Navigating Regulatory Challenges:

Recent Enforcement, Risk Mitigation, and FDA Developments for Clinical Laboratories

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Caitlin Forsyth: Partner, Davis Wright Tremaine LLP

Caitlin has more than a decade of experience working with clinical laboratories, leveraging her background in clinical research to provide in-depth advisory services. She specializes in:

- **Regulatory Compliance:** Advising on CLIA and state lab licensing requirements to ensure laboratories meet federal and state standards.
- **Healthcare Law Navigation:** Guiding clients through the complexities of the Physician Self-Referral Law (Stark Law) and the Anti-Kickback Statute to maintain compliance and mitigate legal risks.
- **Billing & Operational Compliance:** Providing strategic guidance on client billing and in-office phlebotomy to ensure adherence to state regulations and best practices.
- **Audit & Payment Disputes:** Assisting clients with medical record audits and overpayment demands from private payers, streamlining issue resolution and compliance efforts.

Darla Wanitschke: Vice President, Customer Success, TELCOR

Darla joined TELCOR in January 2010 and has held multiple roles across sales, implementation, and special projects. She also managed the Claim Resolution team for TELCOR Revenue Cycle Services, further strengthening her expertise in laboratory billing and reimbursement. Darla brings a strong leadership presence and a strategic mindset to revenue cycle management in the laboratory industry. Her expertise includes:

- **Revenue Cycle Optimization:** Driving efficiencies and innovation to enhance financial performance across a diverse range of laboratories.
- **Strategic Leadership:** Providing guidance and solutions that improve operational workflows and reimbursement outcomes.
- **Industry Experience:** Serving as a Senior Director of Revenue Cycle Management for two molecular diagnostic laboratories, demonstrating a deep understanding of laboratory billing complexities.
- **Cross-Functional Expertise:** Applying experience in sales, implementation, and special projects to deliver comprehensive RCM solutions.

Speakers

Caitlin Forsyth

Partner, Davis Wright Tremaine LLP

Darla Wanitschke

Vice President, Customer Success, TELCOR

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Agenda

- Regulatory Scrutiny of Business Arrangements
- Coverage and Reimbursement Challenges
- New Developments in FDA Regulation

Practices That May Be Scrutinized by Regulators

Provider Favors

Sales Compensation

Specimen Collection

Client Billing

Patient Costs

Pathology Arrangements

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EKRA

- No regulatory guidance or advisory opinions.
- A few published enforcement actions:
  - To convince drug-addicted individuals to travel to and enroll in rehabilitation when they otherwise would not have, recruiters offered to bribe them – often as much as several thousand dollars. Once the patients agreed to enroll in drug rehabilitation in exchange for the offered bribe, the marketers would arrange and pay for cross-country travel to the drug treatment centers. The marketers would stay in touch with the y patients at the facilities and specifically instruct them to stay at the facilities long enough to generate referral payments.
  - The office manager of a substance abuse treatment clinic solicited kickbacks from the CEO of a toxicology lab in exchange for urine drug test referrals.

https://www.justice.gov/usao-nj/pr/two-california-men-admit-roles-multi-state-recovery-home-patient-brokering-scheme

https://www.justice.gov/usao-edky/pr/jackson-woman-pleads-guilty-soliciting-kickbacks-making-false-statements-law

Sales Representative Compensation – AKS and EKRA

- AKS *bona fide* employee safe harbor protects compensation made to W-2 employees.
- AKS independent contractor safe harbor requires that compensation paid to 1099 not vary with volume or value of referrals.
- EKRA employee/independent contractor safe harbor protects compensation made to ***employees*** or ***independent contractors***, ***but only if*** such compensation is ***not determined by*** and ***does not vary by*** the ***number of individuals referred*** to the laboratory, the ***number of tests performed***, or the ***amount billed to or received from referrals***.
- In April 2023, a Texas laboratory agreed to pay at least $5.9 million to resolve False Claims Act allegations that it paid volume-based commissions to 1099 sales representatives. The False Claims Act allegation was premised on the theory that the lab's Medicare/Medicaid claims were "false" because they were the result of referrals stemming from violations of the AKS.

EKRA

- A few courts have interpreted the application of EKRA.
- In *S&G Labs Hawaii, LLC v. Graves* (2021), the U.S. District Court for the District of Hawaii ruled that EKRA did *not* prohibit a laboratory from paying commission-based compensation to a sales representative who marketed to physicians.
    - "Graves's commission-based compensation structure induced him to try to bring more business to S&G, either directly through the accounts he serviced himself, or through the accounts of the personnel under his management. However, the "client" accounts they serviced were not individuals whose samples were tested at S&G. Their "clients" were "the physicians, substance abuse counseling centers, or other organizations in need of having persons tested." … However, S&G was not compensated by those "clients"; S&G was "compensated for the testing services on a 'per test' basis by third party insurers, government agencies under the Medicare and Medicaid programs, and direct 'self-pay' by some individuals." There is no evidence that Graves's client accounts included individuals who self-paid for S&G to perform urinalysis on their samples. … Because Graves was not working with individuals, the compensation that S&G paid him was not paid to induce him to refer individuals to S&G." (*internal citations omitted*).

EKRA

- Conversely, in *U.S. v. Schena* (2022), the U.S. District Court for the Northern District of California held that EKRA's prohibitions extend to payments to marketers who target physicians for referrals.
  - "There is no requirement of "directness" in the text of EKRA. Rather, by its terms, it applies to situations where someone "pays or offers any remuneration," to "induce" an individual into using laboratory or clinical services.... Notably missing is any requirement of direct interaction between the marketer and the individual.... It is irrelevant that some of the marketers caused the referral of patients by [marketing] to physicians, instead of to the patients directly. The physicians referred the ... and the marketers received a kickback to "influence" the physician's referrals. This conduct squarely falls within the text of EKRA." (*internal citations omitted*).

Pass-Through Billing Arrangements

(Laboratory – Laboratory)

- When entering into these arrangements, keep in mind the following:
  - *Contract* – The laboratory's contract with the applicable health plan, if any, may prohibit the laboratory from submitting claims for testing the laboratory did not perform.
  - *Medicare's Direct Billing Requirement* – there is an exception permitting a referring laboratory to bill for tests performed by a reference laboratory if:
    - The referring laboratory is located in, or is part of, a rural hospital;
    - The referring laboratory is wholly owned by the entity performing such test, the referring laboratory wholly owns the entity performing such test, or both the referring laboratory and the entity performing such test are wholly-owned by a third entity; or
    - The referring laboratory does not refer more than 30 percent of the clinical laboratory tests for which it receives requests for testing during the year.

Importantly – this should be a true reference arrangement (i.e., the request for testing should have first been made to the referring laboratory).

Pass-Through Billing Arrangements

(Laboratory – Laboratory)

When entering into these arrangements, keep in mind the following: (*continued*)

- Many health plans prohibit
  - Blue Shield of California – "Effective March 26, 2018 Blue Shield of California prohibits pass-through billing as outlined in this policy. Any claim submitted by a provider which includes services that were performed by a person or entity other than the billing provider or a direct employee of that provider will not be reimbursed."
  - Anthem California – "Anthem Blue Cross does not allow pass-through billing for lab services. Claims appended with Modifier 90 and an office place of service will be denied unless provider, state, federal or CMS contracts and/or requirements indicate otherwise. Reimbursement will be made directly to the laboratory that performed the clinical diagnostic laboratory test based on 100% of the applicable fee schedule or contracted/negotiated rate."

Pass-Through Billing Arrangements

(Laboratory – Laboratory)

When entering into these arrangements, keep in mind the following: (*continued*)

- AKS/EKRA risks if one laboratory refers Medicare/Medicaid-reimbursable business to the other.
    - For example, if the purchasing laboratory pays more than FMV for the purchased tests to induce/reward the performing laboratory's referrals of Medicare/Medicaid-reimbursable tests to the purchasing laboratory.

Client Billing Arrangements

(Laboratory – Physician)

- Many health plans expressly prohibit a physician/clinic from billing for a lab test he/she/it did not perform.
  - United Healthcare – "Non-Reference Laboratory physicians or other [qualified health professionals] reporting laboratory services appended with modifier 90 are not eligible for reimbursement."
  - Regence – "Laboratory services billed with modifier 90 will only be reimbursable when billed by independent laboratories."
- Many states restrict or prohibit a physician's/clinic's purchase of tests from the performing laboratory.
  - New Jersey Statutes § 45:9-42.41.a – "A clinical laboratory shall present or cause to be presented a claim, bill or demand for payment for clinical laboratory services directly to the recipient of the services," with limited exceptions.
  - New York Public Health Law § 586 – "It shall be unlawful for any purveyor of clinical laboratory services, directly or indirectly, through any person, firm, corporation or association or its officers or agents, to bill or receive payment, reimbursement, compensation or fee from any person other than the recipient of the services, such recipient being the person upon whom the clinical services have been or will be rendered," with limited exceptions.

Client Billing Arrangements

(Laboratory – Physician)

- AKS risks
  - Unpaid invoices by clients who refer tests reimbursable by Medicare/Medicaid, or free/highly discounted tests for certain patients (swapping).
    - Failure to collect on invoices issued to clients for lab testing performed, or free/highly discounted tests for the referring provider's client-billed tests could be characterized as free/reduced tests to induce referrals of Medicare/Medicaid business .
    - OIG Advisory Opinion 15-04
      - "Under the Proposed Arrangement, the Requestor[laboratory] would enter into agreements with physician practices to provide all laboratory services required by the physician practices' patients, regardless of the patients' health plan coverage. If a physician whose practice has an agreement with the Requestor orders a laboratory test from the Requestor for an Exclusive Plan enrollee, the Requestor would not bill the patient, the physician practice, the Exclusive Plan, or any secondary insurer for the test. The Requestor would bill all other patients, whether privately insured or covered by a Federal health care program, in accordance with fee schedules or contracted rates."
      - "[T]he Proposed Arrangement would completely relieve patients and their Exclusive Plans of any obligation to pay in order to pull through all of the Federal health care program business, which would be charged at the full rate."

Purchased TC/PC Arrangements

- Inform Diagnostics agreed to pay $2.9 million to resolve potential False Claims Act liability in connection with anatomic pathology TC/PC purchased test arrangements (PTAs).
- Under Inform's PTAs, the referring provider (the customers) performed one component while referring the other component to Inform to perform.
- Inform billed commercial insurers for both components, reimbursing the customer at a set price.
- Customers with PTAs also referred other services to Inform, including services that Inform billed to Medicare and federal health care programs.
- The United States alleged that Inform's PTAs resulted in the submission of false claims for payment to federal health care programs because those claims were tainted by violations of the AKS.

https://www.justice.gov/usao-ma/pr/inform-diagnostics-agrees-pay-29-million-resolve-potential-false-claims-act-liability

Purchased TC/PC Arrangements

- **Key point** - Inform did *not* need the customers to perform the component of AP tests for commercial insurers; Inform agreed to purchase the component from the customers to secure the customer's referrals of Medicare/Medicaid-reimbursable tests to Inform.

- **Key takeaway** – Closely scrutinize the purpose for the TC/PC arrangement.
  - Is the lab purchasing the TC/PC because it truly cannot itself perform the TC/PC?
    - If yes, then likely okay.
    - If no (i.e., the lab can itself perform the TC/PC), and the lab is receiving referrals for Medicare/Medicaid business from the entity, the TC/PC arrangement presents risk under the AKS.

Paying for Specimen Collection

A laboratory's offering to pay referring providers for to collect and process specimens for sending to and testing by the lab present risk under the AKS, Stark Law (Physician Self-Referral Law) and EKRA.

OIG Advisory Opinion 22-09

- Laboratory proposed to enter arrangements with hospitals under which the laboratory would pay the hospitals on per-specimen basis to collect, process, and handle specimens that are then sent to the laboratory for testing.
- OIG determined that the arrangements would implicate the AKS because they would involve remuneration from a laboratory to a party that is in a position to make referrals to the laboratory.
- While there is an AKS safe harbor for personal services arrangements, the safe harbor requires that the compensation for the services performed not vary with the volume or value of referrals. Here, the laboratory would be paying a specimen collection fee for each specimen referred for testing.
- While the laboratory certified that the hospitals would be required to represent and warrant that none of their employed physicians, contracted physicians, and affiliated practices would be *required* to refer, or directed to refer, to the laboratory, the OIG concluded this not a sufficient safeguard.

https://oig.hhs.gov/documents/advisory-opinions/1031/AO-22-09.pdf

Paying for Specimen Collection

2015 OIG Special Fraud Alert

Laboratories' payments of specimen collection fees to referring providers/clinics may be evidence of an intent to induce/reward referrals when:

- Payment exceeds fair market value.
- Payment is for services for which payment is also made by a third party.
- Payment is made directly to the ordering physician rather than to the ordering physician's group practice, which may bear the cost of collecting and processing the specimen.
- Payment is made on a per-test, per-patient, or other basis that takes into account the volume or value of referrals.
- Payment is offered on the condition that the physician order either a specified volume or type of tests or test panel.
- Payment is made to the physician or the physician's group practice, despite the fact that the specimen processing is actually being performed by a phlebotomist placed in the physician's office by the laboratory or a third party.

Paying for Specimen Collection

- The risk is not merely theoretical
  - Recent enforcement activity
    - On March 6, 2025, physicians, physician practices and a South Carolina laboratory agreed to collectively pay over $1.9 million to settle allegations that the physicians and physician practices received thousands of dollars in specimen collection payments as remuneration to induce referrals to the laboratory.

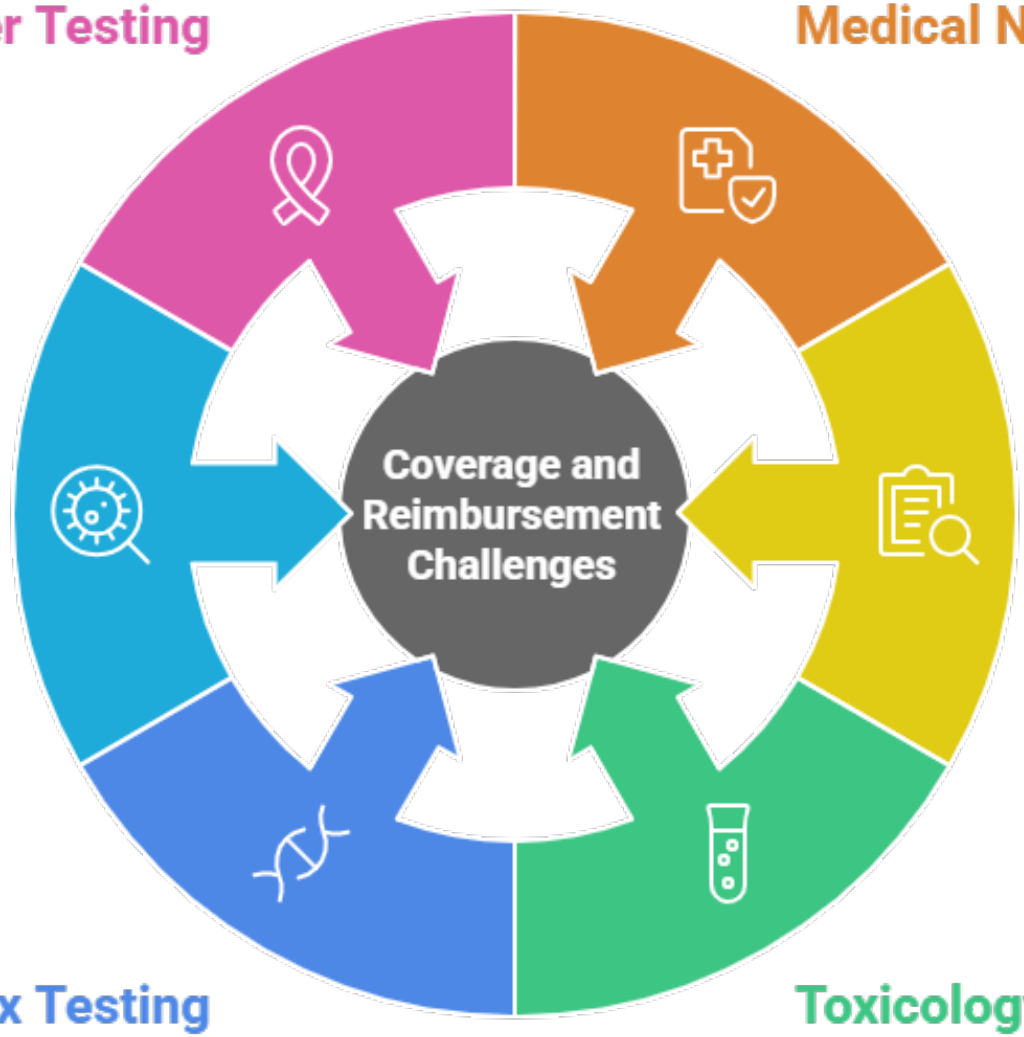
https://www.justice.gov/opa/pr/health-care-providers-and-laboratory-marketers-agree-pay-over-19-million-settle-kickback

- *Paying for specimen collection – should labs ever do it?*
  - Generally, not a great idea.
  - Any payment arrangements should not have any of the suspect characteristics outlined in the OIG Special Fraud Alert.
    - Importantly, payments should *not* be on a per-specimen basis.
    - Any flat rate payments should be closely monitored to ensure the payment is commensurate with services performed.

Other Favors for Referring Providers

- In July 2020, a clinical laboratory paid $900,000 to the federal government to settle allegations that it violated the False Claims Act for submitting claims to Medicare that were “tainted” by referrals in violation of the federal Physician Self-Referral Law (the Stark Law).
- Allegations included that a physician contacted the HR department of the laboratory to recommend a close friend of the physician’s family member for a position as an Account Manager. The laboratory did end up hiring the physician’s family friend as an Account Manager.
- The same physician contacted the laboratory again, this time seeking a position for his step-daughter upon her graduation from college. The step-daughter was considered but rejected for a position. However, about a year later, two laboratory employees arranged for the family friend to be promoted, thereby creating an opening for employment of the step-daughter.
- The physician ordered significantly more tests from the laboratory after both hirings.

Navigating Coverage and Reimbursement Complexities



Medical Necessity Policies/Policies of Limited Coverage

- Many Medicare Administrative Contractors (MACs) and commercial health plans have implemented policies of limited coverage for certain types of laboratory tests.
  - Medicare only pays for services that a reasonable and necessary for the diagnosis or treatment of an illness or injury.
  - MACs' Local Coverage Determinations (LCDs) set forth predetermined criteria for when a service (test) is reasonable and necessary.
- A laboratory's submission of claims for testing services that do not meet the requirements of the applicable payer's medical necessity policy may/will result in nonpayment of the claim at the time of claim processing or payment of the claim but later recoupment by the health plan following the plan's determination that the claim was not properly payable.

Medical Necessity and False Claims Under the FCA

- Failure to meet medical necessity standards established by Medicare Administrative Contractors (MACs) may also result in allegations by the DOJ that the claims to Medicare/Medicaid for such “medically unnecessary” services are “false claims” under the federal False Claims Act.
- *Recent enforcement actions*
  - A laboratory agreed to $4.425 million to resolve allegations that it violated the False Claims Act by causing physicians to order medically unnecessary UDT. Allegations included that the laboratory encouraged medical practices to order UDTs pursuant to blanket orders for all patients without an individualized determination of medical necessity.
    - Specifically, the laboratory created—and encouraged the practices to use—requisition forms that included a simultaneous order for both presumptive and definitive UDTs.

Medical Necessity and False Claims Under the FCA

- *Recent enforcement actions (cont.)*
  - In October 2024, a laboratory paid $27 million to resolve alleged violations of the False Claims Act.
  - The United States alleged that the laboratory "systematically billed federal health care programs for excessive and unnecessary urine drug testing," describing that the laboratory "caused physicians to order excessive numbers of urine drug tests, in part through the promotion of 'custom profiles,' which were, in effect, standing orders that caused physicians to order a large number of tests without an individualized assessment of each patient's needs."

Toxicology Testing

- MAC LCDs
  - Noridian LCD L36707
  - First Coast LCD L36393
  - Novitas LCD L35006
  - CGS LCD 36029
  - Common themes
    - No “blanket orders” – “identical order for all patients in a clinician’s practice without individualized decision making at every visit.”
    - Definitive testing to confirm positive and negative presumptive UDT results is permitted in certain circumstances.
    - Direct to definitive UDT is closely scrutinized.

Toxicology Testing

- Commercial health plan policies
  - **Cigna**
    - Definitive drug testing not to exceed one test per date of service using HCPCS code G0480 or G0659 is considered medically necessary when there is a suspicion of drug misuse by the individual being tested.
    - Definitive drug testing using HCPCS codes G0481, G0482, and G0483 is not covered or reimbursable.

https://static.cigna.com/assets/chcp/pdf/coveragePolicies/medical/mm_0513_coveragepositioncriteria_drug_test.pdf

Toxicology Testing

- Commercial health plan policies
  - **Aetna**
    - These drug tests are considered not medically necessary:
      - Standing or blanket orders of drug tests (i.e., routine orders that are not individualized to the member's history and clinical presentation); or
      - Simultaneous performance of presumptive and definitive tests for the same drugs or metabolites at the same time (Definitive testing should be guided by the results of presumptive testing)…
      - If definitive testing for substances of abuse are medically necessary, HCPCS G0480 (1 - 7 drug classes) or G0481 (8 - 14 drug classes) should be used.
      - Definitive tests G0482 (15 – 21 drug classes) and G0483 (22+ drug classes) are rarely medically necessary for routine testing in the outpatient setting.

https://www.aetna.com/cpb/medical/data/900_999/0965.html

Toxicology Testing –

Tips for Overcoming Coverage and Reimbursement Hurdles

- Become familiar with the laboratory's Medicare Administrative Contractor's coverage policy on UDT.
- Become familiar with the UDT coverage policies of the laboratory's frequently billed health plans.
- Educate (and re-educate) ordering providers on the payers' coverage policies.
- Audit incoming orders and have targeted educational discussions with providers who continue to request testing that will not be reimbursed under payers' coverage policies.

Toxicology Testing –

Tips for Overcoming Coverage and Reimbursement Hurdles

- Design test requisition forms/e-ordering platforms to require that physicians individually select requested definitive tests.
  - Permitting physicians to build and routinely use one-size-fits-all definitive testing panels will likely result in payer denials (and potentially False Claims Act allegations).
- Closely review requests for tests that will result in a claim for G0482 or G0483, as claims with these codes are the most obvious targets for payers.
- Some laboratories are considering downcoding but should carefully consider the various healthcare regulatory implications of doing so.

Toxicology Testing

Another Thing!

- Clinical laboratories performing toxicology testing for Opioid Treatment Programs (OTP) cannot separately bill Medicare for the testing services performed because the payment Medicare makes to OTP is a bundled payment intended to compensate the OTPs for the costs of toxicology testing services.
- Laboratories performing testing for OTPs must look to the OTPs, not Medicare, for reimbursement.
- A laboratory paid $1 million to resolve allegations that it billed Medicare for testing that should have been billed to the OTPs.
- Ensure all potential new clients are screened against the OTP list.
- Some Medicaid programs may also pay OTPs a bundled rate that includes toxicology testing services. A laboratory should closely review the provider regulations/manuals of the Medicaid programs it bills.

PGx Testing

- Medicare MolDX LCD
  - PGx testing is eligible for Medicare coverage **only if it has completed technical assessment and been assigned a Z-code.**
  - Medicare covers PGx testing only "when medications are being considered for use (or already being administered) that are medically necessary, appropriate, and approved for use in the patient's condition and are known to have a gene(s)- drug interaction that has been demonstrated to be clinically actionable as defined by the FDA (PGx information required for safe drug administration) or Clinical Pharmacogenetic Implementation Consortium (CPIC) guidelines (category A and B)."
  - Multi-gene panels
    - Medicare will cover/reimburse for multi-gene panels only "if more than one single gene on that panel would be considered reasonable and necessary for safe use of the medication in question or if multiple drugs are being considered (each fulfilling the criteria of actionable gene-drug interactions identified above) that have different relevant genes."
    - A multi-gene panel is not covered "if only a single gene on the panel is considered reasonable and necessary."

https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=38394&ver=9

PGx Testing

Commercial health plan policies on coverage of PGx testing:

- Aetna - https://www.aetna.com/cpb/medical/data/700_799/0715.html
- UHC - https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/pharmacogenetic-testing.pdf

  "The use of pharmacogenetic Multi-Gene Panels (five or more genes) for the evaluation of drug-metabolizer status is unproven and not medically necessary for any indication due to insufficient evidence of efficacy."
- Blue Shield of California - https://www.blueshieldca.com/content/dam/bsca/en/provider/docs/medical-policies/Genetic-Test-Pharmacogenetics.pdf
- Anthem Blue Cross (Carelon) - https://guidelines.carelonmedicalbenefitsmanagement.com/pharmacogenomic-testing-2024-10-20-updated-2025-04-01/

PGx Testing –

Tips for Overcoming Coverage and Reimbursement Hurdles

- Become familiar with and prepare application for MolDx technical assessment process.
  - The entire process may take many months to complete – factor this into business/cash flow planning.
- Become familiar with Medicare (MolDx) coverage guidelines and educate referring providers on the core standard that medications must be being considered for use (or already being administered) and such medications have known clinically actionable gene-drug interactions as defined by the FDA (PGx information required for safe drug administration) or Clinical Pharmacogenetic Implementation Consortium (CPIC) guidelines (category A and B).
- Become familiar with health plans' coverage policies (they might differ from MolDx guidelines) and educate referring providers regarding the same.

Infectious Disease Testing

- **Medicare MolDX LCD - Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing**
  - Urinary Tract Infection (UTI) Panels are covered only if the patient is symptomatic AND at higher risk for UTI complications (i.e., the elderly, patients with recurrent symptomatic UTIs and/or complicated urinary tract anatomy) AND/OR is seen in urogynecology or urology specialty care settings.
  - Medicare guidelines note there are currently no FDA cleared/approved indicated uses for UTI panels (and there are no covered predicate UTI tests), and, as such, **molecular UTI panel tests must submit for a Z-code and undergo a technical assessment.**

https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39044

Infectious Disease Testing

False Claims Act Enforcement

A laboratory (and three of its individual owners) paid $13.6 million to resolve allegations the laboratory billed Medicare for UTI panels that were not medically necessary.

- For its nursing home clients, the laboratory automatically performed a UTI panel anytime there was a positive urinalysis result, notwithstanding that the UTI panels were not ordered by the nursing home patients' treating providers.
- The laboratory's fee for urine cultures was $28.66 and for PCR tests was $417.52.
- The government noted - "One published study on the efficacy of PCR vs. urine culture found only that PCR is no less accurate than traditional urine culture."

https://www.justice.gov/archives/opa/pr/gamma-healthcare-and-three-its-owners-agree-pay-136-million-allegedly-billing-medicare-lab

Infectious Disease Testing –

Tips for Overcoming Coverage and Reimbursement Hurdles

- Only perform the tests requested by the ordering provider.
- Design test requisitions to require that the ordering provider individually select requested tests.
- While clinical information can be offered by laboratories to referring providers (e.g., information describing the utility of certain types of tests), laboratories should not otherwise attempt to influence the ordering practices of providers.

New Developments in FDA Regulation

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New Developments in FDA Regulation

- On May 6, 2024, the FDA issued a Final Rule to "make explicit that in vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) including when the manufacturer of the IVD is a laboratory." In conjunction with the Final Rule, FDA announced that it is "phasing out its general enforcement discretion approach for laboratory developed tests (LDTs) so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs." 89 Fed. Reg. 37286.
- Phaseout of LDT enforcement discretion in five stages:
  - Stage 1 – May 6, 2025 – LDTs must comply with medical device reporting (MDR) requirements, correction and removal reporting requirements, and quality system (QS) requirements regarding complaint files.
  - Stage 2 – May 6, 2026 – LDTs must comply with requirements not covered during other stages of the phaseout policy, including registration and listing requirements, labeling requirements, and investigational use requirements.

New Developments in FDA Regulation

- Phaseout of LDT enforcement discretion in five stages: (*continued*)
  - Stage 3 – May 6, 2027 – LDTs must comply with QS requirements (other than requirements regarding complaint files which are already addressed in Stage 1).
  - Stage 4 – November 6, 2027 – LDTs must comply with premarket review requirements for high-risk IVDs offered as LDTs (IVDs that may be classified into class III or that are subject to licensure under section 351 of the Public Health Service Act), unless a premarket submission has been received by the beginning of this stage.
  - Stage 5 - May 6, 2028 – LDTs must comply with premarket review requirements for moderate-risk and low-risk IVDs offered as LDTs (that require premarket submissions), unless a premarket submission has been received by the beginning of this stage in which case FDA intends to continue to exercise enforcement discretion for the pendency of its review.

New Developments in FDA Regulation

ACLA and AMP Lawsuit -

- Following FDA's issuance of its final rule on LDT regulation, the American Clinical Laboratory Association (ACLA) and the Association for Molecular Pathology (AMP) sued the FDA, arguing that laboratory developed testing services are services *not* medical devices, and therefore are not within the FDA's authority to regulate. ACLA and AMP sought to vacate the rule and prevent enforcement.
- ACLA and AMP explained to the court in briefings and oral argument that Congress created a separate statutory and regulatory framework to regulate laboratory testing services: the Clinical Laboratories Improvement Act of 1967, which was significantly expanded by the Clinical Laboratory Improvement Amendments of 1988 – "CLIA."
- According to ACLA and AMP, Congress's enactment and expansion of CLIA in 1967 and 1988 confirms that it did not understand the Medical Device Amendments in 1976 as authorizing FDA to regulate laboratory testing services as medical devices.
- The District Court for the Eastern District of Texas heard oral argument on February 19, 2025 in the consolidated lawsuits.

LDT Rule Vacated by District Court on March 31!!

- "The Court VACATES and SETS ASIDE, in its entirety, the FDA's Final Rule titled Medical Devices; Laboratory Developed Tests."

- The order to vacate the rule means that **the LDT Final Rule issued by FDA is not binding on laboratories**. That is, clinical laboratories with LDTs **do not** need to meet the staged compliance requirements set forth in the FDA's final LDT rule.

LDT Rule Vacated by District Court on March 31!!

Opening paragraphs of the District Court's order vacating the FDA's LDT rule:

> Laboratory-developed test ***services*** are in-house diagnostic tests developed, validated, and performed by trained professionals within a single clinical laboratory. They are performed on blood, urine, tissue, or other types of specimens at the request of an individual physician, in the context of a specific doctor-patient relationship. Treating doctors rely on such laboratory-developed test services for patient diagnosis, care, and treatment, ranging from routine tests such as pap smears and gram stains, to sophisticated molecular and genetic sequencing tests for cancer, heart disease, and rare and infectious diseases.
>
> ***For many years, laboratory-developed test services have been comprehensively regulated*** by both the States and by the Centers for Medicare and Medicaid Services ("CMS"). CMS administers the ***detailed requirements*** that Congress enacted in the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") that were ***specifically tailored to and targeted at clinical laboratories and their tests***. ***After decades of comprehensive CMS oversight***, the Food and Drug Administration ("FDA") issued a final rule on May 6, 2024, announcing its intent to treat all laboratory-developed test services as medical devices and to regulate them under the Federal Food, Drug, and Cosmetic Act ("FDCA").

(***emphasis added***).

But Don’t Celebrate Too Hard Just Yet!

- The Department of Health and Human Services might appeal the District Court’s order.
- Hard to say how the Trump Administration will want to proceed, but the layoff of 10,000 HHS workers (including FDA workers) is currently in progress.

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telcor@telcor.com

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