Clinical Laboratory and Pathology in the Age of Covid-19

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AMERICAN HEALTH LAW ASSOCIATION

Agenda

- Background on lab regulation / oversight
- Refresher on key laboratory principles
- Covid-19 and implications for laboratory industry
- Responses from key agencies on lab / Covid-19 issues
- Regulation of lab developed tests
- Update on PAMA
- Update on EKRA
- Other changes of note for labs
- Interesting enforcement developments

Refresher on Fundamental Laboratory Issues

- 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 Laboratory Issues

- 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 Laboratory Issues

- 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)
    - Threatened lawsuits (e.g., Anthem v. Sonoma West Medical Center)
    - Requiring hospital labs to be credentialed as reference labs
  - State laws on "direct accessing testing"

Refresher on Fundamental Laboratory Issues

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

Developments for Labs During Covid-19 Public Health Emergency

Terms & Terminology

- SARS-CoV-2: severe acute respiratory syndrome coronavirus 2
  - Initially known as “2019 novel coronavirus”
- Covid-19: coronavirus disease
- Diagnostic test: molecular or antigen tests (both of which can be used to diagnose infection with SARS-CoV-2 virus)
- Molecular test: detects presence of viral RNA
- Antigen tests: detects presence of viral proteins that are part of SARS-CoV-2 virus
- Serology or antibody tests: detects antibodies (part of body’s immune response to exposure) to the SARS-CoV-2 virus
- Lab Developed Test: in vitro test that is intended for clinical use and designed, manufactured and used within a single laboratory
- PGx: pharmacogenetics
- CGx: cancer genomics

Covid-19: Public Health Declaration and Immediate Aftermath

- As of Dec. 31, 2019, no FDA approved or cleared clinical lab tests that could detect or diagnose active 2019-Novel Coronavirus in United States
- Jan. 9, 2020: WHO announces discovery of coronavirus related pneumonia in Wuhan, China
- Jan. 20, 2020: US airports begin screening
- Jan. 21, 2020: CDC confirms first US case
- Jan. 31, 2020 Public Health Emergency Declaration
- Public Health Services Act Sec. 319 Authority
- CDC developed test to detect 2019-nCoV (Feb. 4, 2020)
- On Feb. 6, 2020 CMS issued guidance to surveyors regarding authorization for emergency use of CDC's 2019-nCoV Real-Time RT-PCR Diagnostic Panel Assay and deployment into CDC labs

Covid-19: Public Health Declaration and Immediate Aftermath

- Development of new billing codes for Covid-19 testing:
  - On Feb. 13, 2020, CMS released first HCPCS code (U0001) for labs to use to test patients for COVID-19. On Feb. 29, 2020 FDA issued new policy for certain labs to develop their own validated COVID-19 diagnostics
  - On March 5, 2020, CMS announced second HCPCS code (U0002). U0002 allows labs to bill for non-CDC lab tests for SARS-CoV-2
  - On March 13, 2020 AMA CPT Editorial Board announced approval of CPT code 87365
  - On April 10, 2020 AMA announced two new codes for serology testing: 86328 and 86769
  - High Throughput testing codes (U0003, U0004) effective Apr. 14, 2020; (U0005) effective Jan. 1, 2021

Covid-19: Public Health Declaration and Immediate Aftermath

- Medicare claims processing system able to accept codes in spring 2020 (retroactive coverage)
- MACs responsible for developing payment rates for claims under new codes (until national rates established)
- No beneficiary cost sharing (similar to most CLFS testing under Medicare)
- Various state insurance regulators and Medicaid agencies began to take steps to remove patient financial responsibility for testing
- HHS Sec. 1135 blanket waivers (retroactive to Mar. 1, 2020)
- States / territories permitted to request waivers of Medicaid / CHIP requirements under Sec. 1135 authority
- Other state options for flexibility

Covid-19: Public Health Declaration and Immediate Aftermath

- Series of FDA publications related to testing
- Public Readiness and Emergency Preparedness (PREP) Act
  - Liability shield for providers furnishing unapproved / unauthorized "covered countermeasures"
  - Available for lab developed tests operating under active / pending FDA emergency use authorization
- Families First Coronavirus Response Act (FFCRA) & Coronavirus Aid, Relief and Economic Security Act (CARES)
- Series of rulemakings. For example:
  - May 8, 2020 Interim Final Rule
  - September 2, 2020 Interim Final Rule

Covid-19: CMS Waivers, Enforcement Discretion & Other Changes

- Can CLIA requirements be waived as result of Public Health Emergency?
- Areas of enforcement discretion for clinical labs
- Generally applicable CMS waivers / flexibilities
  - Medicare enrollment, postpone revalidation, screening requirements, expedite applications, telephone enrollment for pharmacies to set up labs
- Waivers of Medicare requirements specific to clinical labs
- Regulatory changes
  - Coverage of diagnostic tests without order from treating provider
  - Adjustments to documentation / recordkeeping requirements
  - Ability of pharmacists to order diagnostic tests
  - Reporting results directly to patients
  - Coverage of serology tests

Covid-19: CLIA Developments

- 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
  - Exercise of enforcement discretion
  - CMS working to evaluate labs with CLIA certificates approaching expiration to address extensions

Covid-19: CLIA Developments

- Laboratory reporting obligations
  - CARES Act obligations to report results (positive and negative) to HHS through duration of PHE
  - Jun. 4 2020 HHS guidance on reporting obligations for all labs performing SARS-CoV-2 testing
  - Sep. 2 2020 Interim Final Rule modified CLIA to add reporting obligations
  - State survey memo QSO 20-37
  - Follow-up state survey memo QSO 21-10
  - Condition level deficiency, civil monetary penalties for failure to report
- State survey agency developments
  - Priorities for surveys during PHE (QSO-20-20, QSO-20-35)
  - Failure to report results required by new CLIA regulations results in mandatory sanctions

Covid-19: Other Flexibilities of Interest to Clinical Labs

- Accreditation organization inspections
  - April 2020, lab inspections (except immediate jeopardy) suspended by CAP
  - June 2020, resumption of CAP announced inspections
  - October 2020, CAP begins virtual inspections
- HIPAA
  - OCR enforcement discretion to permit business associates to engage in good faith uses / disclosures of PHI for public health and health oversight activities during PHE
- Stark Law and Anti-kickback Statute
  - Stark Law & AKS waivers
  - Dec. 2020 Stark Law, AKS and CMP rulemaking
- OIG's Frequently Asked Questions
  - Two inquiries specifically focus on lab arrangements

Covid-19: Reimbursement Developments

- Families First Coronavirus Response Act ("FFCRA") & Coronavirus Aid, Relief and Economic Security Act ("CARES")
- Commercial payor reimbursement for Covid-19 testing under CARES / FFCRA
  - Diagnostic test coverage without cost sharing, prior authorization
  - Tests must meet one of the following:
    - FDA approved, cleared, authorized
    - Developer has requested EUA (until denied or request not timely submitted)
    - State reviewed LDTs
    - Other tests HHS determines appropriate
  - Reimbursement at rate negotiated with payor if rate negotiated before PHE declared
  - If no negotiated rate, reimbursement at amount equal to cash price for service listed by provider on website
  - Providers required to make cash price public on internet
  - Fines of up to $300 per day for violations

Covid-19: Reimbursement Developments

- 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

Covid-19: Reimbursement Developments

- 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
  - Biden Administration FAQs

Covid-19: Reimbursement Developments

- 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.
  - HRSA program applies same definition of “Covid-19 testing” as CARES / FFCRA
  - Providers generally reimbursed at Medicare rates
  - HRSA has already reimbursed more than $3 billion for testing / treatment of uninsured
  - Individuals enrolled in Medicaid’s optional Covid-19 testing group not considered uninsured

Covid-19: Reimbursement Developments

- Changes in Medicaid policy:
  - FFCRA / CARES expanded Medicaid coverage:
    - Optional Covid-19 testing eligibility group (states can elect to furnish targeted benefits to individuals)
    - No cost sharing for diagnostic testing / serology
    - Fully funded by federal govt. for duration of PHE
    - States must elect under State Medicaid Plan
    - Offered beginning Mar. 18, 2020
    - 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
  - Some states' Medicaid expansions specifically requires EUA for tests to be covered

Covid-19 Reimbursement Developments

- Medicare:
  - "Time out" on PAMA
  - Covers diagnostic testing / serology (no cost sharing)
  - MACs responsible for developing payment amounts until national rates set
  - CMS has set amounts for high throughput technology CDLTs
  - Expanded definition of "homebound" (not specific to lab)
  - Coverage of specimen collection and travel
- Medicare Advantage:
  - Covers diagnostic testing / serology (no cost sharing)
  - No prior authorization / utilization management requirements
- Commercial Payors:
  - Health plans required to cover Covid-19 diagnostic testing without beneficiary cost-sharing, prior authorization, medical management
  - Many states taking other steps (additional funding for testing, expanded coverage, cost-sharing waivers, partnering with private sector / academic institutions)

Biden Administration Developments

- Jan. 21 2021 Exec. Order on Establishing Covid-19 Pandemic Testing Board and Ensuring a Sustainable Public Health Workforce for Covid-19 and Other Biological Threats
  - Pandemic Testing Board
  - Addressing Cost of Testing
- Updated Joint FAQs from HHS / DOL
- American Rescue Plan of 2021
  - Funding to HHS for diagnosing, tracing and monitoring cases / infections
  - HHS directed to implement national testing, contact tracing, surveillance strategy
  - Grants to state / local public health departments
  - Funding for genomic sequencing for SARS-CoV-2

Lab Developed Tests: Background, What's Happened During PHE and What Might be Next

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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

Developments in FDA Regulation of Covid-19 Testing

- Background on Emergency Use Authorization ("EUA")
- Key FDA guidance during PHE:
  - "Policy for Coronavirus Disease-1029 Tests During the Public Health Emergency" (May 4, 2020, May 11, 2020 Revised)
- FDA's Policy for Covid-19 Tests during PHE:
  - High-complexity (CLIA) labs: Lab developed diagnostic tests can be performed prior to EUA request so long as test validated and EUA request submitted within 15 days.
  - State authorization of labs to run LDTs (no validation to FDA and no EUA request)
  - Commercial manufacturer development / distribution of diagnostic test kits prior to EUA request (validation + 15 days)
  - Serology (antibody) tests:
    - Commercial manufacturer development / distribution of serology tests (validated) with follow-up (10 day) EUA submission
    - High complexity (CLIA) labs: laboratory developed serology tests (validated, EUA submission not required)

Current Status of Covid-19 EUAs

- FDA has authorized more than 340 Covid-19 tests / collection kits under EUAs (Mar. 9, 2021)
  - 253 molecular tests / sample collection devices
  - 72 antibody tests and other immune response tests
  - 15 antigen tests
- Of the molecular authorized tests, 38 can be used with home collected samples
- Mar. 5, 2021: first authorization of molecular test for use at home without prescription (over the counter)
  - One at home, prescription-based molecular test
- Dec. 2020: first EUA for at-home antigen test (no prescription / over the counter)
  - Two antigen prescription, at-home tests
- HHS has also directly issued several EUAs
- FDA has issued warning letters related to serology and diagnostic Covid-19 testing

Covid-19: Update on Lab Developed Tests

- Settings where SARS-Cov-2 Tests (under EUA) can be performed
  - EUA will clarify appropriate setting (e.g., waived, moderate high complexity)
  - Testing personnel must meet appropriate CLIA testing personnel qualification requirements, depending on which EUA-authorized tests are in use at lab
  - Where EUA granted for point of care test, deemed to be CLIA-waived. Waived testing does not have any personnel requirements
  - Tests offered prior to or without EUA considered high complexity by default
- FDA has published guidance (Jan. 2017) outlining how it prioritizes EUA requests for review

Covid-19: Update on Lab Developed Tests

- Aug. 19, 2020 HHS publishes “Recession of Guidance and Other Informal Issuances Concerning Premarket Review of Laboratory Developed Tests”
  - FDA will not require premarket review of LDTs absent notice and comment rulemaking
  - Change applies to all LDTs, not just Covid-19 tests
- HHS followed up with FAQs on LDTs

Covid-19: Update on Lab Developed Tests

- Implications of HHS publication:
  - PREP Act
  - Reimbursement
  - Others?
- 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 an FAQ on its website indicating it was “declining to review EUA requests for LDTs at this time”
- Guidance has now been 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”

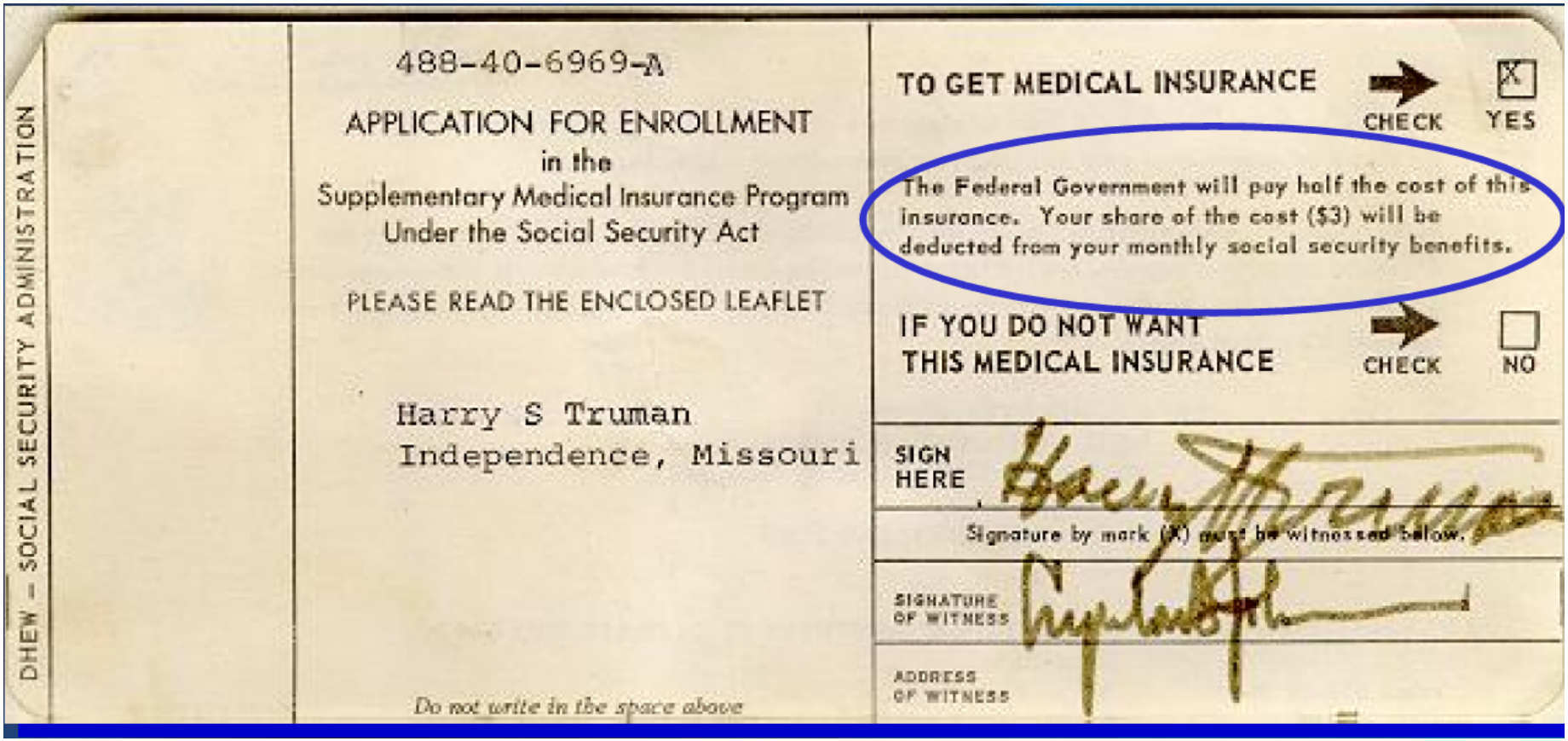
Future of LDT Regulation?

- 2020 VALID Act
  - 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 technological certification)
  - Includes provisions related to quality systems, technology certification, adverse event reporting, EUAs and others
  - Would grandfather existing LDTs
  - Implications of VALID Act for clinical labs v. manufacturers
  - Introduced in House and Senate (Mar. 5, 2020)

Direct to Consumer Testing

- FDA reviews some (not all) DTC tests
  - Tests for moderate / high risk medical purposes v. tests for non-medical, general wellness, low risk medical purposes
    - E.g.., FDA does not review ancestry tests; it does review pharmacogentics tests
  - Specific regulatory requirements depend on risk classification of test
- FDA oversight:
  - FDA issued warning letters in 2010 to several different companies
  - 2018 warning letter to consumers about genetic tests that claim to predict responses to specific medications
  - August 2019 FDA requested Myriad Genetics to make changes to GeneSight (PGx that assesses suitability of antidepressants based on pharmacogenetic profiling)
    - Followed decision by United Health Care to cover the test
- FDA approvals:
  - Apr. 2017, authorized first DTC genetic health risk test (10 diseases / conditions)
  - Oct. 2018, authorized first DTC test for detecting genetic variants associated with medication metabolism

PAMA: 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.
- Future of PAMA?
  - American Clinical Laboratory Association v. Azar
    - 931 F.3d 1195 (D.D.C. 2019)

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

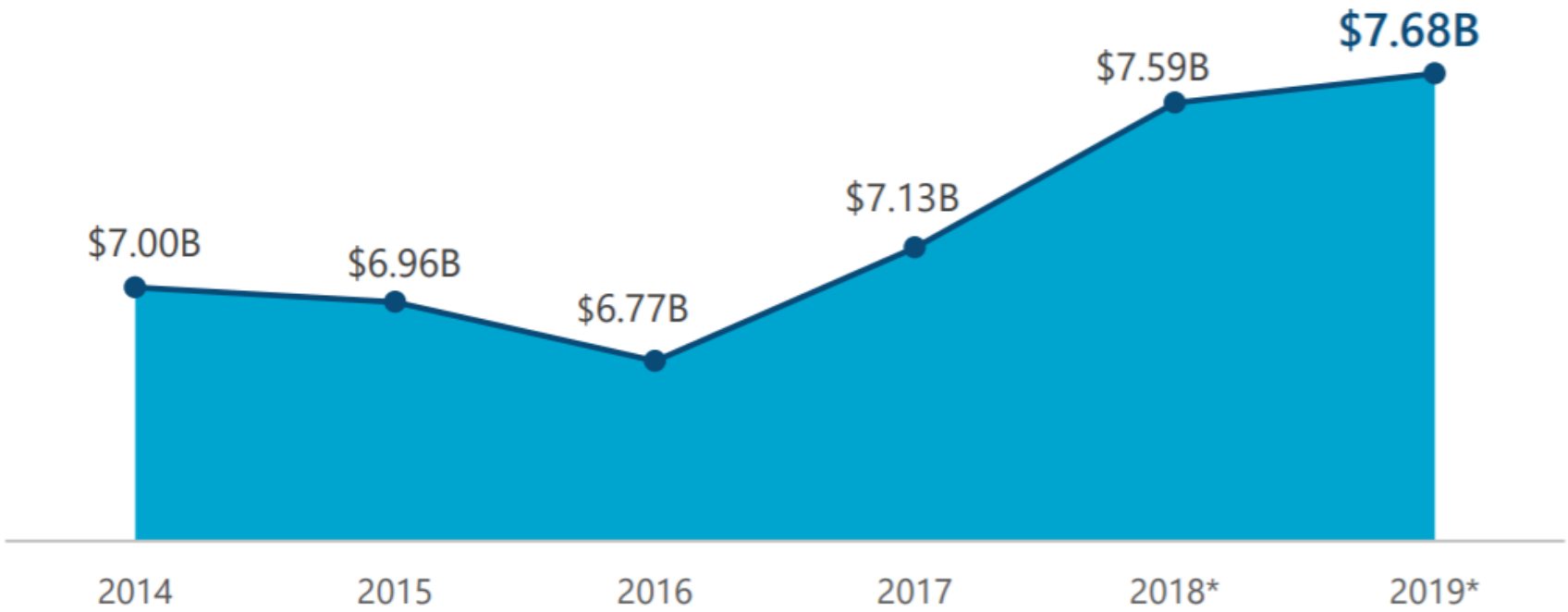
- Data Collection Period
  - 6 month window (Jan.1 → Jun. 30 during which Applicable Information collected)
- Data Reporting Period
  - 3 month window (Jan. 1 → Mar. 31), following most recent Data Collection Period, during which Reporting Entity reports Applicable Information to CMS)
- CMS calculates 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 and 2019
  - In 2019, Medicare spent $93 million more on lab than 2018 ($
- 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)
  - Directs CMS to study PAMA reimbursement and report to Congress

PAMA—what have the results been?

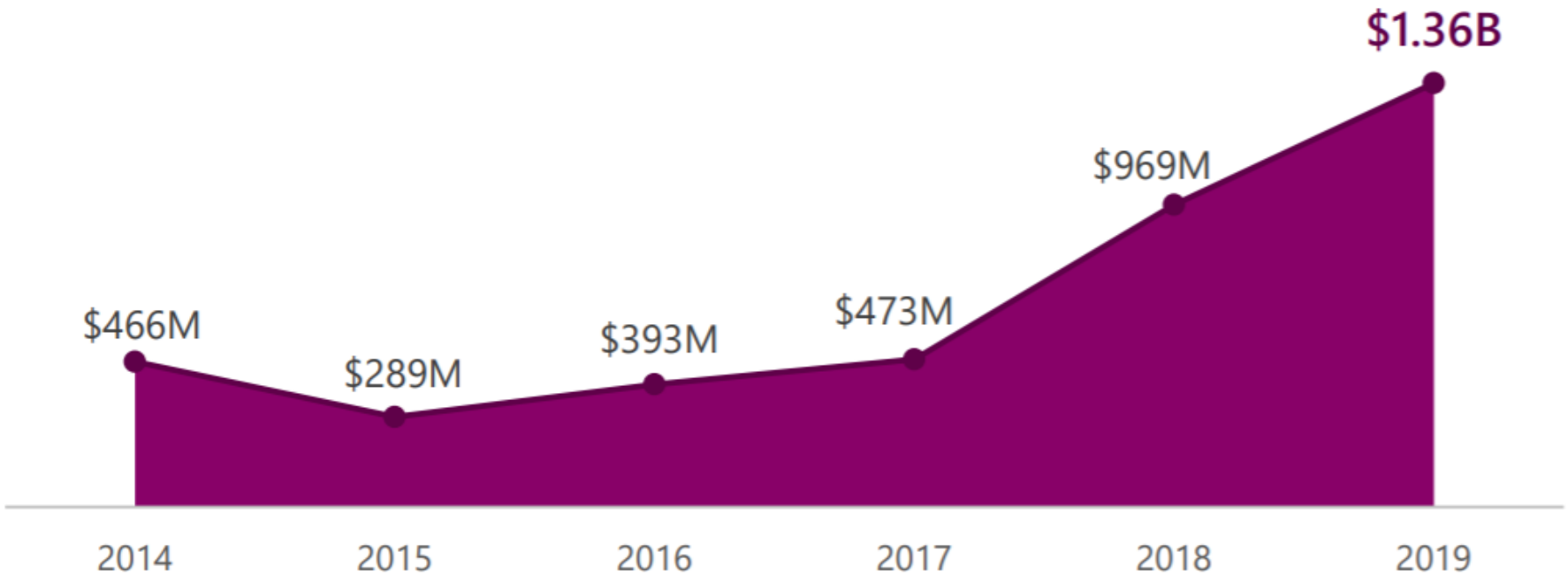
Exhibit 1: Medicare spending for lab tests continued an upward trend in 2019.



*In 2018 and 2019, lab payment rates were subject to the rate reductions required by PAMA.
Note: Medicare spending dollar values are rounded.
Source: OIG analysis of 2014–2019 spending on lab tests in Medicare Part B, in billions, 2020.

PAMA—what have the results been?

Exhibit 2: Medicare spending on genetic tests increased for the fourth year in a row and reached its highest point of $1.36 billion in 2019.



Source: OIG analysis of 2014–2019 spending on lab tests in Medicare Part B, 2020.

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	Test Description (Procedure Code)	2019 Payment Rate	Rate Change From 2018	2019 Test Volume (Millions)	2019 Test Spending (Millions)	Spending Change From 2018 (Millions)
1	Blood test, comprehensive group of blood chemicals (80053)	$11.74	-10%	42.17	**$491.62**	-$45.48
2	Blood test, lipids (cholesterol and triglycerides) (80061)	$14.88	-10%	28.69	**$418.83**	-$44.75
3	Blood test, thyroid stimulating hormone (TSH) (84443)	$18.67	-10%	21.37	**$391.45**	-$43.26
4	Complete blood cell count (red cells, white blood cell, platelets), automated test (85025)	$8.63	-10%	41.24	**$354.14**	-$36.95
5	Drug test(s), definitive, 22 or more drug class(es), including metabolite(s) if performed (G0483)	$246.92	0%	1.28	**$307.06**	-$6.38
6	**Genetic Test:** Molecular pathology procedure level 9 (81408)	$2,000.00	0%	0.15	**$290.42**	$172.50
7	Vitamin D-3 level (82306)	$32.89	-10%	8.92	**$286.13**	-$32.81
8	**Genetic Test:** Gene analysis (colorectal cancer) (81528)	$508.87	0%	0.48	**$239.40**	$71.73
9	Testing for presence of drug (80307)	$64.65	-10%	3.43	**$216.51**	-$19.56
10	Hemoglobin A1C level (83036)	$10.79	-10%	20.11	**$213.78**	-$18.54
11	Drug test(s), definitive, per day; 15–21 drug class(es), including metabolite(s) if performed (G0482)	$198.74	0%	0.82	**$158.19**	-$1.13
12	**Genetic Test:** Gene analysis (breast cancer 1 and 2) full sequence and duplication or deletion variants (81162)	$2,027.64	-10%	0.06	**$119.55**	$70.02
13	Blood test, basic group of blood chemicals (80048)	$9.40	-10%	12.54	**$118.44**	-$14.08

Data Collection & Reporting → New CLFS Rates & Under LAB Act (Pre-CARES)

Data Collection Period	Six-Month Review and Validation Period	Data Reporting Period	Used for CLFS Rate Years
1/1/2019—6/30/2019	7/1/2019—12/31/2019	1/1/2021—3/31/2021	2022--2024
1/1/2023—6/30-2023	7/1/2023—12/31/2023	1/1/2024—3/31/2024	2025--2027
Continues every third subsequent calendar year	Continues every third subsequent calendar year	Continues every third subsequent calendar year	New CLFS rate every third year

CDLT Rates	Based on Reporting Period	Reduction Cap
2020	Jan. 1, 2017—May 31, 2017	10%
2021	Jan. 1, 2017—May 31, 2017	15%
2022	Jan. 1, 2021—March 31, 2021	15%
2023	Jan. 1, 2021—March 31, 2021	15%

CARES Act Changes to PAMA

- CARES Act modified timing for private payor reporting periods and phase in of reimbursement cuts under PAMA:
  - CDLT data that was set to be reported between Jan. 1 2021—Mar. 31 2021 delayed (must be reported between Jan. 1 2022—Mar. 31 2022)
  - Data reporting period of Jan. 1, 2022—Mar. 31, 2022 based on original data collection period of Jan. 1, 2019—Jun. 30, 2019
  - After 2022 data reporting period, there is a three-year data reporting period for CDLTs (not ADLTs): 2025, 2028, etc.
  - Phase-in of payment cuts resulting from private payor rate implementation is extended through 2024
  - 0% payment for reduction for 2021
  - Payment cannot be reduced more than 15% for coverage years 2022—2024

Data Collection & Reporting → New CLFS Rates & Payment Reductions (Post CARES & LAB Act)

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	15%
2023	January 1, 2019 – June 30, 2019	January 1, 2022 – March 31, 2022	15%
2024	January 1, 2019 – June 30, 2019	January 1, 2022 – March 31, 2022	15%
2025	January 1, 2019 – June 30, 2019	January 1, 2022 – March 31, 2022	0.0%

Advanced Diagnostic Laboratory Tests

- Lab must apply for ADLT status and provide information about actual charge
- Defined at 42 C.F.R. § 414.502 as
  - CDLT covered under Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the single laboratory that designed the test (or a successor owner) and is
  - A test that is either: (1)
    - An analysis of multiple biomarkers of DNA, RNA, or proteins;
    - when combined with an algorithm, yields a patient-specific result (patient will develop certain condition or respond to certain therapy);
    - provides new clinical diagnostic information that cannot be obtained from any other test(s);
    - and may include other assays; or
  - (2) FDA-cleared or approved

Advanced Diagnostic Laboratory Tests

- Payment for ADLTs:
  - For the first three calendar quarters after CMS covers an ADLT, (the "new ADLT initial period") paid at the actual list charge, then paid at the weighted median of private payor rates
    - Prior to new ADLT initial period, payment is determined by MAC (based on info submitted by lab seeking new ADLT status)
  - Data collection and reporting is yearly, rather than every three years
  - Identified by a unique code
  - Temporary HCPCS codes for new and existing ADLT; if no existing code, G codes established

Date of Service (DOS) for Clinical Lab Tests

- In general, DOS for clinical lab tests is date of specimen collection
- However, if physician orders test at least 14 days following patient's discharge from hospital DOS is the date the test is performed (not date specimen collected)
- If test performed on a stored specimen, DOS depends on:
  - If stored 30 days or less the DOS is date test was performed if test ordered by physician at least 14 days following discharge, specimen collected during hospital stay and certain other conditions met
  - If stored more than 30 days, specimen considered archived and DOS is date specimen obtained from storage
- Chemotherapy sensitivity tests subject to similar 14-day rule

Date of Service (DOS) for Clinical Lab Tests

- In 2018 OPPS/ASC rulemaking, CMS established exception for ADLTs and molecular pathology tests. 2021 OPPS / ASC added MAAAs. DOS is date test was performed only if
  - Test was performed following hospital outpatient's discharge from hospital department
  - Specimen collected from hospital outpatient during encounter
  - Was medically appropriate to have collected sample from hospital outpatient during hospital outpatient encounter
  - Results of test do not guide treatment provided during hospital outpatient encounter
  - Test was reasonable and medically necessary for treatment of illness
- CMS exercised enforcement discretion on DOS for ADLTs and molecular pathology through Jan. 2, 2020.
- Where exception met, lab test separated from encounter which means lab bills Medicare directly under CLFS

Other Developments of Interest for Labs

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

CLIA Developments: Lab Co-Location & Shared Laboratories

- Background on “shared laboratories”
- Revisions to CLIA regulatory guidance for use of multiple-site CLIA certificates
    - Exceptions for laboratories within hospitals
- 2018 Memorandum to State Survey Agency Directors, Clarification of the Operation of Multiple Laboratories at the Same Location and the Discontinued Use of the Term ‘Shared Laboratory’

CLIA Developments: Lab Co-Location & Shared Laboratories

- Multiple labs that operate "at the same physical location and use the same testing personnel and equipment must meet the following conditions":
  - All records (e.g., quality control, procedure manuals, personnel competency) must be kept separate and distinct for each laboratory and must clearly show that each laboratory is operating independently.
  - The hours of operation must be specified for each laboratory.
  - The hours of operation for each laboratory must be separate and distinct. The times of testing cannot overlap and cannot be simultaneous.

Other CLIA Developments

- Proficiency Testing (proposed regulations)
  - Feb. 2019 CLIA proposed regulations would add 29 analytes to the list for which PT is required.
  - First changes since 1992.
- Proficiency Testing referral
  - 3 categories of penalties for PT referral:
    - Category 1: lab reports another lab's results as its own. Revocation of lab, owner/operator and CMPs.
    - Category 2: lab reports its own PT samples, but received another lab's results on or before cut off date. Suspension or limitation on CLIA certificate and alternative sanctions.
    - Category 3: referring lab does not receive test results from another lab prior to cut-off date

Other CLIA Developments

- Revisions to Medicare State Operations Manual, Ch. 6 (Special Procedures for Laboratories)
  - Updated Immediate Jeopardy Standards. IJ requires three components:
    - Noncompliance: an entity has failed to meet one or more federal health, safety and/or quality regulations; and
    - Serious Adverse Outcome or Likely Adverse Outcome: as a result of the identified noncompliance, serious injury, serious harm, serious impairment or death has occurred, is occurring or is likely to occur to one or more identified recipients at risk; and
    - Need for Immediate Action: the noncompliance creates a need for immediate corrective action by the provider/supplier to prevent serious injury, serious harm, serious impairment or death from occurring or recurring.
  - Other Changes to Special Procedures for Laboratories

Laboratory Enforcement Matters

- EKRA enforcement
  - Jan. 10 2020 DOJ announced criminal prosecution against manager of substance abuse treatment center in Kentucky
  - Alleged arrangement with toxicology lab involving kickbacks for urine drug test referrals
- "Traditional" (False Claims / Anti-kickback Statute / Stark Law) Enforcement
  - Sept. 2019 joint DOJ. OIG & FBI crackdown on cancer genetic testing arrangement. Alleged $2.1 billion fraudulent Medicare billing.
  - Jan. 2020 Reddy / Personalized Genetics pled guilty to $127 million Anti-kickback Statute criminal scheme. Agreement to pay $77 million restitution.
  - Nov. 2019 Boston Heart Diagnostics agreed to pay $26.67 million to resolve False Claims Act case alleging violations of Stark Law and Anti-kickback Statute

Laboratory Enforcement Matters

- "Traditional" (False Claims / Anti-kickback Statute / Stark Law) Enforcement
  - Feb. 2020: Drummond v. BestCare Laboratory Services: $30.6 million False Clams Act case involving billing Medicare for specimens using allegedly false millage reports
  - Jun. 2020: DOJ indictment of hospital administrators lab owners and billing co. executives, alleged $1.4 billion in fraudulent pass-through billing claims
  - Jan. 2021: AutoGenomics agrees to pay $2.5 million for Anti-kickback Statute violations involving payment of percentage-based fee to marketing firm for delivering molecular genetic testing. Nursing home, residential facilities targeted for testing.

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