G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

NATIONAL INTELLIGENCE REPORT™

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 37th Year of Publication

Vol. 16, Iss. 12, June 30, 2016

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G2 INTELLIGENCE Upcoming Events

Lab Institute 2016
Oct. 26-28, Hyatt Regency
Washington on Capitol Hill
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CMS Issues Final PAMA Rule, Delaying Implementation of New Rates to 2018

After much lobbying and debate from stakeholders in the laboratory industry, the Centers for Medicare & Medicaid Services (CMS) released its final rule implementing the Protecting Access to Medicare Act of 2014 (PAMA). Labs must now begin preparing to comply with private payor rate reporting requirements under the rule, which will lead to the first major changes in the Clinical Laboratory Fee Schedule (CLFS) in decades.

The good news is that the final rule delays the effectiveness of new payment rates under the CLFS to Jan. 1, 2018, rather than a mere six months away in January 2017, as planned in the proposed rule. But there are still many details to be resolved as the industry waits for subregulatory guidance to supplement the final rule. Here is a summary of what the final rule does and doesn't definitely address:

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Largest Strike Force Takedown in History Charges 300 Individuals

Nearly a year to the day after another nationwide Strike Force takedown, the Department of Justice announced last week what it says is a takedown involving "the most defendants charged and largest alleged loss amount in Strike Force history."

While not directly involving labs, some of the allegations in this takedown are not unfamiliar to labs: submitting claims to Medicare and Medicaid for services that weren't medically necessary or weren't even performed, paying kickbacks for referrals or to get beneficiary information to facilitate fraudulent claims, and allowing nonqualified individuals to perform services billed to Medicare. Most of the cases involved allegations linked to home health, mental health, physical/occupational therapy, durable medical equipment, and prescription drug-related Medicare and Medicaid claims.

Here's a rundown on the details of this takedown:

- 301 individuals charged in civil and criminal cases (includes 61 physicians, nurses and licensed medical professionals)
- $900 million in total losses alleged

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CMS Issues Final PAMA Rule, Delaying Implementation of New Rates to 2018, *from page 1*

Data Collection and Reporting 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 CDLTs and every year for Advanced Diagnostic Laboratory Tests (ADLTs, defined below). Based on reported data, in early September 2017, CMS will publish preliminary CLFS rates for public comment with final CLFS rates published in November 2017 and effective Jan. 1, 2018.

Hospital outreach laboratories will need to report if at least 50 percent of Medicare revenues are from CLFS and PFS services, with at least $12,500 from the CLFS.

Applicable Labs and reporting entities

CMS clarified some details about what entities must collect applicable data and who must report it. Here's a rundown on some of the key details in the final rule that address who qualifies as an Applicable Lab and who reports data under the rule:

- Applicable Labs are those that receive more than 50 percent of total Medicare revenues under the CLFS or Physician Fee Schedule (PFS) (unchanged from proposed rule).
- Applicable Labs will be determined by Medicare revenue under their National Provider Identifier (NPIs) (rather than by Taxpayer Identification Numbers (TINs) as proposed). Commentators predict this change may bring more hospital outreach rates into the data collected.
- While applicable labs are determined by their NPI, the entity that reports the required data is now referred to as a Reporting Entity which will report data under its TIN for all entities within its organization that have their own NPI and qualify as an Applicable Lab.
- Applicable Labs will not include labs paid less than $12,500 under the CLFS during the six-month data collection period. (The proposed rule included a $25,000 threshold for the initial six-month collection period and $50,000 threshold for subsequent 12-month collection periods). Note that this threshold doesn't apply with regard to ADLTs that need to be reported—as discussed more fully below.
- Hospital outreach laboratories will need to report if at least 50 percent of Medicare revenues are from CLFS and PFS services, with at least $12,500 from the CLFS.

So the change to using NPIs rather than TINs means that entities that bill Medicare under their own NPI must apply the criteria to determine if they are an Applicable Lab and, if so, collect the required Applicable Information. Then organizations must aggregate the data from all entities within their organization that have their own NPI and qualify as Applicable Labs—and then report that data under that umbrella organization's TIN. 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.

Data to be reported

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. Payment made on a capitatated basis isn't included.

Under PAMA, the new payment amount for CDLTs will be equal to the "weighted median of private payor rates determined for the test" based on the payor information labs report for the collection periods.

Treatment of ADLTs

ADLTs are tests covered under Medicare Part B that are only offered by a single laboratory, not sold for use by other laboratories other than the one that designed the test, and meet other specific criteria. Those other criteria originally included tests that measure biomarkers in RNA and DNA but excluded tests for protein-only analysis. Many industry comments criticized the definition of ADLTs in the proposed rule and argued that protein-only based tests should be included. CMS responded by including protein only tests in the final definition of ADLTs.

So, now ADLTs 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."

The proposed rule described a new ADLT initial period as "a period of 3 calendar quarters beginning on the first full calendar quarter following the first day on which a new ADLT is performed." However, to facilitate a new ADLT being paid actual list charge during the initial period, CMS changed that in the final rule. Instead, the initial period for a new ADLT now begins "the first day of the first full calendar quarter following the later of the date a Medicare Part B coverage determination is made or ADLT status is granted by CMS."

Changes to payment rates

Under PAMA, the new payment amount for CDLTs will be equal to the "weighted median of private payor rates determined for the test" based on the payor information labs report for the collection periods. The statute set limits on how much rates can change in the initial years of implementation and those are not changed in the final rule but are rather adjusted for the year they will apply to accommodate the new Jan. 1, 2018 implementation date. So, rates can't be reduced by more than 10% in 2018, 2019 and 2020 or by more than 15% in the following three years.

Takeaway: With the much-awaited arrival of the final rule implementing PAMA, labs must now get to work preparing there systems to generate the date needing to be reported and bracing for the changes to come for the CLFS.

Editor's Note: 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.

U.S. Supreme Court Says Failure to Disclose Noncompliance Can Lead to False Claims Liability

While preparing to comply with newly released final rule implementing the Protecting Access to Medicare Act's changes to the clinical laboratory fee schedule, labs also need to heed a new U.S. Supreme Court decision that holds labs and all health care providers can face liability for False Claims Act (FCA) violations based on implied false certifications of compliance. In *Universal Health Services, Inc. v. Escobar*, the Court ruled the "implied false certification" theory allows FCA liability to be based upon failure to disclose a violation of a "material statutory, regulatory or contractual requirement." Such a failure to disclose is considered to render a related claim false or fraudulent.

Noting disagreement among federal circuit courts of appeal, the U.S. Supreme Court made two important rulings in the *Escobar* case:

- FCA claims can be based "at least in certain circumstances" on the implied false certification theory. That is, failure to disclose noncompliance with a material statutory, regulatory or contractual requirement can give rise to FCA liability if the omission makes the claim misleading.
- Whether such an omission makes a claim fraudulent doesn't depend on whether the requirement violated is expressly made a condition of payment but rather whether the defendant "knowingly violated a requirement that the defendant knows is material to the Government's payment decision."

Evidence of the government routinely paying a type of claim despite knowing of a particular violation—without expressing a change in position—would favor a finding the requirement isn't material.

The Court's decision arises out of a *qui tam* claim brought by parents of a teen girl against the facility providing her mental health services, who died following seizures after an adverse reaction to antibiotics prescribed by an individual claiming to be a doctor. The family later learned that many professionals at the facility treating their daughter were not properly qualified or licensed to perform those services or to prescribe medication. They also discovered staff were not properly supervised. The family brought a *qui tam* action claiming that the facility billed Medicaid for services using codes for different services than those performed and failed to disclose violations of regulations regarding staff qualifications and licensure requirements relating to the services billed. The trial court dismissed the case saying the family didn't show the regulations violated were conditions of payment. The circuit court of appeals reversed, however, stating that a statutory, regulatory or contractual requirement can be either an express or implied condition of payment. The Supreme Court held the implied false certification theory could support FCA liability under two conditions: a claim makes representations about services or goods provided rather than just seeking payment; and failure to disclose noncompliance with requirements makes those representations "misleading half-truths."

In defining what is material to the government's payment decision, the court explained that something is material if it would have a tendency to influence action—in this case, government payment of claims. It stated that a misrepresentation or omission isn't material just because the government makes the related requirement an express condition of payment. It also isn't material simply because the government could refuse payment if it knew of the violation. Finally, a minor or insubstantial vi-

olation won't be material. What matters most is whether the entity seeking payment knowingly violated a requirement that it knows is material to the government's decision whether to pay the claim. Evidence that a violation is material would include if the claimant knows the government consistently refuses to pay claims because of "noncompliance with the particular statutory, regulatory, or contractual requirement." Evidence of the government routinely paying a type of claim despite knowing of a particular violation—without expressing a change in position—would favor a finding the requirement isn't material.

Ultimately, the U.S. Supreme Court returned this case to the lower court for review to determine whether the facts established FCA liability under the Supreme Court's stated interpretation of the implied false certification theory.

Takeaway: The U.S. Supreme Court adds fuel to False Claims Act enforcement, recognizing an implied false certification ground for liability.

Palmetto Lays Out Analytical Validity Requirements for Liquid Biopsy

Medicare contractor Palmetto GBA (Columbia, S.C.) outlined its coverage criteria for assessing the analytical performance of liquid biopsy tests to detect genetic variants in tumors. The requirements are limited to liquid biopsies using circulating tumor DNA (ctDNA), but can be based on any assessment technology, including next-generation sequencing. Palmetto says the coverage criteria are intended to "complement," but not substitute for MolDX, Palmetto's unique registration system for molecular diagnostic tests.

Central to the coverage criteria is Palmetto's designation of ctDNA-based somatic variant detection tests as a "form of surrogate testing," the contractor explained. Palmetto explains that the ctDNA "analyte" is the surrogate for the "tumor tissue analyte." So, as part of analytical validation considerations, laboratories must both establish performance metrics for the surrogate analyte and demonstrate the agreement between the surrogate and the reference tumor analyte.

The lab must specify its minimum requirements in terms of, for example, cell-free DNA, library concentration, and coverage.

Pre-analytically, the requirements say the laboratory must specify its minimum requirements for reporting results, including minimum library concentration, minimum average coverage, and uniformity across all target areas. Additionally, the test must be validated for all sample types and preservatives accepted for testing.

Analytical requirements say that four general types of sequence variants may be evaluated using liquid biopsy, including single nucleotide variants, insertions and deletions (indels), copy number amplifications, and structural variants (e.g., fusions, inversions and translocations). Laboratories only need to address requirements for molecular alterations that they report out, but the full reportable range of analysis and quality control parameters established in validation studies must be clearly specified, including variant allele frequency, minimum read/molecule counts, indel length, copy number level, and test target regions.

Additionally, only variants that can be detected by both the ctDNA assay and the independent reference method should be included in the analyses, but the technolo-

gy platform and/or sequencing chemistry used for the orthogonal reference method must be different than what is used for the ctDNA assay. Palmetto detailed criteria for how labs should establish a test's positive percent agreement, analytical positive predictive value, and negative percent agreement.

Reporting of "exceptions," including incidental findings or variants below the reported limit of detection needs to "clearly state" that the test is not validated to report these results.

Post-analytical requirements say a physician board certified in molecular genetic pathology must identify variants detected through ctDNA testing, and interpret them clinically to make therapeutic recommendations. Palmetto writes, "A Ph.D. is not a recognized Medicare provider."

The analytical validation criteria outlined by Palmetto apply only to qualitative assessment of ctDNA performed and are not intended for the analysis of circulating tumor cells or CTC-derived tumor DNA, matched tumor-normal testing with ctDNA, or quantitative ctDNA analysis for drug response, disease monitoring, or minimal residual disease.

Reporting of "exceptions," including incidental findings or variants below the reported limit of detection needs to "clearly state" that the test is not validated to report these results.

Interestingly, experts say this is the first time a Medicare contractor has "encouraged" reporting of somatic variants to the National Institutes of Health's ClinVar variant clearinghouse. This is part of a trend on the part of payers. It was recently reported that Aetna is requiring that all newly contracted laboratories submit their variant interpretations to ClinVar as a condition of participation in the Aetna network for BRCA1 and BRCA2 genetic testing.

Palmetto has Jurisdiction M covering North and South Carolina, Virginia and West Virginia.

Takeaway: Liquid biopsy testing continues to attract attention with more detailed coverage criteria from Palmetto.

Senior Medicare Patrol Projects Show Low ROI in Fighting Fraud and Abuse

An Office of Inspector General report detailing results of 2015 enforcement efforts by the Senior Medicare Patrol (SMP) show success but not overwhelming recoveries. However, the report cautions that SMP projects "may not be receiving full credit for recoveries, savings, and cost avoidance attributable to their work." That's because it isn't always easy to track enforcement referrals from beneficiaries to the projects. The SMP program operates in every state and recruits and trains volunteer retired professionals and senior citizens to "prevent, recognize, and report health care fraud, errors, and abuse." The trained volunteers also educate other Medicare and Medicaid beneficiaries to similarly ferret out fraud and abuse.

For 2015, the OIG reported the following data on SMP enforcement efforts:

- "$2.5 million in expected Medicare recoveries" attributable to SMP Projects, which is 282 percent increase from 2014 recoveries. Most of that was attributable to one project involving a hospice company whose owner was convicted of Medicare fraud.
- $35,059 savings to beneficiaries and others, which is a 56 percent decline from 2014 savings (Kentucky had $28,500 in savings to beneficiaries).
- $21,533 in cost avoidance for Medicare, Medicaid, beneficiaries, and others, which is 89 percent better than 2014 totals for cost avoidance.

These findings continue a downward trend. Last year, the OIG indicated 2014 recoveries had declined from those achieved in 2013 for the program. See "Senior Medicare Patrol Had Significant Drop in Fraud Recoveries Last Year," *National Intelligence Report*, 8/20/15, p. 4. Funding for SMP in 2015 on the other hand was $17.6 million with $8.7 million of that coming from the Health Care Fraud and Abuse Control Program. That's an increase from 2014 funding of $15.5 million. The SMP program has yielded $117.6 million in expected recoveries thanks to 72 SMP projects that reported performance data over an 18 year period. Total savings was $7 million and cost avoidance on behalf of beneficiaries was $9 million.

Takeaway: Government efforts to use trained beneficiaries to detect and report fraud and abuse achieve modest results in comparison to investment made; though OIG questions whether results truly reflect program's achievements.

Largest Strike Force Takedown in History Charges 300 Individuals, *Continued from bottom of p.1*

- Payment suspension authority exercised by Centers for Medicare & Medicaid Services against numerous providers
- Criminal charges brought include conspiracy to commit health care fraud, anti-kickback statute violations, money laundering, and aggravated identity theft.

"While it is impossible to accurately pinpoint the true cost of fraud in federal health care programs, fraud is a significant threat to the programs' stability and endangers access to health care services for millions of Americans," said Inspector General Daniel Levinson in a statement. Medicare's Fraud Strike Force took the lead, but 36 federal districts and 23 state Medicaid Fraud Control Units also participated in the enforcement initiative. In addition, 26 U.S. Attorney's Offices were involved in bringing cases related to the enforcement effort. The Strike Force is part of the Health Care Fraud Prevention & Enforcement Action Team (HEAT) which is a collaborative effort between the Department of Justice and the Department of Health and Human Services. Working out of nine locations, the Strike Force takes credit for charges brought against 2,900 individuals for false Medicare billing totaling over $8.9 million since it began in 2007.

"Taxpayers and Congress provided CMS with resources to adopt powerful monitoring systems that fight fraud, safeguard program dollars, and protect Medicare and Medicaid," Deputy Administrator and Director of CMS Center for Program Integrity Shantanu Agrawal, M.D. explained in a statement—echoing similar comments of fellow government agency heads who commented on the takedown. "The diligent use of innovative data analytic systems has contributed or led directly to many of the law enforcement cases presented here today. CMS is committed to its collaboration with these agencies to keep federally-funded health care programs safe and strong for all Americans."

Just last June, a similarly significant nationwide health care fraud takedown was announced—including 243 individuals charged and $712 million in false billing. Health care attorney Gina L. Simms, of Ober Kaler, explained to *National Intelligence Report's* sister publication, *G2 Compliance Advisor* at that time: "I believe that the 'takedowns' are designed to put health care providers everywhere on notice that the federal government has the resources to aggressively investigate and pursue fraud." See "Compliance Perspectives: Take Heed: Strike Force Takedowns Signal Aggressive, Coordinated Fraud Enforcement," *G2 Compliance Advisor*, September 2015, p. 5. Like this year's takedown, criminal charges in the 2015 takedown included anti-kickback violations, money laundering, aggravated identity theft and conspiracy to commit health care fraud. The DOJ's announcement of this latest takedown indicates a total of "nearly 1,200 individuals have been charged in national takedown operations which have involved more than $3.4 billion in fraudulent billings."

Takeaway: Coordinated federal and state government enforcement continues to yield large-scale arrests and maintains pressure on providers, including labs, to step up compliance efforts.

Editors note: For tips on how labs can avoid becoming the target of these nationwide takedowns and how targeted labs should respond to such investigations, view G2 Intelligence Training on Demand recording, "Don't Let Your Lab Become a "Take Down" Target for U.S. Law Enforcement Agencies!" featuring Gina L. Simms and Robert E. Mazer, health care attorneys with Ober Kaler. For more information, visit the Webinars and Training on Demand tab at www.g2intelligence.com or contact customer service at 1-888-729-2315.

Supreme Court Rebuffs Sequenom's Efforts to Protect Patent

Sequenom, engaged in a Hail Mary legal effort to protect a patent previously invalidated by legal action, confirmed this week that the U.S. Supreme Court turned down its petition for a review.

The San Diego-based Sequenom had been trying to get a hearing regarding what was known as the "540 patent" surrounding its MaterniT21 test. It is used to analyze cell-free fetal DNA in a mother's blood to diagnose genetic conditions.

"We are disappointed that the Supreme Court denied our petition and will not review the patent eligibility of the groundbreaking techniques embodied in the '540 Patent."

— Dirk van den Boom, CEO, Sequenom

A 2012 case before the high court led to the invalidation of two test-related patents held by Prometheus Laboratories regarding the use of metabolite levels in the bloodstream to guide the dosage levels of certain drugs. The court decided that the process merely described a law of nature and a "well-understood, routine, conventional activity."

The following year, federal courts invalidated the Sequenom patent based on the same legal rationale. The company's petition had essentially asked the Supreme Court to narrow the application of the "routine, conventional activity" rationale.

"We are disappointed that the Supreme Court denied our petition and will not review the patent eligibility of the groundbreaking techniques embodied in the '540 Patent," said Sequenom Chief Executive Officer Dirk van den Boom in a statement. "We believe that the Supreme Court missed an ideal opportunity to clarify patent eligibility criteria not only to protect the significant investments made by Sequenom but also by other innovative organizations to advance the standard of patient care and treatment. We fear this decision will discourage such investments in the future."

The company's finances have taken a hit since the 2013 decision. For the first quarter of 2016, its revenues were down 27 percent compared to the first quarter of 2015, and it reported a $13.4 million loss compared to net income of $14.3 million.

Last month, Sequenom announced it was pursuing a patent infringement lawsuit in Australian federal court against Sonic Healthcare, Australian Clinical Labs and Ariosa Diagnostics, Inc. alleging that the use of the Harmony™ non-invasive prenatal test infringed Australian Patent 272,919. Citing its pooling with Illumina of intellectual property regarding NIPT testing, van den Boom stated "We are committed to preserving the value of the intellectual property of the patent pool for the benefit of our licensees, and this lawsuit adds to suits already filed in the U.K. and Europe."

Takeaway: Sequenom faces another setback in protecting its intellectual property in the U.S. yet still seeks to enforce patents in other countries.

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

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