Clinical Lab & Pathology Update: What Was New in 2022 (And Where Things Might Be in 2023)

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AMERICAN HEALTH LAW ASSOCIATION

Agenda

- Refresher on fundamental lab concepts
- Update on (some) lab policy changes during Public Health Emergency
- Clinical lab enforcement actions and initiatives
- Physician orders for lab tests
- EKRA Developments
- 14-Day Rule
- PAMA Updates
- Proficiency Testing
- Laboratory developed tests

Refresher on Fundamental Lab Concepts

Refresher on Fundamental Lab Concepts

- Key CLIA Concepts
  - Scope and applicability
  - Regulatory requirements depend on testing complexity
  - Obtaining CLIA certificate and enrolling in Medicare
- Key Medicare Coverage and Payment Principles
  - Clinical Lab Fee Schedule for clinical lab testing
  - Physician Fee Schedule for physician pathology testing
  - Rules on ordering diagnostic tests
  - Performing Lab generally required to bill for CLFS tests it performs, except:
    - Tests for hospital inpatients are bundled into DRG
    - Tests for hospital outpatients are bundled under OPPS, unless performed for hospital non-patients (CLFS)
    - Under Arrangements permitted (Anti-Markup Rule at 42 C.F.R. § 414.50 applicable to pathology but carves out clinical lab tests; *see also* 42 C.F.R. § 405.515 for physician-billed clinical lab tests)
    - Referring Lab & Reference Lab Rules
  - Technical component and professional component billing for physician pathology

Refresher on Fundamental Lab Concepts

- Key Medicare Coverage and Principles, continued
  - Who can see the results of clinical lab tests
  - Coverage of screening tests
  - Different categories of labs
    - Physician office lab v. independent lab v. hospital lab
  - National Coverage Determinations
    - NCD Manual, Pathology and Laboratory Ch. 190
  - Local Coverage Determinations
    - MAC specific, coverage for services within jurisdiction
  - Collection fees, travel fees and beneficiary cost sharing

Refresher on Fundamental Lab Concepts

- Medicaid
  - Consistencies / Inconsistencies with Medicare
- Commercial payors / state laws
  - Some states have laws requiring direct billing, some permit pass-through (but no markup) and some just require disclosures
  - Commercial payor approaches:
    - Prohibitions on pass-through billing
    - Lawsuits (e.g., Aetna v. People's Choice, BCBS of MS v. Issaquena Community Hospital)
    - Requiring hospital labs to be credentialed as reference labs
  - State laws on direct accessing testing

Refresher on Fundamental Lab Concepts

- Who regulates what in the laboratory world? Examples:
  - CMS /FDA/CDC = CLIA
  - State agencies / CLIA
  - Lab accreditation organizations
  - Proficiency testing organizations
  - State regulation

Physician Office vs. Independent Lab – Medicare Consequences

- Categorization of the laboratory as chosen for the Form 116 has consequences for Medicare enrollment and billing.
  - Physician office lab (POL) shares the Medicare enrollment of the physician practice (although the Form 855B must include the CLIA number. Claims are submitted by the physician group.
    - Defined in MCPM, Ch. 16, § 10.1 as "a laboratory maintained by a physician or group of physicians for performing diagnostic tests in connection with the physician practice."
      - CMS interprets this to limit services to patients of the practice..
      - POLs (and qualified hospital labs) are carved out of reference laboratory billing, per MCPM, Ch. 16, Sec. 50.1.
  - Independent Lab must get its own enrollment and own Medicare number.
    - Query Stark implications

Lab Policy Developments During PHE

Lab Policy Developments During PHE

- Examples of changes in CLIA requirements during Public Health Emergency:
  - Specimen collection
  - Physical location of labs / parking lots
  - Accelerated processing of CMS-116
  - Using a single CLIA certificate to cover multiple sites
  - Surveillance testing
  - Pathologists reviewing slides remotely
  - Delay in proficiency testing without penalty to lab / restrictions on patient testing
  - Accreditation organizations can conduct remote surveys
  - Exercise of enforcement discretion on various issues
  - CMS working to evaluate labs with CLIA certificates approaching expiration to address extensions
  - Additional CMPs

Laboratory Enforcement During COVID-19 (New Civil Monetary Penalties)

- Noncompliance with cash price reporting – CMP up to $300/day, 45 C.F.R. Part 182
- Laboratory failure to report test results
  - QSO 20-37-CLIA, NH
  - 42 C.F.R. §§ 493.1804 and 1834 amended
    - Applies to all laboratories, including those with certificates of waiver
  - 42 C.F.R. § 493.41 – during the PHE, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 must report the results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.
    - Condition level requirement (*See* 42 C.F.R. 493.2)
  - 42 C.F.R. § 493.1100 Facility Administration [for non-waived testing]
  - 42 C.F.R. § 493.1834(d)(2)(iii) – CMP = $1,000/day for first day of noncompliance and $500/day for each additional day of noncompliance

Example PHE Lab Policy Developments Pathology: Remote Reads

Enforcement Discretion

CMS Exercises Enforcement Discretion Regarding Remote Reads

CMS has exercised enforcement discretion to facilitate pathologists' ability to review pathology slides remotely without the need for a separate CLIA certificate for the remote location. Enforcement discretion is not contingent on PHE authority; CMS will continue to exercise enforcement discretion that allows pathologists to examine digital images and laboratory data at remote locations.

https://www.cms.gov/files/document/laboratories-cms-flexibilities-fight-covid-19.pdf (updated 2/24/2023); *See also*, QSO-22-13-CLIA (Feb. 28, 2022), https://www.cms.gov/files/document/qso-22-13-clia.pdf

Enforcement Discretion for Remote Reads (cont.)

- 42 C.F.R. § 493.1274(a) – CLIA regulations for cytology require that slide preparations must be evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.
- Per QSO-22-13-CLIA, labs utilizing testing sites for remote review and reporting may do so if certain requirements are met, including record retention, written procedure manual for all tests; equipment, supplies, reagents, and similar items are not permanently kept at a remote testing site; remote site complies with other applicable Federal laws, including HIPAA.
  - The guidance does not apply to pathologists who have already obtained CLIA certificates for their home or other sites.
  - The guidance includes a reminder as to how to file a formal complaint against a laboratory.

CLIAC: The Clinical Laboratory Improvement Advisory Committee

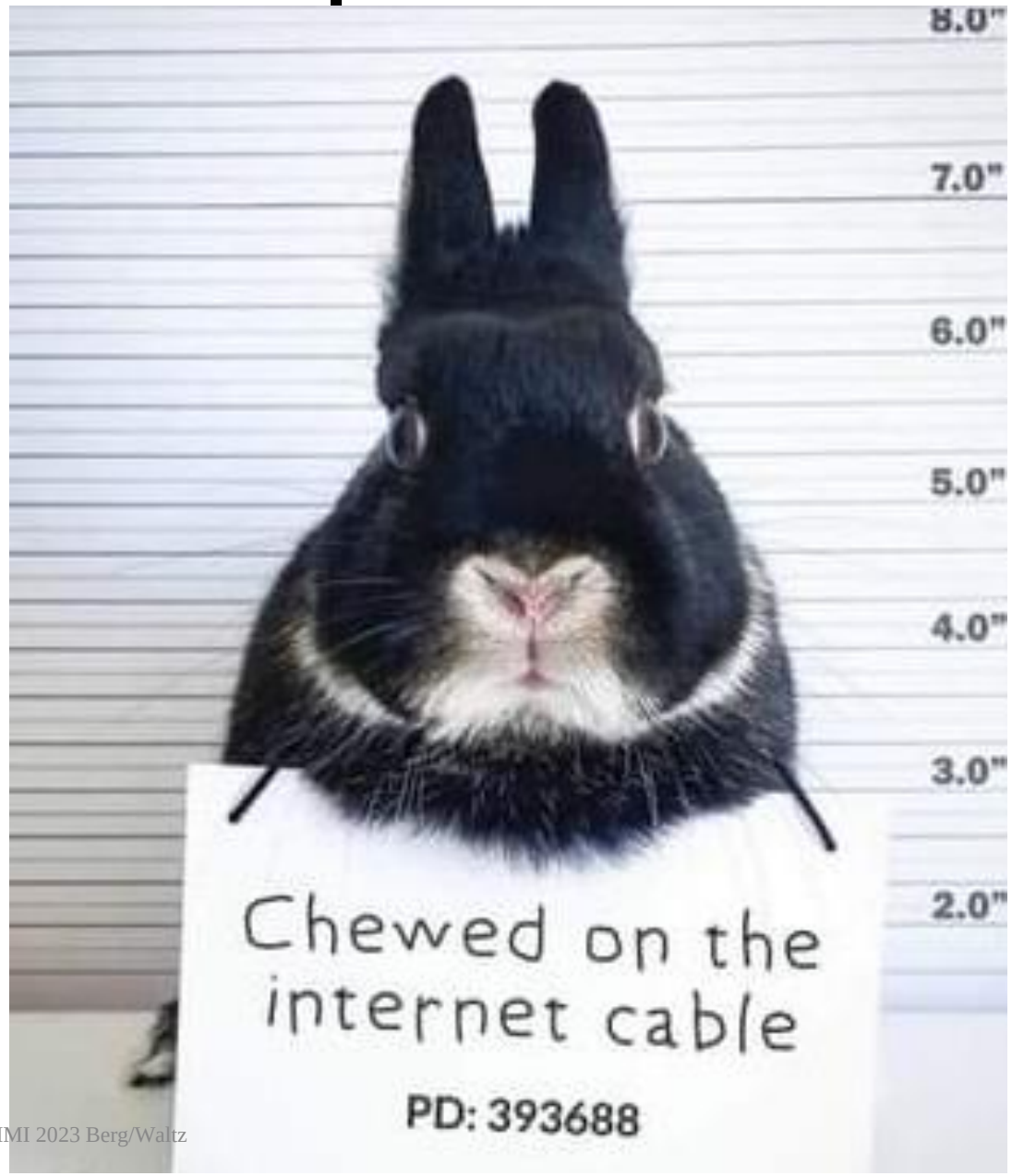
The Clinical Laboratory Improvement Advisory Committee (CLIAC), managed by the Centers for Disease Control and Prevention (CDC), provides scientific and technical advice and guidance to the Department of Health and Human Services (HHS). The Committee includes diverse membership across laboratory specialties, professional roles, (laboratory management, technical, physicians, nurses) and practice settings (academic, clinical, public health), and includes a consumer representative.

- Established by Section 222 of PHS Act (42 U.S.C. § 217a).
- The next meeting will be April 12-13, 2023. https://www.cdc.gov/cliac/upcoming-meeting.html
- Nov. 2022 Summary Report, https://www.cdc.gov/cliac/docs/november-2022/CLIAC_SUMMARY_NOV2022.pdf

Example: PHE Lab Policy Developments

- HRSA Covid-19 Uninsured Program
  - Reimbursement for labs performing tests on uninsured individuals
  - Providers must meet certain requirements (Terms & Conditions):
    - Checked for health care coverage eligibility and confirmed patient is uninsured;
    - Accept defined program reimbursement as payment in full;
    - Agrees not to balance bill patient;
    - Agrees to program terms and conditions and may be subject to post-reimbursement audit review.
  - Providers generally reimbursed at Medicare rates
  - Individuals enrolled in Medicaid's optional Covid-19 testing group not considered uninsured
  - HRSA uninsured program stopped accepting claims due to a lack of sufficient funding (March / April 2022)

Enforcement Update



JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Wednesday, July 20, 2022

Justice Department Charges Dozens for $1.2 Billion in Health Care Fraud

Nationwide Coordinated Law Enforcement Action to Combat Telemedicine, Clinical Laboratory, and Durable Medical Equipment Fraud

- Lab examples included:
  - Orders for CV and cancer genetic tests used to submit more than $174 million in false claims
  - Operator of clinical labs charged for involvement in scheme to pay over $16 million in kickbacks to marketers who paid kickbacks to telehealth companies and call centers in exchange for orders from physicians

Covid-19 Lab Enforcement: OIG Report

- Dec. 2022 OIG Report, *Labs with Questionably High Billing for Additional Tests Alongside COVID-19 Tests Warrant Further Scrutiny*
- Key Takeaway:
  - Certain labs billed Medicare Part B for questionably high levels of add-on tests alongside COVID-19 tests in 2020. This significantly increased the payments they received for claims that included COVID-19 tests. Such high levels of billing for add-on tests raise concern about potential waste or fraud, suggesting a need for further scrutiny of billing by these labs

OIG Report: Questionable Billing & Covid-19

- Examples of OIG's findings:
  - 378 labs billed Part B for add-on tests at questionably high levels as compared to other 19,199 labs that performed Covid-19 testing
  - Includes 276 labs that billed for high volumes of add-on tests on claims for Covid-19 tests and 263 labs that billed for high payment amounts from add-on tests on claims for Covid-19 tests
  - 161 labs had claims that suggest both of these questionable billing patterns
  - Medicare paid $67 million to the 378 labs (over 11 months in 2020)
  - 378 labs paid on average $227 per claim (compared to $89 per claim to other labs). One lab paid average of $1,000 per claim.
  - Report provides 5 separate "Outlier Lab Profiles" that illustrate OIG's findings

OIG Report: Questionable Billing & Covid-19

Outlier Lab Profile #1

Lab Billed Medicare Part B for Add-On Tests With Almost All of Its COVID-19 Tests

97%
of its claims for COVID-19 tests included add-on tests

5 IRT
add-on test codes were billed together on 65 percent of claims for COVID-19 tests

85%
of Medicare payments for COVID-19 claims were for add-on tests

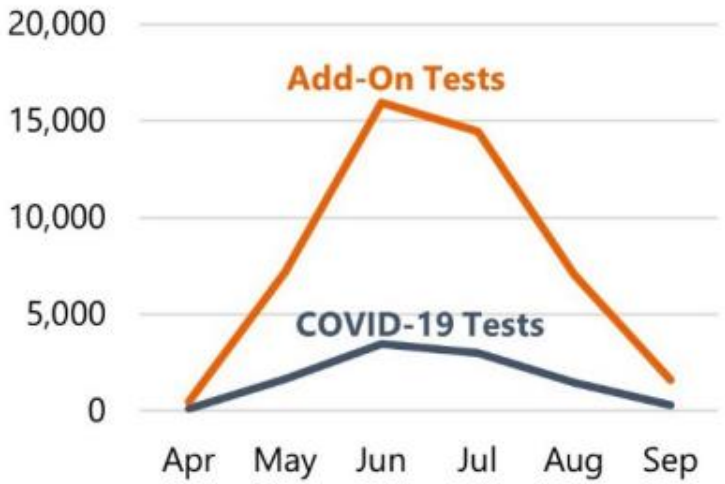
$5.6M
was paid in total by Medicare for add-on tests

Medicare paid 7X more
for COVID-19 claims with add-ons than for COVID-19-only claims

Average Payment Per Claim

$666	$96
COVID-19 + Add-On Test	COVID-19 Test Only

This lab often billed for multiple **add-on tests** with **COVID-19 tests** between April and September 2020, peaking in June 2020.



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Covid-19 Related Lab Enforcement Actions

- Jan. 2022: Florida lab owner pled guilty and paid $6.9 million after allegedly paying kickbacks and bribes (to brokers and referring providers) for orders of medically unnecessary lab tests, which he then billed to government programs. Covid-19 tests were also bundled with other unnecessary testing including genetic tests and rare respiratory pathogens.
- May 2021, an Arkansas lab owner was charged with 16 courts of fraud for defrauding federal health care programs of $88 million, including over $42 million in claims for tests related to Covid-19.
  - Tests were allegedly billed without orders, without being performed, involving patients who were deceased or who had not provided specimens.
- Dec. 2022, two individuals indicted in Texas for healthcare fraud related to Covid-19 testing. Allegedly received more than $7 million from fraudulent testing billed to BCBSTX, Cigna, United Healthcare, Aetna, Humans and Molina Health Care

False Claims Act, Stark Law & Anti-kickback Statute

- Nov. 2022, Modernizing Medicine (EHR vendor) agreed to pay $45 million to resolve FCA allegations related to payment of kickbacks for referrals and causing users to report inaccurate information in connection with incentive payments. Allegedly:
  - Received kickbacks from Miraca Life Sciences in exchange for recommending EHR users to utilize Miraca for lab and pathology services
  - Parties conspired to donate EHR to providers
  - Paid kickbacks to providers, others to recommend EHR and refer customers to Modernizing Medicine
  - Software failed to meet meaningful use standards
- Whistleblower received $9 million

False Claims Act, Stark Law & Anti-kickback Statute

- Oct. 2022, Sutter Health agreed to pay $13 million to resolve allegations of FCA violations due to toxicology screening tests performed by outside labs.
  - Complaint based on arrangement between a Sutter hospital and Navigant Network Alliance. Navigant allegedly referred urine toxicology specimens obtained from physicians / labs across the country to Sutter
  - Sutter allegedly billed for testing of specimens, even though tests were done by outside labs
- Jul. 2022, BioReference Health paid $9.85 million to resolve FCA allegations related to above-market rental rates to physician landlords for office space. Allegations:
  - Done to induce clinical lab referrals and that lease arrangements violated Stark Law and AKS.
  - Space rented from physicians as “patient service centers” where blood draws occurred. Space included disproportionate share of common area space.
  - Internal audits showed payments to lessors exceeded FMV

False Claims Act, Stark Law & Anti-kickback Statute

- Jul. 2022, Metric Lab Services, Spectrum Diagnostic Labs and owners agreed to pay $5.7 million to settle allegations of false claims related to genetic testing. Allegations:
  - Marketers paid kickbacks to solicit genetic testing samples from Medicare beneficiaries. Paid physician to fraudulently attest that genetic testing was medically necessary, labs would perform and bill tests and pay portion of reimbursement back to marketers.
  - Attempted to disguise arrangement through use of sham agreements with marketers for consulting and other services (paid at hourly rate). Marketers would generate sham invoices with bill for hourly services that matched agreed-upon kickback amount.
- Jun. 2022, DOJ settled FCA case with 15 physicians based on Stark Law and AKS violations. Collectively paid $2.83 million. Allegations:
  - Parties used sham MSOs to pay “investment returns” that in reality were payments for referrals
  - Volume-based commissions to referring physicians and efforts to steer lab testing to CAH to take advantage of higher reimbursement

False Claims Act, Stark Law & Anti-kickback Statute

- *U.S. v. Cockrell Dermatopathology* (N.D. Tex., Oct. 20, 2021)
  - Federal court denied motion to dismiss for "reverse" False Claims Act against clinical lab related to failure to return "overpayments" under 60-day rule. Claims were billed to TRICARE.
  - Overpayments allegedly arose from marketing "scheme" involving genomics lab that used network of marketers, who received commission-based compensation for arranging referrals to the clinical lab.
  - Clinic settled with DOJ in Aug. 2022, paying $3.75 million to resolve FCA allegations
- *U.S. v. Patel* (S.D. Fla., Jun. 22, 2021)
  - Lab owner indicted for allegedly paying kickbacks to Medicare beneficiaries to induce beneficiaries to undergo cancer genomic screening tests. Also allegedly paid recruiters for referrals under sham marketing arrangements as well as to telehealth providers who ordered tests even though not treating patients at issue.
  - In Dec. 2022, convicted of various counts of health care fraud for involvement in $463 million in claims billed to Medicare

Other Interesting Health Care Fraud Cases

- Mar. 2022: $4.8 million March settlement resolved allegations that a Connecticut lab violated the state most favored nation prohibition. Redwood Toxicology Laboratory allegedly sought payment from Medicaid for services at a price higher than the lowest price the lab charged for the same or similar services from other third parties. The lab allegedly accepted payments for urine drug screens at the rate of $38 per test for Medicaid, while charging other payors from $2 to $10.50 for the same or substantially similar tests.
- Reminder of the scope of FCA: case originating in Florida involving the owner of a lab whose CLIA certificate lapsed following the purchase of another practice with its own CLIA certificate (*Yates v. Pinelias Hematology & Oncology, P.A.)*
  - Acquired practice continued to run labs after expiration of CLIA certificate.
  - Relator (practice's billing manager) brought a qui tam case based on theory acquired lab billed Medicare for tests with no CLIA certificate in place.
  - $755.54 in actual damages (based on claims billed to Medicare). DOJ declined intervention.
  - The trial jury found 214 knowing violations of the FCA, resulting in treble damages of $2,266.62. However, the trial court imposed statutory penalties of $5,500 for each violation.
  - $1.177 million damages ($5,500 for each of 214 claims filed).
  - 11th Circuit Court of Appeals held that FCA penalties / damages are subject to the U.S. Constitution' Eighth Amendment's prohibition on excessive fines, but that the award as described above did not violate the excessive fines clause

OIG Advisory Opinion 22-09

- Reviews extent to which labs are permitted to compensate, or otherwise support, sources of referrals for specimen collection
- Requestor would pay hospitals (on per-patient, per-encounter basis) to collect, process and handle specimens that are sent to network labs for testing
- Hospital phlebotomists would collect specimens. Payment only available for individuals who require testing and who are not hospital inpatients / outpatients. If testing order did not select the performing lab, hospital could choose.
- OIG concluded AKS risks present:
  - Per-patient fee gave hospital incentive to select requestor's lab
  - Even if per patient fee is FMV, AKS "prohibits the knowing and willful payment [by a clinical laboratory for services] if even one purpose of the payment is to induce or reward referrals of Federal health care program business. This is true regardless of whether the payment is fair market value for services rendered."
  - Proposed safeguards not effective to reduce risks

Physician Orders for Lab Tests

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CLIA Requirements for Orders for Tests

For non-waived tests (per 42 C.F.R. § 493.1240), CLIA regs require that "the laboratory must have a written or electronic request from an **authorized person**." 42 C.F.R. § 493.1241(a) (emphasis added).

- Specific requirements for oral requests.
- Specific requirements for what the test requisition must include, e.g., date and time of specimen collection.
- Regulation provides that the patient chart or medical record may be used as the test requisition or authorization, but must be available to the laboratory at the time of testing and available to CMS upon request.

"Authorized person" means an individual authorized under State law to order tests or receive test results, or both. 42 C.F.R. § 493.2.

Medicare Requirements for Orders for Tests – 42 C.F.R. § 410.32

(a) *Ordering diagnostic tests.* Except as otherwise provided in this section, all diagnostic x-ray tests, **diagnostic laboratory tests,** and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary (see § 411.15(k)(1) of this chapter). [emphasis added]

Physician must maintain documentation relating to orders, certifications, referrals, and prescribes Part A or B services, items or drugs per 42 C.F.R. § 424.516, and provide access at request of CMS/MAC, potentially enforced as discretionary grounds for billing privileges revocation per 42 C.F.R. § 424.535(a)(10).

Recent Cases Involving Alleged Physician Order Inadequacies

Grand Jury Charges Eight People In Spring Hill-Based Crestar Labs, LLC Medicare & Medicaid Fraud Conspiracy (Aug. 5, 2022) (https://www.justice.gov/usao-mdtn/pr/grand-jury-charges-eight-people-spring-hill-based-crestar-labs-llc-medicare-Medicaid

- Marketers, who were not health care professionals, obtained swabs from the mouths of the patients at nursing homes, senior health fairs, and elsewhere. The tests were then purportedly approved by telemedicine doctors who did not engage in the treatment of the patients, and often did not even speak with the patients for whom they ordered tests. Frequently, the patients or their treating physicians never received the results of the tests.
- An indictment is merely an accusation. The defendants are presumed innocent until proven guilty in a court of law.

Recent Cases Involving Alleged Physician Order Deficiencies (cont.)

Renton Doctor Pleads Guilty to Conspiring to Accept Kickbacks in Connection with Fraudulent Genetic Testing Scheme (Sept. 28, 2022), https://www.justice.gov/usao-edwa/pr/renton-doctor-pleads-guilty-conspiring-accept-kickbacks-connection-fraudulent-genetic

- Medicare generally provides coverage for diagnostic laboratory testing only if the test is ordered by a physician who is treating the beneficiary for a specific medical problem, and uses the test results to treat the patient for that specific problem. According to the Plea Agreement and information disclosed in court proceedings, Dr. Bjarke engaged in a conspiracy and scheme through which he placed orders for Medicare for genetic testing for Medicare beneficiaries in the Eastern District of Washington and elsewhere that he was not treating and with whom he had no physician-patient relationship. According to the Plea Agreement and other court documents, Dr. Bjarke's sole contact with these patients was when he was connected with the beneficiaries for a telephone call for a few minutes through telemarketers. After Dr. Bjarke had ordered the tests, the laboratories then billed Medicare for the test, while another company billed Medicare for a purported "telemedicine" visit, sometimes for as much as tens of thousands of dollars.

Recent Cases Involving Alleged Physician Order Inadequacies (cont.)

Polk County Doctor Pleads Guilty To Receiving Kickbacks (Nov. 18, 2022), https://www.justice.gov/usao-mdfl/pr/polk-county-doctor-pleads-guilty-receiving-kickbacks

According to court documents, O'Rourke, a licensed medical doctor, entered into an illegal agreement in 2018 with Company #1 in which Company #1 would make available to O'Rourke completed doctors' orders for Medicare and CHAMPVA patient-beneficiaries via an internet-based platform. O'Rourke would then access the platform, open the completed orders, and electronically sign the orders, in exchange for a payment of $25 per patient-beneficiary. Notably, the system platform did not permit O'Rourke to add or modify any information in the already completed orders other than to input his authorizing electronic signature.

As just one example, in or around May 2019, O'Rourke received a payment of $5,500 from an entity associated with Company #1 for electronically signing and ordering cancer genomic tests and durable medical equipment for multiple Medicare beneficiaries. O'Rourke had no interaction with any of the Medicare beneficiaries prior to ordering the tests and equipment.

Recent Cases Involving Physician Orders (cont.)

Doctor Pays $720,000 and Agrees to 15 Year Exclusion from Federal Health Care Program (Oct. 20, 2022), https://www.justice.gov/usao-wdky/pr/doctor-pays-720000-and-agrees-15-year-exclusion-federal-health-care-programs-violating

- "The United States further alleged that Dr. Kanvinde had no physician-patient relationship with the Medicare beneficiaries, often did not speak with the beneficiaries, and knew his prescribed goods and services were not medically necessary."
- Exclusion under the (b)(7) authority (frauds, kickbacks, etc.)

EKRA Developments

Overview of Eliminating Kickbacks in Recovery Act (EKRA)

- Part of 2018 SUPPORT Act
- Fines of up to $200,000 and 10 years imprisonment for “whoever, with respect to services covered by a health benefit program … knowingly and willfully (1) solicits or receives any remuneration … for referring a patient to a … laboratory; or (2) pays or offers any remuneration … to induce a referral … to a laboratory; or in exchange for an individual using the services of that … laboratory”
- Remuneration includes any kickback, bribe or rebate
- Prohibition applies to all CLIA-regulated labs (not just those involved in substance use disorder testing)
- EKRA definition of “health benefit program” broader than “Federal health care programs” to which Anti-kickback Statute applies

Overview of EKRA

- EKRA exceptions (statutory) narrower for labs than Anti-kickback Statute safe harbors (regulatory)
- Eight exceptions, including:
  - Properly disclosed discounts
  - Qualifying employment / independent contractor arrangements
  - Drug manufacturer discounts (Part D)
  - AKS personal services arrangements
  - Limited coinsurance / copayment waivers
  - Qualifying FQHC remuneration
  - Remuneration under alternate payment models
  - As permitted by HHS via regulation
- To date, no regulations or sub-regulatory guidance on EKRA

EKRA Exception for Employment / Independent Contractors

- Exception for payments to employees / independent contractors, if payment not determined by or does not vary by:
  - Number of individuals referred to a … laboratory
  - Number of tests or procedures performed
  - Amount billed to or received from (whole or part) the health care benefit program from individuals referred to a … laboratory
- Unlike AKS, employees and contractors are treated the same
- Has been focus of several enforcement actions because of proliferation of commission-based compensation

EKRA Update

- Extent to which EKRA will be enforced against clinical labs generally (as opposed to labs engaged in substance use disorder testing) remains unclear
- Growing number of enforcement actions under EKRA
- One trend in cases is focus on blatant patient-brokering schemes in addiction treatment and recovery
- Nov. 2021, a federal jury convicted the operators of several addiction treatment facilities in Florida for a scheme in which patient brokers paid patients and offered them illegal drugs in order to increase admissions to treatment facilities
  - $112 million in medically unnecessary urine / blood drug tests

EKRA: Focus on Marketing Payments

- Oct. 2021, Hawaii federal court issued the first opinion interpreting prohibition on commissions for employees and contractors of clinical laboratories.
  - *S&G Labs Haw. LLC v. Graves*
- Lab (urinalysis for controlled substances and Covid-19 testing) ceased compensating an employee via commission
  - Paid commissions for introducing lab to physicians, counseling centers, employers, and other entities who referred patients,
  - Shifted to flat fee structure.
- Suit alleged new structure was inappropriate; EKRA does not apply to employment contracts with no direct patient involvement
- Court agreed, held that because the employee did not have contact with any individuals who had specimens tested, the incentive payments did not violate EKRA
  - Drew a distinction between compensation structures based on the recruitment of specific individual patients, versus organizations.

EKRA: Focus on Marketing Payments

- *U.S. v. Schena* (May 2022)
- Variety of alleged issues, including Covid-19 testing fraud, medically unnecessary tests, securities charges and payments to marketers in violation of EKRA
- Payments made to marketing companies for blood samples collected from patients and testing orders from physicians
- Issue: whether EKRA requires marketers to work directly with patients
- Defendant argued that EKRA does not apply where marketers obtain referrals from physicians and not directly from patients
- Court rejected this view, finding EKRA applies to situations where marketer secures referrals through physicians. No requirement for direct interaction with patients.

14-Day Rule
Exception to Medicare's Laboratory "Date of Service" Rule

Laboratory Date of Service Exception (14-Day Rule)

See discussion,https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy; 42 C.F.R. § 414.510(b)

- In general, the date of service (DOS) for clinical diagnostic laboratory tests is the **date of specimen collection** unless the physician orders the test at least 14 days following the patient's discharge from the hospital. When the "14-day rule" applies, the DOS is the **date the test is performed**, instead of the date of specimen collection.
- Applies to both in-patient and out-patient services, with somewhat different parameters.

Laboratory Date of Service Exception (14-Day Rule) (cont.)

Inpatient DOS – 42 C.F.R. § 414.510(b)(2)

In the case of a test performed on a stored specimen, if a specimen was stored for - (i) Less than or equal to 30 calendar days from the date it was collected, the date of service of the test must be the date the test was performed only if - (**A) The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;** (B) The specimen was collected while the patient was undergoing a hospital surgical procedure; (C) It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted; (D) The results of the test do not guide treatment provided during the hospital stay; and (E) The test was reasonable and medically necessary for the treatment of an illness. (ii) More than 30 calendar days before testing, the specimen is considered to have been archived and the date of service of the test must be the date the specimen was obtained from storage.

Laboratory Date of Service Exception (14-Day Rule) (cont.)

Outpatient DOS – 42 C.F.R. § 414.510(b)(5)

In the case of a molecular pathology test performed by a laboratory other than a blood bank or center, a test designated by CMS as an ADLT under paragraph (1) of the definition of an advanced diagnostic laboratory test in § 414.502, a test that is a cancer-related protein-based Multianalyte Assays with Algorithmic Analyses, or the test described by CPT code 81490, **the date of service of the test must be the date the test was performed only if -** (i) The test was performed following a hospital outpatient's discharge from the hospital outpatient department; (ii) The specimen was collected from a hospital outpatient during an encounter (as both are defined in § 410.2 of this chapter); (iii) It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter; (iv) The results of the test do not guide treatment provided during the hospital outpatient encounter; and (v) The test was reasonable and medically necessary for the treatment of an illness.

Laboratory Date of Service Exception (14-Day Rule) (cont.)

DOJ Enforcement - *Caris Life Sciences Pays over $2.8 Million to Settle False Claims Act Allegations from Delay in Submission of Genetic Cancer Screening Tests,* https://www.justice.gov/usao-edny/pr/caris-life-sciences-pays-over-28-million-settle-false-claims-act-allegations-delay (June 1, 2022)

- Note that regulation has been revised since time period involved for outpatient tests.
- Settlement with no admission of liability.
- Services billed by the laboratory and not the hospital.

PAMA: How Did Things Get So Complex?

Clinical Laboratory Fee Schedule (CLFS) (Pre-PAMA)

- The CLFS applies to all clinical laboratory testing payable under Medicare Part B for non-hospital patients
- Prior to PAMA, the CLFS used payment rates based on lab charges from 1984-1985
- Previous approach resulted in 57 separate local fee schedules
- New tests are priced using “crosswalking” or “gapfilling”
- Through December 31, 2017, tests under the CLFS have been paid at the lesser of (1) the billed amount, (2) the local fee schedule amount established by the Medicare contractor or (3) a National Limitation Amount (percentage of the median of all the local fee schedule amounts)

CLFS (Pre-PAMA)

- Rationale behind PAMA (Protecting Access to Medicare Act):
  - Medicare paid out $7 billion for clinical diagnostic lab tests (“CDLTs”) under the CLFS (as of 2014).
  - CLFS had grown from 400 tests to approximately 1300.
  - CMS projected $3.9 billion in savings over ten years.
  - CMS estimated approx. $670 million in savings for lab payments (2018)

Protecting Access to Medicare Act ("PAMA")

- Established 42 U.S.C. § 1395m-1 (SSA § 1834A) with a new method for setting rates on the CLFS
  - Applicable Laboratories required to report Applicable Information to CMS every three years
  - Rates intended to bring CLFS in line with what private payors pay for the same tests
  - CLFS rates determined based on the weighted median of private payor rates and the associated volumes reported by applicable laboratories
  - Advanced Diagnostic Laboratory Tests get special pricing treatment initially, then they also are paid based on a weighted median of private payor rates

Overview of PAMA

- Reporting must be complete and accurate. Civil Monetary Penalties of up to $10,000 per day failure to report or inaccurate reporting.
- Reporting done at the TIN level for all associated NPIs.
- No voluntary reporting and no optional reporting.
- Update on ACLA PAMA lawsuit:
  - American Clinical Laboratory Association v. Azar / Becerra—focused on definition of “Applicable Laboratory”
  - May 2021, ACLA appealed D.C. District Court dismissal of case on mootness grounds
  - May 2022, D.C. Court of Appeals ruled in ACLA’s favor, found 2016 PAMA rule was arbitrary and capricious. Remanded case to district court.
  - Relief is prospective only. 2016 PAMA final rule did not need to be vacated because already replaced with 2018 rule.

What is an "Applicable Laboratory"?

- Defined at 42 C.F.R. § 414.502 as follows:
  - A laboratory, as defined under CLIA (42 C.F.R. § 493.2);
  - Bills Medicare Part B under its own NPI and for hospital outreach labs, bills Medicare Part B on the CMS 1450 Type of Bill (TOB) 14x (which is for non-patient laboratory specimens);
    - 2019 hospital outreach lab change
  - Meets the "Majority of Revenues Test"—In a data collection period, receives more than 50 percent of its Medicare revenues, (Parts A, B, and D) and any associated beneficiary deductible or coinsurance for services furnished during the data collection period, from the CLFS and/or PFS;
    - 2019 Medicare Advantage change
  - Meets the "Low Income Threshold"—Receives at least $12,500 of its Medicare revenues during the data collection period from the CLFS. Except, for a single laboratory that furnishes an Advanced Diagnostic Laboratory Test, this $12,500 threshold—
    - (i) Does not apply with respect to the ADLTs it offers and furnishes; and
    - (ii) Applies with respect to all the other tests it furnishes.

What is “Applicable Information?”

- Defined at 42 C.F.R. § 414.502 as follows:
  - Each private payor rate for which final payment is made during a data collection period
  - The Associated volume of tests corresponding to each private payor rate; and
  - The specific HCPCS code associated with the rate
  - Does not include payments made on a capitated basis
- Applicable Information includes: multiple payment rates for same test, resolved appeals, non-contracted amounts for out-of-network labs services, etc.
- Applicable Information excludes: unresolved appeals, denied payments, price concessions applied by lab, etc.
- Applicable laboratories submit applicable information on most laboratory tests every three years (started Jan. 1, 2017)
- For ADLTs that are not new ADLTs, reporting is every one year (starting Jan. 1, 2017)
- For ADLTs that are new ADLTs, reporting is initially quarterly than annually

Data Collection & Reporting → New CLFS Rates

- Data Collection Period
  - 6 month window (Jan.1 → Jun. 30 during which Applicable Information collected)
- Data Reporting Period
  - 3 month window (Jan. 1 → Mar. 31), following most recent Data Collection Period, during which Reporting Entity reports Applicable Information to CMS)
- CMS calculates weighted median private payor rates (for each test), which becomes new CLFS rate
- Where CMS receives no Applicable Information for CDLT/ADLT, applies crosswalking or gapfilling to determine the new payment rate
- Results in updated payment rates for next CLFS rate years
- PAMA provides for public consultation on CLFS rates
- 2018 was first year of payments under PAMA

Data Collection & Reporting → New CLFS Rates Under PAMA

- Has it worked?
  - OIG required to release annual analysis of top 25 tests based on Medicare spending
  - OIG issued reports in 2018—2021
  - In 2019, Medicare spent $7.6 billion on clinical lab ($93 million more on lab than 2018)
  - In 2020, Medicare spent $8 billion on clinical lab. Subtract Covid testing, and spend dropped 16% ($1.2 billion)
  - In 2021, Medicare spent $9.3 billion on clinical lab (17% increase over 2020). Covid-19 tests, genetic tests and chemistry tests largely responsible for the increase.

PAMA: What Have the Results Been?

Exhibit 1: Overall Medicare Part B spending increased by 17 percent in 2021, driven by increased spending on COVID-19 tests, genetic tests, and chemistry tests.

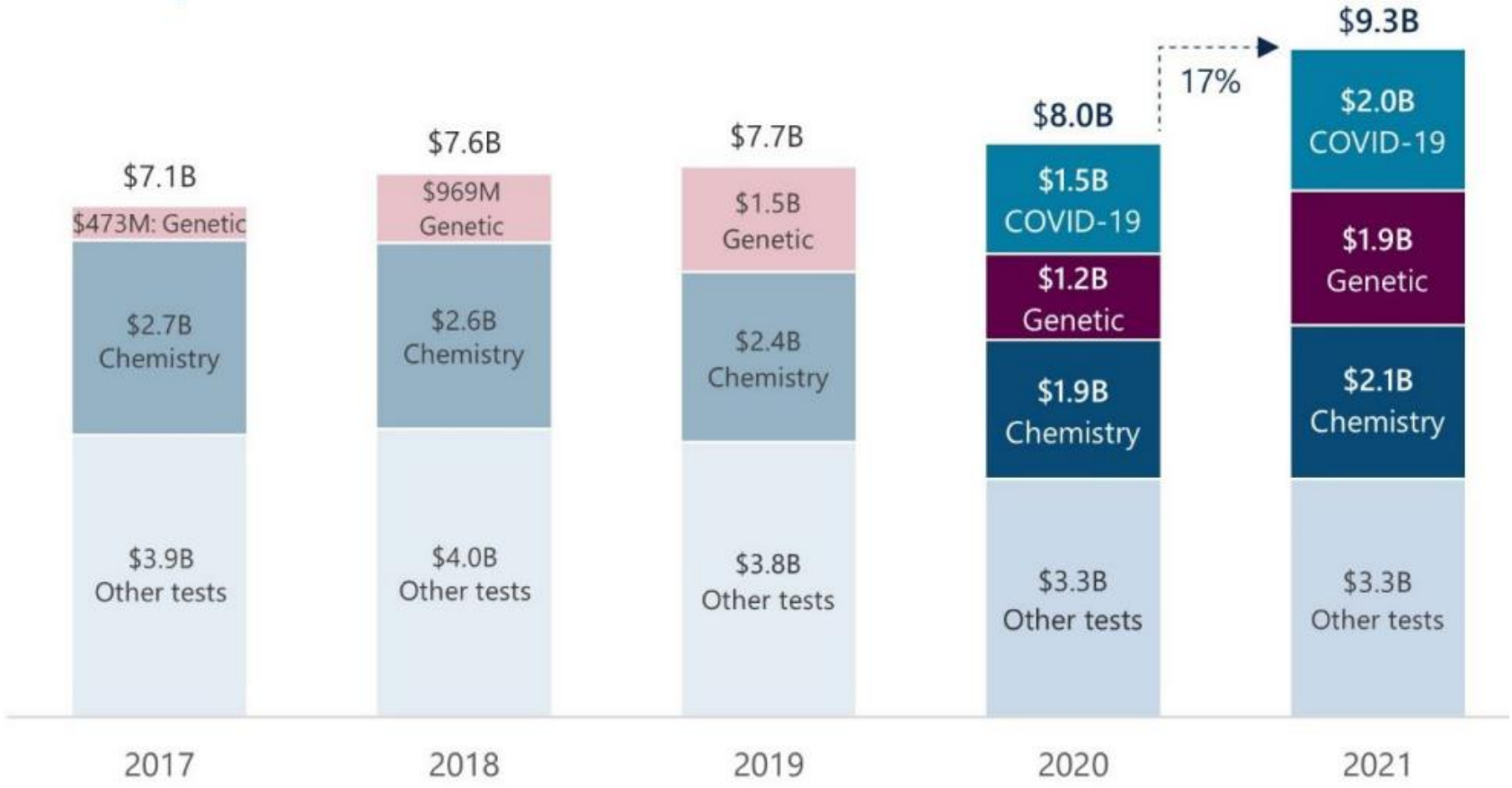

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Exhibit 5: Medicare Part B spent $5.48 billion on the top 25 lab tests in 2021.

	Test Description (Procedure Code)	2021 payment rate	2021 volume (millions)	Volume change from 2020	2021 spending (millions)
1	COVID-19 test: Infectious agent detection by nucleic acid for COVID-19, high-throughput (U0003)	$75.00	12.5	↑ 22.2%	$935.9
2	Blood test, comprehensive group of blood chemicals (80053)	$10.56	39.5	↑ 4.7%	$425.3
3	Blood test, lipids (80061)	$13.39	26.5	↑ 4.9%	$355.2
4	Blood test, thyroid stimulating hormone (84443)	$16.80	19.9	↑ 5.3%	$334.4
5	COVID-19 test: Add-on payment for high throughput tests completed within 2 calendar days of specimen collection (U0005)	$25.00	12.3	New in 2021	$305.4
6	Complete blood cell count, automated test (85025)	$7.77	37.8	↑ 3.1%	$300.2
7	Genetic test: Molecular pathology procedure level 9 (81408)	$2,000.00	0.1	↑ 36.4%	$282.2
8	Vitamin D-3 level (82306)	$29.60	9.1	↑ 11.8%	$267.2
9	Genetic test: Gene analysis (colorectal cancer) (81528)	$508.87	0.5	↑ 20.6%	$252.6
10	COVID-19 test: Any technique, high-throughput technologies (U0004)	$75.00	2.9	↑ 20.7%	$220.8
11	Detection test for organism (87798)	$35.09	6.1	↑ 16.2%	$213.7
12	Drug test(s), definitive, 22 or more drug class(es) (G0483)	$246.92	0.8	↓ -9.2%	$203.0
13	Hemoglobin A1C level (83036)	$9.71	18.6	↑ 5.9%	$182.3
14	Testing for presence of drug (80307)	$62.14	2.5	↓ -3.6%	$156.4
15	Drug test(s), definitive, 15-21 drug class(es) (G0482)	$198.74	0.7	↑ 1.3%	$130.2
16	COVID-19 test: Amplified probe technique (87635)	-	2.0	↑ 46.9%	$104.8
17	COVID-19 test: ELISA detection of severe acute respiratory syndrome coronavirus 2 (COVID-19) (87426)	-	2.6	New to top 25	$101.5
18	Parathormone (parathyroid hormone) level (83970)	$41.28	2.5	↑ 8.6%	$101.4
19	Genetic test: Gene analysis (breast cancer 1 and 2) (81162)	$1,824.88	0.05	↑ 7.7%	$94.0
20	Genetic test: Test for detecting genes associated with breast cancer (81519)	$3,873.00	0.02	↑ 20.1%	$92.7

PAMA: Delays (Round 1)

- 2019 Laboratory Access for Beneficiaries ("LAB") Act delayed reporting for CDLTs that are not ADLTs for one year
  - CDLT data that was set to be reported between Jan. 1 and Mar. 31, 2020 delayed until 2021 (reporting from Jan. 1, 2021—Mar. 31, 2021)
  - Updated payment rates under CLFS to take effect in 2022 (instead of 2021) and remain through 2024
  - Data reporting for these tests to resume on 3-year cycle (in 2024)
  - LAB Act also limits adjustments to CLFS reimbursement over 2019 rates (10% in 2020; 15% in 2021, 2022, 2023)
  - Directed CMS to study PAMA reimbursement and report to Congress

PAMA: Delays (Rounds 2 and 3)

- 2020 CARES Act adjusted timing on the reporting period for private payor data and the phase-in of reimbursement cuts:
  - Delayed reporting period from 2021 to 2022, to be based on data collected during 2019
  - Medicare payment rates determined by 2017 data would continue through 2022
  - Delayed 15% cuts that were to become effective in 2021 to 2022
- Protecting Medicare and American Farmers from Sequester Cuts Act in December 2021 implemented additional delays:
  - Data reporting period of Jan. 1, 2023—Mar. 31, 2023 will be based on Jan. 1, 2019—Jun. 30, 2019 collection period
  - No reduction in payments in 2022 and reductions to be capped at 15% for 2023 through 2025

PAMA: Delays (Round 4)

- Consolidated Appropriations Act of 2023
  - Suspended payment cuts that were to go into effect under PAMA on Jan. 1, 2023
    - Had this not occurred, 15% cut in payment for more than 800 clinical lab tests would have become effective at beginning of 2023
    - 15% cut now scheduled for beginning of 2024
  - Next data reporting period (Jan. 2024—Mar. 31, 2024 will be based on the original data collection period (Jan. 1, 2019—Jun. 30, 2019)
  - 3-year reporting cycle for CDLTs that are not ADLTs
  - Extended phase-in of payment reductions through 2026 coverage year

Data Collection & Reporting → New CLFS Rates

Year for CDLT Rates	Based on Data **Collection** Period	Based on Data **Reporting** Period	Reduction Cap
2020	January 1, 2016 – June 30, 2016	January 1, 2017 – May 30, 2017	10%
2021	January 1, 2016 – June 30, 2016	January 1, 2017 – May 30, 2017	0.0%
2022	January 1, 2016 – June 30, 2016	January 1, 2017 – May 30, 2017	0.0%
2023	January 1, 2016 – June 30, 2016	January 1, 2017 – May 30, 2017	0%
2024	January 1, 2016 – June 30, 2016	January 1, 2017 – May 30, 2017	15%
2025	January 1, 2019 – June 30, 2019	January 1, 2024 – March 31, 2024	15%
2026	January 1, 2019 – June 30, 2019	January 1, 2024 – March 31, 2024	15%

PAMA: Will SALSA Prevent a Round 5?

- Saving Access to Laboratory Services Act (SALSA)
  - Bipartisan support in both houses of Congress
  - Would change the way private sector lab rates are collected and used in adjusting Medicare payment
  - CMS would be required to use statistically valid sample of Applicable Laboratories for “widely available” clinical lab tests
    - “Widely available” – tests that are performed by at least 100 labs (measured by NPIs) and are reimbursed at less than $1,000 per test
  - Certain information excluded from the definition of “Applicable Information” (including Medicaid managed care rates)
  - Data reporting would be every 4 years (instead of 3)
  - Maximum payment cuts would be capped at 5% annually (as opposed to current cap of 15%)
  - SALSA’s limits on reimbursement cuts would apply in future years (not just 6 years after implementation)
  - Did not pass Congress in 2022

Proficiency Testing Developments

Proficiency Testing Developments

- Proposed regulations issued in Feb. 2019. Added 29 new analytes to the list while only removing 5 analytes.
- CMS announced in January (Jan. 19, 2022) that the timeline for publication of proficiency testing final rule has been extended to Feb. 2023.
- Final rule issued in July 2022. Changes include:
  - Changes made to the regulations addressing microbiology subspecialties to remove the types of services listed for each microbiology subspecialty and to add categories of testing for which PT is required.
  - For non-microbiology analytes, CMS added 29 analytes to Subpart I of the CLIA regulations
  - Tightened acceptance limits for PT
  - Moderate / high complexity labs that enroll in PT for waived testing are required to comply with PT referral and inter-lab communication restrictions for waived testing
  - New requirements for PT programs
  - Delayed effective date (Jul. 2024) for much of rulemaking. Requirements related to PT for waived testing became effective in Aug. 2022

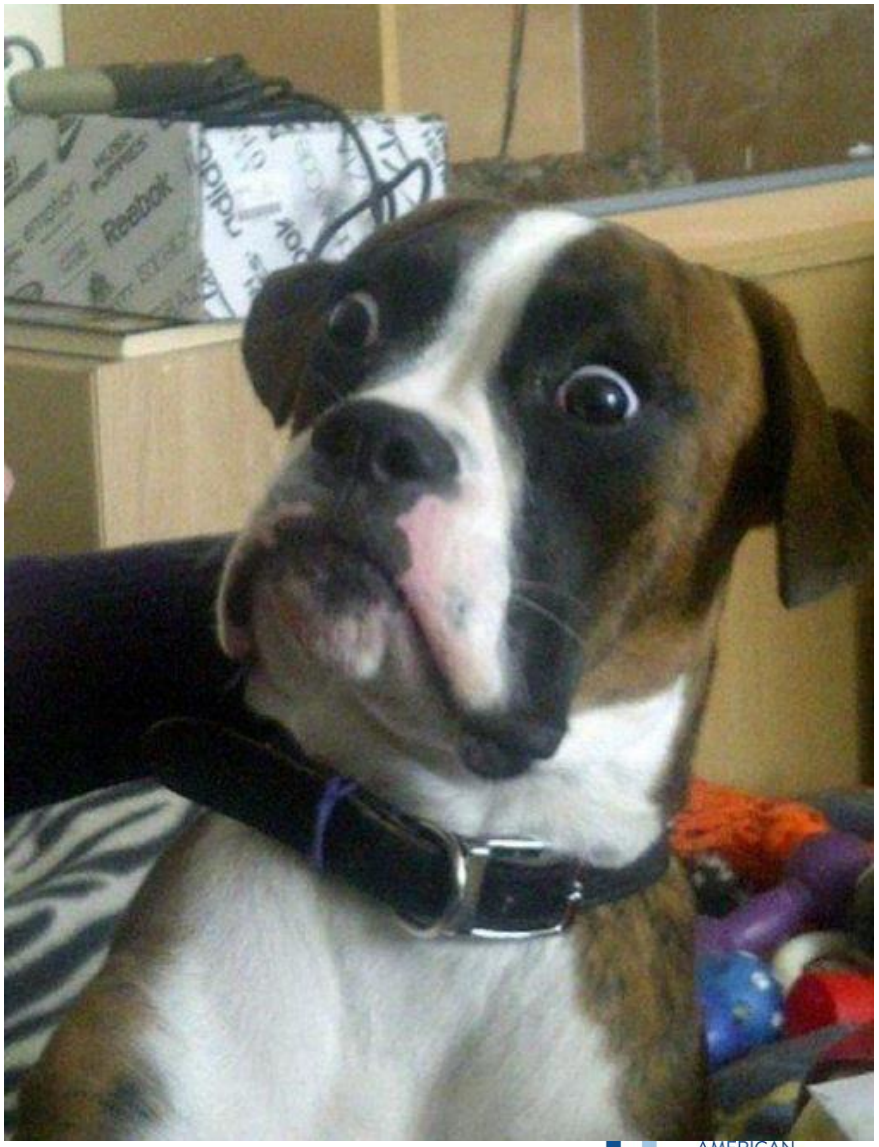
Proficiency Testing Developments

- New rulemaking (proposed) released in July 2022 to address PT and various CLIA items. Among other things, proposed rule would:
  - Increase variety of user fees (e.g., follow-up surveys, substantiated complaint surveys, desk review of unsuccessful PT) and tie fees to CPI-U
  - Make changes to personnel requirements (for example, to expand the ability of nurses to function as testing personnel
  - Eliminate certain regulations applicable to histocompatibility labs
  - Permit alternative sanctions on CoW labs

Proficiency Testing Developments

- *Laboratorio Concordia Lugaro v. CMS* (HHS DAB, Jul. 8, 2022)
  - CLIA certificate revoked, right to receive Medicare payments were cancelled and CMPs were imposed for instances where Lab either improperly referred PT samples or falsely reported PT results
  - Allegations included that Lab referred all of its PT samples for 2018 and the first PT event of 2019 to another lab and reported the results of testing by that second lab as its own
  - Director told surveyor that PT samples were referred "because it was like an internal procedure" since she was the director at both of the labs
  - Lab argued that any referrals of PT samples were not "intentional" because Hurricane Maria had struck the area which meant that no testing could occur due to a lack of electricity
  - DAB rejected argument, noting the longstanding principle that "the Lab's motive for referring proficiency testing is not relevant"
  - No exception to the anti-referral restriction for natural disasters or temporary loss of testing capabilities. Rather, an "intentional" referral happens when it is made "knowingly and willfully"

Lab Developed Tests



What is a Lab Developed Test?

- One definition:
  - In vitro diagnostic test that is intended designed, manufactured and used within a single site CLIA-certified laboratory that meets the requirements for high complexity testing
- Compared to commercially marketed lab tests (manufactured by medical device companies and sold to providers)
  - Need to be cleared by FDA through premarket notification / premarket approval process
- 1976 Medical Device Amendments Act granted FDA jurisdiction over commercially distributed test kits as in-vitro diagnostic devices
- FDA has claimed that statute gives agency jurisdiction over LDTs
- Agency has historically exercised enforcement discretion over LDTs
- Some labs and various other parties have asserted LDTs are clinical services (not medical products) and thus not within scope of FDA authority

Why are LDTs Important?

- Often developed in response to the lack of an FDA cleared or approved assay, lack of available tests compatible with lab instrumentation or lack of tests that meet performance goals
  - As of Dec. 31, 2019 there were no FDA approved/cleared tests available that could detect or diagnose the active 2019-Novel Coronavirus (2019-nCov) clinical specimens in the United States.
- LDTs developed, validated and used for in house pathology and diagnostic purposes and are intended only for use by the lab that developed them.
- Labs may create necessary reagents themselves or purchase from vendors, but the tests are not to be sold to other labs, hospitals, doctors, etc.
- If tests developed and used as LDT are marketed in any way or distributed, FDA could consider it outside the scope of an LDT and regulate accordingly.

How Are LDTs Regulated?

- Potential role of CMS and FDA as relates to LDTs
  - CMS regulates quality of testing labs and analytical validity and ability to provide accurate / reliable testing results
  - FDA review includes analysis of clinical validity of tests, accuracy with which it identifies measures or predicts absence / presence of condition
- Regulation of LDTs?
  - 2014 Draft Guidance
  - 2017 FDA "Discussion Paper on Laboratory Developed Tests"
  - April 2019, FDA issues warning letter to Inova Genomics Laboratory for marketing genetic tests that have not been reviewed for safety / effectiveness
    - Tests claimed to predict patient responses to specific medications based on genetic variants, reducing side effects and other benefits
  - Follows Oct. 31, 2018 FDA Safety Communication discussing changing patient medication regimens based on genetic testing and making recommendations to providers and patients
- Previous legislative efforts (e.g., 2018's DAIA)
- FDA warning letters related to LDTs

LDTs & Covid-19

- HHS declaration of PHE triggered FDA authority under various sections of FD&C Act
- Sec. 564 allows FDA to grant "emergency use authorization" for medical products agency has not cleared / approved
- EUAs have been in use since 2009
- In Feb. 2020, FDA issued *Policy for Coronavirus Disease-2019 During the Public Health Emergency* detailing the process for obtaining EUAs for Covid-19 tests.
  - Seven editions of this guidance have been issued
  - Most recent edition is from Jan. 12, 2023 (renamed, *Policy for Coronavirus Disease-2019 Tests (Revised*))
- During PHE, hundreds of EUAs issued for diagnostic and serology or other immune response tests
- Importance of EUAs amplified issues around LDT regulation

LDTs & Covid-19

- FDA policy on EUAs for Covid-19 tests evolved during PHE and reflected changing landscape of pandemic
- Early versions of guidance created two policies (later expanded) for accelerating development of lab tests:
  - One leading to EUA
  - The other not leading to EUA where test was developed under authority of state in which lab resides and state takes responsibility for testing performed by state labs
  - Third policy was created for commercial manufacturers to more rapidly distribute diagnostics to labs for specimen testing after validation but while EUA application is being prepared for submission
  - Fourth policy created regarding serological testing
- Mar. 10, 2020 PREP Act immunity declaration for covered countermeasures, including EUA products
  - PREP Act immunity does not end at end of PHE.
  - Will continue to earlier of Oct. 1, 2024 or HHS revokes immunity

LDTs & Covid-19

- Aug. 2020 HHS published “Recession of Guidance and Other Informal Issuances Concerning Premarket Review of Laboratory Developed Tests”
  - FDA would not require premarket review of LDTs absent notice and comment rulemaking
  - Change applied to all LDTs, not just Covid-19 tests
- HHS followed up with FAQs on LDTs
- Oct. 2020, FDA statement in weekly town hall: no longer reviewing SARS-CoV-2 LDTs EUAs
- Nov. 2020, HHS directed to review voluntary EUA submissions for LDTs. Overflow to National Cancer Institute.
- FDA had FAQ on its website indicating it was “declining to review EUA requests for LDTs at this time”
- Guidance later updated indicating FDA has “hundreds of pre-EUA and EUA requests … under review” and receives new submissions daily
- Reviewing requests “as quickly as we can”

LDTs & Covid-19

- HHS (Aug. 2020) policy subsequently removed from website without public notice
- Nov. 2021, HHS formally announced that it would withdraw previous policy that prevented FDA from requiring premarket review of LDTs absent formal rulemaking
  - "HHS no longer has a policy on LDTs that is separate from FDA's longstanding approach in this area"
- Nov. 2021, FDA released 5th version of *Policy;* addressed how HHS change affected review of LDTs
  - Newly offered Covid-19 tests (including LDTs) expected to have EUA or traditional authorization such as granted De Novo or 510(k) prior to clinical use
  - FDA to focus review on EUA requests for following tests
    - At-home / POC, with or without prescription that can be made in high volumes
    - Certain high-volume, lab-based molecular diagnostics that can detect multiple respiratory viruses at once
    - Certain lab-based / POC tests for fully quantitative antibody / neutralizing antibodies
    - Tests supported by certain agencies (e.g., NIH)

LDTs & Covid-19

- Jan. 2023 version of Policy (seventh edition)
- FDA intends to review EUA requests for a small subset of tests based on specific review priorities
  - Prioritize the review of EUA requests and supplemental EUA requests from experienced developers for diagnostic tests that are likely to have a significant public health benefit (e.g., employ innovative technology) or are likely to fulfill an unmet need (e.g., diagnosing infection with a new variant or subvariant
  - Review EUA requests from / supported by experienced US government stakeholders
- Confirmation of Nov. 15, 2021 change no longer applying policy on state authorization (of labs within the state to develop their own Covid-19 tests and perform testing) going forward
- Addresses distribution and offering of diagnostic and serology tests during FDA review
- FDA “believes that the number of EUA requests that fall withing FDA’s current review priorities described in this guidance are likely limited and generally encourages developers to submit Covid-19 tests through traditional premarket review pathways”.

LDTs & Covid-19

- End of PHE raises issue of what happens with various flexibilities
  - EUAs not directly affected by end of PHE (remain in effect for duration of relevant EUA declaration)
  - Termination of EUA declaration requires separate determination
  - When EUA declaration terminates, all EUAs issued under that declaration also terminate
- Dec. 2021, FDA issued two pieces of draft guidance intended to address potential end of PHE and implications for EUAs:
  - Transition Plan for Medical Devices Issued Emergency Use Authorizations During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency
  - Transition Plan for Medical Devices that Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency
- Transition plans address many items provided during PHE
- Both were open for comment through Mar. 23, 2022
- Final guidance not yet released, though both Transition Plans were included on FDA's A-List for release in 2023 FY
- Final guidance likely to be fairly consistent with drafts

Highlights of Transition Plan (EUA)

- Advance notice of termination of each EUA to be published in Federal Register 180 days before date on which EUA is terminated
- During period between EUA termination date and date of advance notice, manufacturers must continue to comply with terms of existing EUA
- At EUA termination date, EUA-authorized devices to be discontinued unless manufacturer has submitted marketing submission that has been accepted for review. Ok if review still in process
- Commercial distribution may continue, but must stop if manufacturer receives negative decision (FDA final action), withdraws submission or fails to respond
- Exceptions to rule that normally requires manufacturers to dispose of devices after EUA termination date (where manufacturer does not intend to continue distribution)
  - Covid IVDs may remain in distribution and be used by end users until earlier of two years after the EUA termination date, or until the test's expiration date

Highlights of Transition Plan (Devices)

- Addresses device guidance documents only intended to be in effect during PHE
- Applicable to certain lab devices (e.g., Enforcement Policy for Remote Digital Pathology Devices, Enforcement Policy for Modifications to FDA Cleared Molecular Influenza and RSV Tests)
- FDA outlined three-phase approach (occurring over 180-days) beginning on a TBD implementation date
- Implementation date depends on whether Transition Plan is finalized before May 11, 2023 end of PHE
- Phase 1
  - Begins on implementation date. Manufacturers to follow adverse event reporting requirements (21 CFR Part 803), begin preparation of marketing submissions
- Phase 2
  - Begins 90 days after implementation date. Manufacturers. Before phase 2, manufacturers should submit reports of corrections / removals (21 CFR 806), register establishments and list devices, submit marketing application and have it accepted before Phase 3
- Phase 3
  - Begins 180 days after implementation date. If application accepted, continued distribution is permitted. Manufacturers must comply with QSR and other applicable requirements
- FDA outlines process for manufacturers who do not intend to distribute

Future of LDT Regulation?

- Verifying Accurate, Leading-edge IVCT Development ("VALID") Act
  - Introduced in 2020 and 2021. Included in legislation reauthorizing FDA user fee program, but stripped from bill in Sept. 2022.
  - Would create new test product category, in vitro clinical tests ("IVCTs") and give FDA authority to approve IVCTs. Risk-based framework for IVCT regulation.

Test Category	Summary of Definition	Approval Process
High-Risk Tests	Inaccurate results likely to cause death, serious harm, other serious negative outcomes; no sufficient mitigating measures	Subject to FDA premarket review
Moderate-Risk Tests	Inaccurate results cause non-life threatening or medically reversible injury or treatment delay (or qualifies as high-risk but sufficient mitigating measures exist)	Brought to market through voluntary technology certification program requiring companies to demonstrate appropriate internal test validation processes
Low-Risk Test	Inaccurate result cause minimal or immediately reversible harm (or sufficient mitigating measures exist so that test meets above standard)	Exempt from premarket review

VALID Act (continued)

- Existing LDTs are grandfathered (no review required)
- Use of “mitigating measures” to move tests into lower tiers of regulation (e.g., appropriate labeling, performance testing, submission of clinical data, clinical studies, etc.)
- Other exemptions from premarket review for low-volume tests, modified tests, manual interpretation tests, humanitarian tests
- FDA prohibited from infringing on practice of medicine
- FDA directed to issue regulations (cannot be duplicative of CLIA)
- Effective date 5 years after passage
- Public hearings to occur related to LDT oversight
- Bipartisan support in House & Senate

Another Approach to LDT Regulation

- 2021 VITAL Act (S.1666)
  - Verified Innovative Testing in American Laboratories Act of 2021
  - Would transfer all aspects of regulation over LDTs to HHS / CLIA
  - Specifically removes authority from FDA
  - CMS directed to hold hearings (within 90 days of legislation passing) related to updating CLIA regulations to reflect new oversight over LDTs
  - HHS directed to issue report to Congress within 6 months of passage
  - One sponsor (Rand Paul, R-KY)
  - No progress on legislation in 2022
  - Will VITAL Act be reintroduced in 2023?

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