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. 11, June 9, 2016

INSIDE THIS ISSUE

www.G2Intelligence.com

OIG Mid-Year Work Plan Update Adds PAMA-Focused Lab Item

The U.S. Department of Health and Human Services Office of Inspector General released its mid-year update to the Annual Work Plan, adding and revising items relevant to lab enforcement efforts. The OIG released the 2016 Work Plan late last year (see *National Intelligence Report*, 11/12/16, p. 1).

First, not surprisingly, a new item in this update focuses on the much anticipated implementation of the Protecting Access to Medicare Act of 2014 (PAMA). The OIG says it will consider CMS' "ongoing activities and progress toward implementing" the new market-based payment system under PAMA for clinical diagnostic laboratory tests. PAMA also requires the OIG to analyze "the implementation and effect of the new payment system." It predicts a report to be issued this fiscal year. CMS' final rule implementing PAMA was submitted for OMB review and its release is widely expected to be imminent. G2 Intelligence and ACLA are co-presenting a webinar addressing the final rule, on June 28.

Continued on page 2

Genomic Data Commons Promotes Personalized Cancer Care

The Genomic Data Commons (GDC) was recently launched, as a core component of the National Cancer Moonshot and the President's Precision Medicine Initiative to promote data sharing between cancer researchers and accelerate the pace of discovery in personalized oncology care. The data platform's initial release included genetic and clinical information from more than 14,000 cancer patients and tumors. The hope is that the GDC will form the basis of a "comprehensive knowledge system for cancer" to elucidate insights into cancer biology and effective therapy.

"With the GDC, the National Cancer Institute (NCI) has made a major commitment to maintaining long-term storage of cancer genomic data and providing researchers with free access to these data," said NCI acting director Douglas Lowy, M.D., in a statement. "Importantly, the explanatory power of data in the GDC will grow over time as data from more patients are included, and ultimately the GDC will accelerate our efforts in precision medicine."

Continued on page 7

OIG Mid-Year Work Plan Update Adds PAMA-Focused Lab Item, *from page 1*

Revised items in the update include a review of histocompatibility laboratories (which was a new item in the initial 2016 Work Plan)—with the resulting report now expected in 2017 fiscal year rather than 2016 fiscal year as originally reported in the 2016 Work Plan. The OIG is concerned about accuracy of costs reported by histocompatibility labs—which reported $131 million in reimbursable costs on recent cost reports. The OIG explains such costs must be reasonable, necessary and proper and detail provided regarding such costs must sufficiently justify payments made.

Recurring items include review of independent clinical lab billing requirements and the OIG's annual mandatory review of the top 25 lab tests (per Medicare expenditures). The update notes the OIG's concern with independent clinical lab billing, which was also included in the 2015 Work Plan as well. The OIG is looking for labs that "routinely submit improper claims" and will seek repayments of overpayments. The OIG notes that prior "audits, investigations and inspections have identified independent clinical laboratory areas at risk for noncompliance with Medicare billing requirements."

The review of the top 25 test ties in to the OIG's oversight of PAMA. The OIG first performed this review last year and in September 2015 issued its baseline analysis of the top 25 lab tests according to review of 2014 data. That report indicated that $7 billion was paid to 63,000 labs under Medicare Part B in 2014 for 451 million lab tests performed for 27 million Medicare beneficiaries. Medicare paid $4.2 billion in payments for the top 25 lab tests.

The OIG update also notes it may have new and expanded reviews of U.S. Food and Drug Administration oversight, including the agency's oversight of blood establishments and laboratory-developed diagnostic tests. It also added new items focused on FDA review of networked medical devices for cybersecurity risks and controls over networked medical devices in hospitals.

The OIG's *Fiscal Year 2016 Work Plan Mid-Year Update* is available on the OIG Website under Reports and Publications.

Takeaway: Labs continue to be a significant focus with several lab payment items highlighted in the latest update to the OIG's Work Plan.

Lab Sector Continues to Actively Fight Potential Medicare Co-Payment Collections

While laboratory developed tests and PAMA's impact on Medicare reimbursement are front of mind for most laboratories, there remains a lingering concern within the industry that the government hasn't given up on the idea that laboratories should be on the hook to collect co-payments and deductibles from patients enrolled in Medicare.

The most recent trigger for that concern is a report released in April by the U.S. Department of Health and Human Services' Office of the Inspector General, known as the Compendium of Unimplemented Regulations. Within the report is a list of the 25 top unimplemented regulations. Buried on page 50 of the 74-page report is a yet-to-be implemented recommendation for Medicare Parts A and B: "(The Centers for Medicare & Medicaid Services) should ... reinstate beneficiary deductibles and coinsurance (and notifications of amounts paid on their behalf) as a means of

controlling utilization." (See "OIG Highlights Top 25 Unimplemented Recommendations," *Lab & Pathology Insider*, March 23, 2015). Such a measure could reduce costs to the Medicare program by as much as $2.4 billion a year. Co-payments for lab tests were eliminated when the Clinical Laboratory Fee Schedule was implemented in the mid-1980s.

"Collecting coinsurance is uniquely difficult for labs because, unlike all other health care providers, labs typically do not have face-to-face encounters with patients."

— Alan Mertz, President, ACLA

However, given the often tiny co-payments associated with common laboratory tests that are performed on the Medicare population—essentially nuisance charges many enrollees would ignore—the sector sees it as a sort of slow death by millions of tiny cuts.

"The way it would usually be proposed, CMS would just cut the reimbursement by 20%, and we would be expected to collect it from the beneficiary," said Alan Mertz, president of the American Clinical Laboratory Association, which pushed back against the long unimplemented proposal with a letter to the HHS Inspector General Daniel Levinson expressing its concern that this would be a misstep. It has careened through the HHS corridors since about 1990 and Congress killed co-pay legislation about a dozen years ago.

"Collecting coinsurance is uniquely difficult for labs because, unlike all other health care providers, labs typically do not have face-to-face encounters with patients. Most of the time, a Medicare beneficiary's specimen is obtained somewhere else, such as a physician's office, and sent to the lab, which then performs the prescribed testing," Mertz wrote. "As such, labs must rely on billing and collections to obtain the cost-sharing amount from beneficiaries. If those good faith efforts do not succeed, laboratories must absorb those losses along with the added costs of collecting the cost-sharing."

And Mertz noted that nearly a third of such co-payments would be completely uncollectible. About 18 percent of Medicare enrollees have incomes so low they are also eligible for Medicaid, and another 14 percent do not have Medigap or other supplementary insurance, suggesting again a financial obstacle toward making collections. Moreover, the amounts to be collected by labs would in many instances be minute: Mertz compared it to "that annoying phone bill for 72 cents." Specifically, he mentioned the highly routine PT test for blood clotting times. According to Mertz, it is run about 24 million times a year for Medicare enrollees. Total reimbursement for that test is $5.36. A 20 percent co-payment would be $1.07. The cost of collecting such small sums would often be more than the payment itself, Mertz said.

And finally, Mertz noted, imposing co-payments would not actually control utilization, primarily because the decisions to run lab tests are made by clinicians, with relatively little input coming from patients. The ACLA also raised objections to another unimplemented regulation on the list: A periodic evaluation of the national fee schedule to ensure reimbursement is aligned with prices. "It's a fairly outdated proposal," Mertz said, adding that it really didn't take the pending implementation of the Protecting Access to Medicare Act of 2014 (PAMA) into consideration. "They just threw everything in there that's ever been suggested." In the meantime, it remains clear that the ACLA will be providing significant input anytime such proposals resurface.

Takeaway: The ACLA is zealously guarding the turf of the laboratory sector regarding even the discussion of implementing co-payments and deductibles for Medicare patients for services.

focus on: *Enforcement*

OIG and CMS Tout Recent Enforcement Successes and the Pivotal Role of Data Analytics

In recent reports, both the U.S. Department of Health and Human Services' Office of Inspector General (OIG) and the Centers for Medicare and Medicaid Services (CMS) plugged their successes at routing out fraud and abuse involving federal reimbursement programs and preventing improper Medicare payments. A common theme emerging from the OIG and CMS updates is that data analytics have been critical to these successes.

OIG Semiannual Report

The OIG touted its efforts and achievements for the six-month period ending March 31, 2016—that is, the first half of the fiscal year 2016—in its most recent Semiannual Report to Congress released May 31, 2016. The OIG is required by law to semiannually report to Congress about significant findings and recommendations.

This latest report cites the following enforcement results:

- $2.77 billion in recoveries ($554.7 audit receivables, $336.6 non-HHS investigative receivables such as Medicaid restitution)
- 428 criminal actions against individuals and entities
- 338 civil actions such as False Claims cases and Civil Monetary Penalties settlements and self-disclosure program recoveries
- 1,662 exclusions from federal health care programs
- Strike Force efforts yielding 87 individuals and entities charged, 100 criminal actions and $116.8 million in investigative receivables

"CMP recoveries have increased almost five fold over the past 3 years, and the OIG is on track to exceed prior recoveries in FY 2016."

— OIG Semiannual Report

This year's report also spotlighted OIG guidance for the industry released in the first half of the fiscal year. Guidance relevant to the laboratory sector included an OIG policy reminder about information blocking—which is critical to achieving interoperability and facilitates coordination of health care services.

The OIG asserted in this latest report that "CMP recoveries have increased almost five fold over the past 3 years, and the OIG is on track to exceed prior recoveries in FY 2016." Last year's semiannual report predicted the OIG would recover more than $1.8 billion from investigations and enforcement actions for the first half of fiscal year 2015 and reported 422 criminal actions and 320 civil actions involving health care compliance issues. Yet, the agency did see declines from some of last year's achievements. Exclusions for the first half of 2015 were 1,735 and Strike Force was credited with yielding $163 million, and 124 criminal actions. See "OIG Enforcement for First Half of Fiscal 2015 Expected to Yield $1.8 Billion in Recoveries," *National Intelligence Report*, 6/11/15, p. 5.

Enforcement cases highlighted within the report included sentencing of another individual in the Biodiagnostic Laboratory Services case. So far, 20 individuals have been sentenced according to the OIG for an aggregate of 41 years of prison.

OIG Podcast Explains Value of Data Analytics to Enforcement Efforts

The Office of Inspector General's (OIG's) latest podcast posted June 7, 2016, features an interview with Caryl Brzymialkiewicz, the Chief Data Officer for the OIG, who explains the value of data analytics to the agency's investigative and enforcement efforts.

Bryzmialkiewicz explained that the Chief Data Office, which was initiated a year ago, is charged with "providing more and better access to data and analytics to support OIG's mission" and has three functions:

- Advanced analytics—the data scientists who analyze the data. This team has existed for several years.
- Data operations—"behind the scenes data governance, data quality".
- Strategic planning and organizational performance management—which directs strategic plans for the operation.

She added that her office is focused on "how do we help the OIG become even more effective and efficient in what it's doing—which includes improving our access to data"— by determining what datasets are needed and how to ensure high quality data. One strategy employed to utilize data to fuel investigations and enforcement is actionable advanced analytics which Brzymialkiewicz describes as "high quality lead-generation" for OIG investigators, auditors and evaluators. "One of two things can happen with our advanced analytics. Either the data can lead us to somebody that is potentially committing fraudulent activity or our investigators can have a hotline call where they can have a witness or a whistleblower come tell them that they suspect criminal activities happening, and we can bounce that against the data. So it's a really a combination of the data analytics and the data scientists and our statisticians and computer programmers with that field intelligence of our law enforcement agents working in the field—that combination is very powerful," she explained.

The work of the Chief Data Office also allows the OIG to use parameters set using statistical methods to identify high risk providers who will receive closer scrutiny. The office is considering new ways to "democratize data" and make the information gleaned from analytics more useful throughout the OIG. For example, Brzymialkiewicz discussed the ability to plot data geographically to reveal compliance hotspots in the country where fraudulent activity may be happening or an audit or evaluation may be warranted. Another tool the office uses is the peer comparison generator that helps spot providers who are outliers and identify trends. Link analysis is a strategy the agency uses to draw connections among providers. "What I'm really thinking about as well, now that we're going from fee-for-service to value-based care, inherently there are connections between organizations. A lot of them are very good. So when we're trying to find the people that are potentially committing fraud, waste and abuse, how do we need to think about our data in different way—or how do we need to bring a different approach to that problem to see and understand where we might need to look, even further," she explains.

The information revealed through analytics helps the agency internally as well to inform decision makers when setting priorities and allocating resources and staffing. "[T]hen if we need additional resources, we're standing on some very solid ground in terms of our logic of what we need when we go back and ask people for additional money," added Brzymialkiewicz.

The case has also yielded $487,250 in fines and $510,695 in forfeiture and 15 exclusions for an aggregate of 111 years. The OIG also highlighted the Millennium Health $256 million False Claims Act settlement resolving allegations of medically unnecessary drug testing and genetic testing, and kickbacks to referring physicians.

In Inspector General Daniel R. Levinson's introductory message to the report, he notes the "OIG leverages technology and forensic audit techniques to identify and address emerging fraud trends and to support efforts to deter misconduct through administrative actions. OIG investigations, including work on Strike Force cases, target emerging patterns of fraud and help to hold wrongdoers accountable." Utilizing data for enforcement purposes was similarly the focus of the CMS report on its enforcement successes.

Medicare Fraud Prevention System

Just as the OIG emphasized the benefit of using data and technology as enforcement tools, CMS claimed using Big Data in its enforcement and oversight efforts has yielded big savings for Medicare. CMS asserted its Fraud Prevention System (FPS) has identified $1.5 billion in inappropriate payments "through new leads or contributions to existing investigations."

In a recent issue of *The CMS Blog*, the agency explained the FPS uses big data and predictive analytics to proactively ferret out fraud and abuse and prevent improper payments from happening: "Taking 'big data' mainstream has given CMS the ability to better connect with public and private predictive analytics experts and data scientists, as well as collaborate more closely with law enforcement. The Fraud Prevention System's 'big data' effort has had a profound impact on fraudulent providers and illegitimate payments by allowing us to quickly identify issues and take action."

CMS claims that FPS streams 4.5 million prepaid claims daily and yielded a $11.60 return on investment in 2015 for each dollar spent on the system, recovering $1 billion in savings between 2013-2015. CMS also promises contin-

ued focus on use of analytics to fight fraud: "The CMS is now working to develop next-generation predictive analytics with a new system design that even further improves the usability and efficiency of the FPS."

Takeaway: Federal government enforcement efforts are unrelenting, with data and technology serving as tools to ferret out fraud and other improper Medicare claims.

precisionFDA Challenges Support Innovation

The U.S. Food and Drug Administration (FDA) has put its innovative platform, precisionFDA, to work promoting next-generation sequencing (NGS) with two projects inviting industry participants to process datasets with their own sequencing pipelines and comparing results on precisionFDA. The FDA described precisionFDA upon its launch last year as a "crowd-sourced, cloud-based platform to advance the science needed to develop the necessary standards" for evaluating NGS tests. According to the FDA's latest update concerning the platform, the cloud-based "community" encompasses "more than 1,500 users from 600 organizations, with more than 10 terabytes of genetic data stored."

The first of two challenge projects, the Consistency Challenge, required participants to use an informatics pipeline to identify genetic variants in whole genome sequences from a known human sample. Results were to be checked for consistency against results in FDA-provided datasets. This first challenge was completed in April and winners announced at the end of May. Winners included teams from Sentieon and Sanofi-Genzyme and the 21 entries included participants from organizations such as Roche, Pathway Genomics, Avera, and the Broad Institute. The challenge has yielded a dataset that the FDA indicates is available for others to study via archived files accessible on precisionFDA.

The Truth Challenge, closed at the end of May, required participants to "identify genetic variants in one known and one unknown sample dataset." "The goal is to see how close they come to the truth when analyzing data from a human sample with variant results unknown to them, which we will reveal at the end of the challenge," said the FDA. The Genome in a Bottle consortium and the Global Alliance for Genomics and Health worked with the FDA to design this challenge and Genome in a Bottle will provide a "truth dataset"—releasing "for the first time new high confidence variant calls for the unknown sample dataset."

A recent *FDA Voice* blog explained the purpose of these challenges is to encourage collaboration and further the Precision Medicine Initiative: "These competitions are motivating community members to demonstrate the effectiveness of their tools, test the capabilities of the precisionFDA platform, and engage the community in discussions and data analysis that will provide new insights and serve as a comprehensive source of information about reference data and software pipelines used to analyze sequencing results."

Takeaway: The FDA continues to encourage sharing of data and collaboration among industry stakeholders to maximize the potential of genetic testing and next-generation sequencing.

Genomic Data Commons Promotes Personalized Cancer Care, *Continued from bottom of p.1*

GDC centralizes, standardizes, and harmonizes genomic and clinical data on a unified and interoperable platform. Data from large-scale NCI programs such as The Cancer Genome Atlas and the pediatric study Therapeutically Applicable Research to Generate Effective Treatments—some of the largest cancer genomics datasets in the world—will be publicly available to researchers as a result of this effort. GDC launched with 4.1 petabytes of data from NCI-supported research programs. (One petabyte is equivalent to 223,000 DVDs completely filled with data). GDC will also accept cancer-related genomic and clinical data submissions (including imaging and histological data, as well as treatment response information) from researchers internationally.

"Today, making discoveries from cancer genomic data is challenging because diverse research groups analyze different cancer datasets using various methods that are not easily comparable."

— Robert Grossman, Ph.D.

By sharing, researchers will be able to use the "state-of-the-art" analytic methods housed in GDC, hopefully making GDC an important resource for generating potentially actionable information. All data will be harmonized using standardized software algorithms and the raw, stored genomic data will be reanalyzed as computational methods and genome annotations improve.

"Today, making discoveries from cancer genomic data is challenging because diverse research groups analyze different cancer datasets using various methods that are not easily comparable," said GDC principal investigator Robert Grossman, Ph.D., from the University of Chicago, in a statement. "GDC brings together genomic datasets and analyzes the data using a common set of methods so that researchers may more easily make discoveries, and, in this sense, democratizes the analysis of large cancer genomic datasets."

GDC is being built and managed by the University of Chicago Center for Data Intensive Science in collaboration with the Ontario Institute for Cancer Research, as part of a subcontract with NCI-funded Leidos Biomedical Research (Frederick, Md.).

Takeaway: Government initiatives promote sharing of genomic data to personalize the fight against cancer.

FDA Approval of First Liquid Biopsy Companion Diagnostic Furthers Rise of Non-Invasive Testing

The rise of liquid biopsies predicted by G2 Intelligence's *Diagnostic Testing & Emerging Technologies (DTET)* is being borne out by a recent U.S. Food and Drug Administration (FDA) approval. The FDA and Roche both recently announced the FDA approval of the cobas® EGFR Mutation Test v2 "for use with plasma samples, as a companion diagnostic for the non-small cell lung cancer (NSCLC) therapy, Tarceva®." The FDA noted this is "the first FDA-approved, blood-based genetic test" to detect that mutation in such patients.

Lung cancer is the leading cause of cancer-related death for men and the rate of women with lung cancer is rising, said the FDA. NSCLC in particular is the most common form of lung cancer. According to the American Cancer Society, approximately 80-85 percent of lung cancers are NSCLC. Additionally, 10-20 percent of

"Liquid biopsies also have the potential to allow physicians to identify patients whose tumors have specific mutations in the least invasive way possible."

— Alberto Gutierrez, Ph.D.

NSCLC patients have the epidermal growth factor receptor (EGFR) gene mutation that the newly approved cobas test identifies. "The FDA approval of the cobas® EGFR Mutation Test v2 for liquid biopsy for diagnostic use sets a standard in testing for NSCLC patients," said Uwe Oberlaender, head of Roche Molecular Diagnostics, in the company's announcement of the approval.

"Approvals of liquid biopsy tests make it possible to deliver highly individualized health care for patients," said Alberto Gutierrez, Ph.D., director of the Office of In Vitro Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health, in a statement. "Liquid biopsies also have the potential to allow physicians to identify patients whose tumors have specific mutations in the least invasive way possible." Such testing offers a new diagnostic option to patients for whom surgery would be too invasive, who can't travel to surgical locations, or whose tumor would be difficult to surgically biopsy.

Tarceva, the drug for which the newly approved test serves as a companion diagnostic is manufactured by Astellas Pharma Technologies and distributed by Genentech, and was approved by the FDA in 2004 for patients with NSCLC after other chemotherapy failed and in 2013 as a first-line treatment for metastatic NSCLC with EGFR exon 19 deletions or L858R substitution mutations.

DTET reported last year that liquid biopsy technology "holds enormous potential to transform the medical management of oncology patients by providing noninvasive, real-time insights of disease status. Also known as a 'molecular stethoscope,' liquid biopsies are integral to personalizing cancer care." It also predicted that the liquid biopsy field has the potential to quickly become a multi-billion dollar market, with some analysts predicting that it could reach $10 billion and that it could be a part of routine care within five years. See "Special Focus: Liquid Biopsies for Oncology to Gain Clinical Momentum in 2015," *Diagnostic Testing & Emerging Technologies*, February 2015, p. 8.

And this year, *DTET* highlighted liquid biopsy as a trend to watch for 2016, explaining that 2015 was a "breakthrough year in demonstrating the clinical utility of these tests" and that 2016 promised movement towards expanding non-invasive prenatal testing to average-risk markets, clinical adoption of liquid biopsy for multiple applications in oncology monitoring, and further emergence of the technology in post-organ transplantation surveillance. See "Testing Trends to Watch for in 2016," *Diagnostic Testing & Emerging Technologies*, February 2016, p. 1.

Takeaway: FDA approval of liquid biopsy companion diagnostic for lung cancer bears out predictions for increased prevalence of the less invasive testing option.

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.

Kelly A. Briganti, JD, Editorial Director, Kelly@plainlanguagemedia.com; Barbara Manning Grimm, Managing Editor; Lori Solomon and Ron Shinkman, Contributing Writers; Stephanie Murg, Managing Director; Kim Punter, Director of Conferences & Events; Randy Cochran, Corporate Licensing Manager; Michael Sherman, Director of Marketing; Jim Pearmain, General Manager; Pete Stowe, Managing Partner; Mark T. Ziebarth, Publisher.
Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 1-888-729-2315.