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G2 Intelligence Upcoming Events

Lab Reimbursement Summit
December 8, 2017
Holiday Inn Airport (South)
Atlanta, GA
www.lableadershipsummit.com

OPPS 2018: Revised Payment Rates & a New ADLT Date of Service Exemption

With all of the PAMA commotion, CMS's publication of the 2018 Medicare Hospital and Ambulatory Surgical Outpatient Prospective Payment System (OPPS) final rule has flown under the radar. In case you don't feel like reading all 1,133 pages, here is a summary of what managers of labs that provide services to hospital and ambulatory surgical center (ASC) outpatients need to know about the new OPPS rules.

Continued on page 2

PAMA Implementation: PLA Codes for Advanced Dx Tests Are Off to a Flying Start

PAMA implementation is so sweeping that it requires a shift in not just payment paradigm but also CPT codes. This has served as the impetus for development of a new class of codes known as Proprietary Laboratory Analyses (PLA) codes. Here's a quick overview of what's going on with PLA codes.

What PLA Codes Are All About

To the extent that the new PAMA lab payment regime is supposed to be based on market pricing, CMS had to create a coding system that could be used to track and monitor newfangled advanced diagnostic laboratory tests (ADLTs) and FDA-approved clinical diagnostic laboratory tests (CDLTs) reimbursed under PAMA. The new coding system is proprietary-based with codes being issued for specific products at the request of test developers and manufacturers.

PLAs are a new class of CPT codes developed by the American Medical Association (AMA) to meet that demand. The AMA has issued nearly two dozen PLA codes so far, all of which end in "U", including six that went into effect this October. In addition to ADLTs and CDLTs, the AMA has issued codes for "a range of tests" including genomic sequencing procedures and multi-analyte algorithm assays. Interpace Diagnostics, Vermillion, Thermo Fisher, Exosome Diagnostics and the Mayo Clinic are among those that have secured PLAs for their products. Here is the entire PLA roster to date:

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OPPS 2018: Revised Payment Rates & a New ADLT Date of Service Exemption, *from page 1*

1. 2018 OPPS Payment Rates

After last year's 1.65% increase, CMS is hiking overall OPPS rates for 2018 by 1.35% based on the following factors:

- Market basket update of +2.7%;
- Productivity adjustment of -0.6%;
- Update for ACA payment cuts of -0.75%.

Overall, CMS estimates that OPPS payments will increase by 1.4% during CY 2018.

2. Changes to Laboratory Date of Service (DOS) Rules

Current Rule: Lab tests on hospital patients are incorporated into the bundled rate that CMS pays for hospital services. Under the CMS DOS Regulation, aka 14-day rule, labs may not separately bill for tests unless they are ordered at least 14 days after the patient's discharge. That poses big problems for labs when testing takes place after tests are ordered and specimens collected but before the 14-day window closes. This is a very common scenario with molecular and genomic panel and cancer testing.

The Concern: Since its inception about a decade ago, critics have contended that the 14-day rule is overly confusing and chills hospitals from billing for tests provided by outside labs, resulting in care delays for cancer patients. In response to these concerns, CMS has already carved out molecular pathology tests from the rule's scope.

New Rule: The final rule would also exempt advanced laboratory diagnostic tests (ADLTs—aka multianalyte algorithm assays (MAAAs)), i.e., advanced tests performed at a single lab that use a proprietary algorithm to analyze multiple markers, and molecular pathology tests from the 14-day rule. The exclusion would not lead to unbundling abuses, CMS reasons, because these tests "can legitimately be distinguished from the care the patient receives in the hospital."

What It Means: The problem is figuring out exactly what qualifies as an ADLT.

Under PAMA, tests are subject to separate reimbursement as ADLTs if:

- They are offered and furnished by a single lab; AND EITHER
  - Are approved by the FDA; or
  - Evaluate a patient's DNA, RNA or proteins; AND provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests; AND Use a unique algorithm that predicts the chance the patient will develop a condition or respond to a treatment condition or respond to a treatment.

Under the DOS exemption, tests qualify as ADLTs exempt from the 14-day rule if:

- They are offered and furnished by a single lab; AND

NIR

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- Evaluate a patient's DNA, RNA or proteins; AND provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests; AND Use a unique algorithm that predicts the chance the patient will develop a condition or respond to a treatment condition or respond to a treatment.

TAKEAWAY: SCOPE OF NEW 14-DAY RULE EXEMPTION

Tests that Can Be Billed Separately

- ADLTs approved by the FDA and provided by a single lab
- Molecular pathology tests

Tests that Must Be Bundled

- ADLTs that are not FDA-approved
- Protein-based MAAAs that are not deemed molecular pathology tests
- Genomic sequencing procedures (GSPs)
- Tests with Proprietary Laboratory Analyses (PLA) codes (see story on page 1)

In other words, the exemption does not extend to the FDA-approval prong.

Takeaway: The term "final rule" is a misnomer since CMS is legally required to take comments for 60 days after the rule's Nov. 1, 2017 publication.

Distinguished Service: Kellison Award goes to FDA's Dr. Alberto Gutierrez

Dr. Alberto Gutierrez is the 2017 recipient of the Kellison Lab Industry Distinguished Service Award. Dr. Guitierrez retired in August after more than 25 years of public service from his post as director of the Office of In Vitro Diagnostics and Radiological Health (OVID) at the U.S. Food and Drug Adminsitration (FDA).

Scott Liff, president and CEO of Kellison & Company, presented the award, which recognizes an individual who over an extended period of time has served the diagnostic laboratory industry in an outstanding way, especially through his or her organizational leadership, effective management and/or valuable non-profit service to the industry.

The presentation was made in October in Washington D.C. at Lab Institute, a conference for lab leadership that G2 Intelligence has produced for 35 years.

Dr. Gutierrez joined the FDA in 1992 as a researcher. During his tenure at the FDA, the industry saw breakneck advancements in molecular diagnostics and in response to the growing impact of genetic testing on health care delivery, OIVD also greatly expanded.

Are Labs Personally Liable to Data Breach Victims—CareFirst Case May Provide the Answer

While data breaches inside labs and other health care settings happen all the time, lawsuits for money damages by victims have been relatively unusual. But now the U.S. Supreme Court is being asked to rule on a case that could blow the doors off of private data breach litigation; or, it could go in completely the opposite direction and make those suits even harder for victims to win.

The Issue

The *Fair Credit Reporting Act* (FCRA) and other privacy laws give individuals the right to sue for actual and substantial risk of future harms they suffer as a result of data breaches. *The question:* Just how substantial must the risk of future harm be to trigger the right to sue? It is a question for which the federal district and appellate courts have failed to reach consensus. And now the Supreme Court is being asked to settle the issue once and for all.

The CareFirst Case

The case, not surprisingly, involves a data breach involving protected health information. It happened in 2014 when CareFirst BlueCross BlueShield was hit by a cyberattack which exposed protected health information of 1.1 million of its members, including names, email addresses, dates of birth, and subscriber ID numbers.

The victims brought an FCRA class action lawsuit for damages (*Chantal Attias vs. Carefirst, Inc.*) in federal court but the district court dismissed it on the grounds that the customers did not suffer actual harm as a result of the breach. But the appeals court disagreed and allowed the case to proceed. "At the very least, it is plausible to infer that [the cyber attacker] has both the intent and the ability to use that data for ill," the court reasoned.

But CareFirst attorneys claim that the court's reasoning on risks of future harm was too speculative and failed to establish that customers would, in fact, suffer impending injuries as a result of the breach. And now they are asking the Supreme Court to do something it has never done: decide a data breach case.

The Case for the Case

CareFirst contends that the case presents a "substantial question," namely, what constitutes an "injury" giving rise to a legal claim for harm done as a result of a data breach under the FCRA. "The Supreme Court needs to address this area of the law to provide more guidance to federal district and appellate courts. . . . to clarify that an alleged future injury must be imminent to satisfy the substantial risk standard," according to the CareFirst motion petitioning the Court to take the case.

What's At Stake

The issue of an organization's liability to victims of data breaches is certainly a compelling one for the health care industry, in which 30% of all

Data breaches take place at hospitals, insurance companies, private provider offices and, of course, clinical labs.

data breaches in the U.S. occur. *Breach Barometer Report: Mid-Year Review*, published by Protenus, tallied 233 breach incidents reported to the Department of Health and Human Services from January to June 2017. This pace is expected to exceed the 2016 total of 450 breaches. In the first half of this year, 3.1 million patient records were affected.

Data breaches take place at hospitals, insurance companies, private provider offices and, of course, clinical labs. A notable example took place in December 2016, when Quest Diagnostics announced that "unauthorized third party" had gained access to personal client data through the MyQuest Internet application compromising the personal health information (including name, date of birth, lab results, and some telephone numbers) of approximately 34,000 individuals.

Takeaway: Preventing and responding effectively to data breaches is already an obligation under HIPAA, FCRA and other privacy laws. And while the threat of civil lawsuits for money damages by victims is not new, such litigation has been relatively rare due to the uncertainty over and difficulty of showing harm necessary to bring such suits. But a Supreme Court ruling on the question, one way or the other, would have a significant impact on future liability and litigation risks labs face for data breaches. So labs need to keep a close eye on the CareFirst suit—assuming the Court agrees to take it.

Millennium Labs Bankruptcy Plan Stays on Track despite Lender Opposition

It has been nearly two years since Millennium went into Chapter 11 but the case continues to make news. After agreeing to pay $250 million to settle federal fraud claims for false billing of urine tests, Millennium Health LLC filed for bankruptcy in November 2015. During the bankruptcy proceedings, Millennium's non-debtor shareholders worked out a deal with creditors. The debtors would fork over $325 million to pay the DOJ settlement in exchange for a broad release of all claims against them.

While most of the creditors went along, one group of lenders was virulently opposed to the deal. And since there was no opt-out they could use to escape, the opposing lenders cried foul and challenged the bankruptcy court's legal authority to approve a release without the agreement of all the lenders.

The bankruptcy court overrode their objections and confirmed the plan. After pinballing around legal tribunals, the case landed back in the lap of the original bankruptcy court. Last week, the ruling came down: It is, in fact, okay for a Chapter 11 plan to release a non-debtor's claims against a non-debtor, third-party even without releasing party's consent. *Translation:* The release deal was still binding even against the lenders who opposed it.

The case is not necessarily over and the opposing lenders may file yet another appeal. But for now at least, the Millennium bankruptcy plan is a go despite virulent opposition by some lenders.

Report: Outreach Labs Remain Profitable Despite Antiquated Systems & Lack of Exec Respect

Hidden within the basement of your average hospital is a $24 million business, one that provides a top quality, must-have service and operates at a margin of around 25% to 30%. That business is the hospital lab. The so-called outreach model seeks to leverage this potential by positioning the hospital lab as a business and profit center. And if you're into (or thinking about getting into) outreach, you should check out the new report from a firm that's been tracking the sector for 16 years.

The Chi Study

The report, entitled "*16th Annual National Hospital/Health System Laboratory and Outreach Survey Findings*," comes from national consulting firm Accumen Inc. and its subsidiary Chi Solutions Inc. and is based on a proprietary survey system that tracks key metrics of outreach performance and business trends. The goal: Help hospital and health system execs leverage their own labs.

The Positive Findings

The upshot of this year's report: Outreach labs are continuing to perform well despite the difficult business environment and fierce competition from national labs. This year's survey respondents also report that:

- They have the capacity to take on additional testing;
- Operating margins remain at or above historic levels as a result of aggressive cost cutting and synergies from consolidation; and
- They have the opportunity to cut costs and improve strategic performance by reducing blood and/or test utilization.

The Negative Findings

The report also finds that outreach labs face significant challenges not just from the outside but within their own hospitals and health systems. One is the lingering perception of executives of the lab as "cost center" rather than "profit center." Another is the lack of adequate systems for billing, connectivity, incentive compensation and monitoring profitability.

Future Growth Opportunities

The key strategic takeaway from the report is the finding that the physician office business is the most profitable market segment for outreach and its most promising opportunity for future growth.

Labs IN COURT

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

Opioid Prescribing Doctor Convicted in Lab Referral Kickback Scam

Case: Two doctors at a Maryland pain management clinic that prescribed pain relief medications to patients accepted kickbacks to refer all urine tests to a New Jersey lab. Six defendants were charged in the scheme: four of them pled guilty; one of the doctors committed suicide and the other doctor decided to take his chances with a jury. The doctor was convicted of 26 felony charges and now faces the possibility of up to 99 years in prison.

Significance: This case is the most recent example of how the current opioid drug epidemic is influencing the direction of federal health care fraud enforcement. This summer, the Department of Justice unleashed a potent nationwide crackdown on opioid drug abuse, both illegal and prescription. While labs and physicians are not necessarily the primary target, they are well within the range of potential suspects to the extent that urine testing plays a key role in detecting prescription opioid abuse.

Maine Hospital Pays $1.51 Million to Settle False Claims Charges

Case: The feds charged Mercy Hospital with overbilling Medicare and MaineCare for urinalysis tests. Rather than risk a trial, Mercy has agreed to shell out $1.514 million to settle the claims.

Significance: The takeaway is how the supposed scam worked. Mercy allegedly made false use of a billing modifier code to receive payment for multiple same-day urinalysis drug screening tests performed at its affiliate, Mercy Recovery Center that did not arise from separate, medically necessary encounters with the same patients on the same days. *Result:* Mercy separately billed for the urinalysis drug screening tests on a per-test basis instead of bundling and billing the tests as one claim per single patient encounter.

Judgment Day for BLS Bribery Strip Club Doctors

Case: Among the three dozen doctors that have so far been convicted for taking bribes from now defunct Parsippany, NJ, Biodiagnostic Laboratory Services LLC (BLS), the Staten Island brothers treated to lap dances at strip clubs may be the most notorious. Now they and one other physician have received their sentences:

Name	Practice	Allegations	Sentence
George Roussis	Pediatrician, Staten Island, NY	Accepted $175K in BLS cash payments for roughly $1.7 million in lab referrals from Oct. 2010-April 2013; BLS also paid for strip club trips, lap dances and sexual favors	37 months' prison, one year supervised release + $7,500 fine
Nicholas Roussis	OBGYN Staten Island, NY	Accepted $175K in BLS cash payments for roughly $1.7 million in lab referrals from Oct. 2010-April 2013; BLS also paid for strip club trips, lap dances and sexual favors	24 months' prison, one year supervised release + $5,000 fine
Ricky J. Sayegh	Internal medicine, Yonkers, NY	Accepted roughly $400K in cash bribes for generating roughly $1.4 million in lab business from Feb. 2010-April 2013	30 months' prison, one year supervised release + $10,000 fine
Yousef Zibdie	Internal medicine, Woodland, NJ	Accepted $80K worth of monthly bribe checks for generating roughly $930K in illegal lab business for BLS	

Significance: The latest BLS scoresheet: 50 convictions, 36 of them doctors and over $13 million recovered via forfeiture. At least two more doctors are also awaiting sentencing. Stay tuned...

Luminex Settles Trademark Suit against Curiox BioSystems

Case: In late August, Luminex filed a federal trademark-infringement lawsuit against Curiox BioSystems for implementing "a wide-ranging scheme to confuse the market" about its affiliation with Luminex and "trick customers into engrafting Curiox's non-validated parts into the Luminex system. The complaint accuses Curiox of trying "to cobble together an unvalidated Frankenstein-ish system that fails at the very thing assay testing is designed to accomplish —producing accurate test results." Now comes word that the parties have agreed to settle the case.

Significance: The settlement bars Curiox from stating or implying in its advertising that:

- Its Curiox DA-Bead Plate enables equivalent or better sensitivity, reproducibility or detectability than the Luminex system; and
- The DA-Bead Plate is validated for use with the Luminex system.

FDA Watch: Agency Moves to Boost CLIA Waiver Transparency

The CLIA standards that a lab must meet are based on the complexity of the in vitro diagnostic tests it performs. The FDA's primary role in the CLIA system is to categorize IVDs.

Test Category	Get CLIA Certificate	Meet Quality Standards	Submit to Routine Inspections
Moderate complexity	✔	✔	✔
High complexity	✔	✔	✔
Waived	✔		

On Oct. 2, the FDA did two things to enhance the transparency of its CLIA activities.

1. Revised Categorization Guidance

The FDA issued updated guidance providing more details about the procedures it will use to categorize IVDs and respond to applications for CLIA waivers. The key details:

- The FDA will try to notify sponsors of an approved IVD's categorization within two weeks of approval;
- IVDs approved for home or over-the-counter use will be waived automatically;
- Makers of IVDs categorized as moderate complexity can apply for a CLIA waiver;
- To get the waiver, the maker must use clinical and flex studies to show that the test is simple to use and poses "insignificant risk of an erroneous result."

2. Publication of CLIA Waivers

The second thing the FDA did to beef up transparency is launch a pilot program under which it will publish summaries of its CLIA Waiver by Application (CW) decisions. In addition to enabling the public to see how the FDA reviewed the data, publishing the decision summaries will help test makers prepare their future CW applications, according to the agency.

PAMA Implementation: PLA Codes for Advanced Dx Tests Are Off to a Flying Start, *from page 1*

Top 10 Lab Tests Based on Medicare Part B Payments in 2016

CPT Code	Long Descriptor	Proprietary Test Name & Lab(s)/Manufacturer(s)	Effective Date
0001U	Red blood cell antigen typing, DNA, human erythrocyte antigen gene analysis of 35 antigens from 11 blood groups, utilizing whole blood, common RBC alleles reported	PreciseType® HEA Test, Immucor, Inc	Feb. 1, 2017
0002U	Oncology (colorectal), quantitative assessment of 3 urine metabolites by liquid chromatography with tandem mass spectrometry using multiple reaction monitoring acquisition, algorithm reported as likelihood of adenomatous polyps	PolypDX,™ Atlantic Diagnostic Laboratories, LLC + Metabolomic Technologies Inc.	Feb. 1, 2017
0003U	Oncology (ovarian) biochemical assays of 5 proteins (apolipoprotein A-1, CA 125 II, follicle stimulating hormone, human epididymis protein 4, transferrin), utilizing serum, algorithm reported as a likelihood score	Overa (OVA1 Next Generation), Aspira Labs, Inc. + Vermillion, Inc.	Feb. 1, 2017
0004U	Infectious disease (bacterial), DNA, 27 resistance genes, PCR amplification and probe hybridization in microarray format (molecular detection and identification of AmpC, carbapenemase and ESBL coding genes), bacterial culture colonies, report of genes detected or not detected, per isolate	Gram-Negative Bacterial Resistance Gene PCR Panel, Mayo Clinic + Check-Points Health BV, Wageningen, Netherlands	May 1, 2017
0005U	Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score	ExosomeDx® Prostate (IntelliScore), Exosome Diagnostics, Inc.	May 1, 2017
0006U	Prescription drug monitoring, 120 or more drugs and substances, definitive tandem mass spectrometry with chromatography, urine, qualitative report of presence (including quantitative levels, when detected) or absence of each drug or substance with description and severity of potential interactions, with identified substances, per date of service	Aegis Drug-Drug Interaction Test, Aegis Sciences Corpora	Aug. 1, 2017
0007U(*)	Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, urine, includes specimen verification including DNA authentication in comparison to buccal DNA, per date of service *(For additional PLA code with identical clinical descriptor, see 0020U. See Appendix O to determine appropriate code assign*	ToxProtect, Genotox Laboratories LTD	Aug. 1, 2017
0008U	Helicobacter pylori detection and antibiotic resistance, DNA, 16S and 23S rRNA, gyrA, pbp1, rdxA and rpoB, next generation sequencing, formalin-fixed paraffin-embedded or fresh tissue, predictive, reported as positive or negative for resistance to clarithromycin, fluoroquinolones, metronidazole, amoxicillin, tetracycline and rifabutin	AmHPR Helicobacter pylori Antibiotic Resistance Next Generation Sequencing Panel, American Molecular Laboratories, Inc	Aug. 1, 2017
0009U	Oncology (breast cancer), ERBB2 (HER2) copy number by FISH, tumor cells from formalin-fixed paraffin-embedded tissue isolated using image-based dielectrophoresis (DEP) sorting, reported as ERBB2 gene amplified or non-amplified	DEPArray™ HER2, PacificDx	Aug. 1, 2017

CPT Code	Long Descriptor	Proprietary Test Name & Lab(s)/Manufacturer(s)	Effective Date
00010U	Infectious disease (bacterial), strain typing by whole genome sequencing, phylogenetic-based report of strain relatedness, per submitted isolate	Bacterial Typing by Whole Genome Sequencing, Mayo Clinic	Aug. 1, 2017
00011U	Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites	Cordant CORE™, Cordant Health Solutions	Aug. 1, 2017
00012U	Germline disorders, gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood, report of specific gene rearrangement(s)	MatePair Targeted Rearrangements, Congenital, Mayo Clinic	Aug. 1, 2017
00013U	Oncology (solid organ neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, fresh or frozen tissue or cells, report of specific gene rearrangement(s)	MatePair Targeted Rearrangements, Oncology, Mayo Clinic	Aug. 1, 2017
00014U	Hematology (hematolymphoid neoplasia), gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood or bone marrow, report of specific gene rearrangement(s)	MatePair Targeted Rearrangements, Hematologic, Mayo Clinic	Aug. 1, 2017
00015U	Drug metabolism (adverse drug reactions), DNA, 22 drug metabolism and transporter genes, real-time PCR, blood or buccal swab, genotype and metabolizer status for therapeutic decision support	OneOme RightMed Pharmacogenomic Test, OneOme, LLC	Aug. 1, 2017
00016U	Oncology (hematolymphoid neoplasia), RNA, BCR/ABL1 major and minor breakpoint fusion transcripts, quantitative PCR amplification, blood or bone marrow, report of fusion not detected or detected with quantitation	BCR-ABL1 major and minor breakpoint fusion transcripts, University of Iowa, Department of Pathology + Asuragen	Aug. 1, 2017
00017U	Oncology (hematolymphoid neoplasia), JAK2 mutation, DNA, PCR amplification of exons 12-14 and sequence analysis, blood or bone marrow, report of JAK2 mutation not detected or detected	JAK2 Mutation, University of Iowa, Department of Pathology	Aug. 1, 2017
00018U	Oncology (thyroid), microRNA profiling by RT-PCR of 10 microRNA sequences, utilizing fine needle aspirate, algorithm reported as a positive or negative result for moderate to high risk of malignancy	ThyraMIR, Interpace Diagnostics	Oct. 1, 2017
00019U	Oncology, RNA, gene expression by whole transcriptome sequencing, formalin-fixed paraffin embedded tissue or fresh frozen tissue, predictive algorithm reported as potential targets for therapeutic agents	OncoTarget/OncoTreat, Columbia University Department of Pathology and Cell Biology + Darwin Health	Oct. 1, 2017
00020U(*)	Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, urine, with specimen verification including DNA authentication in comparison to buccal DNA, per date of service *(For additional PLA code with identical clinical descriptor, see 0007U. See Appendix O to determine appropriate code assignment)*	ToxLok, InSource Diagnostics + Agena Bioscience, Inc.	Oct. 1, 2017

Continued on page 12

CPT Code	Long Descriptor	Proprietary Test Name & Lab(s)/Manufacturer(s)	Effective Date
00021U	Oncology (prostate), detection of 8 autoantibodies (ARF 6, NKX3-1, 5'-UTRBMI1, CEP 164, 3'-UTR-Ropporin, Desmocollin, AURKAIP-1, CSNK2A2), multiplexed immunoassay and flow cytometry serum, algorithm reported as risk score	Apifiny®, Armune BioScience, Inc.	Oct. 1, 2017
00022U	Targeted genomic sequence analysis panel, non-small cell lung neoplasia, DNA and RNA analysis, 23 genes, interrogation for sequence variants and rearrangements, reported as presence/absence of variants and associated therapy(ies) to consider	Oncomine™ Dx Target Test, Thermo Fisher Scientific	Oct. 1, 2017
00023U	Oncology (acute myelogenous leukemia), DNA, genotyping of internal tandem duplication, p.D835, p.I836, using mononuclear cells, reported as detection or non-detection of FLT3 mutation and indication for or against the use of midostaurin	LeukoStrat® CDx FLT3 Mutation Assay, LabPMM LLC, an Invivoscribe Technologies, Inc. company + Invivoscribe Technologies, Inc.	Oct. 1, 2017

(*) More than one PLA with an identical descriptor

Takeaway: While they make it easier to monitor sales of advanced tests, it remains to be seen whether the issuance of PLAs will have any measurable impact on market performance or persuade payors to cover the products.