



Notable Legislative Developments for Laboratories

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Health Care Transparency Bill in Congress Includes Provisions Governing Laboratory Tests



- H.R. 5378, titled “Lower Costs, More Transparency Act,” was recently introduced in House on September 8, 2023
- Title I, section 102 of the bill addresses clinical diagnostic laboratory test (CDLT) price transparency
- Bill reviewed by House Committees on Energy and Commerce, Ways and Means, and Education and the Workforce

Overview of CDLT Price Transparency Requirements Under Legislation

- Section 102 on CDLT Price Transparency would require applicable laboratories, effective January 1, 2026, to publish and annually update the following information regarding “specified clinical diagnostic laboratory test[s]”
 - Discounted cash price
 - Deidentified minimum payer-specific negotiated charge
 - Deidentified maximum payer-specific negotiated charge between laboratory and third-party payer
- The published information must include the price or rate for any ancillary item or services (e.g., specimen collection) normally furnished by laboratories as part of the specified clinical diagnostic laboratory test

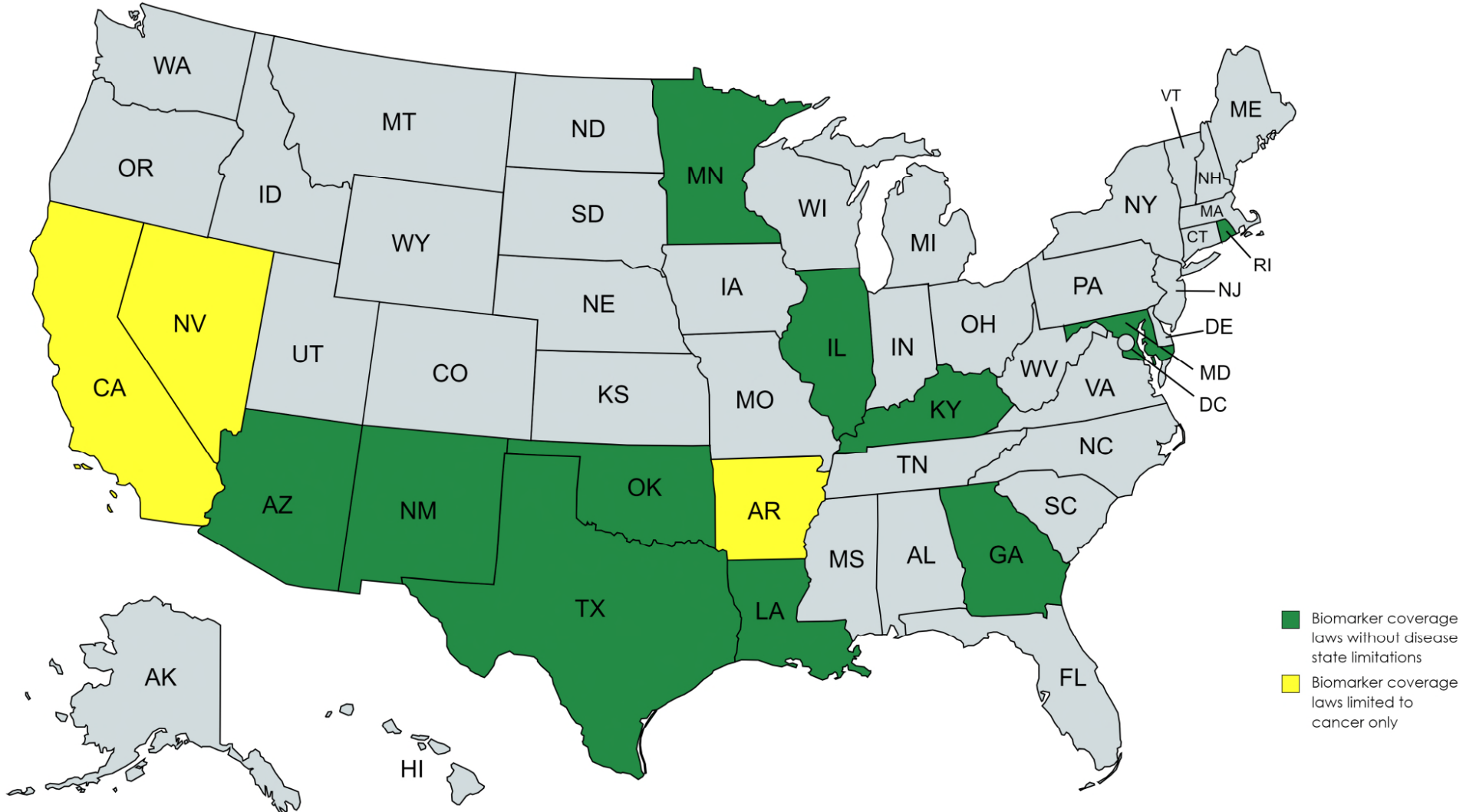
Transparency Requirements Appear Inapplicable to Sole Source Tests

- Reporting requirements apply only to “specified clinical diagnostic laboratory tests”
 - A specified clinical diagnostic laboratory tests defined as a “clinical diagnostic laboratory test that is included on the list of shoppable services specified by [CMS]...***other than such a test that is only available to be furnished by a single provider of services or supplier***”
- This language indicates that sole-source tests are carved out of the definition of “specified clinical laboratory test” and, consequently, out of the legislation’s transparency requirements
 - Sole-source test is “only available to be furnished by a single provider or supplier”
- Transparency requirements also only apply to applicable laboratories as defined in PAMA regulations, excluding all labs that do not receive Medicare payment

Proliferation of State Biomarker Coverage Laws

- Over the past few years, an increasing number of states have enacted laws mandating coverage of biomarker tests under certain circumstances
 - Legislation continues to advance in some states with ongoing sessions, and considerable activity is expected in 2024
- Generally, these biomarker coverage laws require health insurers in the state to cover biomarker testing provided to their enrollees when the testing meets certain evidentiary criteria
 - Laws typically apply to private payers, though recently enacted laws are increasingly made applicable to Medicaid
- 11 states have enacted biomarker coverage laws that apply broadly to all biomarker testing without disease state limitations
 - Three additional states limit biomarker testing coverage to certain cancer-related indications
 - Some states have enacted more targeted laws, applying to areas like screening for hereditary cancer syndromes and whole genome sequencing

Biomarker Coverage Law



Indication and Evidentiary Requirements for Biomarker Testing Coverage

- To be covered, state laws generally require that biomarker testing be:
 - Provided for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of an insured's disease or condition and
 - Supported by “medical and scientific evidence”
- Biomarker coverage laws generally list certain categories of evidence that are sufficient to support coverage of a biomarker test, including:
 - Labeled indications for FDA-approved or cleared tests;
 - Indicated tests for FDA-approved drugs or warnings on FDA-approved drug labels;
 - NCD by CMS
 - LCD by MAC (Illinois is notable in that it does not include LCDs)
 - Nationally recognized clinical practice guidelines and/or consensus statements

Considerations for Implementation of Biomarker Coverage Laws

- Plans have contested whether they are required to cover a test that meets one of the enumerated categories of medical and scientific evidence
 - Some take the view that they are only required to consider these evidentiary categories in performing independent evidence reviews
 - Labs and other stakeholders considering approaches to enforcing requirements of biomarker coverage laws
- Plans may take the position that coverage of a test under an LCD from an out-of-state MAC does not require coverage under the biomarker law
 - E.g., a plan might argue that an LCD from Novitas does not support coverage under the Arizona biomarker law
 - Sole source tests are typically covered under only a single LCD that applies to all beneficiaries nationwide, meaning that even if the LCD is from an out-of-state MAC, it applies to in-state enrollees
- Biomarker coverage laws do not address payment rates for tests subject to coverage requirements
 - Low rates for mandatorily covered tests could impact PAMA reporting

Update on PAMA

- Section 216 of PAMA enacted in 2014, with regulations promulgated in 2016
 - First data collection period was in 2016, with reporting in 2017, setting rates for 2018
- Second data reporting period was scheduled for Q1 2020, but Congress delayed it by a year
 - Congress has delayed PAMA reporting every year since then, each time by one year

Private Payer Rates From	Reported	Set Payment Rate For
January - June 2016	January - May 2017	2018 - 2024
January - June 2019	January - March 2024	2025 - 2027

Potential PAMA “Reform” – SALSA

- “Saving Access to Laboratory Services Act” introduced in March 2023
 - SALSA would move the next data reporting period to 2027 and the corresponding data collection period to 2026
 - Data reporting would be every four years, rather than every three years
- Legislation would modify reporting for a “widely available clinical diagnostic laboratory test” by collecting private payor rate data from a statistically valid sample of applicable laboratories rather than all applicable labs
 - Objective is to account for rates paid to non-independent labs like hospital laboratories, hospital outreach laboratories, and physician office laboratories
- “Widely available CDLT” defined as a CDLT with a payment rate under \$1,000 for which Medicare makes payment to at least 100 labs
 - Likely excludes most molecular diagnostic tests, and all sole source tests
- Legislation would lower the cap on year-to-year rate decreases and make it permanent, while also capping rate increases
- SALSA would also eliminate Medicaid MCOs as a private payor whose rates must be reported to CMS



Sales and Market Access Programs: Current Legal Perspectives

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EKRA Overview

- The Eliminating Kickbacks in Recovery Act (EKRA) enacted in 2018 as part of Support Act, which expanded access to opioid addiction treatment
- EKRA generally prohibits recovery facilities, treatment centers and clinical labs from receiving or offering any remuneration to induce patient referrals
- Statutory definition of laboratory applies broadly to all labs and testing covered by private and public health plans
- Minimal federal guidance and case law interpreting EKRA
- Clinical laboratories can take steps to mitigate level of risk in interactions with patients and providers through established policies and best practices

Key Statutory Requirements:

18 U.S.C. § 220



- For lab tests covered by health care plan, EKRA prohibits anyone from knowingly or willfully:
 1. Soliciting or receiving remuneration “in return for referring a patient” to lab; or
 2. Paying or offering remuneration:
 - a. “to induce a referral of an individual” to lab; or
 - b. “in exchange for an individual using the services” of lab
- EKRA is criminal statute allowing for fines up to \$200,000 and imprisonment

EKRA and Compensation for Sales and Marketing Services

- Must be interpreted in concert with existing AKS exceptions and safe harbors
- In particular, EKRA prohibits soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient to a recovery home, clinical treatment facility, or laboratory
- However, EKRA omits the language that exempted from AKS marketing and sales activities performed by employees
- It is possible that the Attorney General will promulgate regulations to clarify the meaning of “referral” under EKRA so that it more clearly applies to marketing and sales agents in the substance abuse field, consistent with its legislative intent

What to Do About Post-EKRA Sales Commissions?

- Employment and personal services safe harbors to AKS:
 - More permissive for employees versus independent contractors
 - AKS personal services safe harbor requires compensation to be aggregate, set in advance, FMV, unrelated to value or volume of sales
 - In light of the more favorable treatment of employees under the AKS, many laboratory and other marketing and sales arrangements have been structured as employment relationships so that commission-based compensation may be paid in compliance with the AKS.
- EKRA's exception for employees is narrower than the AKS exception and safe harbor for employees:
 - Restricts the ways in which employees can be paid if they are governed by both the AKS and EKRA
 - Employees of a clinical laboratory who historically received commission-based compensation may not comply with EKRA's exception

Recent Federal Case

- In October 2021, federal district court in ***S&G Labs Haw., LLC v. Graves*** found lab sales rep **cannot** induce referral under EKRA unless direct contact with individual patient
- Civil employment lawsuit between lab and former sales rep
 - Lab argued EKRA prohibited commission and fired sales rep when he refused updated compensation structure
 - Sales rep sued lab and asked Court whether EKRA applied to him
- Court ruled EKRA did not apply to sales rep
 - Found “individual” under EKRA means individual patient
 - Sales rep had no direct patient contact as only accounts were ordering providers
 - Commission “induced him to ... bring more business” in but he was not in position to “induce a referral of an individual”

Alternative Court Finding: U.S. v. Schena

- In September 2022, federal district court in CA rejected *Graves*, finding sales rep can induce referral under EKRA without direct patient contact
- Federal criminal action against lab owner
 - DOJ alleged owner paid marketers to induce test orders
 - Owner asked to dismiss EKRA claim as marketers had no direct patient contact
- Court found EKRA applied to payments
 - Contrary to *Graves*, no “requirement of direct interaction” with individual patients
 - Plain language applies “where a marketer causes an individual to obtain a referral from a physician”
- Conflicting rulings in *Graves* and *Schena* increase chance federal appeals court may address EKRA

Recent EKRA Enforcement by DOJ

- In March 2023, DOJ settled federal criminal action against Genotox Laboratories Ltd.
 - Genotox is provider of urine drug, pharmacogenetic, and infectious disease testing
- Case initiated by whistleblower, a former billing manager of lab
- Complaint alleged Genotox paid sales reps and specimen processors (SPs) based on number of tests and revenue they generated
 - DOJ argued payments “designed to induce referrals” of tests in violation of EKRA
 - DOJ also argued SPs performed valuable administrative work for physicians, creating further inducement under EKRA
- In settlement, Genotox paid \$5.9 million and entered 5-year CIA with HHS

Compliance and Patient Financial Assistance Services



What does the OIG say that relates to FAPs?

The Beneficiary Inducements CMP provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. The OIG also may initiate administrative proceedings to exclude such person from Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of the Beneficiary Inducements CMP as including "transfers of items or services for free or for other than fair market value." Section 1128A(i)(6) of the Act contains an exception to the definition of "remuneration" that may apply in the context of the Proposed Arrangement. Section 1128A(i)(6)(A) of the Act includes an exception that carves out from the definition of remuneration under the CMP certain waivers of cost-sharing amounts offered to patients in financial need. The exception protects waivers of cost-sharing amounts that are: (i) not offered as part of any advertisement or solicitation; (ii) not routine; and (iii) made following an individual determination of financial need.

<https://oig.hhs.gov/documents/advisory-opinions/1021/AO-22-02.pdf>

Recent OIG Guidance from the Pharma Side/Part D

- There is little recent formal guidance on laboratory patient financial assistance programs.
 - So we look to what guidance there has been in other contexts, such as programs for pharmaceuticals for Part D enrollees.
- “Pharmaceutical manufacturers may sponsor patient assistance programs (PAPs) that provide financial assistance or drug free product (through in-kind product donations) to low income individuals to augment any existing prescription drug coverage.”
<https://www.cms.gov/medicare/coverage/prescription-drug-coverage/patient-assistance-program> issued September 6, 2023

Best Practices and Potential Pitfalls for FAPS

- Be cognizant of the HHS OIG guidance.
- Provide relevant training and supervision of any program.
- Establish specific protocols to govern decision-making for assistance.
- Promote testing based solely on its quality, performance, and cost-effectiveness.
- Be wary of use of FAP to “prime the pump” of prescriber/patient demand.
- Avoid backing the FAP into an ROI analysis
- Firewall decisions against any actual or perceived influence.
 - Separate the FAP relationship from any sales or marketing activities or personnel.
 - Consider forming a committee to review the program and vet decisions.