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INSIDE THIS ISSUE

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CMS Mulls Stark Law Relief: This Time It May Be for Real

After decades of complaining about the Stark Law, the lab industry may now have an actual opportunity to secure meaningful relief. On June 20, CMS issued a Request for Information (RFI) seeking input on ways to alleviate the law's "undue regulatory impact and burden."

What's at Stake

The Stark Law, aka Physician Self-Referral Law, bans physicians from referring Medicare or Medicaid patients to labs in which the physician or a family member has a financial relationship unless the transaction meets a specific exception or "safe harbor." While nobody disputes the necessity of reining in crooked physician kickback arrangements, the law has drawn criticism for being overly strict and stifling business innovation and critical lab-physician collaboration, particularly regarding new integrated care models.

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Are Genetic Testing Labs Liable for Medical Malpractice?

Consumer-based genetic testing has become a $3 billion business with a seemingly limitless future. But the industry is also facing a legal threat to future growth: malpractice liability. In the past decade, patients and trial attorneys have sought to hold labs and doctors legally responsible for faulty or unwelcome DNA test results. The latest case comes from South Carolina and involves one of the nation's largest labs, Quest Diagnostics.

What Happened

You would be hard pressed to find a plaintiff more sympathetic than Amy Williams. In 2005, the Myrtle Beach mom's 2-year-old son Christian began experiencing regular seizures. Suspecting a mutation in the SCN1A gene, doctors sent Christian's DNA to Athena Diagnostics for genetic testing. The report found a glitch in the gene but described it as a "variant of unknown significance" that, according to

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CMS Mulls Stark Law Relief, *from page 1*

The new RFI signals a sympathy for those views. "CMS is aware," the RFI notes of the Stark Law's effect "on parties participating or considering participation in integrated delivery models, alternative payment models and arrangements to incent improvements in outcomes and reductions in cost." The RFI invites the public to vent their concerns and suggestions for fixing the problem.

What's on the Table

Key issues on which CMS is seeking input:

1. How Stark is affecting commercial alternative payment models and whether additional safe harbors are necessary to protect such arrangements;
2. The effectiveness of the current Stark risk-sharing arrangement exception;
3. Whether CMS should add a "special rule for compensation under a physician incentive plan" within the current Stark personal services arrangements exception;
4. The barriers physicians face in qualifying as a "group practice" under the current Stark Law; and
5. How CMS could interpret the current DHS safe harbor, i.e., exception for remuneration unrelated to designated health services more expansively to cover a broader array of arrangements.

Deadline to comment: Aug. 24, 2018.

Takeaway: It Might Really Happen

"Fool me once, shame on you; fool me twice, shame on me."

Skeptics among you can be forgiven—especially if you've been around this industry long enough. After all, this is hardly the first time that the government has dangled vague promises of Stark relief. Two years ago, Congress held hearings to discuss whether Stark should be rolled back to allow for value-based, coordinated health care service business models and arrangements. (See GCA, Aug. 15, 2016.) Until now, little has come out of this initiative.

But this time things appear to be different. First, consider the broader context of a new administration dedicated to liberating private business from the burden of government regulation. More significantly, while ostensibly focused on new coordinated care and payment models, the RFI signals the CMS's willingness to delve into core principles of the Stark Law covering the entire gamut of covered business arrangements, including:

- The definitions of "commercial reasonableness" and "fair market value";
- When compensation is deemed to "take into account" physician referral volume or value and "other business generated" between parties to an arrangement; and
- Whether requiring greater transparency for business arrangements instead of banning them altogether might allow for achievement of basic Stark Law objectives.

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Keep Your Fingers Crossed & Stay Tuned

The last thing we want to do is get your hopes up. But if—and it's a huge "if"—the agency's actions are in line with its new tone and approach, real and meaningful Stark Law relief may actually come to fruition.

Case of the Month: Patients Can't Sue Labs for Privacy Breaches, Federal Court Confirms

The HIPAA law sets out civil and criminal penalties that can be imposed on labs (and other providers) that commit privacy violations. But one thing the HIPAA law does not specify is whether an individual victim can directly sue the lab for the harm he/she suffers as a result of its privacy breach. A brand new federal case targeting one of the nation's biggest lab companies addresses this crucial question.

The Situation

The case began when a LabCorp technician instructed a Washington, D.C., hospital patient to use an on-premises computer intake station to provide her medical information. The patient complained that the intake station was within eye and earshot of the adjacent station and snapped off photographs of the two stations with her smart phone. After the HHS Office of Civil Rights and DC Office of Human Rights rejected her privacy claim, the patient resolved to take LabCorp to court.

The Ruling

LabCorp claimed that the patient had no right to sue for a HIPAA violation. Or, to state it in legal terms, LabCorp argued that even if the adjacent intake stations did violate HIPAA rules, the patient had no legal case because the HIPAA statute neither expressly nor implicitly grants individuals a "private cause of action, i.e., the right to sue a provider in civil court for a violation. The court agreed and dismissed the case without a trial [*Thomas v. LabCorp*, U.S. District Court for the District of Columbia, No. 18-591 (RC), June 25, 2018].

The Law

The *Thomas* ruling is 100% in line with prior cases ruling against individual plaintiffs seeking to sue providers for HIPAA violations. In other words, any penalties to be handed out under HIPAA must come from the regulators, not the individual victims.

The First Caveat: Risk of Damages Under State Privacy Laws

There's more to medical privacy than HIPAA. Many states have adopted their own privacy laws to protect patients, including mandatory breach notification. In addition to providing for stiff penalties, some states provide broader remedies to individual victims, including a private cause of action for failure to provide timely notification of a privacy breach. Thus, while the doors to federal court may be barred, individuals victimized by lab privacy snafus may be able to sue and win big damages in state court.

The Second Caveat: Risk of Collateral Liability

The other thing labs need to keep in mind is how committing a HIPAA breach can heighten liability risks under *other laws*. For example, failure to properly protect PHI can serve as powerful evidence in a negligence, malpractice or consumer fraud case against a lab.

3 TAKEAWAYS

1. Patients can't sue labs for HIPAA violations.
2. Patients may be able to sue you for state privacy violations.
3. HIPAA violations may make it easier for patients to sue for negligence and other violations.

FDA Says LOINC Coding of IVD Tests Is Voluntary, Not Mandatory

On June 15, the FDA issued a new guidance document clarifying the rules for laboratory coding of *in vitro* diagnostic tests. There are four key takeaways for IVD test makers and labs:

1. No Mandatory Lab Coding of Tests

Laboratory coding is voluntary, not mandatory. However, the FDA recommends that test makers use the Observation Identifiers Names and Codes (LOINC) for coding IVD tests.

2. No Mandatory Lab Coding of Devices

Similarly, the FDA is recommending but not requiring inclusion of LOINC codes for IVD tests in labeling of medical devices. The agency does not intend to perform premarket review of the LOINC codes that manufacturers provide to labs or other users.

3. LOINC Codes Must Be for Test's Approved Indications

According to the guidance document, the LOINC codes the device manufacturer provides should be consistent with the particular IVD test's FDA-cleared or approved indications for use. Dissemination of LOINC codes suggesting an unapproved or uncleared indication may be evidence that the device is adulterated and/or misbranded.

4. LOINC Code Distribution Format Neither Required nor Recommended

While declining to recommend a specific format for distribution, the agency "acknowledges" that LOINC codes may be displayed as simple text in a table format, or in structured formats such as Java Script Object Notification (JSON) or Extensible Markup Language (XML). However, the FDA "strongly encourages" use of an FDA-recognized consensus standard, e.g., the LOINC transmission document for IVDs (LIVD) standard, for communicating or disseminating the LOINC codes provided by manufacturers or others *to labs or other end users.*

CMS Takes 3 New Measures to Bolster Medicaid Program Integrity

With Medicaid spending on the rapid ascent, CMS unveiled a trio of new initiatives to bolster program integrity and make states more accountable for compliance with federal rules.

1. MLR Audits

CMS will step up audits of state claims for federal match funds and medical loss ratios (MLRs). These MLR audits will examine how much a particular state spent on clinical services and quality improvement versus how much it spent on administration and took in profits. The audits will also review states' rate setting methods.

2. State Beneficiary Eligibility Audits

CMS will also conduct new audits of state beneficiary eligibility determinations focusing on states previously found by the OIG to be high risk. Specifically, the agency will examine how the state determines which groups are eligible for Medicaid and whether it did any jiggering of its eligibility criteria in response to recent Medicaid expansions and federal match rate increases.

3. Optimization Claims & Provider Data Provided by States

Last but not least, CMS will utilize advanced analytics and other innovative solutions to improve Medicaid eligibility and payment data. Over the coming months, the agency will validate the quality and completeness of the enhanced data the states are now submitting with an eye to leveraging the data to achieve Medicaid program integrity objectives.

Criminal Charges May Spell the End for Theranos

Four years ago, Theranos was a $10 billion company poised to turn a breakthrough blood testing technology into a diagnostics dynamo to the tune of $70 billion in annual sales. Today, the company and its founding CEO, Elizabeth Holmes, are on the brink of financial and legal ruin.

The latest and most devastating blow came last month when a federal grand jury indicted Theranos CEO Elizabeth Holmes and former COO Sunny Balwani on nine counts of wire fraud and two counts of conspiracy, charges carrying a potential sentence of 20 years in prison, fines of $250,000 per count and restitution.

According to prosecutors, "Holmes and Balwani used advertisements and solicitations to encourage and induce doctors and patients to use Theranos' blood testing laboratory services," all the while knowing that its touted finger-prick blood tests could not consistently produce accurate and reliable results.

Meanwhile, *The Wall Street Journal* reports that Theranos is headed for bankruptcy.

Four months ago, it appeared that Holmes and the company she founded in 2013 might be out of the woods when they settled stock fraud charges with the Securities and Exchange Commission. Now the prospects are far more grave.

Enforcement Trends: New Fraud Takedown Focuses on Opioid Drugs & Sophisticated Financial Schemes

The 2016 health care fraud takedown was the biggest in history; the 2017 version surpassed it; and the June 2018 reprise nearly doubled the 2017 effort, at least in terms of the false claims dollars involved. Here are the numbers, courtesy of a new OIG report:

National Health Care Fraud Takedown Results, 2016 to 2018

Metric	2018 Takedown	2017 Takedown	2016 Takedown
Federal districts participating	58	41	36
State Medicaid Fraud Control Units participating	30	30	23
Doctors, nurses and other health professionals charged	165 (including 32 doctors)	115	61
Total individuals charged	601	412	301
Total false billings involved	$2 billion	$1.3 billion	$900 million

Enforcement Trends

The focus of this year's takedown was drugs and money. Drugs as in the opioid epidemic, which commanded the lion's share of attention, with enforcers focusing on physicians, pharmacists, hospitals, home health agencies, pain clinics and other providers involved in illegal distribution of opioids and other prescription narcotics. Labs providing urine drug testing in connection with these prescriptions were caught up in the dragnet.

While money is a perennial theme, the modern fraud scheme has become bigger and much more sophisticated carried out by elaborate financial networks that extend to not just run of the mill Medicare/Medicaid/TRICARE fraud but also identity theft and money laundering. Of course, the usual suspects—kickbacks, billing of services that weren't medically necessary or performed, upcoding and such—were also amply represented in this year's takedown results.

Local Results

- **Southern District of Florida:** Total of 124 defendants charged for over $337 million in false billings, including the owner of a South Florida sober living facility indicted for a kickback and patient recruitment scheme allegedly generating $106+ million worth of medically unnecessary drug urine tests;
- **Central District of California:** 33 defendants charged in alleged schemes to defraud Medicare out of more than $660 million, including the attorney/marketer indicted in a compounding pharmacy fraud case for allegedly paying kickbacks and offering incentives such as prostitutes to podiatrists in exchange for prescriptions written on pre-printed prescription pads issued regardless of medical need;

- **Southern District of Texas:** 48 individuals charged in cases involving over $291 million, including the pharmacy chain owner, managing partner and lead pharmacist involved in an alleged drug and money laundering conspiracy;
- **Eastern District of Michigan:** 35 defendants face charged in fraud, kickback, money laundering and drug diversion schemes involving approximately $197 million in false claims for services that were medically unnecessary or never rendered;
- **Northern District of Illinois:** 21 individuals charged for over $54 million in fraudulent billing schemes;
- **Eastern District of New York:** 13 individuals charged for kickbacks, services not rendered, identity theft, money laundering and other schemes worth over $38 million;
- **Middle District of Florida:** 21 individuals charged in schemes involving more than $21 million;
- **Middle and Eastern Districts of Louisiana and Southern District of Mississippi:** 42 defendants charged in connection with health care fraud, drug diversion and money laundering schemes involving more than $16 million in fraudulent billings.

U.S. Attorney's Actions

In addition to the state Strike Force locations, 46 U.S. Attorney's Offices from across the country participated in the takedown. Key results:

- **Northern and Southern Districts of Alabama:** 15 defendants charged in eight health care fraud schemes involving compounding pharmacy fraud and unlawful distribution of controlled substances;
- **Eastern District of California:** Four charged for their roles in two schemes, one involving forged prescriptions;
- **Southern District of California:** Seven defendants, including a physician, were charged in three health care fraud and one identity theft scheme;
- **District of Connecticut:** Three defendants, including two medical professionals, charged for in two schemes involving compounding drugs and unlawful distribution of Schedule II and IV controlled substances;
- **District of Delaware:** Physician/owner of a pain management clinic charged with illegally prescribing more than two million dosage units of Oxycodone products;
- **District of Idaho:** Three medical professionals, were charged in separate controlled substances fraud schemes;
- **Northern District of Iowa:** Two medical professionals charged for their roles in opioid-related schemes;
- **District of Kansas and Northern and Western Districts of Oklahoma:** 12 defendants, including four physicians, charged in unlawful distribution of controlled substances schemes;

- **Eastern and Western Districts of Kentucky:** 12 defendants, including five medical professionals, charged with health care fraud, unlawful distribution of controlled substances, aggravated identity theft and money laundering, including one case involving the operation of false-front medical clinics;
- **District of New Jersey:** Eight defendants, including a New York doctor, Philadelphia hospital anesthesiology technologist and owner of a medical billing company charged in five schemes to defraud private insurance companies of over $16 million;
- **Western District of Pennsylvania:** Four physicians charged in various health care fraud and drug diversion schemes, including one involving 32,000 dosage units of buprenorphine; and
- **Eastern District of Washington:** Dentist and another individual indicted for distributing hydrocodone and tramadol without a legitimate medical purpose.

Labs IN COURT

A roundup of recent cases and enforcement actions involving the diagnostics industry

Cancer Center Hit with $4.3 Million HIPAA Fine for Failure to Encrypt

Case: The University of Texas MD Anderson Cancer Center was on the wrong end of the fourth largest HIPAA fine ever dished out by the HHS Office for Civil Rights for a trio of incidents between 2012 and 2013:

- An employee's laptop was stolen;
- A trainee lost a thumb drive; and
- A visiting researcher lost another thumb drive.

Result: Personal data of 33,800 patients was compromised.

Significance: Theft and loss of devices containing patient data is an all too common occurrence. What made this case different and egregious enough to warrant a massive HIPAA fine was that Anderson failed to encrypt the data. MD Anderson implemented an encryption policy in 2006 but didn't begin actual encryption of PHI on its computers until 2011, an effort that took over two years to complete. It argued that since the data was used for research purposes, HIPAA requirements didn't apply. But the HHS administrative law judge disagreed finding the Texas hospital's "dilatory conduct shocking given the high risk to patients resulting from the unauthorized disclosure" of digital PHI. MD Anderson says it plans to appeal the ruling contending that there's no evidence that any unauthorized party actually viewed the PHI.

Whistleblower Sues Montana Health System Officials for Elaborate Kickback Scheme

Case: The CFO of a Montana hospital physician network filed a *qui tam* lawsuit against his employer for paying physicians above-market compensation in exchange for referrals to network labs, hospitals, clinics and specialists.

Significance: The network, the biggest in Montana, denies the charges and contends that the Work Relative Value Units (WRVU) system it uses to measure physician productivity is the same method commonly employed by other hospitals across the country. But the CFO contends that the WRVU system is just a smoke screen to conceal payments based on referrals rather than productivity, citing among other examples, a neurosurgeon paid $900K per year even though collections for his services ranged from $207K to $374K, which is roughly the 10th percentile for neurosurgeons in national productivity metrics.

Insurer Accuses Florida Lab, California Hospital of Toxicology Test Billing Fraud

Case: Anthem Blue Cross Blue Shield is suing Reliance Laboratory Testing for allegedly conspiring with California hospital Sonoma West Medical Center to create a fraudulent billing organization in a bid to get around Anthem's $32 per test fee cap. By billing toxicology tests through the hospital rather than the Florida Reliance lab that performed them, Sonoma West was able to bill $3,500 per claim, the suit charges. Over a nine-month period, Sonoma West submitted more than 15,000 netting $16 million in payments, according to the complaint.

Significance: This is the latest in a growing line of private insurer suits targeting labs for test billing rip offs. (For more details, see *GCA*, May 23, 2018.) Anthem says it got wise to the scheme after receiving a call from a Missouri health plan member saying she had received a statement from Sonoma West even though she had never been to California. After investigating and finding that patients listed on Sonoma West claims were never patients at the hospital, Anthem put a stop to the scheme by implementing a "zero pay" system edit that Anthem into its toxicology claims software system.

Midwest Lab & Pain Clinics Charged in Massive Opioid Distribution Scheme Improprieties

Case: The feds filed criminal charges against a CEO and four physicians as part of an investigation into a $200 million health care fraud scheme involving a network of Michigan and Ohio pain clinics, labs and other providers responsible for the distribution of over 4.2 million doses of medically unnecessary opioid injections, many of which were resold on the streets. The CEO and owner of the clinics and labs allegedly conspired with clinic physicians to prescribe oxycodone, hydrocodone, oxymorphone and other controlled substances to Medicare beneficiaries who did not need them, including addicts. Beneficiaries were also required to submit to expensive, medically unnecessary and painful injections to obtain the drugs, the indictment charges.

Significance: This case is typical of the new face of health care fraud enforcement in the opioid epidemic era. It began when Medicare conducted a medical review of the injection claims and determined that 100% of the claims were not eligible for Medicare reimbursement and summarily suspended the billing privileges of the pain clinics involved. The labs allegedly got involved by performing medically unnecessary urine drug tests ordered by clinic physicians. After medical review of lab claims determined that 95% of claims failed to meet Medicare reimbursement criteria, the lab was ordered to repay $6.9 million to Medicare.

Medicare Reimbursement: CMS Begins Implementing New HOPPS Date of Service Rules for ADLTs & Molecular Pathology Tests

CMS has begun implementing the new rules that exempt advanced diagnostic laboratory tests (ADLTs) and molecular pathology tests from Medicare Hospital Outpatient Prospective Payment System (HOPPS) laboratory 14-day date of service rules. Here's what labs that bill Medicare for outpatient lab tests need to know.

General Rules

The date of service (DOS) for outpatient lab services is normally the date the specimen is collected. *Exception:* The DOS is the date the test is performed if:

- The doctor orders the test at least 14 days after a patient is discharged from the hospital;
- The specimen is collected during a hospital surgical procedure;
- Collecting the sample at another time would be medically inappropriate;
- Test results don't guide treatment provided during the hospital stay; and
- The test is reasonable and necessary for treating an illness.

When the so called "14-day rule" applies, the test is paid separately under Part B; in all other cases, it's bundled into the payment for the hospital stay.

CRITERIA FOR DIRECT BILLING OF OUTPATIENT ADLTs

Under new HOPPS rules, labs can directly bill Medicare under the CLFS for ADLTs delivered to outpatients less than 14 days after hospital discharge if either of the following criteria applies:

Criterion 1: The test:

- Analyzes multiple biomarkers of DNA, RNA or proteins;
- When combined with an empirically derived algorithm, yields a result predicting the probability of an individual patient's development of a certain condition(s) or response to a particular therapy(ies);
- Provides new clinical diagnostic information that can't be obtained from any other test or combination of tests; and
- May include other assays

Criterion 2: The test is cleared or approved by the FDA.

The ADLT & Molecular Pathology Test Exception

Under the new rules, the DOS for roughly 300 molecular pathology tests and ADLTs is the date of testing rather than specimen collection provided that the tests are both:

- Excluded from OPPS packaging rules; and
- Ordered *less than* 14 days after a patient's hospital discharge.

Impact

By removing ADLTs and molecular pathology tests from the 14-day rule, the new CMS rule enables labs to bill Medicare for those tests directly under the Clinical Laboratory Fee Schedule (CLFS).

Implementation

Although the new rules officially took effect on Jan. 1, 2018, CMS did not begin implementing them until July 2. To give labs a little leeway to get used to the rules, the agency will exercise enforcement discretion until Jan. 2, 2019.

Are Genetic Testing Labs Liable for Medical Malpractice?, *from page 1*

Athena's classification "often have no effect" on normal gene activity. What Christian really had, according to Ms. Williams' attorneys, was a rare condition called Dravet syndrome.

Athena could have and should have detected that Christian had Drevet, the complaint alleged; instead, the lab's report led doctors to rule out Drevet and treat him with sodium-channel-blocking medications, which worsened his condition and intensified his seizures. A proper diagnosis would have prevented the fatal seizure Christian suffered on Jan. 5, 2008, according to the complaint.

The real significance of the case is that it portends the larger trend of holding providers of genetic testing to the standards of medical malpractice.

The Plaintiff's Legal Conundrum

After initially blaming herself for Christian's death, Ms. Williams finally decided to sue Athena and its parent company Quest Diagnostics in 2016 (which for simplicity's sake, we'll refer to collectively as "Quest"). The problem: In South Carolina, the statute of limitations for medical malpractice is six years. However, the statue of limitations for negligence and wrongful death is three years from the date the plaintiff discovers he/she has a cause of action. Ms. Williams contended that she didn't discover that she had a legal case against Quest and thus still had time to file her suit as a wrongful death action.

Not so fast, countered Quest, who claimed the case was essentially wrongful death based on medical malpractice and thus subject to the hard six-year cap. The key question thus became whether Quest was acting as a licensed healthcare provider when it performed genetic testing on Christian?

The Ruling

On June 27, the South Carolina Supreme Court ruled 4 to 1 in favor of Quest. "A genetic testing laboratory that performs genetic testing to detect an existing disease or disorder at the request of a patient's treating physician is acting as a 'licensed health care provider' under [state law]," the Court concluded. *Result:* The case was time-barred.

Takeaway: While Quest came away with the win, the significance of the ruling is limited to the extent it was based on procedure and thus didn't address the substance of the malpractice claim. Moreover, the case is legally binding within South Carolina and will likely have little influence in other states.

The real significance of the case is that it portends the larger trend of holding providers of genetic testing to the standards of medical malpractice. This is not the first time that labs and physicians have been sued for malpractice for making a faulty diagnosis from DNA test results. So far, most of these cases have alleged not wrongful death but wrongful birth, i.e., failure to diagnose pre-natal genetic disorders resulting in births that should and would have been aborted had the correct genetic information about the fetus been provided. (See the Scorecard on page 12 for a summary of the leading cases.)

'Wrongful Birth' Litigation Scorecard

Malpractice lawsuits against labs and providers for failing to provide accurate DNA testing information during pregnancy

Florida: Plaintiff Wins $21 Million Malpractice Award (July 2007)
Parents sue Univ. of South Florida doctor for failing to diagnose their son's genetic disorder (called Smith-Lemli-Optiz syndrome) impairing his ability to synthesize cholesterol, leading couple to have a second child with same disorder. **Ruling:** Jury finds malpractice and awards couple $21 million but state law caps damages at $200K.

Virginia: LabCorp Can Be Sued for Malpractice (November 2011)
Parents who are both "carriers only" of thalassemia beta decide to continue their pregnancy after genetic testing confirms that their unborn fetus is also "carrier only." But when the results turn out to be wrong and the child has the more serious "affected person" version of the disorder, they sue LabCorp for "wrongful birth" malpractice. Ruling: The federal court refuses to dismiss the case but also finds that LabCorp is a "health care provider" and thus covered by the medical malpractice damages caps under state law.

Montana: Giving Pregnant Mom Pamphlet Defeats Claim of Negligently Failing to Provide Screening Test Info (February 2016)
After giving birth to a daughter with cystic fibrosis, a mother sues her doctor and prenatal care nurse for $14 million for not providing her any information on the availability of cystic fibrosis carrier screening testing. Ruling: The jury doesn't buy it and finds the defendants did meet the standard of care in delivering prenatal treatment, including giving the patient a cystic fibrosis pamphlet during her first appointment that she never bothered to read.