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IN THIS ISSUE

Genetic Testing: Three Common PGx Compliance Traps for Laboratories to Avoid

By Adam M. Walters

In recent years, many clinical laboratories have started offering Pharmacogenetics Testing (PGx) to assist physicians in avoiding prescribing medication doses that may cause adverse reactions in patients with certain genotypes and/or alleles. For example, people with the HLA-B*1502 allele are at a higher risk of developing toxic epidermal necrolysis (TEN) when using the anti-convulsant Carbamazepine. By using a PGx test for the HLA-B*1502 allele prior to prescribing Carbamazepine, a physician may prevent Carbamazepine induced TEN.

While the PGx test is a highly valuable form of medical test, it is also presently one of the most highly scrutinized tests test by CMS. While not an exhaustive list, following the below referenced guidelines should enable laboratories to minimize compliance risks associated with PGx testing.

1. Documenting Medical Necessity of PGx Tests

Many recoupments, false claims act cases and indictments are based on billing for tests that lack medical necessity. At least for purposes of Medicare, PGx testing is not medically necessary unless a practitioner is considering (or already prescribing) medications that are medically necessary and

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Coding Alert: CMS Adds New PLA Oncology, ELISA, Reproductive Codes to HCPCS

CMS added seven new PLA codes to the HCPCS files, effective July 1, 2021, which will be contractor-priced based on local rates until they undergo the CLFS annual payment determination process for national pricing.

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Genetic Testing: Three Common PGx Compliance Traps for Laboratories to Avoid, *from page 1*

have a known gene-drug interaction that has been demonstrated to be clinically actionable.

While laboratories do not determine medical necessity, they can still get into trouble for encouraging practitioners to order medically unnecessary tests. The following education and documentation actions may help prevent, or assist with the defense of, an audit or investigation:

- Encourage the ordering practitioner to send a letter of medical necessity to the insurance company for pre-approval and that the letter outlines the benefits of the test, a description of the test, relevant clinical notes, FDA information and the primary reason for the test;
- Require the ordering practitioner to sign an acknowledgement: (i) of the limits on the use of PGx testing; (ii) that the practitioner is treating the patient and considering (or already prescribing) medications that are medically necessary and have a known gene-drug interaction that is clinically actionable; and, (iii) that the ordering practitioner is qualified to diagnose the condition being treated and prescribe the relevant medication; and
- Properly educate practitioners on the clinical benefits, proper documentation and appropriate uses of PGx testing.

2. Billing of PGx Tests

In addition to policies and rules that apply to billing for all clinical laboratory test, laboratories should follow these additional steps when billing for PGx testing:

- Ensure that a multi-gene panel is only ordered and billed if more than one gene is clinically actionable for a medication or multiple medications are being prescribed; and
- Properly document the medication at issue on the claim form.

3.. Sales and Marketing of PGx Tests

Several indictments involving genetic testing have involved the use of telemarketers, physician brokering and misleading marketing materials. To avoid such troubles, laboratories should follow these guidelines in marketing PGx testing:

- Use an employed sales force whose compensation is **not** based on the number of tests ordered, amount billed/collected from insurance companies or patients referred from a practice; and
- Review your marketing materials and ensure that they are straightforward, honest and do not overstate the uses and benefits of PGx testing.

Takeaway

Recognize that PGx tests are currently in the crosshairs of federal and state enforcers. Following the guidelines above should help you steer clear

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of trouble. And, as always, laboratories should scrupulously document their compliance efforts for not only PGx tests but all tests and services for which they bill.

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Labs IN COURT

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

Self-Disclosing Saves Kentucky Lab Over $1 Million in False Claims Settlement

Case: A Kentucky-based lab that made heroic efforts to step up its COVID-19 testing early in the pandemic has agreed to shell $1.25 million for falsely billing Medicare, Medicaid, TRICARE and CHAMPVA for urine drug tests between 2016 and 2018. The U.S. Attorney claimed that Bluewater Toxicology:

- Submitted claims for definitive urine drug tests of 22 or more drug classes even though it tested for a lower number of classes to secure higher reimbursement;
- Submitted certain claims without sufficient documentation showing the treating physician's intent to order the test; and
- Billed for specimen validity testing (SVT), a procedure to verify that a urine sample for drug testing hasn't been diluted which isn't covered by Medicare and other federal health programs.

Significance: Even though $1.25 million is a lot of money, the settlement price tag could have been twice as high had the lab not come forward to self-disclose and thereby secure a 1.5 monetary loss rate rather than the triple damages provided for by the *False Claims Act*.

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Labs in Court: A roundup of recent cases and enforcement actions involving the diagnostics industry, *from page 3*

Blue Cross and Blue Shield Sues Lab for COVID-19 Test Price Gouging

Case: Blue Cross and Blue Shield of Kansas City is suing GS Labs for COVID-19 test price gouging, contending that the national testing facility inflated its cash prices and performed medically unnecessary tests on out-of-network members. The $9.2 million federal lawsuit accuses GS Labs of "engaging in an abusive scheme to exploit the COVID-19 pandemic by duping health insurers into paying thousands of COVID-19 diagnostic testing claims at grossly inflated rates." BCBS claims that GS Labs charged it $380 for a COVID-19 antigen test, roughly 10 times what Medicare reimburses for the test and up to $979 for a PCR test.

Significance: Insurers and labs have been waging PR war against each other almost from the moment the federal government mandated that payors cover COVID-19 tests without charging copays, deductibles or other out-of-pocket expenses. Labs have claimed that payors aren't obeying the mandate; insurers have accused labs of price gouging. But this is the first time the conflict has festered into actual litigation. However, this is not the first time that GS Labs' test prices have come under question. Last December, the Kansas Insurance Department began investigating a local facility owned by GS Labs for charging $1,000 for tests. GS Labs has yet to comment on these allegations.

Georgia Lab Owner Must Stand Criminal Trial for CGx Kickback and Billing Scam

Case: In 2019, the feds indicted the owner of a Georgia lab for allegedly paying kickbacks to patient recruiters to engage in telemarketing campaigns and health fairs in an effort to drum up referrals of Medicare patients for medically unnecessary cancer genomic (CGx) BRCA tests and then billing Medicare for the tests. The owner asked the Florida federal district court to toss the indictment, claiming that:

- The payments to recruiters weren't kickbacks but legitimate payments to "patient navigators" under the Affordable Care Act;
- The US Preventive Services Task Force recommends BRCA CGx testing for certain cases and Medicare is legally required to cover any screening tests the Task Force recommends; and
- Labs don't have an independent duty to verify that ordered tests are medically necessary.

Not surprisingly, the court upheld the indictment.

Significance: Although the court suggested that the lab owner's legal theories were way off base, especially the medically necessary argument, the refusal to dismiss the indictment was also based on procedural grounds to the extent that the arguments raised questions of fact that would have to be determined at trial [*United States v. Patel*, 2021 U.S. Dist. LEXIS 115925, 2021 WL 2550477

West Virginia Clinic Becomes Most Recent Provider Fined for HIPAA Right of Access Violation

Case: Instead of the required 60 days, it took a West Virginia diabetes clinic two years to provide access to a minor child patient's mother access to his medical records. In addition to $5,000 to settle a potential HIPAA Privacy Rule violation, the clinic had to agree to implement a corrective action plan providing for two years of Office for Civil Rights (OCR) monitoring.

Significance: This is the 19th fine the OCR has handed out since it launched its HIPAA Right of Access Initiative in April 2019 targeting providers for not granting individuals' access to their own protected health information. Although the initiative remains ongoing, the pace of fines has slowed considerably under the Biden administration. The West Virigina settlement represents the second lowest fine. The highest fine was $200,000. Here's a Scorecard of all the fines issued so far.

OCR Right of Access Initiative Settlements Scorecard (as of July 26, 2021)

Provider	Settlement Amount*	Allegations
Banner Health ACE	$200,000	OCR cites two occasions in which Phoenix-based not-for-profit health system took about 6 months to provide patients their requested PHI
St. Joseph's Hospital and Medical Center	$160,000	Phoenix hospital refused to provide PHI to patient's mother even though she was his legal representative
NY Spine Medicine	$100,000	Neurology practice refuses patient's multiple requests for copies of specific diagnostic films
Bayfront Hospital	$85,000	Florida hospital didn't provide expectant mother timely access to the PHI of her unborn child
Korunda Medical	$85,000	After first refusing to provide it at all, Florida primary care and interventional pain management services provider sent patient's PHI to third party in the wrong format and charged him excessive fees
Renown Health, P.C.	$75,000	Nevada private, not-for-profit health system didn't timely honor patient's request to transfer her EHR and billing records to a third party
Sharp Rees-Stealy Medical Centers	$70,000	California hospital and healthcare network didn't timely honor request to transfer patient's EHR to a third party
Beth Israel Lahey Health Behavioral Services	$70,000	Massachusetts provider ignored request of personal representative seeking access to her father's PHI

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Labs in Court: A roundup of recent cases and enforcement actions involving the diagnostics industry, *from page 5*

Provider	Settlement Amount*	Allegations
Arbour Hospital	$65,000	Massachusetts mental health services provider kept patient waiting 5 months before granting access to his PHI
University of Cincinnati Medical Center, LLC	$65,000	Ohio academic medical center failed to respond to patient's request to send an electronic copy of her medical records maintained in its electronic health record EHR to her lawyers
Housing Works Inc.	$38,000	New York City non-profit services provider refused patient's request for a copy of his medical records
Peter Wrobel, M.D., P.C., dba Elite Primary Care	$36,000	Georgia primary care practice failed to provide patient access to his medical records
Village Plastic Surgery	$30,000	New Jersey practice failed to provide patient timely access to his medical records
Riverside Psychiatric Medical Group	$25,000	California medical group didn't provide patient copy of her medical records despite repeated requests and OCR intervention
Dr. Rajendra Bhayani	$15,000	NY physician didn't provide patient her medical records even after OCR intervened and closed the complaint
All Inclusive Medical Services, Inc.	$15,000	California multi-specialty family medicine clinic refused patient's requests to inspect and receive a copy of her records
Wise Psychiatry, PC	$10,000	Colorado psychiatric firm refused to provide personal representative access to his minor son's medical record
Diabetes, Endocrinology & Lipidology Center, Inc.	$5,000	West Virginia diabetes clinic made the mother of a minor patient wait nearly 2 years for access to his medical records
King MD	$3,500	Virginia psychiatric practice didn't provide patient access to her medical records even after OCR intervened, provided technical assistance and closed the complaint

*In addition to the monetary settlement, each accused provider had to agree to implement a corrective action plan and allow the OCR to conduct close monitoring for one to two years

OIG Report: Federal False Claims Act Enforcement Continues to Gather Steam

Despite the COVID-19 pandemic and continued sequestration of enforcement funds, federal false claims enforcement activity seems to be gathering momentum. Reversing recent trends, the federal Health Care Fraud and Abuse Control Program (Program) reversed recent trends and recovered more money in FY 2020 than it had the year before. In fact, recoveries for the year reached nearly $3.1 billion, the highest return since 2016. Here's a briefing for lab compliance managers on the July 14 OIG report and what it says about the current state of federal health care fraud enforcement.

ROI Increases for Second Year in a Row

The Program was created as part of the *Health Insurance Portability and Accountability Act of 1996* (HIPAA) under the joint direction of the Attorney General and HHS Secretary, acting through the OIG, to coordinate federal, state and local law health care fraud and abuse enforcement activities. The Annual Report describes the Program's financial performance in the previous fiscal year. While the narrative is somewhat helpful, the real value of these annual reports, at least from a lab compliance officer's perspective, are the enforcement and recovery statistics. Tracking these numbers over a three-year period gives a good sense of the current energy and direction of federal fraud activity, including with regard to labs.

Among the most significant metrics in the annual report is Program ROI, which measures how much money the Program returns for every dollar invested. Program ROI is calculated by dividing the total monetary results to the federal government in judgments, sentences, settlements and other recoveries (not including relator payments in *qui tam* lawsuits) by the annual appropriation for the Program Account in a given year (not including portions of CMS funding dedicated to the Medicare Integrity Program). Because the annual ROI tends to vary from year to year depending on the number and type of cases that are settled or adjudicated during the year, DOJ and HHS use a three-year rolling average ROI for results contained in the report.

And since FY 2013 when ROI peaked at $8.10, ROI has been trending steadily down, with five consecutive years of decline. FY 2019 finally saw the losing streak come to an end, with ROI increasing from $4.00 to $4.20 in 2019. The upward movement continued this year, with the three-year rolling average ROI reaching $4.30 in FY 2020.

Annual Program ROI, FY 2013 to FY 2020 (3-Year Rolling Average)

FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
$8.10	$7.70	$6.10	$5.00	$4.20	$4.00	$4.20	$4.30

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OIG Report: Federal False Claims Act Enforcement Continues to Gather Steam, *from page 7*

By the Numbers

During FY 2020, the federal government won or negotiated nearly $3.1 billion ($3,075,834,684) in health care fraud judgments and settlements. That's up from $2.6 billion in FY 2019, even though the number of convictions during the same period actually declined from 528 to 440. Civil actions, which have traditionally been the cash cow of federal health care fraud enforcement efforts, were up sharply in FY 2020, from 1,112 to 1,498, which portends higher recovery levels in the years ahead when these new actions yield judgments and settlements. However, exclusion numbers were fell off by nearly 25 percent to 2,148.

Metric	FY 2020	FY 2019	FY 2018
Total recoveries	$3.1 billion	$2.6 billion	$2.3 billion
New DOJ criminal health care fraud investigations	1,148	1,060	1,139
New DOJ Civil Health care fraud investigations	1,498	1,112	918
New Criminal cases filed	578	485	572
Convictions	440	528	872
Exclusions issued by OIG	2,148	2,640	2,712

The increases in most of the enforcement metrics occurred even though sequestration reduced the enforcement funding available to the DOJ, FBI, HHS and OIG. A total of $11.0 million was sequestered from the Program in FY 2020, for a combined total of $150.6 million in mandatory funds sequestered in the past eight years. Including funds sequestered from the FBI ($70.0 million in the past eight years), $220.6 million has been sequestered from mandatory Program funds since FY 2013.

Takeaway and Impact on Labs

Although labs are a perennial favorite target for enforcers, they were especially prominent for the wrong reasons in FY 2020. Genetic and other testing labs played a prominent role in the Operation Rubberstamp national takedown of telemedicine fraud, the biggest takedown collaboration in history.

In addition to the usual kickback and Stark recoveries that take place each year, enforcers targeted COVID-19 add-on tests, i.e., high-priced and medically unnecessary tests carried out on patients tested for SARS-CoV-2, including the Respiratory Protection Panel (RPP), antibiotic resistance tests, genetic testing and cardiac panels CPT codes. "Providers are also billing respiratory, gastrointestinal, genitourinary, and dermatologic pathogen code sets with the not otherwise specified code CPT 87798," according to the report.

Whistleblowers: "Staying" Discovery Can Save Your Lab Tens of Thousands of Dollars in Baseless *Qui Tam* Cases

The False Claims Act (FCA) litigation process is so time-consuming and expensive that just about any whistleblower lawsuit against your lab is a losing proposition, even if you ultimately prevail in the case. Perhaps the most onerous part of the process is "discovery," the evidence gathering that takes place before the case even gets to trial. It's during discovery that labs must track down, copy and disclose literally reams of internal documents and allow their officers, managers and employees to undergo hours and hours of interrogation in depositions. It seems highly unfair and wasteful for labs to have to go through all of this, especially when whistleblowers have a weak case.

The good news is that an increasing number of federal courts are agreeing and "staying" discovery, i.e., dismissing claims that lack merit early in the proceedings without even giving the whistleblower the chance to drag the accused into discovery. Here's a look at the "stay" rule and its potential to save your lab thousands of dollars.

The Problem: Potential Whistleblower Abuse of the Discovery Process

Litigation Law, 101: As with most civil lawsuits, the so-called pleadings are the opening salvo of whistleblower suits. The plaintiff kicks things off by filing a complaint, essentially a narrative that documents what the defendants allegedly did wrong, the laws they violated and the harms they caused as a result. The plaintiff/whistleblower needn't prove its claims; at that point in the proceedings its only burden is to make out a legally valid claim that, if true, would warrant a finding of liability against the defendant.

If the plaintiff fails to do this, the defendant can ask the court to dismiss the claim. For example, suppose a former employee files a *qui tam* suit accusing your lab of giving a single $10 gift card to the office manager of a referring physician. This isn't a legally valid claim for an Anti-Kickback Statute (AKS) violation because, even if the whistleblower can prove it's true, the gift card would be allowed under the de minimis exception rule of the AKS. But even if the court dismissed the claim, the whistleblower could just go back and amend her pleadings. All the while, discovery continues.

As a result, whistleblowers who clearly don't have real cases, just vendettas, can game the system by getting to discovery in the hopes of finding some kind of dirt to dig up. Adding to the problem is that there are heightened pleading standards in FCA lawsuits. In other words, pleading a valid case in an FCA whistleblower suit is harder than in other forms of civil lawsuits. And that gives whistleblowers added incentive to game the discovery process.

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Whistleblowers: "Staying" Discovery Can Save Your Lab Tens of Thousands of Dollars in Baseless *Qui Tam* Cases, *from page 9*

The Solution: Stay of Discovery

US District Courts have the legal discretion to stay or limit discovery in the interest of justice and managing their caseloads. But because whistleblowers play such an important role in enforcing the FCA, some federal courts have been reluctant to exercise this discretion in whistleblower lawsuits. However, courts won't hesitate to stay discovery in a *qui tam* lawsuit when it's clear that the whistleblower's case is weak, non-existent or speculative.

Accordingly, federal courts have exhibited an increased willingness to stay discovery, i.e., put discovery on ice pending the outcome of the motion to dismiss. Then, if the whistleblower doesn't meet the heightened pleading standards, the court dismisses the complaint "with prejudice," meaning that the case ends then and there, and the plaintiff doesn't get to go to discovery.

In a recent example, a California US District Court stayed discovery in a *qui tam* case against a Los Angeles medical consulting firm. "The idea is that a plaintiff should not be able to use an inadequate complaint to get a foot in the door and discover unknown wrongs," the court explained. Allowing the plaintiff to get to discovery on the basis of a weak claim would be tantamount to allowing "the claim itself claim itself to be used as a means for discovering the wrong" [*United States ex rel. Williams v. Medical Support L.A., Inc.*, 2021 U.S. Dist. LEXIS 89197].

Takeaway

Asking a court to dismiss a whistleblower's claim and stay discovery pending the ruling can help your lab from getting dragged into the pit of the discovery process. The strategy is likely to be effective only when it's clear and obvious that the whistleblower doesn't have a real case and is just engaging in a fishing expedition. Thus, winning the motion to dismiss won't lead to dismissal with prejudice if the whistleblower made a simple pleading or other technical error that can be cleaned up by amending the complaint. Still, the stay can at least buy you time and spare you the need to initiate the process of meeting the whistleblower's discovery demands unless and until the court tells you it's necessary.

Coding Alert: CMS Adds New PLA Oncology, ELISA, Reproductive Codes to HCPCS, *from page 1*

Laboratory	CPT Code	Long Descriptor	Short Descriptor	
3D Predict Glioma, KIYATEC, Inc	0248U	Oncology (brain), spheroid cell culture in a 3D microenvironment, 12 drug panel, tumor-response prediction for each drug	ONC BRN SPHRD CLL 12 RX PNL	5
Theralink Reverse Phase Protein Array (RPPA),	0249U	Oncology (breast), semiquantitative analysis of 32 phosphoproteins and protein analytes, includes laser capture microdissection, with algorithmic analysis and interpretative report	ONC BRST ALYS 32 PHSPRTN ALG	5
PGDx elioTM tissue complete, Personal Genome Diagnostics, Inc, Personal Genome Diagnostics, Inc	0250U	Oncology (solid organ neoplasm), targeted genomic sequence DNA analysis of 505 genes, interrogation for somatic alterations (SNVs [single nucleotide variant], small insertions and deletions, one amplification, and four translocations), microsatellite instability and tumor-mutation burden	ONC SLD ORG NEO DNA 505 GENE	5
Intrinsic Hepcidi IDxTM Test, IntrinsicDx, Intrinsic LifeSciencesTM LLC	0251U	Hepcidin-25, enzyme-linked immunosorbent assay (ELISA), serum or plasma	HEPCIDIN-25 ELISA SERUM/PLSM	5
POC (Products of Conception), Igenomix, Igenomix USA	0252U	Fetal aneuploidy short tandem–repeat comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, and segmental aneuploidy	FTL ANEUPLOIDY STR ALYS DNA	5

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Coding Alert: CMS Adds New PLA Oncology, ELISA, Reproductive Codes to HCPCS, *From Page 11*

Laboratory	CPT Code	Long Descriptor	Short Descriptor	
ERA (Endometrial Receptivity Analysis), Igenomix, Igenomix USA	0253U	Reproductive medicine (endometrial receptivity analysis), RNA gene expression profile, 238 genes by next generation sequencing, endometrial tissue, predictive algorithm reported as endometrial window of implantation (e.g., pre-receptive, receptive, post-receptive)	RPRDTVE MED RNA GEN PRFL 238	5
SMART PGT-A (Preimplantation Genetic Testing - Aneuploidy), Igenomix, Igenomix USA	0254U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using embryonic DNA genomic sequence analysis for aneuploidy, and a mitochondrial DNA score in euploid embryos, results reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, and segmental aneuploidy, per embryo tested	REPRDTVE MED ALYS 24 CHRMSM	5

CMS also added CPT Code G0327, Colorectal cancer screening; blood-based biomarker (Colon ca scm;bld-bsd biomark) to the national HCPCS file, effective July 1.