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INSIDE THIS ISSUE

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Doing More With Less: Despite Sequestration Cuts to Funding DOJ/HHS Enforcement Flourishes

Like providers, even government enforcement entities have faced budget cuts. But it doesn't seem to have slowed down enforcement efforts. In 2014, funding for the Health Care Fraud and Abuse Control (HCFAC) Program was reduced due to sequestration by $21.6 million. But $278.1 million in mandatory funds (after the sequestration reduction) and another $293.6 million in discretionary funds provided enough fuel for HCFAC to generate significant fraud recoveries and the agencies indicated they are pleased with their return on investment.

Report details enforcement successes

The U.S. Department of Justice (DOJ) and the Department of Health and Human Services (HHS) released their joint Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2014 on March 19, 2015. A press release announcing the report declares that in fiscal year 2014, the DOJ and HHS recovered $3.3 billion via federal health care fraud enforcement activities.

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Scenes From a Revolution: Laboratories Focus on Patients, Data, Technology and Strategic Partnerships

A revolution was plotted in Orlando this month. Over the course of four days, laboratory executives, pathologists, consultants, industry experts and others joined to discuss the challenges and opportunities facing the laboratory industry. Common themes emerged including patient engagement, harnessing the power of data and improving information management and sharing, strategic partnerships and arrangements, and making the most of new technology. Pressure breeds innovation and a change in thinking, explained Neal Thornberry, Ph.D., a presenter at the conference and author of *Innovation Judo: Disarming Roadblocks and Blockheads on the Path to Creativity*, of which all attendees received a copy. Thus, reimbursement and regulatory pressures on laboratories are generating new ways of thinking and doing business.

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DOJ/HHS enforcement flourishes, *from page 1*

That amount brings the lifetime total recovery for the HCFAC program to $27.8 billion. The release also claims that for the period 2012-2014, the agencies' return on their investment is $7.70 per dollar spent to fight health care related fraud and abuse. This is a rolling average to account for the variation in the amount and type of cases resolved each year which impacts annual ROI. The agencies claim this is the third-highest return on investment ever for the program and $2 above the average ROI for the program.

Attorney General Eric Holder had praise for the enforcement efforts of HCFAC in the press release issuing the report: "As the innovative and collaborative work of the Health Care Fraud and Abuse Control Program proceeds, more taxpayer money is being recovered, more criminals are facing justice, and more fraud is being punished, prevented, and deterred." The DOJ and HHS credit HCFAC's success to 1) a more proactive strategy promoted by the Affordable Care Act to prevent fraud and abuse before it occurs rather than "pay and chase" which requires recovering sums already paid out and later determined to be fraudulently solicited; and 2) the Health Care Fraud Prevention and Enforcement Action Team, better known as HEAT, which the HHS's Office of Inspector General and the DOJ run together using real-time data analysis, increasing the speed of the investigation, enforcement and prosecution process.

Enforcement numbers

DOJ health care enforcement activities in 2014:

- 924 new criminal investigations
- 496 cases/805 defendants charged with health care related crimes
- 734 convictions
- 782 civil investigations
- 957 pending civil cases at end of year

OIG health care enforcement activities in 2014:

- 867 criminal actions involving Medicare/Medicaid based on OIG investigations
- 529 civil actions (false claims, unjust enrichment, civil monetary penalties, and administrative recoveries)
- 4,017 exclusions (including 1,310 for crimes involving Medicare/Medicaid and 432 for crimes involving other health care programs; the remainder involve patient abuse or neglect, licensure revocations).

FBI health care enforcement activities in 2014:

- 602 health care fraud investigations begun
- 730 criminal health care fraud convictions resulting from FBI investigations
- 849 indictments and informations relating to FBI investigations
- 605 criminal fraud organizations' operations disrupted
- more than 140 criminal health care fraud entities "dismantled"
- 2,771 pending investigations

A little help from their friends

DOJ and HHS credit not only HEAT but other government programs for the continued enforcement success. For example, the report notes efforts of the Medicare Strike Force which DOJ and HHS expanded into nine more geographic areas including Brooklyn, Miami, Los Angeles, Dallas and Chicago. Strike Force's aggregate achievements since its creation are indeed striking: 963 cases against 2,097 defendants, seeking return of $6.5 billion in Medicare billings; 1,443 guilty pleas and 191 convictions with 1,197 sentenced to an average of 47 months jail time. In 2014, the DOJ opened 924 new investigations, prosecutors filed charges in 496 cases against 805 defendants and 734 defendants were convicted.

The DOJ/HHS report also cites the False Claims Act as an effective enforcement tool responsible in 2014 alone for garnering $2.3 billion in settlements and judgments in civil fraud and abuse claims involving Medicare and Medicaid and other federal health care programs. That brings the total recovered since 2009 to $15.2 billion (federal losses only). Separate state

program enforcement efforts also received help from these prosecutions in recovering billions of dollars. The report indicates 782 new investigations were begun in 2014 under the False Claims Act.

"The government alleged that the lab . . . submitted false claims to federal health care programs for medically unnecessary quantitative urine drug tests referred to it by the treatment clinic."

Proactive fraud prevention activities

Fraud prevention measures were also lauded in the report, including provider enrollment provisions and revalidation of existing suppliers and providers—to ferret out improper enrollees who aren't legitimate providers. Through these efforts 470,000 enrollees were deactivated and 28,000 enrollments were revoked. A revoked enrollee can't re-enroll for 1-3 years.

Also another preventive measure the report highlights is use of a Fraud Prevention System similar to that used by credit card companies to "apply advanced analytics to all Medicare fee-for-service claims on a streaming, national basis." It "identifies aberrant and suspicious billing patterns which in turn trigger actions that can be implemented swiftly to prevent payment of fraudulent claims," saving $210.7 million in its second year (almost doubling the first year's achievement).

Enforcement examples involving laboratory services

Some of the cases resolved in 2014 and highlighted in the report include laboratory services. For example:

- A $15.8 million settlement in February 2014 with a clinical laboratory and two physicians owning addiction treatment clinics relating to alleged fraudulent urine testing and False Claims Act violations. "The government alleged that the lab … submitted false claims to federal health care programs for medically unnecessary quantitative urine drug tests referred to it by the treatment clinic." The lab also allegedly sought higher reimbursement by misidentifying the class of drug being tested for. The settlement included a five-year Corporate Integrity Agreement (CIA) for the laboratory which required "substantial internal compliance reforms" and third-party claims review.
- Another settlement, for $4.7 million, relating to alleged false claims relating to unnecessary urine drug testing with a Massachusetts lab in May 2014.
- A $5 million settlement with a Texas laboratory regarding alleged violations of the Civil Monetary Penalties Law for submitting claims with modifier 59, billing for multiple units of a drug test when only one unit could be billed for each patient visit, and billing urinalysis codes for screening tests. That settlement also involved a five-year CIA.

Source

Annual Report of the Departments of Health and Human Services and Justice, Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2014 (March 19, 2015).

Takeaway: Laboratories and other providers beware: Despite sequestration fueled funding cuts, the DOJ and HHS report their enforcement efforts have been vigorous and financially successful in terms of their return on investment. G2

Scenes from a revolution, *Continued from bottom of p.1*

Hospital outreach and molecular diagnostics

The conference began with two workshops—the first focusing on hospital outreach and case studies that gathered data about current outreach programs, highlighting strategies, structures, problems encountered and successes. Some takeaways were that successful programs have control of their IT operations and interfacing capability, reduced expenses and reputations for service. Dr. Steven G. Brodie and Dr. Gyorgy Abel followed up with presentations on molecular diagnostics and new and more affordable technology arriving for sequencing. The caveat is that while the equipment may be more affordable, related data management and bioinformatics issues and explaining the clinical relevance can still present challenges.

Power to the patients

Opening keynote speaker Harry Greenspun, M.D., Director of Deloitte's Center for Health Solutions, noted the consumer is increasingly bearing more of the cost of health care and focuses more on the service aspect of the health care. He emphasized the need for laboratories to give the patient information that will allow them to make better choices about health care and the importance of gathering data and using it to make decisions about population health. He also queried whether health care providers are looking at the right data concerning patients and noted the relevance and value of data about purchasing habits, finances and other aspects of daily life that can inform health care delivery. Several other speakers carried this theme of patient engagement throughout the conference.

Using and sharing information the right way

Discussion of data and information sharing permeated the entire conference. Speakers consistently emphasized the value of data—in helping physicians and patients with health care decision making but also for allowing laboratories to demonstrate their value to potential partners and payers. Much discussion surrounded the ways data is used and the way information is shared with physicians and others in the health care delivery system. Speakers emphasized the need to find ways to clearly convey information gained from test data to physicians and patients.

Innovation in technology and affiliations

Other speakers focused on business and operational strategies that have proven successful for some laboratories trying to respond to the challenging reimbursement and regulatory environment. Discussions addressed strategic partnerships and affiliations as well as new technologies such as next generation sequencing, specialized testing, lab automation, blood products, managing sepsis, quality control and general business strategies. See the March 24 issue of *Lab and Pathology Insider* regarding Quest Diagnostic's lab of the future which was detailed during the conference.

Creating a *PathForward*

Themes of patient engagement and the importance of data carried through to the last day which focused on issues for pathology groups. Strategic mergers, acquisitions and business models demonstrated how pathology groups are responding to market changes. Reiterating the importance of patient involvement, two

speakers discussed ways for pathologists to engage directly with patients and the benefits of doing so for the patient and the health care delivery system. Finally, the event ended with a discussion of pathology and laboratory reimbursement and how ACO models are being implemented.

Takeaway: Through regulatory and reimbursement uncertainty, laboratories are finding ways to revolutionize their industry, creating opportunities from disruptive changes in their environment. If you missed the Lab Revolution, you still have an opportunity to network and learn with your colleagues at Lab Institute 2015, The Big Reset: Compete and Win in the Emerging Value-Driven Market, in Washington, D.C., October 14-16, 2015. G2

MedPAC Issues Recommendations for Medicare Payment Issues

The Medicare Payment Advisory Commission (MedPAC) has issued its annual report to Congress recommending updates and changes to Medicare payment policies. The report's Executive Summary identifies its focus as "the Commission's recommendations for the annual payment rate updates under Medicare's various [fee-for-service] FFS payment systems and aligning relative payment rates across those systems so that patients receive efficiently delivered, high-quality care."

Spending analysis

The 14-chapter report, *March 2015 Report to the Congress: Medicare Payment Policy*, provides analysis of Medicare and overall health care spending and how it affects federal health care program spending; "trends in enrollment, plan offerings, and payments in Medicare Advantage plans"; and trends in prescription drug plan enrollment and plan offerings.

The report cites an oft-noted trend in Medicare spending—while spending per beneficiary has slowed to an increase "of less than 1 percent per year on average," the overall Medicare spending "is projected to increase 5 percent to 7 percent annually over the next decade as the baby-boom generation ages into Medicare." Compounding the costs generated by the increase in beneficiaries from the current 54 million to a projected 80 million in 2030 is the fact that many beneficiaries have multiple chronic conditions.

Managing fee-for-service while it remains

In some areas, the report relies on prior recommendations or recommends no new payment update for 2016. For example, it reiterates prior recommendations for hospital inpatient and outpatient and home health. It also did not recommend any update for inpatient rehabilitation facility (IRF) services or ambulatory surgical center (ASC) payment rates for 2016. As to ASCs, the commission noted that it could not "calculate a Medicare Margin" and assess payment adequacy because ASCs do not report cost data relating to ASC services for Medicare beneficiaries. So it recommended CMS "begin collecting cost data from ASCs without further delay."

The report indicates payment reform and delivery-system reform are both necessary to address the problem that fee-for-service payment models reward the provision of more services regardless of the value of those services. MedPAC calls for

monitoring of new delivery models such as ACOs, medical homes and bundling but acknowledges that fee-for-service will remain in some form for some period of time and thus must "be managed carefully." Noting that change will come slowly, MedPAC's report warns: "This fact alone makes unit prices—their overall level, the relative prices of different services in a sector, and the relative prices of the same service across sectors—an important topic. In addition, constraining unit prices could create pressure on providers to control their own costs and to be more receptive to new payment methods and delivery system reforms."

The report recommends that HHS "[a]djust payment rates for certain services provided in HOPDs so that they more closely align with the rates paid in physician offices for certain select services."

Adjusting the site of service incentives

A major theme throughout the recommendations addresses differing payments depending on the site of service. Hoping to provide a disincentive for providers to shift services to more highly reimbursed sites of service, MedPAC espouses site-neutral payments.

Specifically recognizing the difference in payment rates for services rendered in a hospital out-patient department (HOPD) versus a physician office, and the incentive that difference creates for hospitals to acquire physician offices and then convert them to HOPDs, the report calls for uniform payment rates. The report recommends that HHS "[a]djust payment rates for certain services provided in HOPDs so that they more closely align with the rates paid in physician offices for certain select services."

And with regard to post acute care, MedPAC notes reform will take time as data is collected under the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. Therefore, it recommends that HHS develop site-neutral payments between IRFs and skilled nursing facilities (SNFs) for specific conditions. Specifically, the Commission recommends that the IRF base rate match the average SNF payment per discharge for the condition and implement this policy over three years.

SGR must go

Addressing the sustainable growth rate (SGR) formula, the fact that the 21.2 percent fee cut is due to take effect this April and the prior years' reductions have not been made, the Commission "reiterates its long-standing position that the SGR should be repealed" and emphasizes that "[t]he budgetary cost of repeal remains near historic lows, providing a clear opportunity." The Commission recommends the following SGR reforms:

- implement a 10-year plan of legislative updates instead of the SGR (and "higher updates for primary care services than for other services");
- "[c]ollect data to improve the relative valuation of services";
- "[i]dentify overpriced services and rebalance payments";
- incentivize ACO participation by "creating greater opportunities for shared savings."

MedPAC's entire report can be reviewed on its website at www.medpac.gov.

Takeaway: Opposition to SGR continues and neutral site-of-service payments are promoted to fix incentives that increase costs. G2

CMS Introduces Next Generation of ACOs

Playing on some terminology very familiar to laboratories, the Center for Medicare and Medicaid Innovation Center (CMS Innovation Center) has announced a new accountable care organization (ACO) model titled the "Next Generation ACO Model" as part of its continuing efforts to coordinate care and reduce costs. While the new model has nothing to do with next generation sequencing technology or precision medicine, like precision medicine, it does afford some personalization or tailoring to meet the specific needs of participating ACOs. In this next generation of ACOs, the ACO can pick the level of risk best for their organization with the goal being an increased level of risk while maintaining stable benchmarking. "This model is part of our larger effort to set clear, measurable goals and a timeline to move the Medicare program—and the health care system at large—toward paying providers based on the quality, rather than the quantity of care they give patients," said U.S. Department of Health and Human Services Secretary Sylvia M. Burwell, in the press release announcing the Next Generation ACO Model.

Structure and goals

The Next Generation model includes higher risk levels and consequently also higher potential rewards. Benchmarking will be initially set based on a year of historical expenditures then will shift to using regional projections regarding trends, a risk adjustment step and then finally a discount applied based on "quality and efficiency adjustments." The discount is based on quality, and regional and national efficiency, and can range from .5% to 4.5%.

Additionally, the model includes four payment methods including capitation (available in 2017) but participants aren't required to choose the capitation payment method. The other three payment models are fee-for-service, fee-for-service with a monthly infrastructure payment and population based payment. "This ACO model responds to stakeholder requests for the next stage of the ACO model that enables greater engagement of beneficiaries, a more predictable, prospective financial model, and the flexibility to utilize additional tools to coordinate care for beneficiaries," said Patrick Conway, deputy administrator for Innovation and Quality and chief medical officer for CMS, in the press release.

The model provides the following methods for achieving its goals:

- beneficiary choice is preserved—they don't have to stay within the ACO for services;
- beneficiaries are rewarded for choosing providers within the ACO for their health care services (rewards for obtaining a specific percentage of care from Next Generation ACO providers; for example, a projected reward is $50/year if the beneficiary has 50% of patient encounters with ACO providers);
- "coverage of skilled nursing care without prior hospitalization";
- more telehealth and post-discharge home services covered; and
- beneficiary ability to discuss care preferences with providers directly.

The ACOs will need a compliance officer and a CMS-approved compliance plan. CMS will share Medicare data to allow coordination and quality improvement and will provide reports that may include benchmarking, utilization, expenditures, and beneficiary alignment.

Applications

CMS will accept applications for the Next Generation ACO Model in 2015 and 2016. For the first round of participation, a letter of intent must be submitted by May 1, 2015, and applications submitted June 1, 2015. Round 2 deadlines are the same dates in 2016. CMS anticipates 15-20 participants in this model and the duration is for five years—an initial three-year period with an option for two one-year extensions—with a minimum of 10,000 aligned beneficiaries.

For more information on the Next Generation ACO Model, please visit CMS's Next Generation ACO Model web page. Questions regarding this model can be directed to CMS at nextgenerationacomodel@cms.hhs.gov.

Getting a better understanding

CMS held an Open Door Forum to discuss this new model on March 17 which was repeated on March 24, providing an overview of the model. You can review the forum presentation slides and other additional information on CMS's Next Generation ACO web page. Future Open Door Forums will be held on the following dates: March 31, 2015, at 4-5 p.m. EST (focusing on the financial methodology of the ACO model); April 7, 2015, from 4-5 p.m. EST (addressing benefit enhancements and beneficiary care coordination rewards); April 14, 2015, from 4-5 p.m. EST (discussing letters of intent and the application process). Information about attending these forums or reviewing slide presentations from the forums is available on the web page.

Relevance for laboratories

CMS's continuing development of ACO models signals the anticipated importance for these models in shifting from volume to value. G2 Intelligence's report *Laboratory Services in Accountable Care Organizations* reveals that interviews with industry experts indicate "ACOs will continue to grow in counts, covered lives, and reach" and that commercial ACOs may "grow more rapidly and potentially outpace government ACOs." The development of yet another option for providers seeking to participate in ACOs may be further evidence supporting this prediction. The Report also notes that research indicates laboratory participation in ACO discussions influences the perception of the value of laboratory services in ACOs. G2 Intelligence's ACO report thus advises laboratories to review options for ACO participation and in order to increase their value to potential ACO partners, to consider the following recommendations:

- "Engage more actively in value initiatives across the care continuum,
- Develop metrics to quantify laboratory value contribution,
- Be proactive in approaching ACOs, and
- Get a seat at the table early."

Takeaway: ACO models continue to proliferate and are obviously a favored means of CMS for achieving a shift from volume-based to value-based reimbursement. Thus, laboratories not already considering ACO participation or affiliation may be wise to start investigating these options.

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