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OIG Releases 2016 Work Plan, Again Targeting Laboratory Billing

Last week the OIG released its 2016 Work Plan that continues to name laboratories as a source of concern with regard to Medicare billing and payment. The OIG's annual Work Plan provides a summary of new and continuing reviews that the agency is undertaking to protect the integrity of, and find opportunities to improve the efficiency of, U.S. Health and Human Services programs.

This year's Work Plan contains a holdover from last year's Work Plan: "Selected independent clinical laboratory billing requirements." The agency is concerned about Medicare payments to independent clinical laboratories—specifically, it's looking for labs that "routinely submit improper claims." The OIG claims that audits and investigations indicate independent clinical laboratories are at risk for noncompliant Medicare billing.

Once again, the OIG also promises to review Medicare payments for clinical diagnostic laboratory tests, including the top 25 clinical diagnostic laboratory tests by Medicare expenditures. This item was added in the OIG's mid-year update to the 2015 Work Plan and is required by the Protecting Access to Medicare Act. The OIG says it has found in the past that Medicare "pays

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CMS Estimates 2016 PFS to Have Positive Impact on Pathology, Independent Labs

While laboratories await a final rule for the 2016 Clinical Laboratory Fee Schedule implementing the Protecting Access to Medicare Act, the Centers for Medicare & Medicaid Services (CMS) recently released the 2016 Physician Fee Schedule final rule, the first physician fee schedule issued since the Sustainable Growth Rate repeal. CMS predicts that the changes in the physician fee schedule will have a positive impact for pathology services and independent laboratories, 8% and 9% respectively. CMS predicts that for pathology, work relative value units (RVU) changes and Practice Expense RVU changes will each have a 4% positive impact. For independent laboratories, CMS predicts a 1% impact due to Work RVU changes and a 7% positive impact due to Practice Expense RVU changes. CMS indicates the 1% and 7% don't precisely equal the 9% predicted due to rounding.

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more than other insurers for certain high-volume and high-expenditure laboratory tests." In September, the OIG 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. Over half of Medicare beneficiaries receive at least one lab test in 2014; the average was 17 tests per beneficiary. One percent of beneficiaries received 95 or more tests. Lab tests generated approximately 3 percent of total Medicare Part B payments and the majority of Medicare payments for the top 25 laboratory tests went to independent labs.

A new item focuses on ACO participation in the Medicare Shared Savings Program. The OIG will review participation with regard to savings achieved and performance measures for the first three years.

The newest laboratory-related item in the OIG Work Plan indicates the OIG is focusing on the propriety of payments to histocompatibility laboratories, which reported $131 million in reimbursable costs on recent cost reports (covering March 31, 2013 through Sept. 30, 2014).

For all three projects specifically mentioning laboratories, the Work Plan predicts review reports will be issued in fiscal year 2016.

Other projects included in the OIG Work Plan that could impact laboratories directly or indirectly include:

- Enhanced enrollment screening process—the OIG is concerned about the implementation of enhanced enrollment screening procedures which are intended to use site visits, fingerprinting and background checks to prevent fraud and abuse.
- EHRs in ACOs—the OIG will be checking to see if Accountable Care Organization (ACO) participants are using electronic health records (EHRs) to share health information and increase coordination, and identify best practices and barriers concerning interoperability.
- ACO performance—A new item focuses on ACO participation in the Medicare Shared Savings Program. The OIG will review participation with regard to savings achieved and performance measures for the first three years. Examples of ACOs that performed well will be reported as well as difficulties encountered in ACOs. A report is anticipated in 2017.
- ICD-10—A new item also indicates the OIG will examine how well the new ICD-10 codes were implemented, including guidance offered to providers and impact on claims processing. Note that CMS recently added a Frequently Asked Question to its website that indicated CMS won't require that an ordering provider "rewrite the original order with the appropriate ICD-10 code for lab, radiology services or any other services" –so for orders written prior to October 1, 2015, an ICD-9 code might have been used on the order and it will not have to be rewritten. If the order is for a repetitive service that will be continued after October 1, 2015, providers can "use the General Equivalence Mappings (GEMS) posted on the 2016 ICD-10-CM and GEMS web page to translate the ICD-9-CM codes on the original order into ICD-10-CM diagnosis codes."

Takeaway: Laboratories continue to remain a concern for the OIG with regard to appropriateness of Medicare billings, particularly for independent clinical laboratories. G2

EEOC Proposes GINA Amendment for Wellness Programs

With the rise in popularity of precision medicine, the use of information gathered from genetic testing gives rise to legal issues—such as the potential risk for discrimination based on genetic testing results. With the ability for genetic testing to identify health risks before they cause harm, such a diagnostic tool can be useful for wellness programs. The U.S. Equal Employment Opportunity Commission (EEOC) is accepting comments on a proposed rule amending how wellness plans comply with the Genetic Information Nondiscrimination Act of 2008 (GINA). The amendment allows wellness plan managers to offer "limited incentives" to gather genetic and medical history information from the spouses of covered employees. This represents an expansion of the exceptions to GINA.

Under the proposed rule, the EEOC will permit employers to offer "limited" incentives (in the form of rewards or penalties) to an employee whose covered spouse, voluntarily receives health or genetic services provided by the employer's wellness program.

GINA is a federal law that protects individuals from discrimination in health insurance and employment because of misuse of genetic data. It explicitly prohibits employers from requesting, requiring, or purchasing genetic information, barring exceptions. One of these exceptions has been if an employee voluntarily accepts health or genetic services offered by an employer, including when these services are offered as part of a wellness program.

Employee wellness programs are an increasingly popular way for employers to incentivize employees to lead healthier lives, with the ultimate aim to reduce the costs of group health coverage. The latest proposed amendment, the EEOC says, defines the extent to which an employer may offer incentives for an employee's spouse to provide information about "his or her current or past health status" as part of an employer-sponsored wellness program.

Under the proposed rule, the EEOC will permit employers to offer "limited" incentives (in the form of rewards or penalties) to an employee whose covered spouse, voluntarily receives health or genetic services provided by the employer's wellness program. The EEOC rule says incentives can include in-kind options, such as paid time off from work, gift cards, and prizes, or financial incentives, such as premium reductions, but incentives are limited to 30 percent of the total cost of self-only coverage.

The EEOC rule still restricts collecting medical and genetic information about the employer's children, which the EEOC says, increases the chances of discrimination. The EEOC will accept comments on the proposed amendments until Dec. 29.

Takeaway: EEOC supports genetic testing as a wellness resource but continues to emphasize need for protection from discrimination based on genetic information.

focus on: *DTC Genetic Testing*

FDA Paves a Path for Some DTC Genetic Tests; Challenges Others

At the same time that 23andMe (Mountain View, Calif.) received U.S. Food and Drug Administration (FDA) approval to launch a revamped direct-to-consumer (DTC) genetic test that includes reports on 60 carrier status, wellness, trait, and ancestry findings, the agency kept up its scrutiny of DTC genetic testing, issuing letters to three manufacturers of DTC genetic tests questioning their marketing of specific tests.

That same day, the FDA also issued a Notice in the *Federal Register* requesting comment regarding its intent to exempt from the premarket notification requirements autosomal recessive carrier screening gene mutation detection systems, subject to certain limitations.

23andMe's late October launch of its overhauled test comes nearly 2 years after the FDA ordered the company to stop providing its health risk assessment test. The revamped test costs $199 for 35 carrier status reports for autosomal recessive conditions including cystic fibrosis, sickle cell anemia, and hereditary hearing loss; four wellness reports including assessments related to caffeine consumption, lactose intolerance, alcohol flush reaction, and muscle composition; and more than 19 trait reports on hair, facial features, and taste and smell preferences. Notably, the new product lacks disease risk testing and pharmacogenomic evaluation.

In the Oct. 27 *Federal Register*, the FDA issued a final order confirming its earlier statements in February about autosomal recessive carriers screening tests and explaining how labs can legally commercialize carrier screening tests that are 510(k) exempt. The agency classifies an autosomal recessive carrier screening gene mutation detection system as a class II medical device with special controls. The device is assigned the generic name "autosomal recessive carrier screening gene mutation detection system," and the FDA defines this over-the-counter test as "qualitative in vitro molecular diagnostic system used for genotyping of clinically relevant variants in genomic DNA" and says they are not intended for copy number variation, or cytogenetic or biochemical testing.

That final order set forth the FDA special controls which require, among other things, the device manufacturer provide information about how to obtain access to a board-certified clinical molecular geneticist or equivalent to assist in pre-and post-test counseling; specific labeling about the gene and associated variants tested along with evidence of "scientifically established clinical validity;" and the manufacturer must conduct a study that assesses user comprehension of the device's labeling and test process, with a minimum of a 90 percent or greater overall comprehension rate. Additionally, the manufacturer must provide warnings recommending consultation with a health care provider, particularly for positive results.

The FDA also issued a Notice in the *Federal Register* requesting comment regarding its intent to exempt from the premarket notification requirements autosomal recessive carrier screening gene mutation detection systems, subject to certain limitations.

The FDA explained that the special controls described above mitigated the risks of false positives and false negatives of the testing. The special controls requiring scientifically established clinical validity and public posting of that information lowered the risk of false and misleading claims "for autosomal recessive inheritance." The FDA also explained that the diseases tested for are very rare and only reveal the carrier status of the

person tested. Further, information about both parents is needed to determine risk for future children. Thus risks due to false positives are limited, the FDA explains—i.e., not just one parent but both must receive false positive test results to affect the course of action taken and even in the unlikely event that both parents receive false positive results, a potential child still only has a 25 percent chance of having the tested disease. Additionally, the controls requiring the tested individuals comprehend the limitations of the testing, and be advised how to access counseling from board-certified clinical molecular geneticists or equivalent professionals about the testing, also reduce the risks of false positives. Risks created by false negatives were mitigated by the special controls imposing labeling requirements and performance specifications and because of inherent limitations in the testing—i.e., not every potential mutation is known and tested for and thus "there will be a proportion of carriers who will not be detected." Finally, the likelihood of inaccurate testing is reduced by Clinical Laboratory Improvement Amendment requirements, requirements regarding collection devices used and other controls regarding analytical performance. Thus, the FDA concluded that the special controls "reasonably assure that a legally marketed device of this type will have the characteristics necessary for its safe and effective performance without the need for premarket notification."

In addition to its recent history of issuing warning letters to direct-to-consumer genetic testing companies, the FDA has indicated its intent to expand its oversight and regulate high-risk, laboratory-developed tests, which would likely include pharmacogenetic testing.

FDA Issues Letters to DTC Genetic Test Makers

While providing the exemption discussed above, the FDA continues to question DTC test makers about their products. DTC DNA4Life (Mandeville, La.) received a letter from the FDA questioning the company's marketing of an unapproved genetic test. The test, which predicts response to 120 commonly prescribed medications based on analysis of 12 genes tied to drug metabolism, is being marketed as an unapproved medical device, the FDA says. The agency said it is unable to identify any FDA clearance for the company's test and requested either a clearance number or the reasons DNA4Life believes that FDA clearance is not required for its test.

The company believes it is filling a need for affordable pharmacogenomics information, given the high rates of adverse drug reactions. Richard Zimmer, DNA4Life's CEO, told Reuters that he and his advisors don't believe the test needs to be approved by the FDA, as it is a laboratory-developed test. In addition to its recent history of issuing warning letters to direct-to-consumer genetic testing companies, the FDA has indicated its intent to expand its oversight and regulate high-risk, laboratory-developed tests, which would likely include pharmacogenetic testing.

In addition to the DNA4Life letter, the FDA also issued a letter to DNA-Cardiocheck, Inc. noting that its direct-to-consumer test, DNA-CardioCheck, which tests for DNA genetic markers relating to cardiovascular disease, deep-vein thrombosis and stroke is a device for which no FDA clearance has been sought. It also sent a letter to Interleukin Genetics Inc. regarding three separate genetic tests which detect predisposition for increased risk to heart attack and diabetes and other obesity related conditions. Those letters made the same claim that these tests appear to be devices subject to FDA regulation and there's no record of FDA clearance being granted. The FDA advised both companies to either provide a clearance number or advise why the company believes no clearance number is required.

Takeaway: While genetic testing is gaining ground in passing FDA scrutiny, the FDA is unrelenting in its oversight of direct-to-consumer genetic testing. G2

Latest Major False Claims Act Settlement Involves 457 Hospitals in 43 States

The Department of Justice (DOJ) recently announced another major settlement of False Claims Act allegations, involving hundreds of providers. This time, it's 70 settlements with 457 hospitals across 43 states, yielding over $250 million. The allegations related to implanted cardiac devices that the government claimed violated Medicare billing rules.

"In terms of the number of defendants, this is one of the largest whistleblower lawsuits in the United States and represents one of this office's most significant recoveries to date."

— Wifredo A. Ferrer, U.S. Attorney, Southern District of Florida.

The government alleged that between 2003 and 2010, implantable cardioverter defibrillators were implanted in Medicare beneficiaries during 40- and 90- day waiting periods following heart attacks and bypass/angioplasty, respectively. A National Coverage Determination generally bars implantation of ICDs during those waiting periods. The DOJ statement announcing the settlement cited an "extensive investigation" involving thousands of patient records and a panel of leading cardiologists. The settlement arises out of qui tam cases brought against most of the hospitals, filed in Florida federal court. The DOJ reports that still more hospitals and health systems remain under investigation. "In terms of the number of defendants, this is one of the largest whistleblower lawsuits in the United States and represents one of this office's most significant recoveries to date," said U.S. Attorney Wifredo A. Ferrer of the Southern District of Florida.

The settlements were achieved through collaboration of the Florida U.S. Attorney's Office and the Department of Health and Human Services' Office of Inspector General and is credited by the DOJ as "another achievement for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative."

This settlement announcement doesn't implicate laboratories but it's another example of coordinated federal, state and local enforcement efforts that involve hundreds of entities and significant recoveries. An upcoming G2 Intelligence webinar will address how laboratories can avoid being a target of one of these large scale investigations and what to do if they do get caught up in one of these investigation. Attend *Don't Let the Government "Take Down" Your Lab: Understanding and Responding to the Current Enforcement Environment*, with Robert E. Mazer, Esq. and Gina L. Simms, Esq. of Ober Kaler, on Wednesday, December 9, 2015 (NEW DATE!), at 2-3:30 p.m. Eastern. For more information or to register, visit http://www.g2intelligence.com/take-down-webinar/ or call G2 Intelligence customer service at 888-720-2315.

Takeaway: Coordinated federal and state, large-scale enforcement efforts and the whistleblower claims that fuel such enforcement regarding Medicare compliance continue to yield big recoveries. G2

Lab Owners Indicted in Connection with Alleged Unnecessary Drug Testing

Five former owners of a Kentucky clinical laboratory were indicted by a federal grand jury earlier this month on 100 counts—one count of conspiracy and 99 counts of health care fraud—in connection with allegations they billed for medically unnecessary urine drug tests. The allegations relate to claims filed with Medicare, Medicaid and private payors and the indictments follow a joint investigation between the OIG and the Kentucky Attorney General's Medicaid Fraud and Abuse Control Unit. The government alleges the defendants collected urine samples but didn't perform testing until months later when the results were no longer relevant for treatment. The indictment merely sets forth allegations and the government must prove these allegations beyond a reasonable doubt.

CMS Estimates 2016 PFS to Have Positive Impact, *Continued from bottom of p.1*

In evaluating the practice expense and work RVUs for pathology services, as we mentioned in our coverage of the proposed rule (see *National Intelligence Report*, July 23, 2015, p. 1), CMS discussed the potential effect of block numbers and batch size on those expenses. CMS proposed standard times for certain clinical labor activities related to pathology services and stated it believed certain activities require the same time commitment regardless of the service they are performed in connection with and regardless of the number of blocks or the batch sizes involved. CMS held fast to that position in the final rule noting that in reviewing recommendations it didn't find information that convinced the agency that some tasks "take significantly more or less time depending on the individual service for which they are performed." CMS further explained: "We developed the proposed standard times based on our review and assessment of the current times included for these clinical labor tasks in the direct PE input database. We believe that clinical labor tasks with the same work description are comparable across different pathology procedures." The agency therefore finalized standard times for several clinical labor tasks it believed did not depend on number of blocks or batch size. It continues to seek public comment, however, on other clinical labor tasks that might be affected by block number or batch size. The block and batch size issue was also discussed in connection with prostate biopsy reimbursement under G0416 with CMS accepting the RUC's recommendations for practice expenses but soliciting evidence regarding "typical batch and block size used in furnishing this service" because it received comments that the typical batch and block size can be "significantly lower" than accounted for in the RUC recommendations.

On a related note, several commenters stated CMS's estimated per-minute labor cost inputs are too low for laboratory technicians (L033A), cytotechnologists (L045A) and histotechnologists (L037B). "The commenters stated that the complexity of many laboratory services demands highly-skilled, highly-trained, certified, and experienced personnel who typically must be paid higher wages than the current rates provided by CMS." CMS responded, however, that the clinical labor costs per minute are based on data from the Bureau of Labor Statistics and the agency believes "that it is important to update that information uniformly among clinical labor types and will consider updating the clinical labor costs per minute in the direct PE database in future rulemaking."

2016 OPPS Final Rule Indicates Payment Update Affected by Laboratory Test Payment

The Centers for Medicare & Medicaid Services' 2016 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System final rule, released at the end of October, provides updates to Medicare policy and payment rates for hospital outpatient departments and ASCs. While the final rule is getting a lot of coverage for its update to the Two Midnight Rule it's also noteworthy that CMS imposed an additional 2.0 percentage point adjustment to the conversion factor "to redress inflation in the OPPS payment rates resulting from excess packaged payment for laboratory tests that continue to be paid separately outside of the OPPS." CMS found that despite packaging laboratory services previously paid outside the OPPS according to the Clinical Laboratory Fee Schedule, $1 billion in lab tests were paid separately outside the OPPS in 2014. So the 2.0 per cent adjustment is designed "to account for the approximately $1 billion inflation in OPPS Payments."

CMS also indicated in its fact sheet concerning the final rule that "CMS is creating a new conditional packaging status indicator for laboratory tests that will make it easier for hospitals to receive separate payment for laboratory tests that are provided without other OPPS services." The new status indicator is Q4. CMS also reports that the L1 modifier is still in use for "unrelated" lab tests. The rule also finalized a proposal to conditionally package ancillary services including certain pathology services.

CMS also finalized changes to the Self-Referral law we discussed in our coverage of the proposed rule, implementing knowledge CMS has gained through the self-disclosure protocol. Those changes address physician recruitment, requirements for written agreements, the definition of remuneration, and time share arrangements.

While CMS did increase work values for add-on codes for immunohistochemistry and in situ hybridization services, College of American Pathologists noted in its Oct. 30 *STATLINE* that a 24% discount from the base code for the add-on services was also included and asserted that "these reductions should not be taken for the add-on services," criticizing "arbitrary calculations" and "urg[ing] the agency to accept the RUC recommendations that relied on survey data."

Takeaway: CMS asserts that the physician fee schedule provides good news for pathologists and independent labs but criticisms regarding decisions on factors affecting reimbursement still remain. G2

Final Rule Addresses MSSP Self-Referral and AKS Waivers

The Office of Inspector General and the Centers for Medicare & Medicaid Services recently issued a final rule finalizing five waivers introduced in 2011 which help Accountable Care Organizations (ACOs) take advantage of the Medicare Shared Savings Program while avoiding violations of the physician self-referral law and the federal antikickback statute. Those waivers are the:

- Pre-Participation Waiver for ACO-related start up activities when there is intent to participate in the Shared Savings program
- ACO Participation Waiver for ACO's participating in the Shared Savings Program during such participation and for a period afterward.
- Shared Savings Distributions waiver for use of shared savings payments.
- Compliance waiver that protects from kickback liability arrangements that could violate the physician self-referral law but satisfy an exception to that law.
- Patient Incentive Waiver that protects incentives offered to beneficiaries to encourage preventive care and treatment compliance.

CMS stated in the final rule that "[t]hese five waivers provide flexibility for ACOs and their constituent parts to pursue a wide array of activities, including start-up and operating activities that further the purposes of the Shared Savings Program." For more information about these waivers and their conditions and limitations, see the Final Rule published in the Oct. 29, 2015 *Federal Register*.

Takeaway: CMS finally solidifies waivers designed to make it easier for ACOs to achieve shared savings goals without risking fraud and abuse violations. G2

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