Robinson+Cole

2025 Legal Updates for Laboratories

NEW YORK STATE CLINICAL LAB ASSOCIATION

Danielle H. Tangorre, Esq.

9/10/2025

Of Note

We note that in this presentation we are only providing general information; the information contained in this presentation does not constitute legal advice. No attorney-client relationship has been created. If legal advice or other assistance is required, please contact us directly.

ANNUAL MEETING

NYSCLA

SEPTEMBER 9-10, 2025

THE NEW YORK STATE CLINICAL LABORATORY ASSOCIATION

Speaker Disclosures

Choose one

- [x] **I have no financial conflicts of interest to disclose**
- [ ] **I have the following to disclose**

Agenda

1) Renewal of DOJ FCA workgroup
2) EKRA Updates
3) 2025 Enforcement Actions
4) Audit Trends
5) Compliance
6) Recission of the FDA LDT Rule

Renewal of the DOJ FCA Workgroup

DOJ FCA Work Group

The U.S. Department of Health and Human Services (HHS) and the U.S. Department of Justice (DOJ) partner to use the False Claims Act (FCA) to combat healthcare fraud.

The group will be comprised of leadership from the HHS Office of General counsel, Centers for Medicare and Medicaid Services (CMS) Center for Program Integrity, the office of Counsel to the HHS Office of Inspector General (HHS-OIG), and DOJ's Civil Division with designees from U.S. Attorneys' offices.

https://www.justice.gov/opa/pr/doj-hhs-false-claims-act-working-group

DOJ FCA Work Group Cont.

The Working Group has established several priority enforcement areas including

- Medicare Advantage
- Drug, device and biologics pricing
  - This includes discount and rebate arrangements, service fees, formulary placement, and price reporting
- Barriers to patient access to care
- Drug, medical device, and durable medical equipment (DME) related kickbacks
- Medical device defects that impact patient safety
- Manipulation of Electronic Health Records (EHR)

The work group seeks to leverage HHS resources via enhanced data mining and analysis of HHS and HHS-OIG reports including the Health Care Fraud Data Fusion Center

The work group is encouraging whistleblowers to report FCA violations involving priority enforcement areas

https://www.justice.gov/opa/pr/doj-hhs-false-claims-act-working-group

EKRA Updates

Eliminating Kickbacks in Recovery Act (EKRA)

- EKRA penalizes anyone who "(1) solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility or laboratory; or (2) pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind… to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory..."

  18 U.S.C. § 220

First Appellate Court interpretation of EKRA

- Defendant operated, a medical testing laboratory that conducted allergy blood tests that could detect up to 120 allergens. Defendant hired marketers paid on revenue-based percentages to pitch the lab's test to physicians who lacked allergy experience despite knowing that the blood tests were a secondary measure rather than a primary one. In 2020 during the COVID-19 Pandemic the lab's testing volume decreased substantially so defendant began conducting COVID testing and marketed his blood test as superior to PCR tests and bundled the lab's allergy and COVID tests together. The lab would bill for the COVID test even if patients specifically requested only the COVID test.
- At issue in this case was:
  - Whether EKRA applies to payments made to marketing intermediaries rather than to referring physicians
  - If payments to marketing intermediaries are covered, what does it mean to "induce a referral" in the context of that specific payment relationship.

United States v. Schena, 142 F.4th 1217 (C.A.9 (Cal.), 2025

First Appellate Court interpretation of EKRA Cont.

The 9th Circuit decision is the first appellate court interpretation of EKRA and affirms that the statute applies to both traditional payors and private insurers

The Court held:

- "Under EKRA , there is no requirement that the payments be made to a person who interfaces directly with patients"
- "A percentage-based compensation structure for marketing agents, ***without more***, does not violate [EKRA]." However, "at a minimum, when percentage-based payments are made to marketing agents who are directed to ***mislead*** those making the referrals about the nature of and need for the covered medical services, those payments would violate EKRA"

Notably this decision clarifies the reach of EKRA to include third-party marketers who improperly influence patient referrals

United States v. Schena, 142 F.4th 1217 (C.A.9 (Cal.), 2025

Recent Laboratory Indictments

U.S. v. Kimberly Mable Sims, No. 4:25-CR-15-FL (E.D.N.C. Mar. 28, 2025) and U.S. v. Francine Sims Super, No. 4:25-CR-28 (E.D.N.C. Jun. 16, 2025)

- Both defendants worked for Life Touch, LLC (Life Touch) which contracted with Eastpointe Human Services (Eastpointe), a MCO, to provide substance abuse services to Medicaid Recipients. By 2018 Life Touch allegedly began providing gift cards to Medicaid recipients to incentivize them to receive substance abuse services. The value of the gift cards varied on each patient's weekly attendance for treatment.
- Kimberly Sims formerly employed by Life Touch established 1st Choice, a clinical laboratory, which billed NC-Medicaid almost exclusively for lab services provided to Life Touch patients. The government alleges that Sims falsely identified herself as the sole owner of 1st choice when Sims, Super and a third person were all equal partners in the lab and shared profits from 1st choice equally.
- Both Sims and Super have been charged with Conspiracy to pay or receive illegal kickbacks or remuneration in violation of 42 USC § 1320a-7b(b)(2)(B) and 18 USC § 220(a)(1) (EKRA) and failure to file a tax return in violation of 26 U.S.C § 2703
- All parties have plead guilty

2025 Takeaways from Updates and Enforcement Actions

Labs and Ordering Providers

- Labs need to understand their responsibility as the billing entity for medical necessity
- Collaborate with your ordering providers

Medicare and Medical Necessity

"…no payment may be made under part A or part B for any expenses incurred for items or services, which…are not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member…"

42 U.S.C. § 1395y(a)(1)(A)

Medicare: Medical Necessity and the Relationship to LCDs, NCDs

- National Coverage Determination (NCD)
- Local Coverage Determination (LCD)
- “Absent a regulation, [an NCD], or an LCD, the Medicare contractor proceeds on a case-by-case basis to determine whether a service is reasonable and necessary”

FCA and Medical Necessity

- Clinical Lab provides diagnostic testing focused on respiratory and gastrointestinal diseases. The relators allege that the lab was routinely billing for medically unnecessary service by "(1) bundling unnecessary laboratory tests with … medically necessary [tests]; (2) furnishing services and lab tests [beyond] the patient's needs . . .;(3) performing lab tests in excess of what was requested by the ordering [p]rovider; (4) billing for duplicative tests; and (5) using non-compliant [l]aboratory [r]equisition [f]orms to promote and market the medically unnecessary tests and panels."
- The court dismissed the relator's action because the relators had failed to (1) satisfy the "falsity element required for their FCA claims to proceed based on the medically unnecessary testing theory;" and (2) sufficiently plead their FCA claims based on the anti-kickback theory."
    - Since Relators failed to adequately plead an underlying FCA violation the conspiracy claim was also dismissed

https://law.justia.com/cases/federal/district-courts/new-jersey/njdce/3:2020cv15121/449640/54/

Medical Necessity

- Reference laboratory and its owners and officers entered into a settlement agreement to pay more than $1.2 million to resolve allegations that they submitted false and fraudulent claims for medically unnecessary urine drug tests. Lab accepted tests from sober homes for “residential monitoring” and submitted claims for “medically unnecessary duplicative urine drug testing”.
- “[Lab] routinely performed more expensive CBC with WBC differential tests when, in fact, medical providers had ordered less expensive CBC with no WBC differential tests and then billed federal healthcare programs for the more expensive and medically unnecessary tests.”

  https://www.justice.gov/archives/opa/pr/bioreference-health-and-opko-health-agree-pay-704349-settle-allegations-they-billed

Focus on top ordered tests

December 2024 | OEI-09-24-00350

Total Medicare Part B Spending on Lab Tests Decreased in 2023, Driven in Part by Less Spending on COVID-19 Tests

Top 25 Lab Tests by Medicare Part B Spending

	Test Description (Procedure Code)	2023 payment rate	2023 volume (millions)	Volume change from 2022	2023 spending (millions)
1	Blood test, comprehensive group of blood chemicals (80053)	$10.56	38.6	0%	$405.1
2	Blood test, lipids (cholesterol and triglycerides) (80061)	$13.39	25.3	-1% ↓	$332.3
3	Blood test, thyroid stimulating hormone (TSH) (84443)	$16.80	19.2	0%	$316.0
4	**Genetic test:** Gene analysis (colorectal cancer) (81528)	$508.87	0.6	13% ↑	$301.0
5	Detection test by nucleic acid for organism, amplified probe technique (87798)	$35.09	8.5	32% ↑	$292.4
6	Complete blood cell count (red cells, white blood cells, platelets), automated (85025)	$7.77	36.5	-1% ↓	$282.3
7	Vitamin D-3 level (82306)	$29.60	8.7	-2% ↓	$250.9
8	Hemoglobin A1C level (83036)	$9.71	18.4	0%	$176.0
9	**Genetic test:** Test for detecting genes associated with cancer (81455)	$2,919.60	0.05	59% ↑	$145.2
10	Drug test(s), definitive, 22 or more drug class(es) (G0483)	$246.92	0.6	-13% ↓	$145.1
11	Testing for presence of drug, by chemistry analyzers (80307)	$62.14	2.1	-8% ↓	$129.1
12	**COVID-19 test:** Infectious agent detection by nucleic acid (DNA or RNA); severe acute (U0003)	$75.00	1.6	-83% ↓	$115.0
13	Drug test(s), definitive, 15-21 drug class(es) (G0482)	$198.74	0.6	-9% ↓	$110.5
14	**Genetic test:** Gene analysis of 55-74 genes associated with solid organ cancer in cell-free (0242U)	$5,000.00	0.02	31% ↑	$104.8
15	**COVID-19 test:** Detection test by multiplex amplified probe technique for severe acute (87637)	$142.63	0.7	**New to top 25**	$103.6
16	Parathormone (parathyroid hormone) level (83970)	$41.28	2.6	1% ↑	$103.1
17	**Genetic test:** Test for detecting genes associated with breast cancer (81519)	$3,873.00	0.03	2% ↑	$94.7
18	Cyanocobalamin (vitamin B-12) level (82607)	$15.08	6.2	5% ↑	$91.9
19	**COVID-19 test:** Respiratory infectious agent detection by RNA for severe acute respiratory (0241U)	$142.63	0.6	-1% ↓	$79.9
20	Blood test, basic group of blood chemicals (calcium, total) (80048)	$8.46	9.3	-4% ↓	$79.4
21	Drug test(s), definitive, 1-7 drug class(es) (G0480)	$114.43	0.7	-4% ↓	$77.8
22	**COVID-19 test:** Amplified DNA or RNA probe detection of severe acute respiratory syndrome (87635)	$51.31	1.5	-17% ↓	$76.4
23	PSA (prostate specific antigen) measurement, total (84153)	$18.39	4.2	0%	$76.2
24	**Genetic test:** mRNA gene expression analysis of 22 genes in prostate tumor tissue (81542)	$3,873.00	0.02	**New to top 25**	$71.7
25	Drug test(s), definitive, 8-14 drug class(es) (G0481)	$156.59	0.5	**New to top 25**	$70.5
	Total Medicare Part B spending on the top 25 lab tests in 2023: $4.0 billion				

Sources: OIG analysis of 2022–2023 spending on lab tests in Medicare Part B, 2024. Payment rates are from the 2023 CLFS. *CPT copyright*

2025 Enforcement focus: genetic testing

- On April 23, 2025, DOJ **announced** a $6 million settlement with a laboratory, its parent company, and marketing firm, as well as two top executives. The government alleged the defendants engaged in a kickback scheme with several medical laboratories and telemedicine healthcare providers under which the labs billed Medicare for fraudulent genetic testing.
- On June 6, 2025, DOJ **announced** that it filed an FCA suit against AIMA Business and Medical Support LLC, a Florida medical billing and compliance services company, for allegedly filing claims to Medicare for more than $15 million in medically unnecessary genetic laboratory tests. The government stated that Selecta Laboratory paid AIMA to submit fraudulent claims to Medicare on its behalf and to advise Selecta on how to maximize profits and ensure its claims got paid

2025 National Health Care Fraud Takedown

PRESS RELEASE

National Health Care Fraud Takedown Results in 324 Defendants Charged in Connection with Over $14.6 Billion in Alleged Fraud

Monday, June 30, 2025

Share

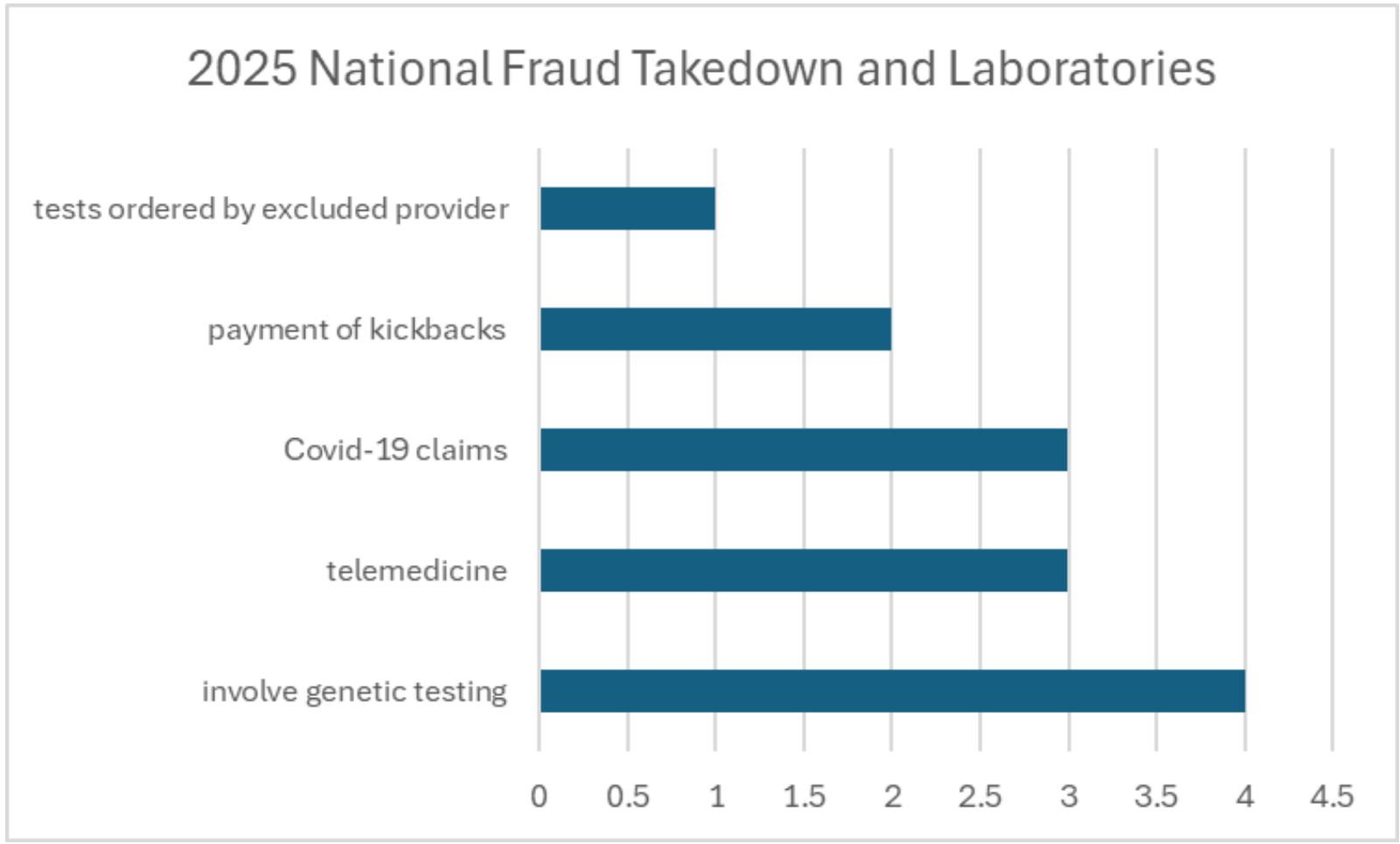
For Immediate Release

Office of Public Affairs

Largest Justice Department Health Care Fraud Takedown in History

More than Doubles Prior Record of $6 Billion

https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-324-defendants-charged-connection-over-146


2025 National Fraud Takedown and Laboratories
tests ordered by excluded provider
payment of kickbacks
Covid-19 claims
telemedicine
involve genetic testing
0
0.5
1
1.5
2
2.5
3
3.5
4
4.5

2025 Enforcement examples: Automatic/Standing Orders

- "The United States Alleges that… [Lab] created –and encourages practices to use- requisition forms that included a simultaneous order for both presumptive and definitive UDTs. [Lab] also employed and placed in-office urine collectors in the practices, and the collectors typically filled out the blanket orders before submitting them to [lab]. As a result, the practiced ordered medically unnecessary and non-covered UDTs from [lab], and [lab] knowingly submitted these claims to Medicare.

  https://www.justice.gov/usao-wdmi/pr/2025_0103_physicians_toxicology_laboratory_settlement

- The Government alleged that "[lab] knowingly submitted false claims for MammaPrint testing to [Federal Health Care Programs]. The United states contends that the MammaPrint claims were false because [lab] caused physicians and providers (referring providers) to order MammaPrint testing that was not reasonable or medically necessary through standing or automatic orders."

  https://www.justice.gov/usao-edtn/pr/agendia-inc-knoxville-comprehensive-breast-center-pllc-and-knoxville-0

2025 Enforcement examples: Kickbacks

"[Lab owner] implemented a scheme to pay marketers a percentage of Medicare reimbursements and incentivize them to obtain doctors' orders for expensive drug testing panels. [Owner] concealed [Lab's] payments to marketers by routing the payments through nominally independent marketing companies that [owner] secretly controlled. To maximize [the lab's] profits and their own commission payments [the lab's] marketers trained staff members at doctors' offices to send [the lab] orders for medically unnecessary urine drug tests that doctors did not actually want or authorize." The scheme cause federal health care programs to pay over $4 million to the lab.

https://www.justice.gov/opa/pr/lab-operator-convicted-4m-medicare-fraud-scheme

"[Doctor] admitted to allegations in the indictment, including that he worked for multiple 'telemedicine' companies and signed doctor orders or prescriptions for… cancer genetic tests based on only a brief conversation with a patient, or often no conversation at all. [Doctor] signed those orders… in exchange for illegal kickbacks and bribes."

https://www.justice.gov/usao-mdtn/pr/ashland-city-doctor-sentenced-3-years-conspiracy-commit-health-care-fraud

Preparing For and Responding to Audits; Trends to Know

Auditing Trends

- High cost or high-volume services
- Medical necessity
- Inaccurate or inconsistent coding
- Unusual billing patterns
- Testing specific

Why a Provider Might Be Audited?

- Sudden increase in volume
- Significant changes to testing menu/panels
- Adding a new service or service line
- Significant change in clientele
- Use of an uncommon code or modifier

Before the Audit: Be Proactive

Implement	Implement regular internal audits
Monitor	Monitor MACs' lists of services they may audit
Require and verify	Require and verify medical necessity documentation
Enhance	Enhance requisition form design
Review and stay	Review and stay atop of payor policies

How To Respond To an Audit

- Prepare requested documentation and supplemental documentation
- Review the documentation proposed to be submitted
- Communicate early and often – ask for extensions if necessary
- Consult legal counsel
- Prepare cover letter and be specific
- Audit yourself and look for trends – know your data!

Be Compliance Focused

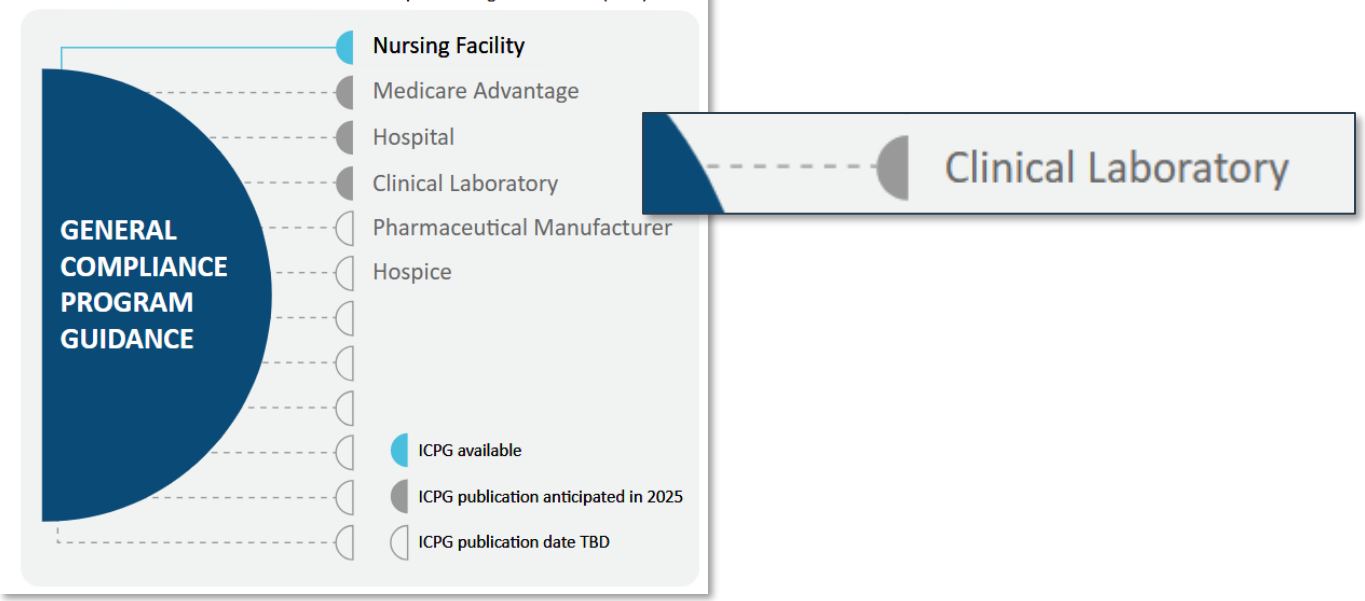
OIG General Compliance Program Guidance

Compliance Guidance

Below are OIG's existing CPGs and supplemental CPGs, available for use as an ongoing resource to help identify risk areas in particular industry segments as we develop new ICPGs. Existing CPGs will be archived but still available on our website when new ICPGs are issued.

The CPGs are listed below.

Industry Segment-Specific Compliance Program Guidance (ICPG)



Internal Auditing

- 6th Element of the voluntary compliance guidance – risk assessment, auditing and monitoring
- 1998 Guidance: Audit laboratory's compliance with laws governing kickbacks arrangements, physician self-referral prohibition, coding and billing, claim submission, medical necessity and marketing

2. Auditing and Monitoring

The Compliance Committee should include in the compliance work plan a schedule of audits to be conducted based on risks identified by the annual risk assessment. The Compliance Committee also should ensure that the compliance officer has the capacity to perform or oversee additional audits based on risks identified throughout the year, for example, as part of an investigation into an overpayment that uncovers a potential systemic issue. The audits may be conducted by internal or external auditors who have expertise in Federal and State health care statutes, regulations, and Federal health care program requirements.

Tip

Medicare requires, as a condition of payment, that items and services be medically reasonable and necessary. Therefore, entities should ensure that any claims reviews and audits include a review of the medical necessity of the item or service by an appropriately credentialed clinician. Entities that do not include clinical review of medical necessity in their claims audits may fail to identify important compliance concerns relating to medical necessity.

OIG Work Plans for Laboratories

Announced or Revised	Agency	Title	Component	Report Number(s)
October 2024	Centers for Medicare and Medicaid Services	Audit of Medicaid Reimbursement for Clinical Laboratory Services	Office of Audit Services	OAS-25-01-004
Completed	Centers for Medicare and Medicaid Services	Medicare Payments for Clinical Diagnostic Laboratory Tests in 2023	Office of Evaluation and Inspections	OEI-09-24-00350
Revised	Centers for Medicare and Medicaid Services	CMS's Emergency Preparedness Related to Clinical Laboratories During the COVID-19 Public Health Emergency	Office of Audit Services	WA-22-0010 (W-00-22-35889)
Revised	Centers for Medicare and Medicaid Services	Medicare Part B Add-On Payments for COVID-19 Tests	Office of Audit Services	W-00-22-35884
Completed	Centers for Disease Control and Prevention	Audit of CDC's COVID-19 Awards to Selected State Departments of Health	Office of Audit Services	W-00-22-59469; A-04-22-02035; A-04-22-02037
Completed (partial)	Centers for Disease Control and Prevention	Audit of the Centers for Disease Control and Prevention Grants to Recipients for COVID-19 Screening Testing at Schools	Office of Audit Services	W-00-22-59468; W-00-23-59468; A-05-22-00010; W-00-24-59468
Completed	Centers for Medicare and Medicaid Services	Audit of CMS Clinical Laboratory Fee Schedule Rate-Setting Process for Public Health Emergencies	Office of Audit Services	W-00-21-35875; W-00-22-35875
Completed	Centers for Medicare and Medicaid Services	Audits of Medicare Part B Laboratory Services During the COVID-19 Pandemic	Office of Audit Services	A-09-21-03004
Completed (partial)	Centers for Medicare & Medicaid Services	Audits of Selected Independent Clinical Laboratory Billing Requirements	Office of Audit Services	A-06-16-02002; A-09-16-02034; A-06-17-04002; A-04-18-08063; A-09-19-03027; A-06-20-04000; A-09-20-03027; A-09-21-03006; A-09-22-03010; W-00-17-35726; W-00-20-35726; W-00-22-35726; W-00-21-35726; W-00-21-35829; W-00-22-35829; WA-24-0023 (W-00-24-35726); various reviews
Completed	Centers for Medicare & Medicaid Services	Review of Medicare Part B Urine Drug Testing Services	Office of Audit Services	A-09-20-03017
Announced or Revised	Agency	Title	Component	Report Number(s)

Recission of the FDA LDT Rule

Recission of the FDA LDT Rule

The FDA Laboratory Developed Test (LDT) rule sought to regulate LDTs as in vitro diagnostic products (IVDs) and thus also as medical devices under the Food, Drug and Cosmetic Act (FDCA)

The U.S District Court for the Eastern District of Texas found that LDTs did not meet the definition of a medical device under the FDCA which was designed to regulate items moved in interstate commerce

The Court stated, “there is no likelihood the FDA can justify its decision on remand, given that the final rule exceeds its authority under the FDCA.”

The FDA declined to appeal and requested that the LDT rule be rescinded.

Presenters

Danielle Tangorre
Partner
E-mail: dtangorre@rc.com
Phone: 212-451-2964