**
    - Defined as "any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity" with certain very limited exceptions.
      - Remuneration = any payment, directly or indirectly, overtly or covertly, in cash or in kind.
  - **Bottom line – almost anything can be considered a "financial relationship"**

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The Stark Law

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- **"Referral"** is defined very broadly, and includes:
  - A request for, or ordering of, DHS by a physician
  - Establishment of a plan of care
  - A request for a consultation and any test or procedure ordered by a physician-consultant
  - Indirect referrals by a physician who has reason to know the identity of the actual provider of the service

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The Stark Law

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- Major Stark exceptions:
  - Rental of office space & equipment
    - Lease must be **in writing** with a term of at least 1 year; FMV rent w/out considering referrals; commercially reasonable.
  - Bona fide employment (employed physicians)
    - Employment for "identifiable services"; FMV compensation w/out considering referrals directly or indirectly; commercially reasonable.
  - Personal service arrangements (e.g., medical director, speaker program, etc.)
    - In writing specifying all services provided and for at least 1 year; FMV compensation w/out considering referrals.

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The Stark Law

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- Major Stark exceptions:
  - Isolated Transactions
    - Isolated financial transactions OK if amount of remuneration is FMV, does not take into account volume/value of referrals or other business generated between parties; commercially reasonable; no additional transactions b/t parties for 6 months.
  - Remuneration unrelated to DHS
    - Entity can provide remuneration to physician if does not relate (directly or indirectly) to furnishing of DHS. Must be **wholly** unrelated and not take into account volume/value of referrals.
- If arrangement does not fall **squarely** w/in an exception (including all requirements under that exception), then you are violating Stark, regardless of intent or lack thereof!
  - Burden on party claiming exception

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The Anti-Kickback Statute

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- Prohibits **knowingly & willfully** paying, offering, soliciting or receiving remuneration in return for referral
- **Criminal**, civil & administrative remedies (including damages + penalties + exclusion)
- Predicate to FCA liability
- Safe Harbors & exceptions similar to Stark exceptions (space & equipment rental, personal services & mgmt. contracts, bona fide employment, etc.)
- Applies to **all** federal healthcare programs
- "One Purpose" rule

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The False Claims Act ("FCA")

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- Prohibits, among other things:
  - Knowingly presenting, or causing to be presented, false or fraudulent claims for payment or approval
  - Knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim
  - Knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the government
    - Retention of overpayment
    - 60-day rule
- *Qui tam* actions

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The False Claims Act ("FCA")

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- Consequences of violating: Treble damages, per-claim penalties (b/t $11,181 and $22,363), exclusion
- "Knowing" and "knowingly" includes actual knowledge, deliberate ignorance, or reckless disregard. **No proof of specific intent to defraud required**.

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The False Claims Act ("FCA")

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- Examples of FCA violations:
  - Submitting claims for medically unnecessary services
  - **Violating Stark or AKS**
  - Submitting claims for services provided by excluded persons
  - Improper retention of overpayment for more than 60 days

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False Claims Act Trends

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Healthcare-specific statistics:

FY	NEW MATTERS [2]		SETTLEMENTS AND JUDGMENTS [3]					RELATOR SHARE AWARDS [4]		
	NON QUI TAM	QUI TAM	NON QUI TAM	QUI TAM			TOTAL QUI TAM AND NON QUI TAM			
			TOTAL	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL		WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL
2008	60	231	162,972,022	962,461,088	6,852,571	969,313,659	1,132,285,682	185,933,162	1,522,164	187,455,327
2009	34	279	238,061,424	1,364,911,522	30,283,452	1,395,194,974	1,633,256,398	155,440,550	8,669,822	164,110,372
2010	42	385	546,963,733	1,955,805,336	15,478,518	1,971,283,854	2,518,247,587	335,084,132	4,373,489	339,457,621
2011	38	417	178,287,545	2,182,785,375	88,291,393	2,271,076,768	2,449,364,313	446,646,645	24,055,563	470,702,208
2012	25	414	557,273,967	2,504,096,869	37,563,668	2,541,660,538	3,098,934,505	280,816,748	10,527,293	291,344,041
2013	27	504	61,354,329	2,523,689,075	119,260,369	2,642,949,443	2,704,303,773	465,027,975	28,526,451	493,554,426
2014	32	470	88,054,490	2,271,159,011	66,322,326	2,337,481,337	2,425,535,827	382,745,316	10,877,186	393,622,502
2015	26	426	154,658,714	1,472,783,885	472,604,555	1,945,388,440	2,100,047,154	258,821,659	132,218,688	391,040,347
2016	69	501	97,579,302	2,427,980,533	71,931,554	2,499,912,087	2,597,491,389	431,263,484	19,254,883	450,518,367
TOTAL	507	6,683	6,127,157,067	26,639,454,777	1,139,519,880	27,778,974,658	33,906,131,725	4,371,321,590	260,253,992	4,631,575,542

Source: DOJ Civil Division Fraud Statistics

False Claims Act Trends

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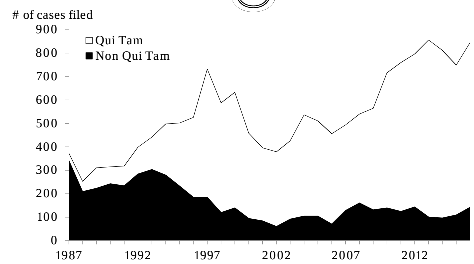

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Govt. Enforcement in the Lab Space

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- **"Recent" examples:**
  - **April 2018:** Biotheranostics (Cali.) agrees to pay $2M to settle FCA action alleging that it submitted claims for Breast Cancer Index tests that were not reasonable and necessary b/c being performed on patients who did not meet certain qualifications.
  - **Feb. 2018:** CEO of HDL and owners of HDL's marketing partner found liable by federal jury in SC for violating FCA and AKS by paying "processing & handling" fees to ordering providers.
    - HDL & Singulex paid $48.5M settlement in April 2015.

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- **Main focus on relationship b/t labs and referring physicians (i.e., AKS and Stark)**
- **Guidance from OIG:**
  - 1994 Special Fraud Alert
  - 2014 Special Fraud Alert
  - Numerous Advisory Opinions

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- **October 1994 Special Fraud Alert: "How Does the Anti-Kickback Statute Relate to Arrangements for the Provision of Clinical Lab Services?"**
  - "Whenever a laboratory offers or gives to a source of referrals anything of value not paid for at FMV, the inference may be made that the thing of value is offered to induce the referral of business. The same is true whenever a referral source solicits or receives anything of value from the laboratory."
  - FMV must reflect an arms-length transaction which has not been adjusted to include the additional value which one or both of the parties has attributed to the referral of business between them.

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- **October 1994 Special Fraud Alert**
  - Practices that implicate AKS:
    - Provision of phlebotomy services to physicians
      - While the mere placement of a laboratory employee in the physician's office would not necessarily serve as an inducement prohibited by the AKS, the statute is implicated **when the phlebotomist performs additional tasks that are normally the responsibility of the physician's office staff**. These tasks can include taking vital signs or other nursing functions, testing for the physician's office laboratory, or performing clerical services.
      - Where a phlebotomist performs **clerical or medical functions not directly related to the collection or processing of laboratory specimens**, a strong inference arises that he or she is providing a benefit in return for the physician's referrals to the laboratory.
      - The mere existence of a contract b/t the laboratory and the provider that prohibits the phlebotomist from performing services unrelated to specimen collection does not eliminate the OIG's concern, where the phlebotomist is not **closely monitored by his employer or where the contractual prohibition is not rigorously enforced**.

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- **October 1994 Special Fraud Alert**
  - Practices that implicate AKS:
    - Free pickup and disposal of bio-hazardous waste products **unrelated to collection of specimens for outside laboratory**.
    - Provision of computers or fax machines, unless equipment is **integral to, and exclusively used for**, performance of the outside laboratory's work.
    - Provision of **free laboratory testing** for healthcare providers, their families and their employees.

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- **June 2014 Special Fraud Alert: "Laboratory Payments to Referring Physicians"**
  - Addresses compensation paid by laboratories to referring physicians and physician group practices for **blood specimen collection, processing, and packaging**, and for submitting patient data to a registry or database.
  - When a lab pays a physician **more than FMV for the physician's services or for services the lab does not actually need or for which the physician is otherwise compensated**, the AKS is implicated.
  - Specimen processing arrangements: where lab pays physicians, either directory or indirectly, to collect, process, and package blood specimens. **Also covers urine specimen collection and provision of POC cups**.
  - Medicare reimburses physicians for processing and packaging specimens for transport to a clinical lab through a bundled payment (CPT 99000). CPT 99000 is intended to reflect the work involved to prepare a specimen prior to sending it to a laboratory.

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- **June 2014 Special Fraud Alert**
  - AKS implicated when lab pays a physician for services. Whether actual violation occurs depends on intent of parties (one purpose rule). This is true regardless of whether payment is FMV. The probability that payment is for illegitimate purpose is increased, however, if payment **exceeds FMV or if payment is for service which is paid by third party (e.g., Medicare).**
  - When determining FMV, clinical lab should consider whether services for which it may compensate the physician have been, or may be, paid for, including through a bundled payment, by Medicare.
  - Additionally, lab should consider whether payment is appropriate at all; if services for which lab intends to compensate physician are paid for by third party through other means (e.g., payments intended to reimburse physician for overhead expenses), any payment by lab to physician may constitute double payment for physician's services and be considered evidence of unlawful intent.

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- **June 2014 Special Fraud Alert**
  - Characteristics of specimen processing arrangement that may be evidence of unlawful intent under AKS:
    - Payment exceeds FMV
    - Payment is for services for which payment is also made by a 3rd party such as Medicare
    - Payment is made directly to ordering physician rather than group practice, which may bear cost of collecting & processing

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- **June 2014 Special Fraud Alert**
  - Characteristics of specimen processing arrangement that may be evidence of unlawful intent under AKS:
    - Payment is made on per-specimen basis for more than one specimen collected during a single patient encounter or on a per-test, per-patient, or other basis that takes into account volume/value of referrals
    - Payment is offered on condition that physician order either specified volume or type of tests or test panel, especially if panel includes duplicative tests or tests that are not reasonable and necessary
    - Payment is made to physician or physician group despite fact that specimen processing is actually being performed by a phlebotomist placed in physician's office by lab or third party

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- **June 2014 Special Fraud Alert**
  - OIG's concerns regarding specimen processing arrangements not abated when arrangements apply only to specimens collected from non-Federal healthcare program patients.
  - Arrangements that "carve out" FHP beneficiaries or business from otherwise questionable arrangements implicate AKS and may violate it by disguising remuneration for FHP business through the payment of amounts purportedly related to non-FHP business.
  - Because physicians typically wish to minimize the number of labs to which they refer, specimen collection arrangements that carve out FHP business may nevertheless be intended to influence referrals of FHP business.

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- **OIG Advisory Opinion 05-08**
  - OIG addresses lab's proposal to (1) provide physicians with blood drawing supplies at no charge to the physicians; and (2) pay the physicians a per-patient amount for the physicians' services in collecting the blood specimens.
  - OIG notes that Medicare reimburses for specimen collection but that the reimbursement is payable only to person/entity that actually extracted specimen.
  - Amount of remuneration being offered by lab up to double what Medicare pays.
  - OIG says that proposed arrangement would "clearly" implicate the AKS, and that there is a "substantial risk" that lab would be offering remuneration in exchange for referrals.

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- **OIG Advisory Opinion 05-08**
  - Under arrangement, physician could receive up to twice the amount that Medicare pays for blood specimen collection, plus any necessary blood-drawing supplies free of charge. This provides an "obvious" financial benefit to the referring physician.
  - "Where a laboratory pays a referring physician to perform blood draws, particularly where the amount paid is more than the laboratory receives in Medicare reimbursement, an inference arises that the compensation is paid as an inducement to the physician to refer patients to the laboratory."
  - Further, proposed arrangement would give physician opportunity to earn a fee otherwise earned by lab. This leads to risk of overutilization.

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- **OIG Advisory Opinion 05-08**
  - Any specimen collection claims submitted by lab to Medicare for blood draws performed by referring physicians would also implicate FCA and CMPL, because Medicare pays only the person/entity that actually extracted specimen from patient.
  - While under certain conditions physicians can bill Medicare directly for collecting blood specimens, if lab were to pay physician for such services, physician would be improperly "double dipping" if physician also billed Medicare.

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- **Note on "pass-through" or "account" billing**
  - Lab bills physician for services directly, and then physician bills third-party payors (typically at reimbursement rate higher than what physician paid lab).
  - Generally not permitted with Medicare b/c, except under very limited circumstances, Medicare reimburses only person/entity that actually performed the service.

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- **Note on "pass-through" or "account" billing**
  - **OIG Advisory Opinion 99-13:** Account billing arrangement with FHP carve-out (e.g., lab bills FHPs directly and account bills for commercial payors) could be problematic under AKS.
    - Both parties have "motives for agreeing to trade business: the physicians have the opportunity to make a larger profit on the non-FHP business, and the lab is able to secure profitable FHP business in a highly competitive market."
  - Follow-up letter from OIG (4/26/00):
    - Although concerns in AO 99-13 stand, it's not an automatic AKS violation, but merits very close scrutiny. There must be evidence to support linkage b/t discounts on commercial payor side and referral of non-discounted FHP business.
      - Is there substantial enough Medicare business referred to lab to infer connection?
      - Is discount large enough to infer connection?

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Building an Effective Compliance Program

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Building an Effective Compliance Program

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- OIG Compliance Program Guidance for Clinical Laboratories (August 1998)
  - Seven elements of an effective compliance program:
    - Implement written policies, procedures, and standards of conduct
    - Designate a compliance officer and compliance committee
    - Conduct effective training and education
    - Develop effective lines of communicate
    - Enforce standards through well-publicized disciplinary guidelines
    - Conduct internal monitoring and auditing
    - Respond promptly to detected offenses and develop corrective action

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Building an Effective Compliance Program

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- OIG Compliance Program Guidance for Clinical Laboratories (August 1998)
  - While physicians can order any tests they believe are appropriate, Medicare will only pay for those tests which are covered, reasonable, and necessary
  - Physicians are required to submit diagnostic information to laboratory when ordering many – although not all – lab tests
  - Emphasizes need for testes performed in accordance with standing orders to be reasonable and necessary
  - Clarifies that labs should not charge physicians a price below FMV for non-FHP tests in order to include their FHP business

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Questions?

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