G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

# G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

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### G2 Upcoming G2 Events

**Lab Institute 2016**
Oct. 26-28. Hyatt Regency Washington on Capitol Hill, Washington, DC
**www.labinstitute.com**

**Webinar:**
**Lab and Pathology Coding and Billing Update for 2017**
Diana W. Voorhees, M.A., CLS, MT, SH, CLCP
Nov. 9, 2016, 2–3:30pm EST

## Why the New Massachusetts Law Matters, Regardless of Where Your Lab or Practice is Located

Massachusetts recently signed into law An Act to Establish Pay Equity, S.2119, which takes effect on July 1, 2018. The new law prevents wage discrimination based on gender.

The law includes several noteworthy changes related to the employment process, but perhaps the most significant is that it prohibits employers from requiring applicants to provide their salary history before receiving a formal job offer.

The intention is to close the salary gap. Women have historically been paid less than men, and once a salary gap is established, typically early in a woman's career, it's difficult to close that gap.

Although the law only applies to Massachusetts employers and employees, it is expected to have far-reaching implications. As with other changes related to hiring, large companies will likely amend their policies to ensure they do not inadvertently violate the law. In addition, given the national attention this law has garnered, these companies will want to be viewed as non-discriminatory—or better yet, pro-equality.

*Continued on page 9*

## Social Media and Hiring: Can You Use Facebook to Screen Job Applicants?

The consensus seems to be that the popular employer practice of demanding Facebook passwords from job applicants and screening their pages is both morally "wrong" and "illegal." Although we are not qualified to pronounce judgment on morality, we do have a decent grasp of the law.

**Bottom Line on Top:**
**You Can But That Does Not Mean You Should**
There is no law that expressly bans you from demanding job applicants' passwords and using them for a background check. But as a practical matter, once you start checking a job applicant's profile on Facebook or another social network site (which for simplicity's sake, we will refer to collectively as "Facebook"), you bring privacy and EEOC laws into play. And, given the limited value of the information you are likely to find on Facebook, the risks may very well outweigh any benefits you accrue from the search.

*Continued on page 2*

## Social Media and Hiring: Can You Use Facebook to Screen Job Applicants?, *from page 1*

### Facebook Screening & Privacy Laws

Federal laws like the *Fair Credit Reporting Act* ban employers from conducting personal background checks on employees and job applicants without their written authorization. Comments, photos and other Facebook postings are arguably among the personal information that cannot be collected without authorization. Doing a Facebook check without authorization could also get you into trouble in states like California that impose even stricter restrictions on employer collection of personal information about job applicants from third parties.

**Job applicants' privacy rights are also subject to the employer's right to collect, use and disclose personal information to perform legitimate business functions.**

But there is a huge loophole in the privacy laws: Consent is not generally required to collect personal information that is publicly available. Postings on a social networking site have been consistently recognized as publicly available information by courts, arbitrators and privacy commissions.

### Reasonable Expectations of Privacy

Job applicants might also have privacy rights under collective bargaining agreements, individual employment contracts or common law, i.e., case law made by judges. To hold you liable for a privacy infraction, job applicants would have to show they had a "reasonable expectation" of privacy in their Facebook postings.

The operable word is "reasonable." Thus while there are plenty of Facebook users who assume otherwise, postings on social networks are not private communications. Thus it would not be reasonable to expect Facebook postings to be kept confidential. However, the job applicant would have a stronger argument to the extent the employer circumvents the host site's privacy controls to gather the information.

**Example:** Margie, a recent college grad who has opted to limit her Facebook network to other recent grads, applies for a job with XYZ Labs. Finding its access to Margie's network blocked, XYZ has an employee pose as a grad so he can "friend" Margie and join her network. XYZ then uses the information in processing her application. In these circumstances, Margie would be in a position to argue that she had a reasonable expectation of privacy.

Directly asking for a Facebook password makes it harder for job applicants to claim that your check violated their reasonable privacy expectations. So is directly notifying them of the check in advance.

Job applicants' privacy rights are also subject to the employer's right to collect, use and disclose personal information to perform legitimate business functions.

**Key Question:** Does demanding a job applicant's Facebook password and conducting a pre-employment count as collecting and using personal information for a legitimate business purpose?

**Answer:** It depends.

**Impact on You:** To avoid liability, you must make sure *your* particular use falls on the "reasonable" side of the "it depends" line.

### What to Do

The best way to do this is to conduct a privacy assessment *before* searches to determine if they are reasonable. Consider these eight factors in your assessment:

**1. Does the Search Serve a Legitimate Business Purpose?** YES ☐ NO ☐
Searching Facebook is faster and simpler than traditional background check methods. But simplicity is not enough. To justify a search as reasonable, you must consider what information you can collect about the job applicant that they cannot get from traditional screening methods such as reference checks and interviews.

**Decide in advance what websites you plan to check and make sure each site provides access to the exact relevant information you are seeking.**

**2. Does the Search Collect Only Relevant Information?** YES ☐ NO ☐
For a Facebook search to be reasonable, it must provide relevant information and *only* relevant information. Relevant means information about the applicant's qualifications. Personal information typically found on Facebook may be not only irrelevant, like what the applicant looks like or her recipe for lasagna, but *illegal* to look at during the course of a hiring process. Especially dangerous are photographs and other materials that reveal the applicant's race, gender, religion, family status, disability, age, and other personal characteristics protected by anti-discrimination laws.

Moreover, once you come into possession of such information, you cannot un-possess it. Electronic search records will show that you accessed the information and wind up as Exhibit A in the rejected applicant's discrimination suit. You can argue that you did not look at the information; the problem is that merely possessing it is evidence that it factored into your employment decision.

**3. Are You Searching Only Relevant Sites?** YES ☐ NO ☐
Social media site checks can range from simple Facebook profile checks to sweeping searches of blogs, micro-blogs and file sharing sites. Decide in advance what websites you plan to check and make sure each site provides access to the exact relevant information you are seeking.

**4. Is Information Collected Current and Accurate?** YES ☐ NO ☐
Ensure that the information you collect is current and accurate. The problem is that social media sites tend to be littered with inaccurate information like mislabeled photographs and out of date bios. Moreover, simply *looking* at the information is deemed the equivalent of collecting it. So you need to have safeguards in place before doing your search.

**5. Will Search Reveal Information Only About the Applicant?** YES ☐ NO ☐
One of the biggest challenges you face when getting access to a job applicant's Facebook profile is to keep the search focused on just that individual and avoid capturing information about third parties like the individual's "friends" who did not provide their password or consent for your search.

**6. Do You Notify Applicants of the Search?** YES ☐ NO ☐
While demanding a password notifies the applicant that you plan to do the search, you should also disclose key aspects of the search, including:

- All the sites you intend to search;
- The information you are seeking and why you deem it relevant;
- How you intend to use the information you collect; and
- A statement that your lab is an equal opportunity employer and that the search is not intended to collect information about the applicant's race, sex, age, religion and other personal characteristics protected by employment discrimination laws.

Consider asking applicants to sign a form giving express consent to the search. (See the Model Notification below for language you can add to your job application.) And keep in mind that applicants can withdraw their consent at any time; when and if they do, you can no longer use the information to make your decision on their application.

**7. Are Your Search Methods on the Level?** YES ☐ NO ☐

Actual searches must be appropriate, consistent with the methods described in the application notification and in line with the host site's use restrictions and applicant's indicated privacy preferences. Practices that make Facebook searches "unreasonable" would include having individuals at your lab "friend" applicants to gain access to their privacy-protected information (as in the Margie example above) and doing the search from a personal account to hide your tracks.

**8. Do You Limit Use of Information Collected to Stated Purpose?** YES ☐ NO ☐

Remember that privacy restrictions apply not just to the information's collection but also its use. To be reasonable, the use must be consistent with the stated purpose for which it was collected, i.e., to evaluate the applicant's fitness for the job. *Example:* Your Facebook search reveals that the applicant is the regional director of a notorious hate group:

- **Appropriate:** Rejecting the applicant on the basis of the information;
- **Inappropriate:** Sending the applicant's file to the police.

## Conclusion

You have every right to demand Facebook passwords to check job applicants as long as you keep your search "reasonable" under privacy laws. But when you trawl social networks, you are likely to dredge up irrelevant, outdated and off-limits information that undermines the "reasonableness" of your search.

*Takeaway: At the end of the day, labs determined to use the internet for pre-employment screening are better advised to concentrate on professional rather than social network sites.*

## TOOL

## Notification of Pre-Employment Screening

**THE PROBLEM:** Collecting information about job applicants from social media sites like Facebook can get you into legal hot water. The information you collect may be considered protected, personal information to the extent applicants can show they had a reasonable expectation of privacy in the material.

**HOW THE TOOL HELPS SOLVE THE PROBLEM:** It will be much harder for job applicants to claim they had a reasonable privacy expectation if you notify them in advance of your intent to collect the information. So if you do screen Facebook and other social media sites as part of your pre-employment screening, consider adding language like the following to your employment application form.

### XYZ LABS NOTIFICATION TO APPLICANTS OF PRE-EMPLOYMENT SCREENING

Thank you for applying for employment with us. Please understand that XYZ Labs reserves the right to collect information about you that is relevant to your application and qualifications from publicly available internet sources, including the following social networking sites: [*List the sites you intend to check.*]

Such checks will be performed by designated XYZ Labs personnel only after an offer of employment has been made. The information XYZ Labs obtains from this background check will be used to verify that you do possess the professional qualifications and personal background that prompted XYZ Labs to make you the offer of employment in the first place.

XYZ Labs is an equal opportunity employer and your application will be processed without regard to your race, religion, ethnicity, national origin, family status, sex, disability, sexual preference or other personal characteristics protected by employment discrimination laws.

# PAMA—What We Know So Far, What You Need to Know to Comply

After much lobbying and debate from stakeholders in the laboratory industry, the Centers for Medicare & Medicaid Services (CMS) is moving forward with implementation of the Protecting Access to Medicare Act of 2014 (PAMA). Right now, labs are currently in a six-month period between the data collection period (Jan. 1 to June 30, 2016) and the data reporting period (Jan. 1 to March 31, 2017) and CMS says they should be using this time to determine if the lab is an applicable lab and to "review and validate applicable information before it is reported to CMS."

In late July and September CMS issued some guidance documents which offer some assistance but still leave many remaining issues to be addressed in further guidance. As laboratories begin preparations to comply with PAMA requirements, here's a rundown on what we do and don't know about how this will play out.

## What's New?

CMS has released the following additional information since the June final rule:

- The list of HCPCS codes to be used in reporting. That list was accompanied by a short explanatory key to the Medicare Status Indicators that apply to the codes.
- Medicare Part B Clinical Laboratory Fee Schedule: Guidance to Laboratories for Collecting and Reporting Data for the Private Payor Rate-Based Payment System.
- Fee-for-Service Data Collection System: Clinical Laboratory Fee Schedule Data Reporting Template.

## What are the Deadlines?

The timeline for implementation now requires data be collected for the period Jan. 1 through June 30, 2016 (data collection period). This six-month collection period will be repeated in subsequent collection periods rather than the one-year periods originally contemplated.

Labs must then report their payor data to CMS for the first time between Jan. 1 and March 31, 2017 (reporting period). That Jan. 1 through March 31 reporting period will repeat every three years for Clinical Diagnostic Laboratory Tests (CDLTs) and every year for Advanced Diagnostic Laboratory Tests (ADLTs, defined below). Based on reported data, in early September 2017, CMS will publish preliminary Clinical Laboratory Fee Schedule (CLFS) rates for public comment with final CLFS rates published in November 2017 and effective Jan. 1, 2018.

## Who's Reporting?

In the June final rule, CMS clarified some details about what entities must collect applicable data and who must report it. In the July guidance, CMS described four steps to determining Applicable Laboratory status. CMS advises labs ask the following four questions to determine if they are an Applicable Lab:

1. Does the lab have a CLIA certificate?
2. Does the lab have its own National Provider Identifier under which it bills Medicare?
3. Does the lab get more than 50 percent of its total Medicare revenue under the CLFS and the Physician Fee Schedule (PFS)?
4. Does the lab get at least $12,500 in CLFS Medicare revenue (NOT including PFS revenue) during the six month data collection period?

> *"It's great CMS made the change because that will open it up for hospital lab outreach programs."*
>
> **— Jane Pine Wood**

The July guidance also provides an equation to help labs calculate the 50 percent billing threshold:

CLFS revenue + PFS revenue/total Medicare Revenues > 50 percent

Note the numerator includes all PFS revenue even if it isn't related to lab services, so it could include pathology services, evaluation and management or even radiology services. The denominator includes all fee for service revenue under Medicare Parts A, B, C and D as well as Medicare Advantage and any beneficiary deductible or coinsurance. The July guidance also provides seven examples of scenarios involving labs to show how the calculations work in hypothetical situations.

### Hospital Labs: Will They or Won't They Report?

What initially was hailed as good news has come under further scrutiny—CMS now requires Applicable Laboratory calculations we just discussed be made for an entity that has its own NPI. This change to using NPIs rather than Taxpayer Identification Numbers (TINs) means that entities that are part of a larger organization but have their own NPI must apply the criteria to determine if they are an Applicable Lab and, if so, collect the required Applicable Information. Reporting is still done at the TIN level. CMS doesn't dictate how the TIN reporting entity coordinates the data from entities with their own NPI but the reporting entity is the one that certifies compliance and will be subject to civil monetary penalties for noncompliance.

Major criticism of the proposed rule was that it wouldn't capture hospital-based laboratories. Under the final rule, a hospital lab that bills under its own NPI rather than the hospital's NPI may be an Applicable Lab. Hospital-based labs can be paid at much higher rates than standalone labs so their inclusion on a large scale would be economically advantageous for the sector as a whole. But it is up for debate how many hospital based labs will actually end up reporting.

"We know there are more hospital labs that have their own NPI than TIN," said Alan Mertz, president of the American Clinical Laboratory Association, which had supported the change in the PAMA final rules to help include hospital laboratories. "We don't know how many hospital labs have their own NPI, but we also know a lot of them don't."

Barry Portugal, president of Health Care Development Services, a Florida-based consulting firm, said he has contacted operators of many hospital-based labs. Most are not participating in PAMA, he noted. "Everyone with whom I have spoken has said they do not plan to participate in the PAMA data collection process because their hospital laboratory does not meet the definition of an applicable lab," Portugal said. He added that there are exceptions. Those are primarily hospital-owned labs located outside of the hospital, and where the lab performs both inpatient, outpatient, and outreach testing. But he believes there are no more than 100 in operation nationwide.

Finally, this month CMS provided a template for reporting the data. The template doesn't provide new information, simply addressing the four elements that must be reported: HCPCS Code, payment rate, volume of tests, and the labs NPI. It does provide a User Guide however, addressing how to navigate the template CMS does note that the data col-

lection system. CMS notes that the data collection system is undergoing testing and won't be accessible to labs until November 2016.

### What does or doesn't get reported?

As labs already know, beginning Jan. 1, 2017, private payor data for CDLTs must be reported every three years and every year for ADLTs. The information collected and reported for CDLTs is defined in the final rule to include private payor rates "for which final payment has been made" during the collection period plus the number of tests performed at that rate and the HCPCS code for the test. Use of the term "final payment" means that some post-payment activity can affect the reported amount. For example, an erroneous initial payment made before the data collection period but corrected and final payment made during the data collection period would be reported for that period. CMS clearly lays out for labs in the July guidance what does and doesn't qualify as reportable:

Here's what does need to be reported:

- Tests paid under the CLFS
- Secondary insurance payments
- Non-contracted or out of network payments for lab services
- Patient cost sharing amounts are included in determining the final payment amount
- Final payments determined as a result of an appeal and paid within the data collection period

The following don't get reported:

- Private payor payments for test codes payable only under the PFS
- Payment rates adjusted by waivers of patient' deductibles, copays or coinsurance
- Denied payments (what CMS calls "zero payments")
- Any claims still under review or under appeal during that data collection period (even appeals concluded in the data collection period aren't reported if the payment isn't made within the data collection period)
- Capitated payments
- Payments made when the volume of tests associated with that payment can't be determined
- Bundled payments –where HCPCS codes are bundled into single encounter that isn't characterized by a single HCPCS code

### What qualifies as an ADLT?

As we went to press we are still waiting for subregulatory guidance from CMS addressing Advanced Diagnostic Laboratory Tests (ADLTs). What we do know is that ADLTs now include either A) tests that are cleared or approved by the Food and Drug Administration or B) tests that 1) analyze multiple biomarkers of DNA or RNA or proteins, 2) "when combined with an empirically derived algorithm yields a result that predicts the probability a specific individual patient will develop a certain condition or respond to a particular therapy" and 3) provide new clinical diagnostic information not available from other tests and 4) "may include other assays."

## What we still don't know

Many questions still remain unanswered about the details of how the reporting and rate setting will be achieved. CMS has promised to provide those remaining details in subregulatory guidance. CMS doesn't indicate when that subregulatory guidance will be issued except to state that "we now expect to issue the subregulatory guidance prior to January 1, 2018."

Here are the issues that CMS indicates in its final rule will be the subject of more detailed guidance in subregulatory guidance:

- Details for applying for ADLT recognition: including information about how to prove the test is offered only by single laboratory, evidence needed to meet the criteria for ADLT qualification, timing for submitting and processing of applications and issuing decisions about ADLT status, and the process for assigning unique HCPCS codes to ADLTs (CMS says it will consider requests that ADLT applications be submitted and reviewed on a quarterly basis);
- How to notify CMS of ADLTs and CDLTs that do not have a unique HCPCS code;
- Guidance on compliant reporting, how to avoid civil monetary penalties, and when such penalties will be imposed (though CMS reiterates it doesn't intent to impose CMPs for minor errors);
- Details for certification process when submitting applicable information (CMS said it will consider commenters' suggestion that the certification form state "the information and statements submitted are accurate and complete to the best of the laboratory's knowledge and the submission is made in good faith");
- Instructions on what not to include in reporting applicable information, such as private payor identities and individual claims (CMS rejected requests to explicitly include in the final rule the prohibition against identifying private payors because it said it wasn't necessary and would be addressed in the subregulatory guidance); and
- If CMS decides to publish raw data ("actual, unaggregated data that is reported as applicable information for an applicable laboratory") in addition to aggregate-level private payor data and volume data, it will detail the process for public review of this data in the guidance. (CMS indicates it is investigating feasibility of releasing such raw data which it believes will afford greater transparency during public review of the proposed rates).

The guidance documents referenced in this article can be found on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.

***Editor's Note:*** *For the latest insight on PAMA, attend G2 Intelligence's 34th Annual Lab Institute, Oct. 26-28 in Washington D.C. A Thursday general session featuring Alan Mertz, President of the American Clinical Laboratory Association, Tim Kuruvilla, Co-Founder and Chief Commercial Officer of Viewics, Inc., and Rina Wolf, Vice President, Commercialization Strategies, Consulting and Industry Affairs, at XIFIN, Inc. will discuss the latest updates on PAMA implementation and how labs will play a role in supporting MACRA's implementation. Can't attend Lab Institute? A G2 Intelligence webinar, hosted June 28, 2016 in partnership with the American Clinical Laboratory Association, provides analysis of and tips for complying with the new final rule. To purchase a recording of the webinar, The PAMA Final Rule: What You Need to Know and Do NOW to Comply with the New Payment Rules and Protect Your Lab Revenue, visit our website or contact customer service at 1-888-729-2315.*

### Why the new Massachusetts law matters, *from page 1*

Because large companies will adopt new policies and procedures, job candidates will expect small and midsize employers to follow suit. Like other human resource trends, the changes as a result of this law, and other state and federal legislation that may follow, will eventually impact your lab or pathology practice. It is therefore prudent to familiarize yourself with what is happening in Massachusetts, and even get ahead of the curve and make necessary adjustments to your hiring processes.

Here are some highlights of the provisions in the new Massachusetts Law:

- "Comparable work" is defined to mean work that is "substantially similar," performed under similar conditions and "requires substantially similar skill, effort and responsibility."
- Employers can't discriminate based on gender when paying wages for comparable work unless the difference in wages is based on certain factors such as seniority, level of training or a bona fide merit system.
- Employers can't a) ban employees from talking about their salaries, b) screen job applicants based on salary history, such as by asking applicant to reveal salary history, c) ask prior or current employers for salary history of applicants until a formal job offer is made and the prospective employee consents, d) retaliate against employees for bringing a complaint under this law or raising an objection to practices that violate this law or testifying in a case under this law or discussing their own or other employees' wages.
- Employers who violate the law can be liable for unpaid wages, liquidated damages and attorney's fees.
- Employers get credit for evaluating their own practices and showing successful efforts to get rid of any gender based differences in pay for comparable work.
- Employers must post notice of this law at their workplace.

***Takeaway: Labs and pathology practices need to consider how laws such as Massachusetts' pay equity law affect what job applicants are asked during the interviewing process.***

## G2 Compliance Corner

### Use Comparison Testing to Catch Coding Errors

While regular billing and coding audits should already be a part of your laboratory's compliance plan, to keep compliant you must supplement those activities with informal monitoring. One approach is comparison testing:

- **Step 1:** Select a random sample of five to 10 recent claims;
- **Step 2:** Give the supervisor of the coder who processed the claims the claim backup without the actual codes selected;
- **Step 3:** Have the supervisor code the claims;
- **Step 4:** Compare the results.

If discrepancies exist, a red flag should go up. Determine who made the mistake—or ask a third person to recode the claim in case they *both* got it wrong. Identify the cause of the mistake, fix it, e.g., by providing extra training, and make sure none of your other coders are making the same error.

## OIG Highlights $25.1 Million Settlement to Promote Self-Disclosure Protocol

In its latest Eye on Oversight video, the Health and Human Services Office of Inspector General highlights a $25.1 million settlement achieved under the self-disclosure protocol, the largest settlement to date under that protocol. The case involved a company operating pharmacies nationally that self-disclosed it had employed individuals excluded from Medicare and filled prescriptions ordered by excluded physicians, which were paid for under federal programs. The video touts that since 1998 when the proto-

col was launched, the government recovered $552 million—in cases involving alleged kickbacks, self referrals and overbilling of services.

"OIG recognizes that good compliance programs find issues. It's a sign of an effective compliance program to self-disclose your issues to the government. For over two decades the OIG's self disclosure protocol has been a quick and efficient place for providers to bring their issues and resolve them and move on."

Without the self disclosure, the video notes a company can face larger penalties, exclusion from federal programs and a Corporate Integrity Agreement with "intensive OIG oversight going forward." Self-disclosure also resolves cases more quickly—on average about 12 months.

*Takeaway: The OIG uses its largest settlement in history under the self-disclosure protocol, to urge labs and other providers to self-report their own compliance issues and garner more favorable settlement terms.*

# LABS IN COURT: A roundup of recent cases and enforcement actions involving the diagnostics industry

## Continuum Waves White Flag on Medicaid Overpayments Delay Case

**Case:** A software glitch caused Continuum to submit roughly 450 erroneous claims to Medicaid between 2009 and 2010 resulting in $800,000 worth of overpayments. Continuum paid back all the money. But instead of paying a lump sum within the 60-day repayment deadline, Continuum paid it back in dribs and drabs via 30 installments made over the course of two years. The government claimed the delay was deliberate and brought a "reverse false claims act" action against Continuum. In September 2015, a New York federal court denied Continuum's request to toss out the case without a trial. Facing an uncertain trial, Continuum has officially settled the case for $2.95 million [*U.S. v. Continuum Health Partners, Inc.*, 11 Civ. 2325 (ER), USDC (S.D.N.Y.), August 23, 2016].

**Significance:** Continuum is a landmark case because it was the first federal enforcement action against a provider for failing to meet the *Affordable Care Act* requirement that overpayments be repaid in full within 60 days of identifying the overpayment. And the case was launched before the CMS issued guidance to help providers comply. Although it came too late for Continuum, the CMS finally laid down some guidelines in February 2016. *Bottom Line:* According to the Final Rule, providers must exercise what CMS calls "reasonable diligence" in identifying, calculating and repaying overpayments. (For a list of six specific things you should do to meet reasonable diligence criteria, see "Avoid False Claims Liability: CMS Clarifies How to Comply with 60-Day Deadline for Returning Overpayments," GCA, April 2016.)

## Coastal Pays $7.4 Million to Settle Charges of False Billing for Drug Tests

**Case:** Quantitative drug tests that count illicit drug particles in urine are rarer and more expensive than qualitative tests that simply detect the drug's presence. So when data analytics showed that a Florida pain clinic was a statistical outlier for Medicare billing of Quantitative tests, federal investigators swooped in. The DOJ filed False Claims Act charges, claiming the clinic did Quantitative tests on elderly patients routinely, regardless of medical necessity, even when patients' Qualitative tests came back negative. Rather than slug it out in court, the clinic settled the case for $7.4 million [*Physicians Group Services, P.A., dba Coastal Spine and Pain*, USAO, M.D. Fla., Aug. 31, 2016].

**Coastal is the latest in a series of enforcement actions for false billing of medically unnecessary urine drug screening tests.**

**Significance:** Coastal is the latest in a series of enforcement actions for false billing of medically unnecessary urine drug screening tests:

- Two lab former lab professionals convicted at trial of such charges were sentenced to 36 months in prison and ordered to pay $1.437 million in restitution; and
- Similar charges were among the allegations of a pair of whistleblowers settled by PremierTox 2.0, Inc. for $2.5 million in April.

[See Drug Testing Enforcement Cases Lead to Costly Settlements and Convictions, *GCA*, May 2016]

## DOJ Nets $250K from Urologist in FISH Testing Settlement

**Case:** A Florida urologist agreed to pay $250,000 to settle claims of falsely billing Medicare and Tricare for medically unnecessary *fluorescence in situ hybridization*, aka, FISH tests, which are performed on urine to detect genetic abnormalities tied to bladder cancer. The case, which began as a former medical assistant's whistleblower suit, also alleged that the urologist received bonuses based on the number of FISH tests he ordered [*Robert A. Scappa*, USAO, M.D. Fla., Aug. 17, 2016].

**Significance:** FISH tests conducted by a urologist are deemed medically reasonable and necessary for Medicare coverage purposes in only two limited situations:

- To monitor for tumor recurrence in patients previously diagnosed with bladder cancer; or
- Where after a full workup of a patient with hematuria, i.e., blood in the urine, the urologist has reason to suspect bladder cancer.

# News at a Glance

**HIMSS Says Hospitals Slow to Adopt Precision Medicine.** Precision medicine is slowly taking hold at the nation's hospitals, but the need to build up information technology to make it an organic part of the delivery of medicine would likely prove burdensome. That's the conclusion of HIMSS Analytics, which surveyed 137 health care organizations last month to gauge their approach toward the use of precision medicine—typically molecular-based tests for identifying specific disease variations in order to tailor care pathways. Respondents included standalone hospitals, academic medical centers, specialty hospitals and integrated delivery networks. According to the survey, only 29 percent of those providers surveyed conducted precision medicine onsite. Slightly more than a third of large academic medical centers performed it. "The limited adoption of precision medicine programs across the U.S. hospital market is understandable as very few organizations have the funds, technology or expertise to conduct precision medicine on site," the survey said.

As an alternative, 26 percent of respondents said they performed precision medicine through the use of third party laboratories, while a third used a combination of in-house and third-party services. The primary focus of the precision medicine efforts has been on cancer, with nearly 80 percent of respondents saying they used it for that purpose. Large numbers of the survey respondents said they were challenged with integrating genomic data with a patient's overall clinical data. Nearly 36 percent said they had yet to complete such an integration. Moreover, many organizations have uncertain plans regarding the future of their precision medicine initiatives. Nearly 43 percent said they had yet to develop a concrete strategy regarding their patients and the use of precision medicine. Another 21.4 percent were unsure about the strategy they would develop. Only 14.3 percent said they planned to develop a comprehensive marketing campaign to tout their precision medicine initiatives.

**State Laws Seek to Improve Price Transparency.** Despite the fact that the majority of state legislatures have passed some laws relating to pricing transparency for health care services, only seven states are receiving passing grades for both the statute's design and implementation, according to the report, Report Card on State Price Transparency Laws. Price transparency is necessary to combat significant pricing variation for health care services and the increasing financial burden individuals face, according to the study authors, the Health Care Incentives Improvement Institute (HCI3; Newtown, Conn.) and Catalyst for Payment Reform (Berkeley, Calif.). Many recent studies highlight regional variation in health care costs, including for laboratory tests. This variation is receiving more attention as of late as patients become responsible for a larger percent of their own bills as a result of high deductible health insurance plans. "The lack of information on the price of care hurts the pocket books of Americans every day," writes François de Brantes, HCI3 executive director and lead author of the report.

Analysts from the Source on Healthcare Price and Competition at the University of California, Hastings College of the Law and the University of California San Francisco assessed each state's enacted and proposed legislation on health care price transparency. Each state is given a letter grade with an explanation of the shortcomings that are holding back transparency. The authors say the scoring methodology rewards states that both have an all-payer claims databases (APCDs) and that publish that data on a well-designed, searchable website. The researchers found that all but seven states (Alaska, Alabama, Hawaii, Idaho, Mississippi, Oklahoma, and Wyoming) have passed some price transparency legislation. However, the quality of transparency varies due to differences in design and implementation of state laws.





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