G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

NATIONAL INTELLIGENCE REPORT™

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 36th Year of Publication

Vol. 15, Iss. 9, May 14, 2015

INSIDE THIS ISSUE

www.G2Intelligence.com

Whistleblowers Can Offer Statistical Sampling to Support Fraud Claims

A federal trial court in Florida has ruled that qui tam or whistleblower plaintiffs can use statistical sampling to prove fraud in a False Claims Act lawsuit. The court explained: "[N]o universal ban on expert testimony based on statistical sampling applies in a *qui tam* action (or elsewhere), and no expert testimony is excludable in this action for that sole reason.…"

The whistleblower in this case had brought claims against entities that operated facilities at which she had worked, claiming they defrauded the U.S. and Florida governments by upcoding or upcharging for services rendered in 53 medical facilities. Arguing that it was too difficult to provide individual analysis of claims from 53 facilities, the plaintiff asked the court to admit expert testimony about statistical sampling she planned to provide. The sampling had not yet been performed but the plaintiff wanted to determine if the court would accept such evidence to prove falsity of claims.

Continued on page 2

CAP and ADASP Recommend Secondary Review of Anatomic Pathology Cases

Current reforms for the health care system aim to increase quality of services. In keeping with that objective, a new guideline aims to reduce errors in pathology. The College of American Pathologists (CAP) and the Association of Directors of Anatomic and Surgical Pathology (ADASP) have developed a "new evidence-based guideline to provide recommendations for secondary and timely reviews of surgical pathology and cytology cases to improve patient care."

The guideline, titled "Interpretive Diagnostic Error Reduction in Surgical Pathology and Cytology," was published on the website of the *Archives of Pathology & Laboratory Medicine* as an Early Online Release. The guideline addresses the analytical phase in which pathologists interpret slides. That interpretation differs from clinical diagnostic testing and requires subjective, "inherent judgment" of the pathologist. Identifying a need for a process to catch potential errors—because the analytical phase doesn't

Continued on page 7

Whistleblowers Can Offer Statistical Sampling to Support Fraud Claims, *from page 1*

History of the case. The defendants had previously succeeded in getting the claims dismissed because the alleged fraud wasn't stated with sufficient particularity. Federal Rules of Civil Procedure require that fraud allegations be stated with particularity – that is, with specific detail. The plaintiff had claimed in her original complaint that she "witnessed false claims submissions and 'flagrant upcoding'" of Medicare and Medicaid claims. The court ruled that she had alleged only a "general scheme to defraud the government" and described only one instance of fraud without giving "'details about the fraudulent substance of the submission or about the time of the submission or about the government's overpaying the claim.'" It ordered the plaintiff to file an amended complaint with more specific details to describe the alleged fraud—including "'who, what, when, and where.'" The government chose not to intervene in the whistleblower's case. The plaintiff refiled the complaint naming more defendants and claiming fraud occurred at 53 facilities—including facilities the plaintiff hadn't visited.

The court denied the motion to admit the expert testimony that didn't yet exist but unequivocally said such testimony, once it did exist, wouldn't be excluded simply because it was based on statistical sampling.

Sampling evidence. In support of her amended complaint, Plaintiff claimed gathering specific evidence of fraud from all 53 facilities and some off-site storage facilities was impossible. Therefore, she proposed using expert testimony based on statistical sampling to prove falsity of claims. The expert alleged that the sampling would estimate the total overpayments: "For example, if 1% of the population is sampled and reviewed, the total overpayment in the population is probably about 100 times the overpayment in the sample."

Court's reasoning. The court relied on a much discussed case from a Tennessee district court in 2014 that allowed statistical sampling due to the "large universe of allegedly false claims" making it "impracticable for the Court to review each claim individually" without using "an unacceptable portion of the Court's limited resources." It also cited a Kentucky case decided earlier this year which allowed statistical sampling.

It rejected defendants' arguments that sampling isn't allowed in a *qui tam* action. Defendants also argued that because the plaintiff was bringing the request before the sample was even conducted, the defendant couldn't challenge the margin of error. The court denied the motion to admit the expert testimony that didn't yet exist but unequivocally said such testimony, once it did exist, wouldn't be excluded simply because it was based on statistical sampling. The court left open the possibility of defendants' successfully challenging the appropriateness of the sampling and the margin for error once the sampling was performed, stating "defects in method, among other evidentiary defects, might result in exclusion."

For information about statistical sampling used in audits, see the January 26, 2015 issue of *National Intelligence Report*.

Takeaway: While this latest decision didn't rule on the admissibility of specific sampling evidence, the court made an unequivocal statement that such evidence can be used to prove fraud in qui tam false claims lawsuits. G2

Study Finds Pioneer ACOs Reduce Utilization, Stem Spending Without Compromising Care

The first wave of accountable care organizations (ACOs) is positioned well to achieve the touted goal of "bending the cost curve," according to a study published May 4 in the online edition of the *Journal of the American Medical Association*. When compared to general Medicare fee-for-service (FFS) beneficiaries, beneficiaries affiliated with Pioneer ACOs "exhibited smaller increases in total Medicare expenditures and differential reductions in utilization of different health services, with little difference in patient experience," the study concluded.

Savings achieved

Researchers from the Centers for Medicare & Medicaid Services (CMS) and the Centers for Medicare and Medicaid Innovation undertook a difference-in-differences approach to analyze data from the first two years of the Pioneer ACO model. Launched by CMS in 2012 as a test of population health management, this model "targets more experienced organizations with greater incentives for motivating the care transformation necessary to improve outcomes," note the authors.

> *"[I]f this rate of savings could be sustained, and achieved throughout a large part of the U.S. health care system, it would be more than enough to 'bend the cost curve' so that health care expenditures do not continue to increase as a percentage of the gross domestic product and the federal budget."*
>
> — Lawrence P. Casalino, M.D., Ph.D.

During the first two performance years, Pioneer ACOs' total spending for their 1,481,970 affiliated beneficiaries increased approximately $385 million ($280 million in the first year, $105 million in the second) less than spending of similar FFS beneficiaries. The researchers attributed this to "decreases in inpatient utilization among ACO-aligned beneficiaries, although greater decreases in primary care evaluation and management office visits, and smaller increases in the use of tests, procedures, and imaging services, also were related to the observed differential changes in spending."

In an accompanying editorial, Lawrence P. Casalino, M.D., Ph.D., professor of health care policy and research at Weill Cornell Medical College, notes that the study reveals that while achieving these savings, beneficiaries reported that "timeliness and ease of obtaining care, access to specialists, and clinician communication, was at least as high as for beneficiaries in the fee-for-service Medicare and Medicare Advantage programs."

The study acknowledges that not every ACO achieved savings—one third of Pioneer ACOs didn't—but posits there were many reasons for those failures, including the fact that some ACOs may need more time to achieve efficiencies in managing populations and CMS may need to tweak ACO design elements to provide better opportunities for improvement and better engage beneficiaries. Casalino points out that the first-year savings of $280 million represents a reduction of 4 percent. "This amount may seem small," he notes, "but if this rate of savings could be sustained, and achieved throughout a large part of the U.S. health care system, it would be more than enough to 'bend the cost curve' so that health care expenditures do not continue to increase as a percentage of the gross domestic product and the federal budget."

For Mark McClellan, M.D., Ph.D., senior fellow and director of the Health Care Innovation and Value Initiative at the Brookings Institution, who also penned an accompanying editorial, the study indicates real progress and highlights the

need for ongoing analysis. "This early evidence moves the effects of ACOs from speculation to reality and highlights the importance of further evaluation as alternative payment models are refined," writes McClellan. "Payment reform moving away from FFS is now part of the policy landscape, but the exact form it will take is less clear."

Recommendations for further action

Casalino's editorial states that for broader success, ACOs "need stronger incentives, closer ongoing connections with patients, better logistical support from Medicare, and regulatory relief." For example, participants must be given reason to believe they "will be at least as well off financially" by participating in ACOs as the status quo and ACOs that achieve success in reducing costs and improving quality should be rewarded—which means that ACOs failing to achieve these goals will in effect be penalized by lower payment increases. Casalino also contrasts Medicare ACOs, where patients can get care outside the ACO to private payer arrangements in which patients are incentivized to stay within the network to obtain care. He argues CMS should do more to encourage patients to seek care within the ACO rather than outside it and to do so should allow waivers of patient cost-sharing amounts like copays and deductibles and other patient incentives and, most importantly through providing better care than available outside the ACO.

> *"[T]here is considerable evidence that more effective medication use can improve outcomes and lower health care costs."*
>
> — Mark McClellan, M.D., Ph.D.

McClellan recommends in his editorial that further efforts to reduce spending and improve care could include models that have "more significant payment reform after at 'startup' period in shared savings." He indicates current models are a "long way from capitated payments that would put health care organizations at full risk for their spending results." He notes the opportunity to include prescription drug coverage plan in the mix could further improve results because "there is considerable evidence that more effective medication use can improve outcomes and lower health care costs." Acknowledging that payment reform "is not easy," McClellan concludes, "[n]onetheless, an increasing number of diverse health care organizations are demonstrating that it is possible."

Laboratories' role in ACOs.

How can laboratories get in on the action and share in benefits of cost reduction? *G2 Intelligence* recommended in its report *Laboratory Services in Accountable Care Organizations* that laboratories should "shift the focus from operational efficiencies to clinical effectiveness" and "develop metrics to capture the true value of laboratory services in ACOs in terms of system-wide contribution to the cost savings and improving patient outcomes and population health." Doing so will help laboratories convince ACO management to "allocate proper financial compensation for laboratory contribution."

To obtain G2 Intelligence's report, *Laboratory Services in Accountable Care Organizations*, please call customer service at 1-888-729-2315 or visit http://tinyurl.com/mrbd7o6

Takeaway: Early evidence shows ACOs can achieve cost reductions while not sacrificing patient care. But more work lies ahead and experts predict further reform and greater risk sharing will be needed to build on these early successes. G2

Report Indicates Patients Seek Transparency, Choices and Convenience in Health Care Billing

A new report released this month by PricewaterhouseCoopers (PwC) describes the U.S. health care industry's billing and payment system as "a horse-and-buggy in a world contemplating driverless cars." Explaining that historically Americans were patients rather than purchasers of their health care services, the report indicates that current reforms and increasing deductibles are putting individual patients in the driver seat. The report indicates they are demanding more transparency, convenience, affordability and options with regard to health care billing and payment.

The report, *Money matters: Billing and payment for a New Health Economy*, was prepared by PwC's Health Research Institute (HRI), based on a survey of 1,000 adults, health care executives interviews and a review of 34 million Americans' commercial payer claims in the Truven Health MarketScan® 2012 database. The survey revealed that individuals find healthcare billing confusing and lacking transparency, convenience and affordability.

HRI's claims analysis revealed that in 2012, 80% of the 34 million Americans whose claims were reviewed didn't hit their $1,000 deductibles. Thus, it concludes that Americans will be paying more out-of-pocket for health care expenses and will demand new billing and payment options. The survey revealed that consumers want a variety of payment options, "seamless" and convenient payment methods, transparency—knowing costs ahead of time and ability to compare prices, and discounts, for self pay and paying up front. Millennials in particular "are more likely to challenge medical bills, search for better deals and make value-based decisions."

The report recommends simplicity in billing and pricing and allowing consumers/patients choices in how they manage and pay their medical bills. For pricing simplicity, the report references Theranos, which lists its pricing online, and Walmart, which has a flat $40 fee for visits. The report concludes that health care organizations that implement some of the recommendations in the report "operate with the assumption that an informed consumer with choices will pay more of their bill more quickly, and that seamless and clear billing and payment can be a differentiator."

You can find the report at www.pwc.com

Update: New Study Credits Criminal Attacks as Source of Most Health Care Data Breaches

As we reported in March, cybersecurity is gaining national attention thanks to notorious data hacks like Sony and Anthem, and now Premera. The President has drawn attention to the issue calling for legislation and sharing of information about security risks and incidents. Our sister publication *G2 Compliance Advisor*, provided tips for taking action now to avoid cyber security incidents and highlighted a 2014 study by Ponemon Institute that estimated the cost of a data breach to be around $200 per record in the United States, with the health care industry having one of the highest costs per record of all industries.

The Ponemon Institute issued a new study in May indicating health care-related criminal attacks on data have increased 125 per cent since 2010 and are "the leading cause of data breach" in health care. Yet, the study also indicates most organizations are still not prepared to respond to this threat to security of patient health information. "We are seeing a shift in the causes of data breaches in the health care industry, with a significant increase in criminal attacks. While employee negligence and lost/stolen devices continue to be primary causes of data breaches, criminal attacks are now the number one cause," said Dr. Larry Ponemon chairman and founder of the Ponemon Institute in a press release announcing the study.

The study involved 90 covered entities and 88 business associates and its findings revealed that over 90 per cent of health care organizations surveyed had at least one data breach over the past two years, and 40 percent had over five breaches in the prior two years. The authors estimated that such breaches create a $6 billion annual cost for the health care industry, with health care organizations incurring average costs per breach of $2.1 million, $1 million for business associates. Forty-five percent of study participants reported that criminal activity was behind their data breach and 12 per cent found "malicious insider" activity behind an attack. While the study reports that the "root cause" of data breaches "is shifting from lost

or stolen computing devices to criminal attacks," "employee negligence remains a top concern when it comes to exposing patient data." Seventy per cent of participants indicated that employee negligence was their top concern, and the authors attribute this concern to the fact that many incidents involve not just lost or stolen devices but also malware attacks and phishing, which relate to employee failure to follow security procedures.

Despite these numbers, the study found that only 40 per cent of health care providers were worried about the risk of cyber attack and only 33 per cent believed they had "sufficient resources to prevent or quickly detect a data breach." Another study about information security from EiQ Networks that surveyed IT decision makers across industries, including health care, backs up these findings. That survey noted that 62 per cent of the professionals surveyed felt their organization had no process or only a "partial process" for detecting and responding to security incidents and only 15 per cent felt their staff were sufficiently prepared to identify and respond to a cyber attack.

The Ponemon study involved interviews of "senior-level personnel at healthcare providers and business associates." This latest study was expanded to include business associates. HIPAA requires both covered entities such as laboratories and their business associates to protect patient's health care information. "According to the FBI, criminals are targeting the information-rich healthcare sector because individuals' personal information, credit information and protected health information (PHI) are accessible in one place, which translates into a high return when monetized and sold," Ponemon's press release indicates.

Ponemon's *Fifth Annual Study on Privacy & Security of Healthcare Data* can be obtained at www2.idexpertscorp.com/ponemon.

Takeaway: The health care industry faces a significant threat to security of patient information and laboratories and other health care organizations need to ramp up efforts to protect patient information.

Americans Worry Medicare Can't Handle the Rising Elderly Population

A recent Harris Poll reveals Americans are worried that Medicare and Social Security will be unable to accommodate the increasing elderly population as medical advancements extend life expectancies. The survey queried 2,232 U.S. adults online in January of this year, finding that 51% of adults think the U.S. health care system won't be equipped to handle the sizable elderly population which is likely to include significant numbers of patients with chronic health conditions. Only 24% of those surveyed have faith the health care system can handle the burden. The same percentage indicated they weren't sure.

A 2015 Kaiser Family Foundation report predicts, based on U.S. Census data, that the population aged 65 and older will double between 2010 and 2050 while the number of those 80 or older will triple and the amount of people reaching 90 or above will quadruple. That report concluded that according to 2011 data, beneficiaries 80 or older account for 33% of Medicare spending, while those aged 65-69 generate only 15% of Medicare spending. The report notes that beneficiaries aged

80 or older are likely to have one or more chronic conditions giving rise to higher Medicare expenditures.

The Harris Poll survey also indicated that 59% of survey participants reported they think Medicare funding will run out and 58% don't expect to be able to collect any benefits from Social Security. Those percentages exceed 70% for younger individuals falling into the Millennial and Gen Xer classifications. When consulted about potential solutions, reducing Medicare benefits was the least preferred option (by only 7%). Most preferred solutions included having people work past the age of 65 and raising the age at which individuals are eligible to receive Social Security and Medicare benefits. Only 24% surveyed were in favor of increasing taxes to meet the costs. Even among older Americans, retiring later than 65 was a preferred resolution over increased taxes or raising the age of Medicare and Social Security eligibility.

Most Americans don't have faith that Medicare and the health care system can handle the burden of an increased aging population; but more are willing to work later in life rather than pay more taxes to support the demands. G2

CAP and ADASP Recommend Secondary Review, *Continued from bottom of p.1*

have formal review processes similar to those implemented in pre- and post-analytical phases—CAP and ADASP created an expert panel of pathologists which studied the issue and recommends in the guideline that secondary case reviews be consistently implemented to find potential diagnostic errors. "To assist anatomic pathologists, we developed five high-level recommendations and expert consensus statements to formalize a process for the review of surgical pathology and cytology cases, which pathologists can implement as added quality measures into their institutions and quality assurance programs," said Raouf Nakhleh, M.D., FCAP, CAP's guideline co-chair and a surgical pathologist at the Mayo Clinic (Jacksonville, Fla,), in the press release announcing the guideline.

The guideline notes: "Although numerous studies have shown that case reviews help detect interpretive diagnostic errors, there have been no efforts to formalize this practice as a strategy to reduce errors." The panel studied the impact of differing types of review or no review on error detection, researching literature discussing pathology quality and case reviews through Medline, Google Scholar and manual review of pathology journals. With regard to errors, the panel also considered the "clinical impact on a patient" assessing whether the error led to a change in diagnosis, treatment or patient outcome. Draft recommendations were posted on CAP's website for comment between December 2, 2013 and January 21, 2014.

Five recommendations resulted from the panel's efforts:

1. Anatomic pathologists should institute a procedure for review of cases by at least one other pathologist to "detect disagreements" or errors in interpretation.
2. Reviews should be timely. Ideally, review should occur prospectively, prior to diagnosis, but timely retrospective reviews are also valuable. The guideline stated the ideal time for secondary review "is before cases are signed out." The panel indicated that communication with the treating clinician could justify lengthier timelines for a review if treatment can be deferred until after the

review. (The guideline cautioned that this preference for prospective review shouldn't be taken as a reason to stop retrospective reviews that are standard procedure).

3. Review processes should be crafted with consideration of the needs and limitations of the specialty and practice setting involved. The guideline does recommend that the review process should require documentation of case reviews.
4. "Anatomic pathologists should continuously monitor and document the results of case review." The guideline also suggests it may be appropriate to audit specific case types that are subject to review.
5. Pathologists should take steps to improve areas in which review indicates there is "poor agreement" through methods such as setting diagnostic criteria and holding "intradepartmental consensus conferences with the acceptance and use of uniform diagnostic criteria."

CAP designated the first two statements as a "recommendation" which means that the described action is recommended but there is "[s]ome limitations in quality of evidence … balance of benefits and harms, values, or costs" but there is "sufficient evidence" to justify a recommendation. The third, fourth and fifth statements are designated "expert consensus opinion" which means there were "serious limitations in quality of evidence … balance of benefits and harms, values or costs, but panel consensus is that a guideline is necessary."

The panel concluded: "We recommend that surgical pathology and cytology laboratories adopt a system of secondary timely case reviews that is suited to their practice and helps detect or prevent diagnostic interpretive errors." The guideline will be reviewed every four years unless new evidence arises that could substantially impact the guideline recommendations.

Takeaway: While not stipulating specific details of implementation, a CAP and ADASP created panel of experts reports that secondary reviews of anatomic pathology cases can help detect errors and processes for these reviews should be established. G2

The Dark Report Executive War College Celebrates Milestone

Congratulations to Robert Michel, Editor-in-Chief of *The Dark Report* and his staff, who celebrated the 20th anniversary of the annual Executive War College earlier this month. This year's event, held May 5-6 in New Orleans, brought together representatives from laboratories, hospitals, health systems, academia, and government as well as legal, business and financial advisors for discussions regarding the challenges and opportunities ahead for laboratory and pathology management.

Robert Michel led off the two-day conference, explaining that laboratories are positioned to benefit from an expected increase in spending on services relating to diagnosis, prevention and monitoring. A special session focused on laboratory and pathology mergers and acquisitions while roundtable discussions addressed lab informatics, academic pathology, lab sales and marketing, and issues facing chief financial officers.

General and breakout sessions helped labs discover ways to deliver more value to physicians, payers and patients while increasing or finding new sources of revenue. Regulatory hurdles and the uncertainty surrounding LDTs and PAMA were frequent topics as well.

National Intelligence Report (ISSN 2332-1466) is published by G2 Intelligence, Plain Language Media, LLC, 15 Shaw Street, New London, CT, 06320. Phone: 1-888-729-2315 • Fax: 1-855-649-1623. Web site: www.G2Intelligence.com.

Kelly A. Briganti, JD, Editorial Director, Kelly@plainlanguagemedia.com; Barbara Manning Grimm, Managing Editor; Christopher P. Young, Contributing Writer; Stephanie Murg, Managing Director;
Kim Punter, Director of Conferences & Events; Randy Cochran, Corporate Licensing Manager; Michael Sherman, Director of Marketing; Jim Pearmain, General Manager; Pete Stowe, Managing Partner; Mark T. Ziebarth, Publisher.
Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 1-888-729-2315.