Clinical Lab Update: What Happened in 2021 and Where Things are Headed in 2022

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AMERICAN HEALTH LAW ASSOCIATION

Agenda

- Refresher on regulation of clinical labs
- Update on lab policy changes during Public Health Emergency
- Developments in clinical lab enforcement
- EKRA
- PAMA
- CMS & CLIA developments
- Lab developed tests

Refresher on Fundamental Lab Concepts

Refresher on Fundamental Lab Concepts

- Key CLIA Concepts
  - Scope and applicability
  - Regulatory requirements depend on testing complexity
  - Proficiency Testing
  - 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
    - 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

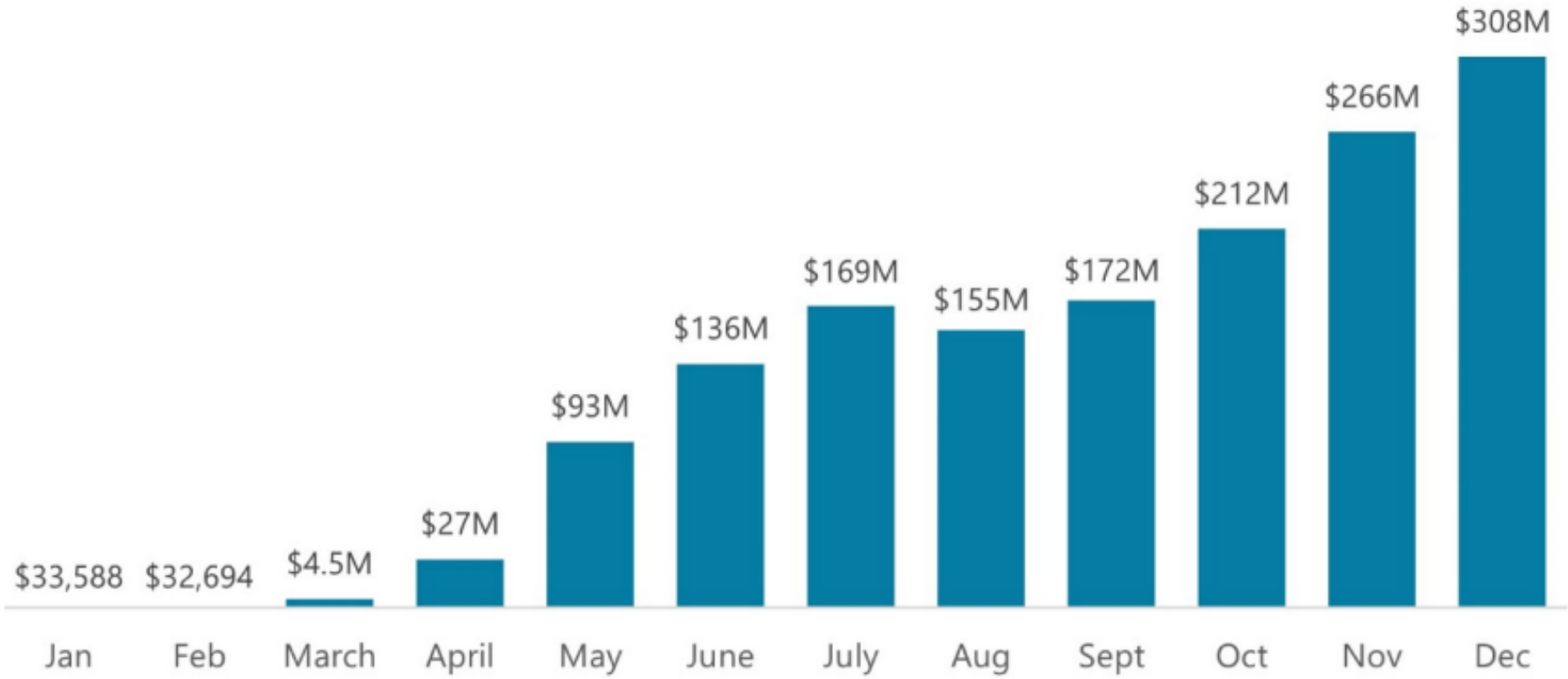
- Who regulates what in the laboratory world? Examples:
  - CMS / CLIA
  - State agencies / CLIA
  - Lab accreditation organizations
  - Proficiency testing organizations
  - State regulation
  - FDA
  - CDC

Clinical Labs and Coronavirus

- Increased access to at home testing for Covid-19 has led to shifting strategies to contain the spread of virus
  - Biden Administration announced a “test to treat” initiative
  - Schools have implemented “test to stay” protocols to shorten quarantine time and keep students in class
    - Many states’ lab oversight agencies working with schools related to clinical lab education / operations
- Readily available at home tests have also resulted in less reliable data on positive rates nationwide
  - CDC is increasingly utilizing the National Wastewater Surveillance System, launched in September 2020, to track the presence of SARS-CoV-2
- How much testing has happened?
  - State based data from the CDC estimates total number of tests since March of 2020 range from 107,100 in low population states like the Dakotas, Wyoming, and Montana to a high of 124.7 million in more densely populated states, like California, Florida, and New York.

Medicare Spending on Covid Testing

Exhibit 2: Medicare Part B spending on COVID-19 tests increased throughout 2020.



Source: OIG analysis of spending on lab tests in Medicare Part B, 2021.

Lab Policy Developments: Covid-19

- Biden Administration "Test to Treat" Initiative
  - Individuals can get tested and, where positive for Covid-19, receive prescription for antiviral medication, all in one location
  - Goal is to make available at FQHCs, pharmacy-based clinics, long term care facilities
  - Started week of Mar. 7, 2022. Website being launched in mid-March for consumer use in finding participating locations
- Variety of changes from CMS Interim Final Rule with Comment Period (85 Fed. Reg. 54820 (Aug. 27, 2020)
  - Updated reporting requirements
    - CLIA labs testing for screening or diagnostic purposes
    - Negative and positive test results must be reported
    - Reporting requirement for non-waived labs
    - Certificate of waiver reporting requirements
    - Ability to impose alternative sanctions on CoW labs
    - Accreditation organizations / exempt states must report within 10 days condition level noncompliance with reporting requirements
    - Civil monetary penalties for failure to report test results
  - Maintain documentation of reporting process

Lab Policy Developments: Covid-19

- 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

Lab Policy Developments: Covid-19

- CARES Act “cash price” requirement
- Nov. 2020 Interim Final Rule (45 CFR Part 182)
  - Providers required to have conspicuous posting of cash price on website
  - “Cash price” = maximum charge that applies to an individual who pays in cash for a Covid-19 test
  - Following information must be made public:
    - Plain language description of each Covid-19 diagnostic test
    - Billing code used for each Covid-19 diagnostic test
    - Provider’s cash price for each Covid-19 test
    - Any additional information as may be needed for public to have certainty of cash price for each test

Lab Policy Developments: Covid-19

- Nov. 2020 Interim Final Rule (45 CFR Part 182) (continued)
  - Information must be easily accessible, available free of charge and without having to enter account / passwords
  - Certain terms must be listed on homepages:
  - For example, the terms “price”, “cost”, “test”, “Covid” and “coronavirus”
  - Limited exception for providers that do not have their own website
  - Rule includes monitoring methods to evaluate provider compliance
  - CMS has discretion to impose various penalties, including corrective action plans and CMPs
- In place for duration of Public Health Emergency (renewed Jan. 14, 2022)

Lab Policy Developments: Covid-19

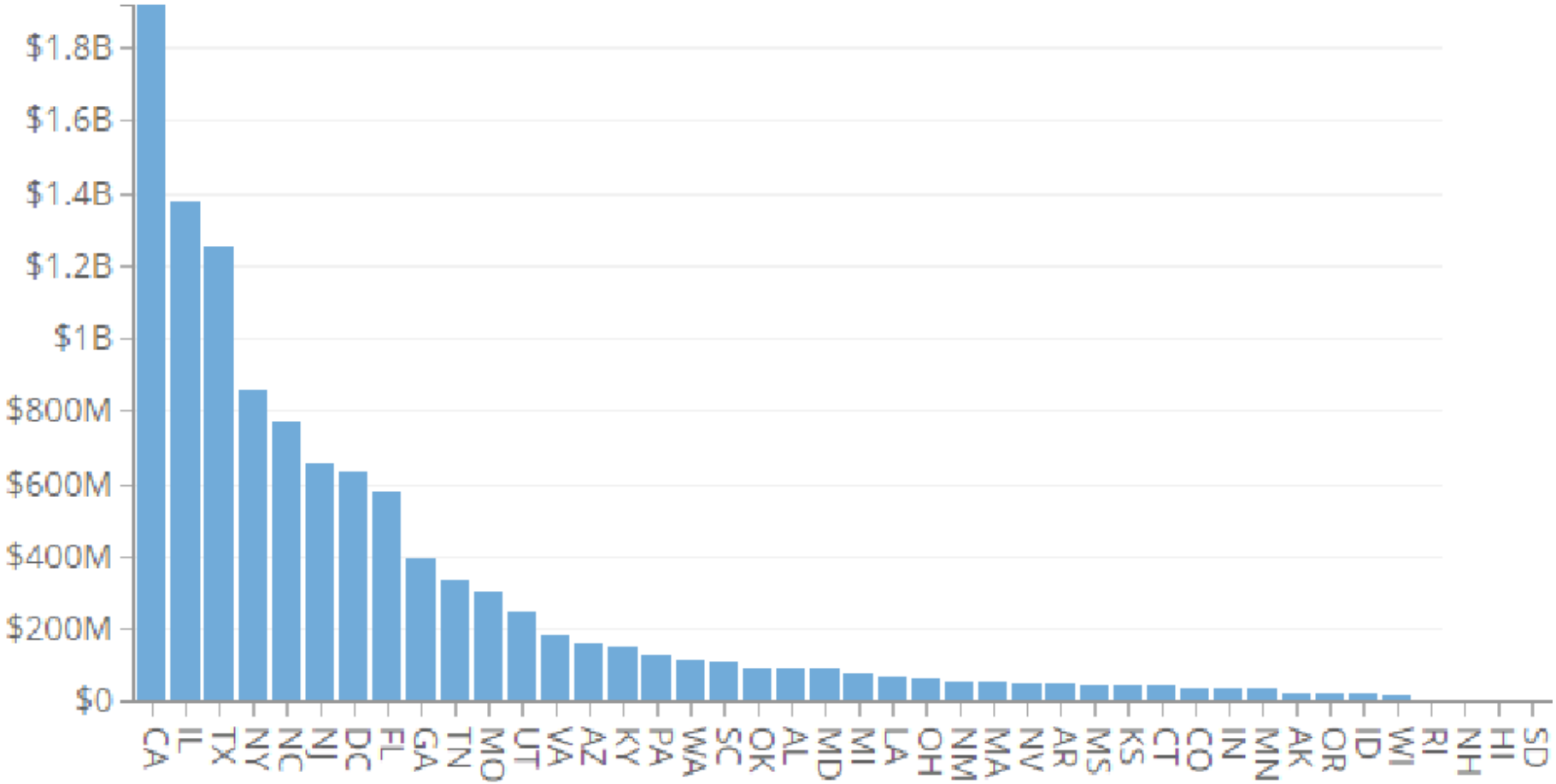
- CARES Act "cash price" requirement
  - Media reporting that some labs are engaging in significant markups (e.g., Covid-19 rapid test ($20 in store) listed at $380 on lab website
  - Lawsuits are proliferating
    - BCBSKC suit against GS Labs; countersuit by GS Labs based on Sec. 3202 of CARES Act;
    - BCBSMN has also sued GS Labs under same theory
    - GS Labs has sued Medica
    - Cigna sued by 24 Hour Covid RT-PCR Lab
- Medicare coverage of Covid testing
  - Traditional Medicare & Medicare Adv. to cover up to 8 at-home Covid tests (per month). Beneficiaries can pick up tests without charge from eligible pharmacies / other entities
  - Until policy implemented, individuals can acquire free tests in other ways (OTC for home delivery at covidtests.gov)
  - 50 million at-home tests provided by HHS to FQHCs, Look-alikes, RHCs
- Beginning Jan. 2022, health plans required to reimburse consumers for tests purchased by consumer (or make tests available without charge) (8 tests per month)

Lab Policy Developments: Covid-19

- HRSA Covid-19 Uninsured Program
  - Reimbursement for labs performing tests on uninsured individuals
  - Providers must meet certain requirements:
    - 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 website shows providers billing / amounts paid under program (more than 52,000 providers have submitted claims)

State	City	Claims Paid for Testi ↓	Claims Paid for Treatm...	Claims Paid for Vaccine
DC	WASHINGTON	$586,931,650	$59,206,200	$0
CA	TEMPLE CITY	$505,412,250	$0	$1,974,688
NC	BURLINGTON	$297,451,262	$6,814,333	$0
CA	SAN MATEO	$227,335,100	$356,375	$0

HRSA Uninsured Program (Testing expenditures, by state)



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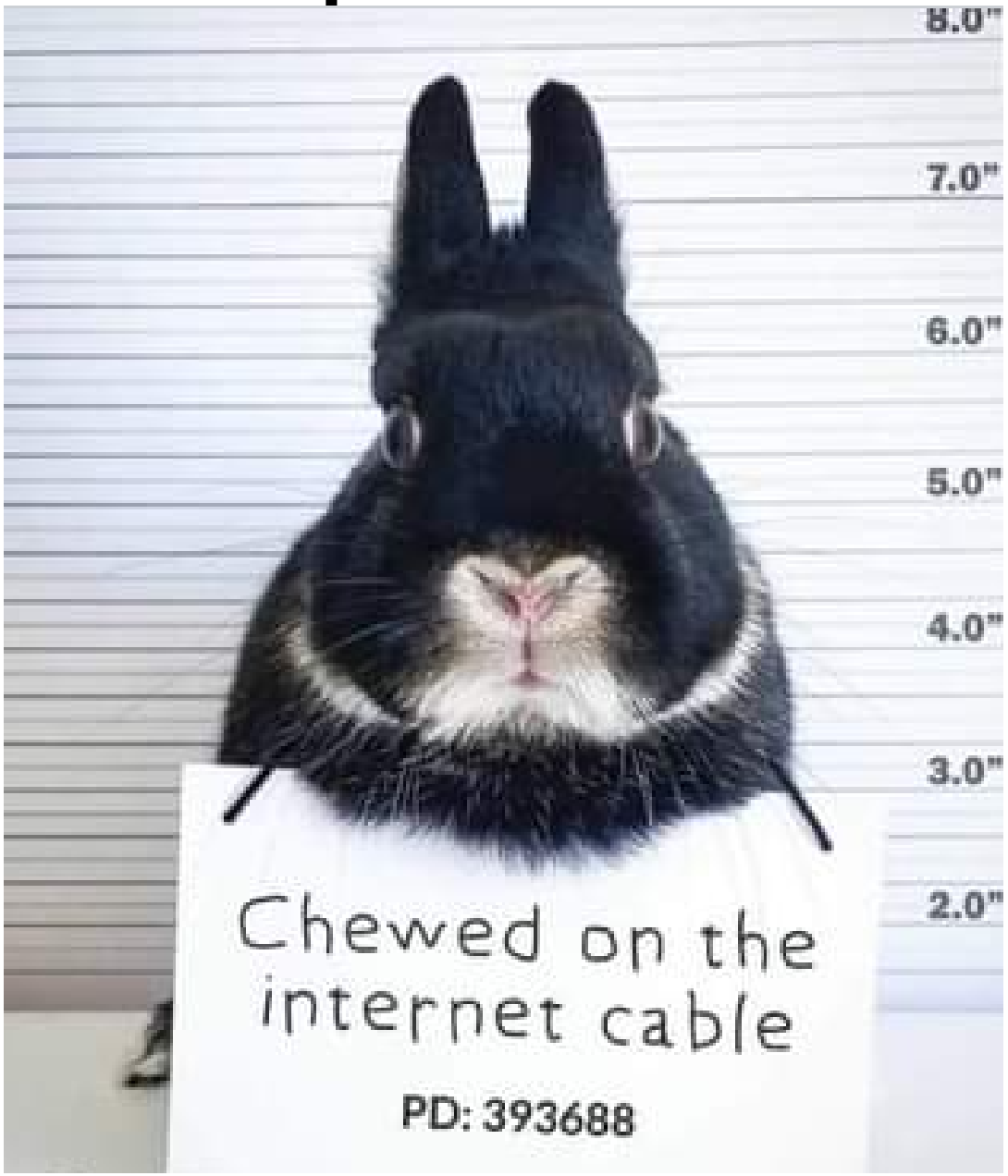
Lab Policy Developments: Covid-19

- Medicaid policy:
  - FFCRA / CARES expanded Medicaid coverage:
    - Optional Covid-19 testing eligibility group (states can elect to furnish targeted benefits)
    - No cost sharing for testing
    - Fully funded by federal govt. for duration of PHE
    - States must elect under State Medicaid Plan
    - Created simplified application process for eligibility
  - May 2020 Interim Final Rule: tests in non-office settings covered, allows states to cover lab processing of self-collected tests that FDA has authorized for home use (including without order from treating physician / NPP), reporting results directly to patients if not ordered by treating provider.
  - Medicaid changes apply not just in Covid-19 PHE but in follow-up surveillance periods. Also apply to future PHEs.
  - Following the Biden Administration requirement that payors cover at home testing with no cost sharing, state Medicaid agencies have instituted provisions to cover over-the-counter tests with no prescription, or with standing prescriptions via pharmacists. State agencies cover the required eight tests per month, and some allow additional tests with appropriate screening or prescriptions.

Enforcement Update



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Covid Related Lab Enforcement Actions

- 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.
- States increasingly cracking down on Covid testing labs:
  - Center for Covid Control (over 300 pop up locations nationwide) under investigation by multiple states, CMS and states attorneys general (Jan. 2022).
    - Claims about lab performance raised by individuals who purchased Covid diagnostic tests from lab as well as from employees.
    - Alleged to have lacked adequate refrigeration, made false claims about their testing process and results.
    - FBI joined with OIG to search the headquarters of the Center and its partner, Doctors Clinical Laboratory in Illinois. The lab subsequently announced a pause in operations in January.

False Claims Act & Anti-kickback Statute

- July 2021: $1.2 million settlement resolved allegations that lab submitted claims for definitive urine drug screens of 22 or more drug classes while testing for far fewer. Lab alleged to have submitted claims without sufficient documentation to support physician intent to order the test that was billed.
- Oct. 2021: lab in Nevada resolved allegations in October with a $16 million settlement. Accused of performing confirmatory urine drug testing without performing presumptive tests, while billing for both.
- Dec. 2021: ALJ upholds exclusion of Texas lab (BestCare Laboratory Services) from FHCPs for 15-years for conduct involving alleged false claims, including billing travel time (400 miles or more) that never occurred.

False Claims Act & Anti-kickback Statute

- Jan. 2022: Florida lab owner pled guilty and paid $6.9 million after allegedly paying kickbacks and bribes for orders of medically unnecessary lab tests, which he then billed to government programs. Tests were also bundled with other unnecessary testing including genetic tests and rare respiratory pathogens.
- 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.
    - 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).

False Claims Act & 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.
  - 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.
- *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.

EKRA Developments

Implications of Eliminating Kickbacks in Recovery Act on Clinical Labs

- 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”.
- Prohibition applies to all CLIA-regulated labs (not just those involved in substance use disorder testing)
- EKRA exceptions (statutory) narrower for labs than Anti-kickback Statute safe harbors (regulatory)
- EKRA definition of “health benefit program” broader than “Federal health care programs” to which Anti-kickback Statute applies
- To date, no regulations or sub-regulatory guidance on EKRA

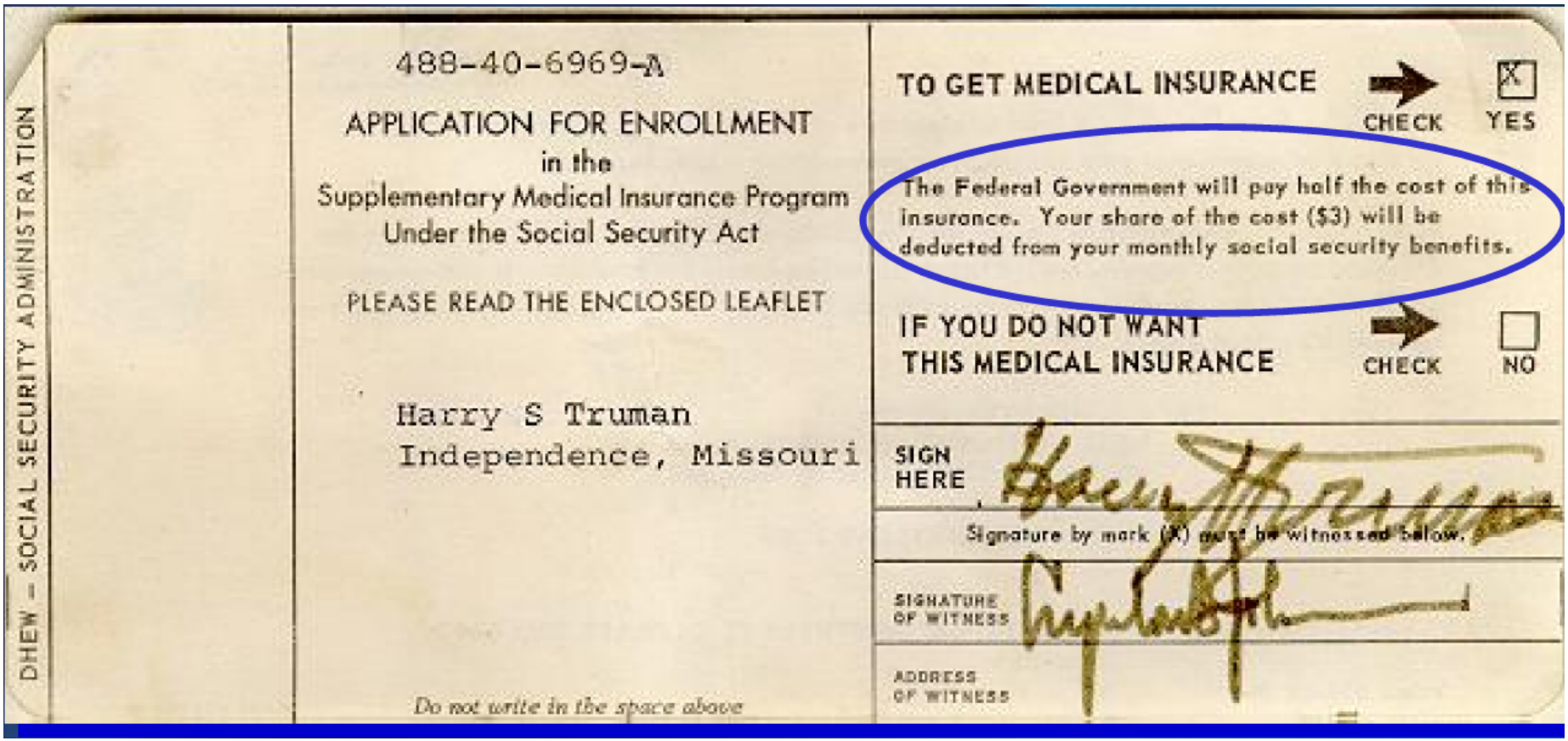
EKRA Update

- Extent to which the EKRA will be enforced against clinical labs generally (as opposed to labs engaged in substance use disorder testing) remains unclear
- Few enforcement actions under EKRA
- Limited cases have generally involved 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 Update

- Oct. 2021, Hawaii federal court issued the first opinion interpreting EKRA's prohibition on commissions for employees and contractors of clinical laboratories
- 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.

PAMA Update: How Did Things Get So Complex?



DHEW — SOCIAL SECURITY ADMINISTRATION

488-40-6969-A

APPLICATION FOR ENROLLMENT
in the
Supplementary Medical Insurance Program
Under the Social Security Act

PLEASE READ THE ENCLOSED LEAFLET

Harry S Truman
Independence, Missouri

Do not write in the space above

TO GET MEDICAL INSURANCE → CHECK [X] YES

The Federal Government will pay half the cost of this insurance. Your share of the cost ($3) will be deducted from your monthly social security benefits.

IF YOU DO NOT WANT THIS MEDICAL INSURANCE → CHECK [ ] NO

SIGN HERE Harry S Truman

Signature by mark (X) must be witnessed below.

SIGNATURE OF WITNESS

ADDRESS OF WITNESS

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)

Clinical Laboratory Fee Schedule (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

Protecting Access to Medicare Act ("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
    - *Am. Clinical Lab. Ass'n. v. Becerra, No. 21-5122, 2021 WL 1997729 (May 28, 2021, D.D.C.).*

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

- Has it worked?
  - OIG required to release annual analysis of top 25 tests based on Medicare spending
  - OIG issued reports in 2018, 2019, 2020
  - In 2019, Medicare spent $93 million more on lab than 2018
  - In 2020, Medicare spent $300 million more than in 2019. Subtract Covid testing, and spend dropped 16% ($1.2 billion)
  - Total lab spend in 2020 was $8 billion ($7.7 billion in 2019)
- 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 now from Jan. 1, 2021—Mar. 31, 2021)
  - Updated payment rates under CLFS will take effect in 2022 (instead of 2021) and remain through 2024
  - Data reporting for these tests then resumes 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: Recent Developments

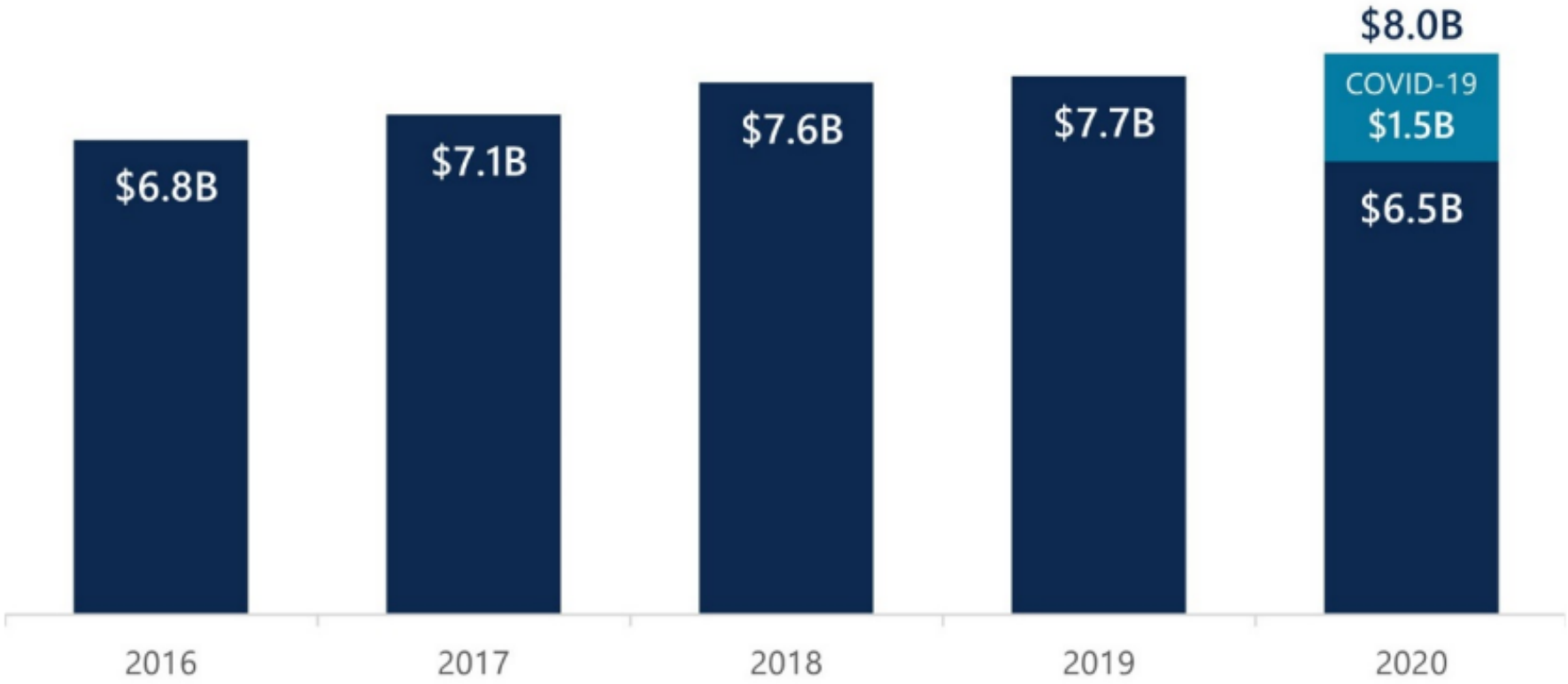
- PAMA implementation continues to be challenging
- Various delays in reporting / reimbursement adjustments in 2020—2021
- 2020 CARES Act adjusted timing on the reporting period for private payor data and the phase-in of reimbursement cuts
- Protecting Medicare and American Farmers from Sequester Cuts Act in December 2021 implemented additional delays
- Next 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 are capped at 15% for 2023 through 2025

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 – March 31, 2017	**0.0%**
2023	**January 1, 2016 – June 30, 2016**	**January 1, 2017 – March 31, 2017**	15%
2024	January 1, 2019 – June 30, 2019	**January 1, 2023 – March 21, 2023**	15%
2025	January 1, 2019 – June 30, 2019	**January 1, 2023 – March 31, 2023**	15%
2026	January 1, 2019 – June 30, 2019	January 1, 2023 – March 31, 2023	N/A

PAMA: What Have the Results Been?

Exhibit 1: Medicare Part B spending on lab tests increased for the fifth year in a row, an increase largely driven by spending on new tests for COVID-19.



Source: OIG analysis of 2016–2020 spending on lab tests in Medicare Part B, 2021.

	Test Description (Procedure Code)	2020 payment rate	2020 volume (millions)	Volume change from 2019	2020 spending (millions)
1	COVID-19 test: Infectious agent detection by nucleic acid for COVID-19, high-throughput (U0003)	$100	10.2	New	$1,017.0
2	Blood test, comprehensive group of blood chemicals (80053)	$10.56	37.8	-10%	$402.7
3	Blood test, lipids (80061)	$13.39	25.2	-12%	$336.2
4	Blood test, thyroid stimulating hormone (84443)	$16.80	18.9	-12%	$315.4
5	Complete blood cell count, automated test (85025)	$7.77	36.7	-11%	$288.5
6	COVID-19 test: Any technique, high-throughput technologies (U0004)	$100	2.4	New	$243.4
7	Vitamin D-3 level (82306)	$29.60	8.1	-9%	$237.6
8	Drug test(s), definitive, 22 or more drug class(es) (G0483)	$246.92	0.9	-29%	$221.9
9	Gene analysis (colorectal cancer) (81528)	$508.87	0.4	-14%	$208.1
10	Molecular pathology procedure level 9 (81408)	$2,000	0.1	-31%	$205.4
11	Detection test for organism (87798)	$35.09	5.2	92%	$183.5
12	Hemoglobin A1C level (83036)	$9.71	17.6	-12%	$170.9
13	Testing for presence of drug (80307)	$62.14	2.6	-24%	$161.0
14	Drug test(s), definitive, 15-21 drug class(es) (G0482)	$198.74	0.7	-20%	$127.7
15	Parathormone (parathyroid hormone) level (83970)	$41.28	2.3	-8%	$92.8
16	Blood test, basic group of blood chemicals (80048)	$8.46	10.3	-18%	$89.6
17	Drug test(s), definitive, 1-7 drug class(es) (G0480)	$114.43	0.8	-26%	$87.8
18	Gene analysis (breast cancer 1 and 2) (81162)	$1,824.88	0.05	-21%	$86.7
19	Drug test(s), definitive, 8-14 drug class(es) (G0481)	$156.59	0.5	-17%	$80.5
20	Cyanocobalamin (vitamin B-12) level (82607)	$15.08	5.2	-11%	$78.4

Other CMS / CLIA Developments

- CMS announced in January (Jan. 19, 2022) that the timeline for publication of proficiency testing final rule has been extended to Feb. 2023. CMS expected to dramatically increase the list of analytes for which PT is required. Proposed regulations added 29 new analytes to the list while only removing 5 analytes.
- COLA approved as AO for pathology / histopathology, cytology, oral pathology
- New 42 C.F.R. Part 413, Subpart L (Medicare payment for organ acquisition costs for histocompatibility labs (and others in transplant context)
- Additional guidance:
  - FAQs on consumer complaints
  - FAQs on applicability of CLIA to at-home testing
  - Enforcement discretion on use of EUA tests outside of test authorization
  - Guidance on applicability of CLIA to workplace testing
  - Enforcement discretion related to use of expired test kits, reagents and swabs
  - Enforcement discretion for surveillance testing
  - Supplement to 2020 / 21 FAQs on 1135 waivers
  - Updated guidance on temporary testing sites / multiple site exception

Other CMS / CLIA Developments

- Camillio v. CMS (HHS DAB, Apr. 29, 2021)—ACN Medical Labs lost CLIA certificate for various alleged condition level deficiencies, including proficiency testing noncompliance
- *Rosenfield v. CMS* (HHS DAB, Oct. 16, 2020)
  - CMS determined lab was out of compliance for not performing sufficient proficiency testing (failed to achieve satisfactory requirements for two consecutive PT events)
  - Imposed sanctions including limiting the CLIA certificate for six months and suspending payments from Medicare for six months

Lab Developed Tests

Lab Developed Tests

- Background on LDTs
- Role of FDA / CMS (CLIA) in LDTs
- 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

Lab Developed Tests & Covid-19

- Since the first EUA for an at home self-test with rapid results was approved in Nov. 2020, the market has proliferated with direct-to-consumer (DTC) and over-the-counter (OTC) options.
- As of Jun. 2021, the FDA had issued over 600 EUAs for molecular diagnostic tests and 90 for antibody tests.
- LDTs continue to evolve to address developing concerns.
  - After CDC warned of a sharp increase in Respiratory Synctial Virus (RSV) coinciding with flu season and called for expanded testing, Avellion launched the first combination test for Covid-19, Influenza A and B, and RSV. It can also detect Covid-19 variants such as Omicron and the "Flurona."
- Dec. 2021, FDA issued draft guidance, "Transition Plan for Medical Devices Issued Emergency Use Authorizations During the Coronavirus Disease 2019 Public Health Emergency."
  - Open for comments through Mar. 23, 2022

Lab Developed Tests & Covid-19

- Transition Plan important because EUA would normally end at end of Public Health Emergency
- Highlights of Transition Plan
  - 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

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 withdrew 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 updated policy / statement regarding how HHS change affected review of LDTs
  - Newly offered Covid-19 tests (including LDTs) are 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)

Future of LDT Regulation?

- 2020 VALID Act / Reintroduced in June 2021
  - Verifying Accurate, Leading-edge IVCT Development ("VALID") Act
  - Would create new test product category, in vitro clinical tests ("IVCTs") and give FDA authority to approve IVCTs
  - Create risk-based framework for IVCT regulation (high-risk tests required to go through premarket review; low-risk tests only need to pass technology certification)
    - 2021 bill has new approach to "high risk"
  - Authorizes use in certain circumstances of validated tests for emergency pending FDA review of EUA
  - Includes provisions related to quality systems, technology certification for lower risk tests, adverse event reporting, transitional tests and others
  - Would grandfather existing LDTs
  - FDA directed to issue regulations within 2 years
  - Bipartisan sponsors in House & Senate

Future of 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)

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