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INSIDE *NIR*

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Happy Holidays from G2!

There is only one issue of National Intelligence Report *this month. Best wishes for a happy holiday from the staff at G2 Intelligence and Kennedy Information!*

Labs Express Concern About New MolDx Policy Requiring Registration of Molecular Test Panels

Groups representing clinical laboratories are coming out in opposition to a new alert issued by Palmetto GBA requiring labs that perform tests in Medicare regions JE or J11 to register molecular test panels and bill with a single CPT code and a unique molecular diagnostic service program (MolDx) identifier.

According to the Dec. 4 alert (M00101), Palmetto considers the performance of multiple molecular biomarkers ordered together to be a panel of tests, regardless of whether the test requisition lists the tests as a panel or individually. Palmetto says that based on data analysis of MolDx claims, labs are submitting multiple biomarker "panels" as individual tests similar to the submission of the previous stacking codes.

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Leaders of Republican Doctors Caucus See No Action on SGR During Lame Duck

Efforts to find a long-term fix for Medicare's Sustainable Growth Rate (SGR) formula for physician payment will have to wait until 2015, the co-chairman of the Republican-formed GOP Doctors Caucus said Dec. 4.

Speaking to reporters, Rep. Phil Roe (R-Tenn.) said he plans to take up the issue in the early days of the 114th Congress. For now, though, SGR reform is "DOA. It's not going to happen this year," Roe said.

Congressional leadership has been under pressure from outside stakeholder groups as well as lawmakers to pass a permanent SGR fix. The American Medical Association, the GOP Doctors Caucus, and a coalition of primary care doctors that includes the American College of Physicians (ACP) and the American Academy of Family Physicians (AAFP) have all pushed for an agreement to be reached this year instead of waiting until the current patch expires March 31, especially since the price to do so keeps rising.

Without any action, Medicare payments to doctors would be reduced by 21 percent, although Congress has passed temporary patches every year to avoid similar cuts.

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Labs Express Concern About New MolDx Policy, *from p. 1*

For example, a lab receives a patient specimen and performs the following tests:

- ❑ CYP2C19, cv (CPT 81225)
- ❑ F2, 20210G>A (CPT 81240)
- ❑ F5, Leiden (CPT 81241)

Palmetto says the panel of three tests listed above should be registered and claims submitted with CPT code 81479 and a single MolDx ID. If a lab also performs one of three panel's biomarkers on patient specimens, each biomarker must also be registered and receive a unique ID to submit on claims when only that biomarker is performed. Again, a single CPT code should be billed with a unique ID.

Palmetto says that to bill correctly for the example above, the lab must register four tests and receive identifiers for MolDx submission (see example below).

EXAMPLE OF MOLECULAR PANEL WITH IDENTIFIERS

TEST NO.	*TEST NAME*	*BIOMARKER*	*ID*	*CPT CODE*
1	Clotting Test Panel	CYP2C19, cv, F2, 20210G>A, F5, Leiden	Z1234	81479
2	CYP2C19	CYP2C19, cv	Z5678	81225
3	F2, 20210G>A	F2, 20210G>A	ZA234	81240
4	F5, Leiden	F5, Leiden	ZA567	81241

Source: Palmetto GBA

Effective Nov. 17, 2014, labs should start to register all panels and obtain a unique MolDx identifier for each panel. If a lab does not perform single biomarker tests, they must notify the registry of this registration error.

CCLA Requests Meeting With CMS

The California Clinical Laboratory Association (CCLA) has requested an urgent meeting with Centers for Medicare and Medicaid Services (CMS) officials about this new policy and is requesting that implementation of the edit alert be delayed until the agency has had an opportunity to review stakeholder comments and determine the impact of the policy on Medicare beneficiaries.

According to CCLA, the new policy would effectively require labs to register as panels all possible combinations of their biomarkers. "This approach makes no sense since it does not base the "panels" in any manner on how the tests are marketed or otherwise grouped by the laboratory," says CCLA in the letter. "Moreover, since Palmetto knows which biomarkers are covered by Medicare, Palmetto is in as good a position to identify and register these 'panels' as are the laboratories that perform the testing. In addition, Palmetto's proposal would needlessly require different laboratories that test for the same biomarkers to separately register what may be identical panels."

CCLA also argues that the alert does not provide "due process" for labs or Medicare beneficiaries that was guaranteed to labs through negotiated rulemaking

and reconfirmed under the Protecting Access to Medicare Act. What's more, the alert is contrary to previously expressed guidance and concerns regarding panels raised by both CMS and the Health and Human Services Office of Inspector General.

MolDx Panel Plan Timeline

- Effective Jan. 1, 2015, Palmetto GBA will start lab notification. Labs that have submitted panel test claims will receive a list of MolDx IDs that require panel registration.
- Each lab will be given 30 days from the receipt of the list to correct test registration.
- Effective April 1, 2015, MolDx will set edits to reject tests performed as panels and registered and submitted with a CPT code for each biomarker in the panel.
- During this period, Palmetto will continue to interrogate the claims data for incorrect submission.

CCLA also believes that the alert violates the molecular pathology (MoPath) coding initiative. "This alert is intended to be a repricing exercise and is in violation of the MoPath coding initiative that was designed to provide granularity to these codes. . . . Prices were set under the MoPath initiative as recently as last year. Utilizing the CMS mandated gap-fill procedure, National Limit Amounts were determined and price protection for codes on the [Clinical Laboratory Fee Schedule] were guaranteed by PAMA through 2016."

Takeaway: Labs are fighting a plan by Palmetto GBA to require them to register molecular test panels.

OIG Efforts Expected to Recover $4.9 Billion In Improper Payments in FY 2014

Investigative and oversight efforts by the Department of Health and Human Services Office of Inspector General are expected to return $4.9 billion in improper payments to the government in fiscal year 2014, according to the OIG's semiannual report to Congress, released Dec. 10.

The expected recoveries include roughly $835 million in improper payments identified through federal health care program audits, as well as $4 billion identified through investigations, the report said. The FY 2014 expected recoveries are about $1 billion less than the expected $5.8 billion in recoveries for FY 2013.

In addition to the recoveries, the OIG excluded 4,017 individuals and entities from participating in federal health care programs and reported 973 criminal actions and 533 civil actions. The report covers the period between April 1 and Sept. 30 and also includes a summary of the OIG's accomplishments for the full fiscal year.

Over the course of FY 2014, the OIG said Medicare Fraud Strike Force efforts led to indictments being filed against 228 individuals, as well as the recovery of $441 million through investigative work. Although the number of FY 2014 indictments dropped off from the 274 filed in FY 2013, the $441 million in strike force recoveries was more than $100 million higher than recoveries from FY 2013 ($330 million).

Takeaway: The federal government has been largely successful in its attempts to recover improper payments made to providers.

CMS Proposes New Shared Savings Risk Model

The Centers for Medicare and Medicaid Services (CMS) has issued a proposed rule making changes to the Medicare Shared Savings Program, including a new risk model for use by participating accountable care organizations (ACOs).

Comments on the 429-page proposed rule, published in the Dec. 8 *Federal Register*, are due Feb. 6, 2015. CMS said the proposal will improve the program "through a greater emphasis on primary care services and promoting transitions to performance-based risk arrangements." The rule would update a 2011 final rule on ACOs.

CMS said the proposed rule will give more flexibility to ACOs seeking to renew their participation in the program. CMS is proposing to give ACOs the option of a longer lead time to transition to a two-sided (that is, sharing of savings and losses) performance risk model after their first agreement period, the release said. ACOs also would have the opportunity to renew under the one-sided model for one additional agreement period.

More Risk Encouraged

The agency also is encouraging ACOs to take on greater performance-based risk and reward by proposing to create a new two-sided risk model, called "Track 3," which integrates some elements from the Pioneer ACO model, such as higher rates of shared savings. The Pioneer ACO model is for providers already experienced in coordinating care for patients across care settings.

"We are seeking comments on a number of care coordination tools that would make two-sided performance risk models more attractive to ACOs such as expanded use of telehealth, beneficiary attestation, and more flexibility around post-acute care referrals to help ACOs better coordinate care for beneficiaries using these services," the press release said.

New Payment Methodologies

CMS also is seeking comment on alternative methodologies that would make ACO benchmarks for determining shared savings and losses gradually more independent of the ACO's past performance and more dependent on the ACO's success in being more cost-efficient relative to its local market, the agency release said.

"For example, we are considering whether shared savings received by an ACO should be added back to the benchmark in future performance periods," the release said. The agency also is proposing to streamline the process for ACOs to access beneficiary claims data necessary for health care operations such as quality improvement activities and care coordination while retaining the opportunity for beneficiaries to decline to have their claims data shared with the ACO.

The Shared Savings Program now includes more than 330 ACOs in 47 states, providing care to more than 4.9 million beneficiaries in Medicare fee-for-service, according to CMS.

Takeaway: CMS is proposing some changes to its Shared Savings Program, including a new two-sided risk model dubbed "Track 3."

Leaders of Republican Doctors Caucus, *from p. 1*

The Congressional Budget Office Nov. 17 said bipartisan, bicameral legislation (H.R. 4015, S. 2000) to replace the SGR would cost $144 billion from fiscal years 2015 to 2024, a jump from the $138 billion, 10-year estimate that the CBO made in February when the identical bills were introduced.

H.R. 4015 passed the House in March but not the Senate, when lawmakers couldn't agree on how to pay for it. The most recent short-term Medicare doc pay patch was signed into law April 1.

Roe said he was in favor of the policies contained in H.R. 4015 and didn't feel like they would need to be negotiated anew next year, especially because they were bipartisan.

"I'm not saying there wouldn't be a tweak or something, but I'm satisfied with the policy," Roe said. "Once you've got a grand slam home run like that one was—an agreement on policy—I don't think you'll revisit that."

How to Pay for It?

Roe said the pay-fors remain the biggest stumbling block to getting a deal done. The House Ways and Means Committee "will have to come up with a plan. They couldn't get that done this Congress," Roe said.

Roe said he would insist on offsetting the costs of a full SGR repeal but also said he was open to only partially offsetting it. Roe wouldn't specify if any other lawmakers shared his view about partial offsets but said he wasn't "a lone wolf."

Roe acknowledged also there's a chance the negotiations will get caught up in acrimonious politics of the Affordable Care Act but said he hopes that isn't the case.

Roe said the last SGR bill "was done in a real bipartisan way. I think both sides of the aisle understand that it needs to get done. We need to replace it with a sustainable system that hopefully will lower costs for people."

Takeaway: Congress is unlikely to find a long-term fix for the SGR any time soon, but a short-term fix is likely before physician payments are cut by 21 percent.

Illumina, Sequenom Settle Suits Involving Prenatal Tests

Illumina Inc. and Sequenom Inc. announced Dec. 3 a settlement of infringement litigation over prenatal testing claims and other disputes between Sequenom and Illumina subsidiary Verinata Health Inc. (*Ariosa Diagnostics v. Sequenom, Inc.*, Fed. Cir., No. 14-01139 and *Verinata Health, Inc. v. Sequenom, Inc.*, N.D. Cal., No. 3:12-cv-00865).

Illumina agreed to pay Sequenom $50 million up front and will make payments through 2020. The companies, both of which are based in San Diego, didn't disclose the amount of those payments.

Under the agreement, the parties will pool their owned and in-licensed intellectual property directed to noninvasive prenatal testing (NIPT), and Illumina will have exclusive worldwide rights to use it to develop and sell in vitro diagnostic kits for NIPT and to license third-party laboratories wishing to develop and sell their own laboratory-developed NIPT tests covered by the pooled patents.

In addition, Sequenom and Illumina will each have rights to use all pooled patents to develop and sell their own laboratory-developed NIPT tests. The parties will share the revenue from the patent pool, and Illumina will pay Sequenom a royalty on sales of in vitro diagnostic kits for NIPT.

The pooled owned and in-licensed intellectual property directed to NIPT includes patents that will remain the subject of ongoing Patent and Trademark Office (PTO) interference proceedings. Illumina also will supply instruments and chemicals to Sequenom for five years.

CAFC, District Court Suits Were Pending

Illumina Chief Executive Officer Jay Flatley said in a statement, "The patent pool established through this agreement eliminates confusion over intellectual property rights and provides a single point of contact for those wishing to license this intellectual property for NIPT testing."

Sequenom CEO Bill Welch said, "This settlement will allow for easier access to both parties' NIPT technology by health care providers and their patients. We believe that pooling our intellectual property will enable us to continue to expand our NIPT laboratory test offerings while allowing Sequenom to participate more broadly in the growing global NIPT marketplace."

The settlement marks the end of a long battle between Illumina's Verinata Health and Sequenom for predominance in noninvasive prenatal diagnostic testing. Both Sequenom and the Verinata Health unit make prenatal tests that detect Down syndrome and other conditions that involve missing or extra copies of chromosomes.

The parties' pending litigation includes Sequenom's appeal to the U.S. Court of Appeals for the Federal Circuit of the U.S. District Court for the Northern District of California's ruling in Verinata's declaratory judgment litigation that it didn't infringe claims of Sequenom's U.S. Patent No. 6,258,540 for prenatal detection methods performed on a maternal sample. The Federal Circuit held that the claims of the '540 patent are invalid because the process is routine and conventional.

In reaching its decision, the district court cited the Supreme Court's decisions in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, which held that claims for methods for administering a drug are patent ineligible as laws of nature unless there is an "inventive step," and *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, which held that isolated DNA is patent ineligible under the judicial exclusion for products of nature.

Oral arguments in that case were heard Nov. 7.

On Aug. 1, Sequenom disclosed in a filing with the Securities and Exchange Commission that it had received favorable decisions from the PTO's Patent Trial and Appeal Board (PTAB) tied to four patent interference proceedings involving the use of DNA sequencing for noninvasive prenatal testing for Down syndrome and other chromosomal abnormalities. Both Sequenom and Verinata use this technology. The PTAB initiates interference proceedings when opposing parties have applied for a patent to the same invention to determine which party was first to invent the subject matter.

Sequenom said in its filing that Verinata appealed the PTAB's ruling to the Northern District of California.

Takeaway: A recent settlement marks the end of a long battle between Illumina's Verinata Health and Sequenom for predominance in noninvasive prenatal diagnostic testing.

CMS Eliminates 50-50 Payment Rule for ESRD Lab Services

Effective April 1, 2015, laboratory services provided in end-stage renal disease (ESRD) facilities will no longer be paid in accordance with the 50-50 rule.

The Medicare ESRD benefit previously provided payment for dialysis and some dialysis-related services under a per-treatment composite rate. Separate payment for automated multichannel chemistry laboratory tests was determined according to the 50-50 rule where separate payment for the lab services was subject to whether 50 percent or more of the tests performed were in excess of the composite rate. ESRD facilities were required to report the following modifiers:

- ❑ CD to indicate if the laboratory test was included in the composite rate;
- ❑ CE to indicate the laboratory tests exceeded the frequency of the composite rate; or
- ❑ CF to indicate the laboratory test was not included in the composite rate.

In addition, ESRD facilities were required to itemize on the claim the individual lab Current Procedural Terminology codes rather than reporting disease panel codes.

With the implementation of the ESRD Prospective Payment System (PPS), ESRD lab services are no longer paid in accordance with the 50-50 rule. Change request 8957, issued Nov. 6, 2014, instructs that for ESRD claims with dates of service on or after April 1, 2015, ESRD facilities will no longer be required to submit the 50-50 rule modifiers CD, CE, and CF. The ESRD PPS requires that all renal dialysis laboratory services be paid in the ESRD facility bundled payment and therefore may only be billed by the ESRD facility.

In addition, ESRD facilities should report organ or disease-oriented panel codes on Type of Bill 072X for codes listed in the following table when performed for an ESRD beneficiary if:

- ❑ These codes best describe the laboratory services provided to the beneficiary, which are paid under the ESRD PPS; or
- ❑ The test is not related to the treatment of ESRD, in which case the facility would append modifier "AY" and the service may be paid separately from the ESRD PPS.

ESRD Test Codes

HCPCS/ CPT Code	*Description*
80047	Metabolic anel ionized CA
80048	Metabolic panel total CA
80051	Electrolyte panel
80053	Comprehen metabolic panel
80061	Lipid panel
80069	Renal function panel
80076	Hepatic function panel

Source: CMS Change Request 8957.

Transmittal R3116CP (CR 8957) is available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals.html*

Takeaway: Effective April 1, 2015, all renal dialysis laboratory services will be paid in the ESRD facility bundled payment.

Health Diagnostic Laboratory Gets Some Good News

Despite going through some tough times lately, Richmond, Va.-based Health Diagnostic Laboratory (HDL) had some good news this month: An independent analysis showed positive results from its model of health care management.

A group of nearly 7,400 patients receiving comprehensive laboratory testing paired with personalized lifestyle consulting from HDL saw a 41 percent decrease in the incidence of heart attacks and significantly lower occurrence of diabetes complication, according to a third-party analysis of insurance claims data.

Optum—the health services platform of UnitedHealth Group—and researchers at the University of Richmond rigorously tested the ability of HDL's model of comprehensive biomarker testing paired with direct patient engagement and physician support to promote positive health and cost outcomes. The study spanned a mean follow-up period of 27 months (with a range of 12 to 42 months).

"The results provide strong evidence that Health Diagnostic Laboratory's model of health management is associated with positive health outcomes. There were very interesting patterns in the data," said Steve Thompson, associate professor of management at the Robins School of Business at the University of Richmond and lead author of the study. "First, improvements in outcomes emerged in a relatively short time frame. Second, although laboratory costs increased, the costs were entirely offset by an expenditure shift away from other medical costs, such as emergent care."

The study included 7,396 patients receiving HDL services who were matched by demographic, clinical, and cost parameters to a cohort of patients who did not receive testing or health management from the company. Both groups were sicker and more expensive (in terms of health care dollars) than the general population.

In addition to the reduction in heart attacks—49 in the HDL cohort compared to 83 in the control group—clinical outcomes for ischemic strokes trended lower by 17 percent while diabetes complications were 15 percent less frequent. Desirable shifts in health system use were also observed, as inpatient admissions fell by 21 percent and emergency department visits were 6 percent less frequent in the HDL cohort.

The report comes on the heels of a series of negative events for the Richmond lab. HDL co-founder and CEO Tonya Mallory stepped down suddenly in September, citing family reasons. Her departure comes while HDL is under scrutiny as part of a federal investigation into reimbursement practices in the clinical laboratory industry.

In October, Connecticut-based health insurer Cigna sued the company, seeking to recover $84 million in insurance claims paid to HDL. And last month HDL announced that it was cutting its overall staff by 132 people, or about 15 percent of its workforce.

Takeaway: The report that HDL's health care management model is having positive effects on patient outcomes comes as good news for the lab, which has been under intense scrutiny in recent months. G2

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