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Medicare Reimbursement: Proposed HOPPS Changes Would Allow Direct Billing of Molecular Pathology Tests & ADLTs

On July 13, the CMS proposed changes to Hospital Outpatient Prospective Payment System (HOPPS) rules for 2018. Here's a look at the three items that would affect laboratories that provide tests to Medicare patients on an outpatient basis.

1. 2.0 Percent OPPS Rate Hike

CMS is proposing an OPPS fee schedule rate increase of 1.75 percent for 2018 based on a projected 2.9 percent increase in the hospital market basket, minus both a:

- 0.4 percent adjustment for multi-factor productivity; and
- 0.75 percent adjustment required by the Affordable Care Act (ACA).

Bottom Line: When combined with other proposed policy changes, hospitals would receive overall OPPS pay increases of 2.0 percent in 2018, according to CMS estimates.

2. 1.9 Percent ASC Rate Hike

CMS is also proposing a similar increase in Ambulatory Surgical Center (ASC) payments based on a CPI urban consumers update of 2.3 percent minus both the 0.4 percent multi-factor productivity adjustment and mandatory ACA 0.75 percent adjustment.

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Enforcement Trends: New Fraud Takedown Shows that Coordinated Enforcement Remains Alive & Well under Trump

Last year at this time, the Justice Department announced the results of a nationwide takedown involving "the most defendants charged and largest alleged loss amount in Medicare Strike Force history." And while the administration has changed, the story hasn't. The new takedown results the DOJ announced on July 13 not only breaks but pulverizes the previous record set in 2016.

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Medicare Reimbursement, *from page 1*

Bottom Line: When combined with other proposed policy changes, ambulatory surgical centers would receive overall 1.9 percent ASC pay increases for lab and other covered outpatient services in 2018.

3. Revised Lab Date of Service Rules

The part of the new HOPPS proposal impacting labs most directly is the proposed changes to the rules for calculating the date of service (DOS) for outpatient lab tests.

Current Rules: The DOS for outpatient lab services is normally the date the specimen is collected. Exception: The date the test is performed is the DOS if:

- The doctor orders the test at least 14 days after a patient is discharged from the hospital;
- The specimen is collected during a hospital surgical procedure;
- Collecting the sample at another time would be medically inappropriate;
- Test results don't guide treatment provided during the hospital stay; and
- The test is reasonable and necessary for treating an illness.

When the so called "14 day rule" applies, the test is paid separately under Part B; in all other cases, it's bundled into the payment for the hospital stay.

Proposed Change: CMS is proposing to carve out exceptions to the 14-day rule that would allow labs to bill Medicare directly under the Clinical Laboratory Fee Schedule (CLFS) for certain molecular pathology tests and advanced diagnostic laboratory tests (ADLTs) that are: i. excluded from OPPS packaging rules; and ii. ordered *less than* 14 days after a patient's hospital discharge. The DOS for those tests would be the date of testing rather than specimen collection. CMS will issue final rules after collecting public comments on the idea.

Takeaway: Most of the proposed HOPPS changes are positive ones for labs. But pathologists didn't make out as well. CMS specifically rejected an industry recommendation to create a pathology composite to pay claims with only multiple pathology services and no other separable payable services such as a clinic visit or surgical procedure. Accordingly, where multiple conditionally packaged services billed on the same claim, paying services will continue to be bundled and payment made on the basis of the highest single paying service.

Criteria for Direct Billing of Outpatient ADLTs

Under the CMS's proposal, labs could directly bill Medicare under the CLFS for ADLTs delivered to outpatients less than 14 days after hospital discharge if either of the following criteria applies:

Criterion 1: The test:

- Analyzes multiple biomarkers of DNA, RNA or proteins;
- When combined with an empirically derived algorithm, yields a result predicting the probability of an individual patient's development of a certain condition(s) or response to a particular therapy(ies);
- Provides new clinical diagnostic information that can't be obtained from any other test or combination of tests; and
- May include other assays

Criterion 2: The test is cleared or approved by the FDA.

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Genomic Testing: Oncologists Want More Education & Less Hype

When it comes to measuring Dx product effectiveness, few things speak louder than the attitudes of ordering physicians. With that in mind, genomic test manufacturers might want to take pause from a new oncologist survey finding that while such testing does represent a major advance, it is also being "significantly overpromoted."

The Survey

Medscape and the Swedish Cancer Institute in Seattle surveyed 132 oncologists representing a range of practice settings including:

- Private practices (25 percent);
- Hospital and hospital-owned group practices (47 percent); and
- Military, research, academic or government institutions (16 percent).

The good news, at least for test makers, is that 71 percent characterized genomic testing as "very" or "extremely" important to oncology practice; the bad news is that 55 percent also said that such testing is "overpromoted" or "very overpromoted," and that its value falls below expectations. The silver lining is that among the roughly one-third of respondents who said that they think genomic testing is not useful now, 89 percent believe it *will be* useful within 10 years.

Oncologists' Concerns with Genomic Testing

Clinical: The biggest clinical concern cited by oncologists about genomic testing: It too often fails to provide clinically actionable information that would result in patient management changes (31 percent). Sixty-one percent say that less than one-quarter of their patients would benefit from genomic testing. But among those who *have* ordered genomic testing, 66 percent said they did so to guide their treatment decisions.

Financial: The oncologists also cited financial concerns with genomic testing, including:

- Insurance coverage is too poorly defined (84 percent);
- Getting approval for unapproved indication is "too great a hurdle" (73 percent);
- Concerns about cost-effectiveness of multiplex genomic testing (73 percent).

Yet, despite these concerns, 78 percent of oncologists say insurers should pay for genomic testing and 73 percent do not believe that patients are willing to pay for the tests out of their own pockets. In practice, the oncologists report that 85 percent of testing is paid for by patients' private health insurance, 35 percent by research funds and 29 percent by self-pay.

Other: A relatively lower percentage cited other practical concerns associated with genomic testing, including not enough tissue to perform testing (18 percent) and too long a turnaround time (17 percent).

Need for More Education & Guidance

Despite the fact that more than two-thirds of respondents reported using genomic testing within the last month, 86 percent felt that more physician education is needed before genomic testing could be widely used. This may

be reflected in oncologists' self-reported lack of confidence in counseling patients on the significance of identified genetic mutations. More than half (53 percent) reported a "4" or lower on a 7-point scale ("no" to "moderate" confidence). In terms of ordering guidance, National Comprehensive Cancer Network guidelines were most used (44 percent), followed by published studies (32 percent). Only eight percent said that their institution's guidance or practice pathways were their primary source for ordering information.

Nearly half (49 percent) said that genomic testing currently should be restricted to research settings. Twenty-seven percent of those who said they ordered testing indicated that they did so to guide patients to clinical trials or in support of clinical research. However, of those that ordered a test to guide patients to a trial, fewer than a quarter of actually had a patient enroll a trial.

"As these tests are a small fraction of all genetic tests at our institution, future studies should broaden the scope of testing evaluated to understand the magnitude of this problem and potential cost savings."

— Kathleen Ruzzo, M.D.

Testing is Ordered Inappropriately

The Medscape survey's revelations of oncologists' lack of comfort regarding genomic testing parallels a new study that shows genetic tests are often misordered.

According to an oral presentation at the 2017 annual clinical and scientific meeting for the American College of Obstetricians and Gynecologists (San Diego, May 6-9), one of every three genetic tests examined by a team of researchers should not have been prescribed. The findings, the authors say, add to a growing body of evidence suggesting that genetic tests are routinely overused and often misinterpreted.

Researchers from the Naval Medical Center San Diego reviewed 114 charts associated with the genetic test billing codes for common genetic tests sent through LabCorp, including cystic fibrosis, BRCA, factor V Leiden, prothrombin, alpha-thalassemia, hemochromatosis, and cell free DNA. The charts were examined for compliance with published clinical practice guidelines identified on Gene Reviews.

Findings: Over the three-month period, 39 percent of tests (n=44) were misordered based on published clinical practice guidelines. Misorders were classified as not indicated (21 percent), false reassurance (7 percent) and inadequate (11 percent). Costs of ordered testing were compared to recommended testing. Had guidelines been adhered to, nearly $21,000 of cost savings could have been achieved, according to the researchers.

"As these tests are a small fraction of all genetic tests at our institution, future studies should broaden the scope of testing evaluated to understand the magnitude of this problem and potential cost savings," writes author Kathleen Ruzzo, M.D., in the abstract. "Genetic counselor review and/or involvement in genetic test ordering can decrease inappropriate healthcare expenditures and improve patient care."

Takeaway: The majority of surveyed oncologists report that genomic testing is not currently living up to expectations and that they feel ill-equipped to order and report the results. This discomfort may be reflected in a separate study's findings that one-third of genetic tests are misordered.

Value-Based Care: AACC Cites Key Role of Lab Professionals in Making It Work

Laboratory professionals have a central role to play in supporting the transition to value-based care, according to a new American Academy of Clinical Chemistry (AACC) position statement.

> *"Laboratory medicine professionals are poised to contribute their expertise to work with clinicians in devising more effective and efficient diagnostic and therapeutic protocols, and should be invited to be part of guideline development panels."*
>
> — American Academy of Clinical Chemistry

Lab Expertise Crucial to Success of Value-Based Care

The AACC notes that clinical laboratorians have expertise that can better inform test utilization and test interpretation, which can benefit the health care system through improved patient outcomes and reduced costs under value-based care.

Unlike inpatient care, which is reimbursed under a single diagnosis-related group (DRG) code, outpatient testing is still primarily reimbursed under fee-for-service models. New payment models — including accountable care organizations and bundled care arrangements — still rely on lab results, but require greater care coordination and cost control. Since lab data informs the majority of clinical decision-making, lab professionals can help ensure it is used most efficiently and effectively.

"Laboratory medicine professionals are poised to contribute their expertise to work with clinicians in devising more effective and efficient diagnostic and therapeutic protocols, and should be invited to be part of guideline development panels," notes the AACC position statement.

AACC's Recommendations for Lab Pros

To enhance test utilization, AACC recommends that lab professionals assist in expanding clinician education, developing disease-specific test ordering guidelines and creating computerized clinical decision support interventions that identify tests not suitable for certain conditions being investigated.

To improve test interpretation, AACC calls for greater interaction among laboratorians and medical practitioners. AACC also suggests that lab professionals can include interpretative comments to enhance test reports when results cannot be understood by the numeric data alone or when the finding is unique. There should be diagnostic management teams that include a clinical laboratory representative to collaboratively interpret the results in conjunction with the clinical symptoms, says the AACC.

The AACC also calls for continued funding of studies at the federal agency level to develop evidence-based testing guidelines, evaluate translational research of the value of new laboratory tests, and assess how wider adoption of collaborative caregiver group models impacts patient outcomes and costs.

Takeaway: AACC urges laboratory professionals to play an active role in demonstrating the value of laboratory medicine during this period of transition to value-based health care delivery.

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Quest-Walmart Deal Latest in Mass Retailing of Lab Tests

Laboratory test products have been appearing on the shelves of mass retail stores with growing frequency. But the newly announced partnership between Walmart and Quest Diagnostics raises eyebrows because of the sheer size and strength of the participants.

For its part, Walmart hailed the deal as making its stores into a "one-stop shop" for customers' everyday health and wellness needs.

Terms of the Deal

The plan is for Quest to open co-branded lab service centers at 15 Walmart stores in Florida and Texas by the end of the year. Initially, the centers will furnish just testing services, but are expected to expand over time to include other basic health care services. "By providing lab testing and healthcare services where people also shop, we will make it easier for Walmart customers to get the quality diagnostic insights they need in convenient locations," noted Quest CEO Steve Rusckowski.

Quest has been a leader in collaborating with mass retail with over 100 company-branded patient service centers (PSCs) at Albertsons companies' grocery stores (Safeway, Vons, Randalls and Tom Thumb) across California, Colorado, Maryland, Oregon, Texas, Virginia, and Washington. By doing the Walmart deal, Quest has expanded the model beyond grocery.

For its part, Walmart hailed the deal as making its stores into a "one-stop shop" for customers' everyday health and wellness needs. The Quest partnership enables the retail giant to extend its current health care offerings which include free health screenings like blood pressure readings at all U.S. stores and vaccines in select stores.

The Brick and Mortar Model

The Quest-Walmart deal follows the typical model for collaboration between labs and mass retailers in which co-branded PSCs are established at store locations. These arrangements have proven to be a positive for both sides. The stores benefit from the extra foot traffic and added customer convenience; labs get to leverage their retail partners' real estate assets to generate incremental volumes and greater exposure.

The Cloud Model

Of course, the strategy is not confined to brick and mortar settings. Not surprisingly, Amazon has been among the most active in adapting the model for online retail. So far, most lab tests on Amazon have been sold through third parties. But last November, Good Start Genetics became the first genetic testing firm to establish a direct partnership with Amazon to provide physician-ordered tests online, namely Good Start's VeriYou next generation

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sequencing test for couples planning to have kids. The dynamic: Customers must register online, furnish family history and provide consent. A licensed physician then reviews the data and decides whether to order the test. The customer can then buy the test on Amazon for $149.

DTC Applications

Both models have also been adapted for direct-to-consumer (DTC) applications allowing customers to order tests without a physician's order in states where such arrangements are permitted by law. The ill-fated Walgreens-Theranos partnership was a notable example of the former to a brick and mortar setting. (See the related item below); online examples include Quest's newly launched QuestDirect empowering consumers in Colorado and Missouri to order designated tests online without a physician's order.

Takeaway: In spite of the recent Walgreens-Theranos fiasco, collaboration between labs and mass retail will continue and likely expand into the retail pharmacy segment. Look for brick and mortar PSC and online arrangements to proliferate, both DTC and physician-ordered.

Case of the Month: Theranos Settles with Walgreens

On June 21, less than a week before the eye-popping announcement about Walmart and Quest teaming up on a new retail venture, a case exemplifying just how badly arrangements between big labs and retail giants can go came to an ignominious and anti-climactic end with the settlement of the Walgreens Theranos lawsuit.

What Happened

It all looked so promising back in 2015. Privately-held Theranos was poised to usher in a new era of diagnostics with its revolutionary fingerprick technology for performing a wide array of tests with just a few drops of blood. Walgreens was (and remains) the nation's largest retail pharmacy chain. So the arrangement to open independent "wellness centers" at Walgreens stores across Arizona and California seemed like a game changer, one that Walgreens hailed as the next step in its "efforts to transform community phar-

THE THERANOS SETTLEMENT SCORECARD

$30,000: Agreed monetary penalty to CMS for CLIA violations at Newark lab (penalty reduced in exchange for agreement not to operate a lab for at least 2 years);

$4.65 Million: Reimbursement to Arizona residents for blood testing payments for services between 2013 and 2016 to settle state consumer fraud lawsuit;

Under $30 Million: Reported settlement with Walgreens for alleged misrepresentations regarding capabilities of Edison platform (subject to final approval);

Undisclosed: Amount for which Theranos has agreed to pay to settle a pair of securities fraud claims filed by a San Francisco hedge fund in connection with investment financing of $96.1 million.

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macy." Arizona's enactment of legislation empowering residents to order tests for themselves without a doctor's order was the icing on the cake.

Just 16 months later, it had all come undone. The Theranos Edison platform failed to meet its lofty expectations. Walgreens ended the partnership in July 2016; in November, it sued Theranos for $140 million claiming that it misrepresented the technology's capabilities. Meanwhile, the Centers for Medicare and Medicaid Services slammed Theranos and its CEO Elizabeth Holmes for a series of infractions at its Newark, CA, lab. The Arizona Attorney General joined the fray by bringing a consumer fraud lawsuit.

After settling with CMS in April and Arizona in April, Theranos has now reached a tentative settlement agreement with Walgreens. Under the deal, which requires official court approval and is also reportedly still subject to negotiation, Theranos would pay Walgreens a sum south of $30 million.

Labs IN COURT

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

Lab Tech and Account Rep Face Jail for Test Fee and Commissions Scheme.

Case: A pair of Texans face criminal charges for allegedly conspiring to cheat Medicare of nearly $837,000 over a 6-month period in 2015. The feds contend that the lab technician at a medical clinic misappropriated patient urine samples and secretly sent them to a toxicology testing company at which his co-conspirator was the account representative to pocket commissions and testing fees. The two allegedly forged physician signatures and medical records to carry out the scheme.

Significance: The defendants have been charged with 8 counts of healthcare fraud each of which carries a maximum penalty of 10 years in prison and a $250,000 fine. They also face 9 counts of aggravated identity theft, at up to 2 years of prison a pop. And those latter years would have to be served consecutively to any jail time for healthcare fraud.

System Pays $6.5 Million to Settle Urine Test Upcoding Charges.

Case: A lab director filed a whistleblower suit claiming that Carolinas Healthcare System upcoded what should have been "moderate complexity" urine screens to "high complexity" tests, resulting in overpayments of $80 per test. Carolinas denied the claims but when the government took over the case decided to settle for $6.5 million, $1.365 million of which will go to the whistleblower.

Significance: The damages could have been much higher but for the fact that Carolinas cooperated in the investigation. Another mitigating factor was that Carolinas had enlisted a pair of separate outside consultants to review its coding process, each of which gave the thumbs up. Accordingly, most of the $6.5 million was for restitution of the overcharges rather than penalties.

Anthem Settles Data Breach Lawsuit for Record $115 Million.

Case: Anthem, the nation's second largest health insurer, has agreed to shell out $115 million to settle a class action lawsuit over a massive 2015 cyberattack in which hackers stole the names, addresses, birthdates,

Social Security numbers and other personal information of roughly 78.8 million plan members and employees. Under the deal, the biggest settlement ever for a data breach, Anthem will furnish 2 additional years of credit protection monitoring to the individuals affected and set aside a $15 million fund to cover victims' out of pocket costs.

Significance: The settlement isn't just about money. It also requires Anthem to make specific improvements to its data security systems over a 3-year period, including:

- Strict access requirements;
- Data retention periods;
- Mandatory information security training for associates; and
- Annual IT security risk assessments.

BLS Bribery Case Gets Criminal.

Case: The massive federal crackdown against doctors who allegedly took bribes from New Jersey-based Biodiagnostic Laboratory Service (BLS) in exchange for Medicare test referrals continues to grow. On June 6, a federal jury indicted a pair of cardiologists with a Patterson, NJ practice for their role in the BLS scheme. One of the doctors allegedly received a $500,000 loan, a free trip to Florida for fishing and visiting strip clubs and other bribes from BLS. His wife was also indicted for setting up the sham company through which the bribes were funneled. The other doctor is accused of taking bribes in exchange for over $900,000 in lab referrals.

Significance: There have been 45 convictions in the BLS case so far, 31 of them physicians. But most of those prosecutions have been civil cases. The new case ups the ante with criminal charges. The Patterson cardiologists are only the fifth and sixth doctors indicted in the scheme.

Fraudster Gets Maximum 10 Years for Lab Billing Ripoff & Obstructing Investigation.

Case: Speaking of criminal charges, the mastermind of a false billing conspiracy was sentenced to the maximum 10 years in prison; his accomplice got 37 months. The defendants pleaded guilty to creating testing "clinics" to bill Medicare for tests that were medically unnecessary or not actually performed. The sham bilked the government out of over $7 million in false claims.

Significance: The details are pretty egregious. The plot, which was apparently planned over a long period of time, involved paying marketers $80 to $100 cash to recruit Medicare beneficiaries to the clinics. Marketers used the money to pay the beneficiaries bribes and pocketed the rest. Adding injury to insult, the co-plotters tried to obstruct the investigation.

MD Practice Manager Fined, Jailed for Testing Ripoff.

Case: The manager of an Oregon ophthalmology practice was fined $2.519 million and sentenced to a year and a day in prison for his role in a six-year scam targeting Medicare, private health insurers and even the IRS. The ophthalmologist, since deceased, who also happened to be the manager's father, performed medically unnecessary diagnostic tests and the manager sent out the invoices, often billing for tests that cost more than were actually performed and double billing insurers for the same test. As icing on the cake, the two concocted a scheme involving a straw company to conceal nearly $8 million in business revenue from the IRS and finance personal expenses including the construction of a posh home.

Significance: The manager was actually hit with a pair of fines—$1.702 million in restitution to Medicare, Care Oregon and several private health insurers and $817,378 to the IRS. And once he gets out of jail, he'll be subject to three years of supervised release.

FDA Approves First NGS Oncology Companion Dx for Multiple Therapies

In May, the U.S. Food and Drug Agency (FDA), the agency known for its stinginess in approving new products, broke new ground by approving Merck's Keytruda (pembrolizumab) PD-1/PD-L1 inhibitor, a cancer drug administered on the basis of a tumor's genomic features rather than its location in the patient's body. Barely a month later, the agency raised eyebrows again, this time on the diagnostic testing front, by issuing its first-ever approval for a next-generation sequencing (NGS) oncology panel for multiple therapies.

On June 22, the FDA issued premarket approval to Oncomine Dx Target Test, Thermo Fisher Scientific's NGS-based companion diagnostic for non-small cell lung cancer (NSCLC) diagnostic that simultaneously screens for biomarkers associated with three FDA-approved therapies. The test was approved to detect multiple gene mutations (BRAF, ROS1, and EGFR) from a single tissue specimen. The results of the test aid in selecting targeted therapies, including IRESSA (gefitinib) for EGFR L858R and Exon 19 deletions, Tafinlar + Mekinist (dabrafenib in combination with trametinib) for BRAF V600E, or XALKORI (crizotinib) for ROS1 fusion.

Thermo Fisher says that the test kit enables quicker matching for targeted therapies, through a single test rather than sequential testing. The company also says the test will be available in the U.S. beginning in July 2017. LabCorp's Diagnostics and Covance Businesses, NeoGenomics Laboratories, and Cancer Genetics, are the first laboratories offering the test. The test is run on Thermo Fisher's Ion PGM Dx System, which received FDA 510(k) clearance in parallel for use on formalin-fixed, paraffin-embedded (FFPE) tissue samples.

"This first iteration of the test is just the beginning since the diagnostic claims of the Oncomine Dx Target Test may be expanded in the future based on the existing panel," said Joydeep Goswami, Thermo Fisher's president of clinical next-generation sequencing and oncology, in a statement. "Thermo Fisher has entered into discussions with several pharmaceutical companies looking to use the panel for FDA-approved targeted therapy applications beyond lung cancer."

The Oncomine Dx Target Test also currently targets an additional 20 NSCLC-associated gene variants currently being investigated in clinical trials that may be actionable in the future. The company expects that as other drugs are approved, the FDA will expand approvals on the panel.

Takeaway: FDA-approved NGS-based companion diagnostics are entering the commercial market both as kits and as laboratory-developed tests.

NGS Companion Dx Tests Approved by the FDA

In late June the FDA also granted approval to Illumina (San Diego, Calif.) for a companion diagnostic test to identify metastatic colorectal cancer patients that could be treated with the targeted therapy Vectibix.

The test, which was developed in partnership with the pharmaceutical company Amgen, marks the third NGS-based companion diagnostic that the FDA has approved and Illumina's first companion diagnostic and premarket approval in the field of oncology. In December 2016 the agency approved Foundation Medicine's FoundationFocus CDxBRCA test to identify advanced ovarian cancer patients with BRCA1 and BRCA2 gene mutations likely to benefit from Clovis Oncology's PARP inhibitor Rubraca (rucaparib).

"The Extended RAS Panel on the MiSeqDx System enables labs to implement an in-house solution for precision oncology and signifies that NGS has reached a milestone as a clinical diagnostic platform to aid therapeutic decision-making in oncology," said Garret Hampton, Ph.D., executive vice president of clinical genomics at Illumina, in a statement.

Enforcement Trends, *from page 1*

Metric	2017 Takedown	2016 Takedown
Federal districts participating	41	36
State Medicaid Fraud Control Units participating	30	23
Doctors, nurses and other health professionals charged	115	61
Total individuals charged	412	301
Total false billings involved	$1.3 billion	$900 million

Targeted Transgressions

Most of the takedown allegations were against providers of home health, mental health, physical/occupational therapy, durable medical equipment and prescription drug-related services. The DOJ report cites only one case specifically involving labs—an alleged fraudulent lab testing scheme involving 10 individuals in Missiouri.

But while not specifically targeting labs, the takedown focuses on violations that have been associated with labs, including submitting claims for services that weren't medically necessary or even performed, paying kickbacks for beneficiary information used for making false claims and allowing nonqualified individuals to perform services billed to Medicare, Medicaid and TRICARE. Another common pattern: charges against medical professionals for the unlawful distribution of opioids and other prescription narcotics.

Local Results

Here's a rundown of key results from different Strike Force locations participating in the takedown:

- **Southern District of Florida:** Total of 77 defendants charged for $141 million in false billings for home health care, mental health services, pharmacy and other services, including over $58 million for drug treatment services;
- **Middle District of Florida:** 10 individuals charged with participating in schemes involving almost $14 million in fraudulent billing;
- **Eastern District of Michigan:** 32 defendants charged for fraud, kickback, money laundering and drug diversion schemes involving approximately $218 million in false claims for services that were medically unnecessary or never provided;
- **Southern District of Texas:** 26 individuals charged in cases involving over $66 million, including a physician and clinic owner indicted for illegally distributing controlled substances and three substantive counts of distribution of controlled substances from a purported pain management clinic claimed to be the highest prescribing hydrocodone clinic in Houston;
- **Central District of California:** 17 defendants charged in alleged schemes to defraud Medicare out of approximately $147 million;
- **Northern District of Illinois:** 15 individuals charged in six different schemes concerning home health care services and physical therapy

fraud, kickbacks, and mail and wire fraud allegedly involving over $12.7 million in false billing;

- **Eastern District of New York:** 10 individuals charged with participating in schemes involving over $151 million in fraudulent billing, roughly $100 million of which involved payment of illegal kickbacks by five health care professionals in exchange for patient referrals to their own clinics.

In addition to the state Strike Force locations, 31 U.S. Attorney's Offices from across the country participated in the takedown, including Alabama (Northern and Southern Districts), Arkansas (Eastern District), California (Northern and Southern), Connecticut, Georgia (Northern and Southern), Illinois (Southern), Indiana (Northern and Southern), Iowa (Southern), Kentucky (Western), Maine, Missouri (Eastern and Western), Nebraska, Nevada, New York (Northern, Southern and Western), Ohio (Southern), Tennessee (Eastern), Texas (Eastern, Northern and Western), Utah, Virginia (Eastern) and Puerto Rico.

Takeaway: Since its inception in March 2007, the Medicare Fraud Strike Force has charged over 3500 defendants for over $12.5 billion worth in false billings to Medicare, Medicaid and TRICARE. The latest takedown is also an unambiguous signal that the new administration will continue and even step up coordinated federal and state government enforcement activity.