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## Taming the 'Wild West': Enforcement Trends and Reimbursement Issues Facing Independent Clinical Laboratories



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In 2014, San Diego-based Millennium Health LLC, one of the nation's largest drug-testing laboratories, employed approximately 1,000 people, tested over 2.5 million specimens annually, and generated roughly \$680 million in annual revenue. On the other side of the country, Health Diagnostic Laboratory Inc. (HDL), a Virginia-based company specializing in cardiovascular blood tests, generated over \$375 million in annual revenue and processed over 3,600 samples per day in 2013. By the end of 2015, both had reached multi-million dollar settlements with the U.S. Department of Justice (DOJ) and promptly declared bankruptcy.

The rise—and swift fall—of Millennium and HDL signals a new juncture for independent clinical laboratories. Rapid advances in science and technology coupled with increased demand for personalized medicine led independent clinical laboratory testing to outpace the

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regulatory and reimbursement framework governing its services. Some even characterized the independent clinical laboratory industry as the “wild west.”<sup>1</sup> Yet, that may be changing: recent DOJ enforcement actions, whistleblower-launched False Claims Act (FCA) lawsuits, commercial payer pre- and post-payment claim reviews, new local coverage determinations (LCDs) restricting Medicare coverage of laboratory tests, recent legislation reducing reimbursement for covered laboratory tests, Centers for Medicare & Medicaid Services (CMS) payment suspensions based on purported credible allegations of fraud, and enhanced scrutiny from the Food and Drug Administration (FDA) as it considers regulating laboratory developed tests (LDTs) suggest a heightened focus on independent clinical laboratory practices and even a threat to their livelihood and survival.

### I. Growth in Utilization of Clinical Laboratory Testing

Medicare spending on clinical laboratory testing rose by an average of 5.6 percent per year between 2003 and 2012, and as much as 9.1 percent in 2012<sup>2</sup> due to increased testing.<sup>3</sup> Private payer spending on clinical laboratory testing likewise spiked. One commercial health plan reported in 2013 that spending on outpatient clinical laboratory testing had increased annually by 8 to 10 percent, estimating that increased utilization accounted for two-thirds of this growth.<sup>4</sup> While many factors no doubt contributed, the advent of new molecu-

<sup>1</sup> Thomas M. Burton, *Is Lab Testing the 'Wild West' of Medicine?*, WALL ST. J. (Dec. 10, 2015), <http://www.wsj.com/articles/is-lab-testing-the-wild-west-of-medicine-1449800707>.

<sup>2</sup> Medicare laboratory payment rates increased only three times between 2003 and 2012 – 1.1 percent in 2003, 4.5 percent in 2009, and 0.65 percent in 2012. MEDICARE PAYMENT ADVISORY COMM'N, A DATA BOOK: HEALTH CARE SPENDING AND THE MEDICARE PROGRAM 198 (2014).

<sup>3</sup> Medicare reimbursement rates remained largely steady during this period. *Id.*

<sup>4</sup> Joseph Burns, *Health Plans Deploy New Systems to Control Use of Lab Tests*, MANAGED CARE, Oct. 2014, <http://www.managedcaremag.com/archives/2014/10/health-plans-deploy-new-systems-control-use-lab-tests>.

lar and genetic tests and increased demand for toxicology testing substantially drove this rise.

According to one estimate, there are currently more than 55,000 tests offered for nearly 4,500 disorders and 5,300 genes.<sup>5</sup> Genetic and molecular biomarker testing, including pharmacogenomics testing, now purport to inform treatment decisions for a variety of health conditions—including cancer, cardiovascular and thyroid disease and diabetes—by identifying genetic predispositions to clinical conditions as well as responses to drug treatment regimens.<sup>6</sup> Clinical laboratory testing is projected to grow as advances in science continue, the clinical utility of tests becomes more established and treatment becomes more intertwined with testing, individualized medicine increases in popularity and new tests are developed for more conditions.<sup>7</sup>

Along with the growth of molecular and genetic testing, greater demand for toxicology testing also has spurred increased independent clinical laboratory utilization rates. Demand for employee drug testing, for example, has risen in response to higher illicit drug use in the general population.<sup>8</sup> Health-care providers increasingly are using urine screening to better manage their patients' pain symptoms and to assess whether patients are compliant with drug regimens.<sup>9</sup>

## II. Enforcement Trends

In response to the growth in laboratory testing, regulators have begun to take a hard look at the types and frequency of testing as well as the aggressive marketing techniques used by laboratories to encourage the ordering of additional tests. Laboratories have been a target for investigative and enforcement efforts in both the 2015 and 2016 United States Department of Health & Human Services Office of Inspector General (OIG) work plans.<sup>10</sup> The heightened attention from regulators has led to an increase in enforcement actions by the DOJ, as well as other federal and state agencies, including the OIG, the CMS and state Medicaid Fraud Control Units. The civil FCA has become the weapon of choice in challenging independent laboratory practices.

<sup>5</sup> GENETESTS, <https://www.genetests.org/> (last visited Jan. 5, 2016).

<sup>6</sup> *Regulation of Genetic Tests*, NAT'L HUMAN GENOME RESEARCH INST., <http://www.genome.gov/10002335> (last visited Jan. 5, 2016).

<sup>7</sup> Some estimate that current genetic tests apply only to two percent of the population, but that they may benefit up to 60 percent of the population in the near future. *Personalized Medicine: Trends and Prospects for the New Science of Genetic Testing and Molecular Diagnostics* 11 (UnitedHealth Ctr. for Health Reform & Modernization, Working Paper No. 7, 2012).

<sup>8</sup> Lauren Weber, *Workers' Drug Use Appears to Rise*, WALL ST. J., June 2, 2015, <http://www.wsj.com/articles/workers-drug-use-appears-to-rise-1433268181>.

<sup>9</sup> Barry Meier, *Increase in Urine Testing Raises Ethical Questions*, N.Y. TIMES (Aug. 1, 2013), [http://www.nytimes.com/2013/08/02/business/increase-in-urine-testing-raises-ethical-questions.html?\\_r=0](http://www.nytimes.com/2013/08/02/business/increase-in-urine-testing-raises-ethical-questions.html?_r=0).

<sup>10</sup> See OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., WORK PLAN: FISCAL YEAR 2016, at 18, 47, 50 (2016), <http://oig.hhs.gov/reports-and-publications/archives/workplan/2016/oig-work-plan-2016.pdf>; OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., WORK PLAN: FISCAL YEAR 2015, at 16 (2015), <http://oig.hhs.gov/reports-and-publications/archives/workplan/2015/FY15-Work-Plan.pdf>.

## a. Civil Enforcement

Recent settlement agreements and complaints reflect several theories of liability brought under the penumbra of the FCA. These include alleged violations of the federal FCA predicated on violations of the Anti-Kickback Statute (AKS) or on the submission of claims for tests that are not covered, not reasonable and necessary for the diagnosis or treatment of a patient, not supported by physician orders, not used by the physician in the care and treatment of the patient, not sufficiently documented, not actually performed and/or miscoded. Allegations under the AKS of knowingly or willfully providing items, services or payments to induce patient or specimen referrals have focused on the unique financial relationships between laboratories and physicians. Other allegations of FCA violations arise out of concerns over lack of physician sophistication and/or incentive to limit orders for laboratory testing, or even conflicts of interest between laboratories and physicians paid to be clinical investigators in clinical research studies.

### i. Medical Necessity as a Basis for FCA Liability

Many recent qui tam lawsuits, false claims allegations brought by whistle-blowers, and government investigations have involved allegations that laboratories billed federal health-care programs for unnecessary tests. Medicare and other federal health-care programs generally pay only for services that are reasonable and necessary for (i) the diagnosis or treatment of an illness or injury, or (ii) to improve the functioning of a malformed body member.<sup>11</sup> This payment limitation is often referred to in Medicare program guidance and the health-care industry at large as “medical necessity.” Medicare regulations and sub-regulatory guidance provide that there are essentially three conditions that must be satisfied in order for a clinical laboratory test to be medically necessary. First, the laboratory test must be ordered by a licensed physician or certain non-physician practitioners, e.g., nurse practitioners and physician assistants, who are operating within the scope of their authority under state law.<sup>12</sup> Second, the test must be used by the ordering physician in the “management of the beneficiary’s specific medical problem.”<sup>13</sup> Third, the test must be safe, effective, not experimental or investigational and furnished in accordance with accepted standards of medical practice.<sup>14</sup> In addition to these three requirements, the ordering physician must maintain documentation of medical necessity in the beneficiary’s medical record and provide such information to the billing laboratory or to the CMS upon request.<sup>15</sup>

Given the medical necessity requirements outlined above, billing federal health-care programs for a bundle

<sup>11</sup> See 42 U.S.C. § 1395y(a)(1)(A).

<sup>12</sup> See 42 C.F.R. § 410.32(a).

<sup>13</sup> See *id.* (emphasis added); see also Medicare Benefit Policy Manual (CMS Pub. 100-02), ch.15, § 80.1 (advising that the ordering physician must use laboratory test results “promptly” in the care of the beneficiary).

<sup>14</sup> See Medicare Program Integrity Manual (CMS Pub. 100-08), ch. 13, § 13.5.

<sup>15</sup> See 42 C.F.R. § 410.32(d)(2), (3).

of tests, which may include both medically necessary and unnecessary tests, can amount to the submission of a false claim under the FCA. Similarly, many routine screenings, as compared to diagnostic tests, are not covered by Medicare, and billing for such services may also amount to the submission of false claims.

Notably, many clinical laboratories have developed “panels” consisting of tests that are commonly ordered together. Traditional panels, such as blood specimen panels testing cholesterol levels, have been reimbursed under the theory that the clinical need for one test suffices to establish the clinical need for the remaining tests in the panel. The use of panel tests, however, has increased dramatically over the last few years as laboratories have sought to encourage physicians to order a variety of molecular biomarker tests that are grouped together in “customized panels.” Indeed, clinical laboratories often design their requisition forms to permit physicians to order a “custom panel” consisting of multiple tests by checking a single box. Regulators have become increasingly skeptical of this practice because the ordering of panels, many of which contain in excess of 20 tests, raises a question as to (i) whether the physician is truly using each of the tests in the panel in the care of the beneficiary’s medical problem, and (ii) whether each of the tests is safe, effective, not investigational and useful in the diagnosis or treatment of the patient. For many tests, laboratory-funded studies are the only clinical evidence of the clinical utility of tests.

In April 2015, the DOJ partially settled an enforcement action against clinical laboratory companies HDL, Singulex and Berkeley HeartLab Inc. Among other theories of liability, the government alleged that the laboratory defendants encouraged physicians to order tests in pre-packaged custom panels rather than choosing tests based on individual patient need. The government asserted that these custom panels allegedly caused physicians to order large numbers of tests without conducting the necessary per-test evaluation of medical necessity. While HDL and Singulex settled with the government by agreeing to pay \$47 million and \$1.5 million, respectively, the case against Berkeley HeartLab is ongoing.

Similarly, in the October 2015 Millennium Health case, the government alleged that Millennium caused physicians to order excessive numbers of urine drug tests, in part through the promotion of “custom profiles,” which, instead of being tailored to individual patients, were alleged to be standing orders causing physicians to order large numbers of tests without an individualized assessment of patient need. The government also alleged that Millennium billed for expensive urine drug testing for all patients, even those who were not suspected of taking any drugs. Millennium settled the case for \$256 million.

Finally, in resolving an FCA lawsuit against Diagnostic Imaging Group in February 2014 for \$15.5 million, the DOJ alleged that the laboratory created standard order forms that bundled its tests together, allegedly causing physicians to order tests in bulk without evaluating whether each test was medically necessary.

## ii. Theories of AKS Liability

The increased FCA enforcement activity in the clinical laboratory industry and heightened scrutiny of the financial relationship between laboratories and order-

ing physicians has been furthered by a provision in the Patient Protection and Affordable Care Act of 2010 (PPACA) that made an AKS violation a per se false claim. Pursuant to that provision, any claim that includes services resulting from a violation of the AKS is by definition “false” under the FCA.<sup>16</sup>

As a result, a number of practices involving laboratory-physician relationships were flagged by the OIG in 2014 and 2015 as potentially problematic. In a 2014 study, the OIG analyzed billing practices for clinical laboratory services and found that more than 1,000 laboratories had unusually high or questionable billing under Medicare Part B,<sup>17</sup> leading the OIG to recommend that the CMS employ stronger oversight of laboratories.<sup>18</sup> That same year, the OIG issued a Special Fraud Alert to address arrangements that might run afoul of the AKS, including providing goods or services to doctors that are below fair market value.<sup>19</sup> The OIG explained that such actions could financially incentivize a doctor to order a test that is not reasonable and necessary for the diagnosis or treatment of a patient.<sup>20</sup> The OIG also took issue with processing and handling fees, which laboratories provide to doctors in exchange for the collection, packaging and processing of specimens, noting that such payment arrangements are usually associated with expensive or specialized tests and could constitute illegal remuneration.<sup>21</sup>

Such fee arrangements were central to the recent HDL and Millennium lawsuits. In the HDL case, the government alleged that HDL and Singulex billed federal programs for tests after paying a processing and handling fee to physicians in connection with the collection and delivery of specimens. The government also alleged that Berkeley HeartLab paid physicians a draw fee of up to \$20 for every sample referred to Berkeley, which exceeded the \$3 draw fee permitted by the CMS. The government asserted that Berkeley hid its excessive fee payments to physicians by charging the \$3 draw fee in addition to a \$4.50-\$8.50 processing and handling fee. In the Millennium case, the government alleged that Millennium violated the AKS by providing free urine drug test cups to physicians in exchange for the physicians’ promise that the specimens be returned to Millennium. The government claimed that the free cups cost \$5-\$6 each, amounting to more than \$1 million dollars allegedly given to physicians in exchange for referrals.

Similarly, Pathway Genomics Corp., a San Diego-based medical diagnostic laboratory, settled kickback-based FCA allegations with the DOJ and various states in December 2015. In that case, the government alleged that Pathway offered physicians and medical groups payment of up to \$20 for each free saliva kit they collected and submitted to Pathway for testing, with some physicians receiving as much as \$13,534. The relator al-

<sup>16</sup> See 42 U.S.C. § 1320a-7b(g).

<sup>17</sup> OFFICE OF INSPECTOR GEN., DEP’T OF HEALTH & HUMAN SERVS., QUESTIONABLE BILLING FOR MEDICARE PART B CLINICAL LABORATORY SERVICES 1 (2014), <http://oig.hhs.gov/oei/reports/oei-03-11-00730.pdf>.

<sup>18</sup> *Id.* at 19.

<sup>19</sup> OFFICE OF INSPECTOR GEN., DEP’T OF HEALTH & HUMAN SERVS., SPECIAL FRAUD ALERT: LABORATORY PAYMENTS TO REFERRING PHYSICIANS (2014), [http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/OIG\\_SFA\\_Laboratory\\_Payments\\_06252014.pdf](http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/OIG_SFA_Laboratory_Payments_06252014.pdf).

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

leged that Pathway's sales force urged physicians to test all of their patients regardless of medical need, claiming that the tests were covered by all government health-care programs and that Pathway would handle all of the billing. As part of the December 2015 resolution, Pathway agreed to pay \$4.1 million and voluntarily discontinue its physician reimbursement program.<sup>22</sup>

### b. Criminal and Civil Enforcement Against Individuals

Consistent with recent directives in the Yates Memorandum,<sup>23</sup> the DOJ has now increased its civil and criminal pursuit of individuals responsible for clinical laboratory misconduct. After settling with HDL, for example, the DOJ intervened in the underlying qui tams and pursued actions against the former founder and CEO of HDL, as well as owners of the sales forces for HDL and Singulex. In June 2015, James Banner, the owner and operator of Oracle Diagnostic Laboratories, was indicted by the U.S. Attorney's Office for the Southern District of Florida. The indictment alleges, among other things, that in 2010, Banner offered and paid bribes to patient brokers and other co-conspirators in exchange for referring Medicare beneficiaries to Oracle for drug screenings, many of which allegedly were not medically necessary. Similarly, in August 2015, a federal grand jury in New York indicted a physician for conspiring to violate the AKS—and for three substantive violations of the statute—after he allegedly accepted monthly bribes from Biodiagnostic Laboratory Services to provide referrals on behalf of the company.<sup>24</sup> In total, 26 doctors have already pleaded guilty to participating in this alleged bribery scheme.

Most recently, in January 2016, the owner of the Virginia-based Bostwick Laboratories settled claims that Bostwick allegedly conducted additional “reflex” testing on urine specimens without the treating physician's knowledge or consent, as well as claims that Bostwick allegedly offered various illegal incentives to physicians in exchange for referrals. The laboratory owner agreed to pay \$3.75 million to resolve these claims.<sup>25</sup>

<sup>22</sup> Dani Kass, *Pathway Genomics to Pay \$4M in FCA Settlement*, LAW360 (Jan. 4, 2016), <http://www.law360.com/articles/741965/pathway-genomics-to-pay-4m-in-fca-settlement>; Press Release, U.S. Att'y's Office, S. Dist. of Cal., *San Diego Genetics Laboratory Pays \$4 Million to Settle Federal Kickback Allegations in Connection with Patient Referrals* (Dec. 30, 2015), <https://www.fbi.gov/sandiego/press-releases/2015/san-diego-genetics-laboratory-pays-4-million-to-settle-federal-kickback-allegations-in-connection-with-patient-referrals>.

<sup>23</sup> Memorandum from Sally Quillian Yates, Deputy Att'y Gen., U.S. Dep't of Justice, to All U.S. Att'y's et al., *Individual Accountability for Corporate Wrongdoing* (Sept. 9, 2015) (“Yates Memo”), <http://www.justice.gov/dag/file/769036/download>.

<sup>24</sup> Press Release, U.S. Att'y's Office, Dist. of N.J., U.S. Dep't of Justice, *New York Doctor Charged with Taking Bribes in Test-Referral Scheme with New Jersey Clinical Lab*, (Aug. 11, 2015), <http://www.justice.gov/usao-nj/pr/new-york-doctor-charged-taking-bribes-test-referral-scheme-new-jersey-clinical-lab>.

<sup>25</sup> See Dani Kass, *Ex-Lab Owner to Pay \$3.75M For Unnecessary Cancer Tests*, LAW360 (Jan. 11, 2016), [http://www.law360.com/health/articles/744712?nl\\_pk=4110bd40](http://www.law360.com/health/articles/744712?nl_pk=4110bd40).

## III. Payer Scrutiny, Payment Suspensions and Coverage Restrictions

Government and commercial payers also have stepped up their scrutiny of clinical laboratory practices. Commercial payers have aggressively targeted independent clinical laboratory testing, mining data to uncover outlier utilization patterns and imposing pre- and post-payment reviews on independent clinical laboratory claims. Often, laboratories subject to pre- or post-payment review have been assigned to the payers' special investigations unit. Pre- and post-payment reviews require additional documentation to support all claims and halt all payments to the laboratory until each claim is validated. These reviews, which often extend for periods of six months or more, require the laboratories to obtain diagnostic and treatment information from physicians. They also impose a significant administrative burden on the laboratories as they require an established administrative support team to collect records and bring appeals of improperly denied claims. Poorly documented medical records, and in some cases, the inability to obtain those records, often lead to payment denials and the need for appeals. Thus, pre- and post-payment reviews often have a devastating impact on revenue.

The CMS also has increased its review of independent clinical laboratory tests and has used a new tool to shut down Medicare payments to clinical laboratories suspected of fraud. Under the PPACA, the CMS may suspend payments to health-care entities when there is a “credible allegation of fraud.”<sup>26</sup> Patterns of abusive billing, high billing error rates, complaints, audits, civil FCA investigations, law enforcement investigations and claims data mining all could lead to what the CMS would categorize as “credible allegations of fraud.”<sup>27</sup> Allegations are considered “credible” when they have “indicia of reliability.” The CMS's decision to suspend payments must be revisited after six months, but often Medicare payment suspensions remain in place for a year or more.

Additionally, both commercial and governmental payers have issued coverage restrictions identifying certain tests as experimental and investigational and, therefore, not covered or reimbursable. These policies are the result of increasing skepticism about the clinical utility of certain laboratory testing. Several of the CMS's Medicare Administrative Contractors (MACs), for example, recently issued LCDs addressing Medicare coverage of molecular biomarker tests. LCDs are binding on all health-care providers within a MAC's jurisdiction.<sup>28</sup> The development of such LCDs will thus bar

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<sup>26</sup> See 42 C.F.R. § 455.23.

<sup>27</sup> See 42 C.F.R. § 455.2; CPI – CMCS Informational Bulletin, Dep't of Health & Human Servs., *Affordable Care Act Program Integrity Provisions - Guidance to States - Section 6402(h)(2) - Suspension of Medicaid Payments Based Upon Pending Investigations of Credible Allegations of Fraud* (March 25, 2011), <http://oig.hhs.gov/fraud/medicaid-fraud-control-units-mfcu/files/payment-suspensions-info-bulletin-3-25-2011.pdf>.

<sup>28</sup> CTRS. FOR MEDICARE & MEDICAID SERVS., PUB. NO. 100-08, MEDICARE PROGRAM INTEGRITY MANUAL § 13.1.3 (2014), <https://www.cms.gov/regulations-and>

Medicare payment for all tests not explicitly granted coverage in the LCD or explicitly excluded from coverage as experimental and investigational. On Oct. 5, 2015, MAC Palmetto GBA issued an LCD identifying certain cardiovascular risk panels and many molecular biomarker tests as experimental and investigational and, therefore, not covered.<sup>29</sup> Noridian Healthcare Solutions, LLC and CGS Administrators, LLC, two other MACs, followed suit with similar LCDs or drafts of similar LCDs.<sup>30</sup> Widespread adoption of such LCDs could result in substantial Medicare payment reductions for laboratories involved in molecular diagnostic testing. In fact, in a proposed rule, the CMS is seeking input from stakeholders regarding its proposal to consolidate MACs for purposes of handling laboratory coverage policy and claims processing specifically for clinical laboratory tests.<sup>31</sup>

The issuance of LCDs restricting coverage in a hot area of laboratory testing is significant because the submission of claims to Medicare for tests explicitly not covered under LCDs could be alleged to constitute a knowing submission of a false claim in violation of the FCA. A similar theory was recently used by the DOJ in claiming that hospitals nationwide violated the FCA by submitting claims for reimbursement for implantable cardiac defibrillators (ICDs) in violation of the ICD coverage rules set forth in Medicare's National Coverage Determination (NCD). The DOJ announced in October 2015 that it had reached 70 settlements involving 457 hospitals and totaling more than \$250 million through enforcement of this NCD. In the same way that the DOJ asserted violations of the FCA for submission of claims that were contrary to the NCD, so too could the DOJ assert violations of the FCA for the submission of claims that are contrary to a binding LCD.<sup>32</sup>

#### IV. Legislative and Regulatory Changes Impacting Reimbursement

In addition to increased enforcement, payment suspensions and coverage restrictions, new legislation

guidance/guidance/manuals/internet-only-manuals-ioms-items/cms019033.html (stating that the LCD represents a MAC's decision "whether to cover a particular item or service on a MAC-wide basis"); 42 U.S.C. § 1395ff(f)(2)(B).

<sup>29</sup> See Palmetto GBA, Local Coverage Determination (LCD): MoIDX: Biomarkers in Cardiovascular Risk Assessment (L36129).

<sup>30</sup> See Noridian, *Local Coverage Determination (LCD): MoIDX: Biomarkers in Cardiovascular Risk Assessment (DL36358)*; Noridian, *Local Coverage Determination (LCD): MoIDX: Biomarkers in Cardiovascular Risk Assessment*; CGS Administrators, *Local Coverage Determination (LCD): MoIDX: Biomarkers in Cardiovascular Risk Assessment (L36139)*.

<sup>31</sup> See Medicare Clinical Diagnostic Laboratory Tests Payment System, 80 Fed. Reg. 59,386, 59,413 (Oct. 1, 2015) (to be codified at 42 C.F.R. pt. 414).

<sup>32</sup> Although LCDs are not binding on administrative law judges, such judges are directed to give them substantial deference if they are applicable to a particular case. See 42 C.F.R. § 405.1062. Courts have enforced LCDs as binding guidance. See *United States ex rel. Ryan v. Lederman*, No. 04-cv-2483, 2014 WL 1910096 at \*4-5 (E.D.N.Y. May 13, 2014) (finding LCD provided mandatory and binding coverage guidance in granting in part government's motion for summary judgment as to physician's submission of a false claim in violation of the FCA).

threatens to reduce Medicare reimbursement of laboratory services.

#### a. Protecting Access to Medicare Act of 2014 (PAMA)

In 2013, the OIG investigated Medicare Part B's payment rates and found that Medicare Part B paid up to 30 percent more for the top 20 tests by volume and expenditure than other public payers.<sup>33</sup> Further, the OIG estimated that Medicare could have achieved over \$900 million in cost savings that year if it had paid the same rate as the lowest paying insurer for these tests.<sup>34</sup> Spurred by these findings, Congress passed PAMA. PAMA not only strives to bring Medicare Part B payment rates in line with those of commercial payers but also to better assess laboratory test utilization.

PAMA requires certain independent clinical laboratories to report data regarding their commercial payer reimbursement to the CMS.<sup>35</sup> The CMS will then use this data to set reimbursement at the weighted median of collected private payer rates,<sup>36</sup> likely resulting in lower federal reimbursement for clinical laboratory tests. On Oct. 1, 2015, the CMS issued a proposed rule implementing PAMA that required applicable laboratories to begin reporting data on commercial payment rates by March 31, 2016.<sup>37</sup>

PAMA also will centralize clinical laboratory claims processing with select MACs, permitting these MACs to issue LCDs for clinical laboratory tests.<sup>38</sup> This will subject more laboratories to the coverage guidance set forth in a select MAC's LCDs. For clinical laboratories, this could result in all jurisdictions following the lead of Palmetto GBA's more restrictive coverage policies on genetic and molecular biomarker testing, among others.

#### b. Potential Changes to Oversight of LDTs

Many highly utilized clinical laboratory tests are LDTs. An LDT is a type of in vitro diagnostic test that is designed, manufactured and used within a single laboratory.<sup>39</sup> The FDA has long taken the position that LDTs are medical devices, but it traditionally has not enforced premarket review and other FDA requirements because the LDTs were considered relatively simple and straightforward tests. Companies have taken advantage of the lack of regulation surrounding LDTs to develop complex genetic tests. However, the

<sup>33</sup> OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., OEI-07-11-00010, COMPARING LAB TEST PAYMENT RATES: MEDICARE COULD ACHIEVE SUBSTANTIAL SAVINGS 1, 9 (2013), <http://oig.hhs.gov/oei/reports/oei-07-11-00010.pdf>.

<sup>34</sup> *Id.* at 10.

<sup>35</sup> See Pub. L. 113-93, 128 Stat. 1040 (adding § 1834A to the Social Security Act (the "Act")).

<sup>36</sup> Medicare Clinical Diagnostic Laboratory Tests Payment System, 80 Fed. Reg. 59,386, 59,399 (proposed Oct. 1, 2015) (to be codified at 42 C.F.R. pt. 414).

<sup>37</sup> *Id.* at 59,400.

<sup>38</sup> Pub. L. 113-93, 128 Stat. 1040 (adding § 1834A(g)(2) to the Act).

<sup>39</sup> See *Laboratory Developed Tests*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm407296.htm>.

FDA has identified problems with what it views as high-risk LDTs, even determining that certain LDTs lacked appropriate controls and yielded erroneous results.<sup>40</sup> Given the increasing complexity of these tests, the FDA has announced plans to regulate LDTs to ensure that they are accurate, precise, clinically relevant and of sufficient quality. In July 2014, the FDA notified Congress of its intent to issue a draft oversight framework for LDTs, including premarket review for LDTs classified as high-risk based upon factors such as the nature of the clinical decision stemming from the test result.<sup>41</sup> Litigation questioning the FDA's authority to regulate these LDTs is anticipated.<sup>42</sup>

If the FDA ultimately implements regulatory oversight over LDTs, the development of LDTs likely will slow, as laboratories will need to collect additional clinical evidence before obtaining FDA approval. Moreover, even if LDTs are subject to, and ultimately receive, FDA approval, the CMS has explicitly stated that such approval will not translate to coverage and reimbursement. Medicare's reasonable and necessary criteria for coverage require a test to have proven clinical utility. While the CMS's contractors note that FDA approval

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<sup>40</sup> *Id.*

<sup>41</sup> FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY, FOOD AND DRUG ADMINISTRATION STAFF AND CLINICAL LABORATORIES; FRAMEWORK FOR REGULATORY OVERSIGHT OF LABORATORY DEVELOPED TESTS (LDTs) 12 (2014).

<sup>42</sup> See Burton, *supra* note 2.

signals that the test has analytical and clinical validity, the FDA itself does not review a test's clinical utility.<sup>43</sup>

## V. Conclusion

In spite of the increased enforcement activity and payment reduction initiatives, independent clinical laboratories continue to support scientific innovation and medical advances. To ensure that this continues and in light of the new environment, independent clinical laboratories should be mindful of new coverage guidelines and of their obligations to submit claims in accordance with them. Independent clinical laboratories should educate physicians regarding which tests are reasonable and necessary for their patients and what documentation is required to support their orders. Such documentation should include the basis for the patient's need for the test, the order for the test, the results of the test and the physician's use of the test results in the care of the patient. Finally, laboratories should review their compliance policies and practices, including sales and marketing, test ordering, relationships with physicians, supplies to physicians and claims submission, as well as the design of their requisitions, to ensure compliance with governmental and commercial payer policies and reimbursement criteria for the testing they perform.

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<sup>43</sup> See Palmetto GBA, *Local Coverage Determination (LCD): MoIDX: Biomarkers in Cardiovascular Risk Assessment (L36129)*.