G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

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Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 37th Year of Publication

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G2 INTELLIGENCE Upcoming Events

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

Conference:

Lab Institute 2017
October 25-27. Hyatt Regency Washington on Capitol Hill, Washington, DC
www.labinstitute.com

Lab Institute 2016 Highlights: Convergence, Compliance and Genetics

Attendees at G2 Intelligence's 34th annual Lab Institute were treated to a history lesson about diagnostics as well as forward-looking discussions that illuminated the current state and the future of the laboratory industry and clinical diagnostics.

Kristin Pothier, EY's Global Head of Life Sciences, Transaction Advisory Services

Convergence with Life Sciences, Patients

Opening keynote speaker, Kristin Pothier, EY's Global Head of Life Sciences, Transaction Advisory Services, highlighted key areas of life sciences that are driving convergence among various previously independent sectors within the health care marketplace: pharmaceutical research and development, precision medicine and patient information. Pothier's presentation demonstrated how new technologies and business models, precision medicine and the increasing prevalence of companion diagnostics are highlighting the value of diagnostics and driving alliances and acquisitions involving in-vitro diagnostics companies. Big data and increased access to patient information, mobile technology and rising consumerism are also revolutionizing patient care, according to Pothier.

In his keynote addressing the state of the laboratory industry, Dr. Gregory Henderson, president of BioReference Laboratories, discussed a conver-

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OIG Reports Medicare Payments for Top 25 Lab Tests

Medicare Part B paid $7 billion for lab tests in 2015, the same amount it shelled out in 2014. But 2015 Medicare payments for the top 25 lab tests dipped slightly to $4.1 billion, as compared to $4.2 billion in 2014. These are among the key conclusions of a new report issued by the Office of Inspector General (OIG) as part of its Protecting Access to Medicare Act of 2014 (PAMA) mandate to monitor Medicare payments for lab tests in advance of the new payment system taking effect on Jan. 1, 2018.

The $7.0 billion paid for lab tests under the Clinical Laboratory Fee Schedule (CLFS) accounted for roughly 3% of all Part B payments made in 2015, according to the report. Where did that money go?

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Lab Institute 2016 Highlights, *from page 1*

Dr. Gregory Henderson, president of BioReference Laboratories

gence of a different kind—the convergence of diagnostics and health care providers with patients and their data. He emphasized the importance of the patient and patient access to data in an increasingly mobile and data-intense age. Henderson discussed the lab industry's need to educate and involve patients in the health care delivery process—providing "actionable medical knowledge" and explaining for patients the data generated in health care. He discussed this challenge in the context of the diagnostic industry's history. He began his presentation highlighting the differing viewpoints of chemists and vitalists about the need for lab testing to assist diagnosis roughly 200 years ago to gain perspective on the industry's current challenges. He concluded that labs must confront similar challenges faced those many years ago to demonstrate the value of diagnostic testing and manage utilization.

Compliance Issues Permeate Discussions Throughout Lab Institute

During three days of presentations, compliance issues for laboratories and pathologists permeated most of the discussions. Beginning with a workshop on workforce issues, speakers addressed compliance risks that can arise in recruiting, hiring, managing and terminating members of the workforce. Panel discussions prepared laboratories for the compliance challenges they'll face with new payment methodologies and regulation and oversight of new technologies such as next generation sequencing, laboratory developed testing and direct-to-consumer testing. Throughout the conference, concurrent and general sessions addressed compliance issues relating to reimbursement, managing data generated by diagnostics, and ensuring patient access to test results.

Health care attorney Karen Lovitch (left) and Kelly A Hardy, Editorial Director, Plain Language Media

Health care attorney Karen Lovitch capped off a morning of general sessions addressing regulatory, reimbursement and policy issues by highlighting three key compliance hotspots for labs to watch out for—medical necessity, arrangements with physicians, and increasing coverage restrictions. Within those key issues, she also discussed increased individual accountability under the Yates memo, private payer enforcement, waiver of copayment amounts and surprise medical bill legislation that addresses patient bills for out-of-network services.

Lovitch was only one of several speakers to address the challenges raised by surprise medical bill legislation. This legislation protects patients from unexpected bills from out-of-network providers after they sought services from an in-network facility. New York and California both have passed such legislation within the last two years. Lovitch and other speakers cautioned labs to make sure they understand state laws and reimbursement policies that govern such out-of-network billing.

Continuing Rise of Genetic Testing

Increasing diagnostic options for providers and patients was a common theme throughout the conference. Speakers noted that more opportunities also require more education and better resources to help providers and patients understand their options, select the most appropriate diagnostics, and properly manage utilization.

Keynote speaker Mara Aspinall, chief executive officer of Health Catalysts and Executive Chairman of GenePeeks, said diagnostics will change with the rising importance of genetic testing. She explained that identification of genetic mutations rather than site of a tumor will drive cancer treatment in the future. The future of diagnostics, Aspinall predicted, will involve algorithms and integrated data gathered from multiple sources—in short, "an information business with a wet lab on the side."

Gillian Hooker, VP Clinical Development, NextGxDx

The final presentation, by Gillian Hooker, vice president of clinical development at NextGxDx, similarly addressed the explosion in the genetic testing market with tens of thousands of tests currently on the market and new genetic tests being introduced every day. NextGxDx research indicates there are more than 65,000 genetic testing products on the market compared to less than 13,000 just three years ago. Hooker addressed challenges providers face in identifying the right test and a need for standardization in terminology not only to simplify ordering but to facilitate coding and reimbursement as well.

Takeaway: Industry leaders indicate the future of diagnostics is patient- and data-focused yet brings familiar compliance and business challenges.

G2 Awards Recognize Diagnostics Leaders and Innovators

Amidst three days of networking, workshops, panel discussions and presentations focused on the challenges and opportunities facing laboratories and pathologists, two leaders in diagnostics were honored for their commitment to the laboratory industry, public service and innovation in diagnostics.


Mark Ziebarth, G2 Intelligence president and publisher; Gregory S. Henderson, M.D., Ph.D, President of BioReference Laboratories; and Scott Liff, chief executive officer of Kellison & Company

Public Service Distinguished Leadership Award sponsored by Kellison & Company

Gregory S. Henderson, M.D., Ph.D. was awarded the 2016 G2 Laboratory Public Service Distinguished Leadership Award, sponsored by Kellison & Company, a revenue cycle management solutions company. Kellison's Chief Executive Officer Scott Liff presented the award at G2's 34th Annual Lab institute Conference at the Hyatt Regency Capitol Hill, Washington, D.C. on Thursday, October 27, 2016.

This annual award is presented to a diagnostic laboratory industry executive exemplifying the traits of leadership, excellence, and service to the industry. Dr. Henderson was named President of BioReference Laboratories, a division of OPKO Health, Inc. in March 2016. He has served as a leader in pathology and laboratory medicine as a pathologist, executive and innovator. He has guided business growth and operations of one of the largest laboratory outreach programs in the United States, served on a team charged with rebuilding healthcare infrastructure in New Orleans after Hurricane Katrina, co-developed the first cloud based anatomic pathology information system, and founded a company that leverages cloud technology solutions to provide digital pathology consultations that afford access to quality diagnostics in the developed and developing world.


Mark Ziebarth, G2 Intelligence president and publisher; Analyte Health Chief Executive Officer Dr. Frank Cockerill; and Jack Redding, senior vice president, sales and marketing, for Halfpenny Technologies

Lab Innovation Award Sponsored by Halfpenny

Dr. Frank Cockerill, Chief Executive Officer of Analyte Health received G2 Intelligence's Lab Innovation Award, designed to recognize innovation in the field of diagnostics. The award, sponsored by Halfpenny Technologies Inc., was presented by Jack Redding, senior vice president, sales and marketing, for Halfpenny, on Friday, October 28 at Lab Institute in Washington, D.C.

Cockerill was recognized for his leadership of Analyte Health in innovating patient access to diagnostic testing. As CEO, Cockerill is leading Analyte Health in pioneering online diagnostic services aimed directly to consumers—including education, diagnostic testing, personalized results and recommendations about next steps. Cockerill previously led the Department of Laboratory Medicine and Pathology at Mayo Clinic and was Chief Executive Officer of Mayo Medical Laboratories, a global reference laboratory operating within Mayo Clinic. He was also the Ann and Leo Markin Professor of Microbiology and Medicine at the Mayo Clinic College of Medicine, having extensive experience and expertise in infectious diseases and antimicrobial resistance.

OIG Surveys How CMS is Doing on PAMA Implementation

With D-day set for Jan. 1, 2018 for implementation of a new payment methodology for lab services under the Protecting Access to Medicare Act of 2014 (PAMA), the Office of Inspector General (OIG) just issued a report documenting the progress the Centers for Medicare and Medicaid Services (CMS) is making in implementing the different aspects of the new payment system. Here is what lab managers need to know about the report to keep on top of their own PAMA implementation efforts.

What CMS Has Done So Far

CMS has already reached a few of the most important implementation milestones: In December, it completed the IT system that labs will use to report their private payer data; and on June 17, 2017, it issued the final rule. And as we reported last month (see *NIR*, Sept. 29, 2016, p. 2), CMS has since issued guidance materials, including: the HCPCS reporting codes; guidance for collecting and reporting private payer data; and the data reporting template.

CMS' 6 Implementation Tasks and the Progress Being Made

The OIG report explains each of CMS' "tasks" it must complete and describes the progress CMS has made on each one, as summarized by the chart below.

PAMA Briefing: Current Status of Part B Payment Changes
Implementation Final Implementation Deadline: Jan. 1, 2018

Task	Status	What CMS Has Done	What CMS Still Must Do
1. Issue final rule and lab industry guidance	**Almost complete**	▪ June 17, 2016: Final rule issued ▪ Issued guidance on data reporting procedures and requirements	▪ By January 2017: issue guidance on process for labs to apply to have a test designated as an ADLT ▪ Determine if additional regulations or guidance is needed
2. Establish and consult with advisory panel	**Complete**	▪ April 2015: Panel created ▪ 2015-2016: Panel met four times ▪ Panel has formed 2 subcommittees: i. One advises CMS on payments for automated "profile" tests ii. Other advises on ADLT application process	▪ Through April 2017: Continue to receive and consider recommendations of panel and subcommittees
3. Collect private payer data reported by labs	**Significant progress**	▪ December 2015: Completed building of data collection system used by labs to report private payer data ▪ Testing of data collection system user experience, security and capacity partially completed—stress testing of user capacity hindered due to limitations of CMS's Presentation Zone	▪ Finish testing of data collection system user experience ▪ October 2016: Independent validation of system ▪ October 2016: Data collection system to be made available for labs to begin registering ▪ By January 2017: Finish educating labs about reporting requirements ▪ January 2017: Reporting begins ▪ January to March 2017: Collect first set of labs' private payer data
4. Ensure accuracy and completeness of reported data	**In progress**	▪ Creation of preliminary plans to conduct checks in mid- to late 2017 after labs submit first round of data ▪ Automated data verification and certification features incorporated into CLFS module	▪ April to August 2017: Conduct checks on first round of data labs submit ▪ September 2017: Publish pricing and volume data ▪ Starting September 2017: Seek public input on accuracy of preliminary Medicare payment rates ▪ CMS does **not** plan to independently verify whether all applicable labs submit their private payer data as required or the accuracy and completeness of the data of the labs that do report their data—*Result:* Risk of inaccurate payment rates

Task	Status	What CMS Has Done	What CMS Still Must Do
5. Determine and publish new Medicare payment rates	**In progress**	▪ Capacity to calculate new rates from data labs report incorporated into data collection system	▪ Early 2017: Collect data reported by labs ▪ Calculate Medicare payment rates from data ▪ November 2017: Publish the new payment rates ▪ January 2018: New payment rates take effect
6. Identify ADLTs	**In progress**	▪ June 2016: Publication of criteria for test to qualify as ADLT (as part of final rule) ▪ July 2016: Advisory panel subcommittee recommends ADLT application procedure	▪ By January 2017: Decide and issue guidance describing ADLT application procedure ▪ Thereafter: Review applications and decide whether tests qualify as ADLTs

Takeaway: 5 Things Labs Should Be Doing to Get Ready for PAMA

At this point, there are five things labs should be doing to get ready for the new Medicare Part B lab test payment system:

1. Familiarizing themselves with the Final PAMA Rule;
2. Getting ready to register on the CMS's new data collection system when registration begins;
3. Looking out for the two sets of materials CMS intends to release by year's end before reporting begins on Jan. 1, 2017:
   a. Educational materials explaining the payer data reporting process; and
   b. Guidance explaining the process to follow when applying to have CMS designate a test as an ADLT;
4. Preparing for the release of the preliminary lab test fee schedule in September 2017 and, if warranted, providing feedback on its accuracy; and
5. Being on the lookout for the final PAMA fee schedule which CMS intends to issue in November 2017.

Takeaway: As the deadline for full implementation of PAMA draws near, the OIG indicates CMS and labs still have much to do. G2

OIG Highlights Largest Self-Disclosure Protocol Settlement

In its latest Eye on Oversight video, the Health and Human Services Office of Inspector General highlights a $25.1 million settlement, the largest settlement to date achieved under the self-disclosure 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 protocol 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."

The video notes that without the self disclosure, 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. G2

OIG Reports Medicare Payments for Top 25 Lab Tests, *Continued from bottom of p.1*

What Medicare's $7 Billion in 2015 Lab Spending Went Toward

Tests	Beneficiaries	Labs	Providers
474 million: number of tests billed **3.7:** average number of tests received by beneficiaries in a day **24:** average number of tests per day for top 1% of beneficiaries	**27 million:** Medicare beneficiaries that received at least one test **17:** average number of tests per beneficiary **109:** average number of tests per beneficiary among top 1% of beneficiaries	**61,040:** labs that received Medicare payments **$113,981:** average payments per lab **$1.0 billion:** payments made to the top three labs	**612,812:** providers that ordered lab tests **570:** average number of tests ordered per provider **7,250:** average number of tests ordered by top 1% of providers

Source: OIG "Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015"

Fees Paid for Top 25 Lab Tests

As required by PAMA, the OIG report includes detailed analysis of the 25 most frequently ordered tests. Key findings:

- 23 of the top 25 tests of 2015 were also in the top 25 in 2014 (the two newcomers were drug confirmation (G6058), and amphetamine or methamphetamine (G6042));
- The $4.1 billion paid on the top 25 constituted 59% of Medicare payments made under the CLFS;
- Four of the top 25 tests posted increases in year-to-year payments of at least $10 million, including:
  - Opiates (drug) measurement (G6056)—up $35 million;
  - Drug screen, qualitative; multiple drug classes by high-complexity test method (e.g., immunoassay, enzyme assay), per patient encounter (G0431)—up $15 million;
  - Vitamin D-3 level (82306)—up $13 million; and
  - Benzodiazepines level (G6031)—up $10 million;
- Three of the top 25 tests posted decreases in year-to-year payments of at least $10 million, including:
  - Gene analysis (cytochrome P450, family 2, subfamily D, polypeptide 6) common variants (81226)—down $105 million;
  - Chemical analysis using chromatography technique (82542)—down $24 million; and
  - Blood test, clotting time (85610)—down $11 million;
- 54% of all Part B payments for the top 25 tests went to 1% of labs, i.e., 292 of 29,101;
- The next 4% of labs accounted for 25% of the payments for top 25 tests;
- The top eight tests *each* accounted for over $200 million in payments and, combined, $2.7 billion or roughly 66% of payments for the entire top 25 (see the table on page 7 for a breakdown of the individual tests).

Payment Trends

Although the $7.1 billion Medicare paid for all lab tests in 2015 was roughly the same as 2014's total, the report cites a couple of significant variances.

Drug tests up 19%: Medicare payments for drug tests were up 19% in 2015, from $910 million to $1.1 billion with 18 different drug tests generating increases of at least $1 million. Six of the year's top 25 were drug tests, as compared to four in 2014. According to the report, the spike "coincides with efforts to monitor drug abuse," according to the report. But, the report adds ominously, it could also be an indication of medically unnecessary testing. In fact, billing of medically unnecessary drug tests has been a focus of recent enforcement activity:

- On Aug. 31, a Florida pain clinic called Coastal Spine and Pain paid $7.4 million to settle claims of routinely billing Medicare for Quantitative drug tests performed on elderly patients regardless of medical necessity;

Top 8 Lab Tests Based on Medicare Part B Payments in 2015

Rank	Test Description and Procedure Code	National Limitation Amount	Number of Tests (millions)	2015 Medicare Payments (millions)	Changes from 2014 Payments (millions)
1	Blood test, thyroid-stimulating hormone (TSH) (84443)	$22.87	21.2	$475	-$3
2	Blood test, comprehensive group of blood chemicals (80053)	$14.37	40.6	$458	+$5
3	Complete blood cell count (red blood cells, white blood cells, platelets) and automated differential white blood cell count (85025)	$10.58	41.5	$428	-$3
4	Blood test, lipids (cholesterol and triglycerides) (80061)	$18.22	27.2	$379	-$8
5	Vitamin D-3 level (82306)	$40.29	8.7	$337	+$13
6	Hemoglobin A1C level (83036)	$13.21	18.6	$241	+$5
7	Opiates (drug) measurement (G6056)	$26.48	8.1	$208	+$35
8	Drug screen, qualitative; multiple drug classes by high-complexity test method (e.g., immunoassay, enzyme assay), per patient encounter (G0431)	$98.96	2.3	$208	+$15

Source: OIG "Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015"

- On Aug. 18, two former lab professionals convicted of false billing of medically unnecessary drug tests 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 in a case settled by PremierTox 2.0, Inc. for $2.5 million in April.

Molecular pathology tests down 44%: On the flip side, Medicare payments for molecular pathology tests analyzing genetic material to determine how patients will respond to treatment decreased 44% from $466 million to $259 million year-over-year. The report says the decline was concentrated in payments for three different tests but does not specify the tests' names. The decline coincides with efforts to prevent medically unnecessary genetic testing, the report adds.

Medicare Lab Test Pay Increases by State

Number of Top 25 Lab Tests that Will Have Higher Medicare Payment Rates	States
0	Alaska, Arkansas, California, Florida, Minnesota, Montana, Nevada, New Jersey, Pennsylvania, Virginia, Wisconsin
1	Colorado, Delaware, Georgia, Hawaii, Louisiana, Maine, Maryland, Massachusetts, New Mexico, North Carolina, North Dakota, Oklahoma, South Dakota, Texas
2	Arizona, Connecticut, Idaho, Illinois, Iowa, Mississippi, Missouri, Oregon, South Carolina, Tennessee, Utah, Washington
3	Indiana, New Hampshire, Rhode Island, Vermont, West Virginia
4	Alabama, Kansas,
5	Ohio, Kentucky, Nebraska
6	New York
7	Michigan, Wyoming

Source: OIG analysis of Medicare's 2015 Clinical Laboratory Fee Schedule.

Looking Ahead

The report includes insight into the new Medicare payment rates for lab tests. The private payer data that CMS will use to set new payment rates is expected to come from 5% of labs, including 1,398 independent labs and 11,149 physician office labs. These 12,547 labs accounted for 69% of Medicare payments for lab tests in 2015. The report also confirms that 0 of 6,994 hospital labs will report private payer data.

Although payment rates will be generally lower under the new payment system, the report states that rates for 22 of the 25 top tests will go up in some parts of the country, with 38 states seeing at least one of the top 25 tests receive increases ranging from $0.02 to $30.27 per test (see the graphic at left).

Note: New York has three local fee schedules, and California, Kansas, and Missouri each have two local fee schedules. For States with more than one fee schedule, the number shown is an average for the State's fee schedules

Takeaway: The OIG's report on the top 25 lab tests doesn't show a major shift in the top tests and mirrors a national focus on drug testing.

CDC and the Diagnostics Industry Continue to Battle Zika

While summer has ended, the battle against the mosquito-borne virus Zika continues. On Oct. 21, the Centers for Disease Control and Prevention (CDC) announced approximately $70 million will be made available to state and local agencies to fight Zika. The funding comes through the agency's Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement and will be used for surveillance and investigation, mosquito control and laboratory capacity. The CDC has also updated prior travel and testing guidance on Zika transmission to cover all of Miami-Dade County in Florida, as mosquito transmission of the virus continues to be reported in that region. The number of locally acquired cases of the virus is low in the United States at 137 according to the CDC's Oct. 19 update, but there are a total of 4,016 cases in the U.S. with 3,878 related to travel. One reported case was laboratory-acquired.

While locally mosquito-transmitted cases in the United States have only occurred to date in Florida, travel related cases have been reported in all 50 states with the most occurring in California, Florida and New York.

While locally mosquito-transmitted cases in the United States have only occurred to date in Florida, travel related cases have been reported in all 50 states with the most occurring in California, Florida and New York. Just as virus transmission has not abated, efforts to develop better diagnostics continue in earnest. The FDA has issued a total of 12 Emergency Use Authorizations for the following in-vitro diagnostics.

- Zika Virus Detection by RT-PCR Test (ARUP Laboratories)
- Sentosa® SA ZIKV RT-PCR Test (Vela Diagnostics USA, Inc.)
- LightMix® Zika rRT-PCR Test (Roche Molecular Systems, Inc.)
- ZIKV Detect™ IgM Capture ELISA (inBios International, Inc.)
- xMAP® MultiFLEX™ Zika RNA Assay (Luminex Corporation)
- VERSANT® Zika RNA 1.0 Assay (kPCR) Kit (Siemens Healthcare Diagnostics Inc.)
- Viracor-IBT Laboratories, Inc.'s Zika Virus Real-time RT-PCR Test
- Aptima® Zika Virus Assay (Hologic, Inc.)
- RealStar® Zika Virus RT-PCR Kit U.S. (altona Diagnostics)
- Zika Virus RNA Qualitative Real-Time RT-PCR (Focus Diagnostics)
- Zika MAC-ELISA (CDC)
- Trioplex Real-time RT-PCR Assay (CDC)

Takeaway: While locally transmitted cases of Zika virus are limited so far to Florida, travel related cases continue to rise and the diagnostics sector continues to seek ways to improve virus detection.

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