G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

NATIONAL INTELLIGENCE REPORT™

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 36th Year of Publication

Vol. 15, Iss. 16, September 10, 2015

INSIDE THIS ISSUE

www.G2Intelligence.com

CMS Reports Latest ACO Performance Results Demonstrate Continuing Success

CMS announced that 2014 quality and financial performance results demonstrate the power of coordinated health care delivery via Affordable Care Organizations (ACOs). The performance data reveals more than $411 million was saved by 20 Pioneer and 333 Shared Savings Program ACOs and 97 ACOs qualified for an aggregate of $422 million in shared savings payments by meeting required thresholds for quality and savings. "These results show that accountable care organizations as a group are on the path towards transforming how care is provided," said CMS Acting Administrator Andy Slavitt in a statement. "Many of these ACOs are demonstrating that they can deliver a higher level of coordinated care that leads to healthier people and smarter spending."

Factors considered in evaluating ACO performance include how patients rate their physicians, "how well clinicians communicated," whether certain screenings are performed and how they use electronic health records. Pioneer ACOs improved in 28 of 33 quality measures and Shared Savings Program ACOs improved on 27 of 33 quality measures.

Continued on page 2

AHRQ Funding Cuts Threaten Evidenced-Based Testing Advances

In what has been called a "devastating attack on health research funding," this summer a U.S. House of Representatives panel approved a spending bill that would eliminate the Agency for Healthcare Research and Quality (AHRQ), while the corresponding Senate Appropriations Committee cut the agency's budget by approximately 35 percent. The agency's elimination would be felt across the health care system, including in the diagnostics industry, where the agency has been active in conducting technology assessments of emerging genetic tests, evidence-based research on effective screening strategies and testing modalities, as well as through its work to improving patient safety by reducing diagnostic errors, through information technology applications to enhance the testing process.

"Americans deserve reliable information on how to deliver the best possible care, at the greatest value, with the best outcomes. AHRQ-funded health

Continued on page 5

CMS Reports Latest ACO Performance Results Demonstrate Continuing Success, *from page 1*

Pioneer ACOs have demonstrated steadily increasing success with $120 million in savings for the third performance year of that ACO model, a significant increase from the prior years' $96 million, and $88 million in the first performance year. Only five Pioneer ACOs generated losses, with only three of those losing enough to owe shared loss payments to Medicare totaling $9 million.

For example, Montefiore Health System reported 3.6 percent in gross savings for its Pioneer ACO in 2014 and achieved a quality score of 86.21 percent, with overall quality scores rising 10 percent from the prior year. Banner Health Network announced it experienced its "best-ever result" in its third performance year, reporting it exceeded predicted benchmarks by $29 million in savings, yielding a 5 per cent savings in cost of care for 2014. It also raised its quality score almost 10 percent from the prior year.

These results bear out predictions in G2 Intelligence's report *Laboratory Services in Accountable Care Organizations* which reported "Medicare Pioneer ACOs that generated savings in the first year reported greater savings in the second year, suggesting that successful ACOs will likely become more effective over time."

Among Shared Savings Program ACOs, 92 ACOs controlled spending enough to qualify for an aggregate of $341 million in performance payments and the program saved Medicare $465 million. No ACOs in the second phase, which includes financial risk sharing, owed any loss payments to CMS.

Predicting further growth in its ACO programs, CMS notes that as of January 1, 2015, there were more than 420 Medicare ACOs serving in excess of 7.8 million beneficiaries. G2 Intelligence's report similarly predicts increasing ACO penetration noting historically steady growth "from 46 [ACOs] in 2010 to 664 in August 2014."

For further assessment of the ACO market landscape, the outlook for future growth and the laboratory's role in ACOs, see G2 Intelligence's report *Laboratory Services in Accountable Care Organizations*.

Takeaway: Data on performance of ACOs continues to emphasize benefits of coordinated care and ability to provide cost savings.

CMS Reports 2014 Savings for Pioneer and MSSP ACOs

2014 Pioneer ACO Data	2014 Medicare Shared Savings Program ACO Data
Number of ACOs: 20	Number of ACOs: 333
Number of ACOs generating savings: 15	Number of ACOs generating savings: 181
Number of ACOs earning shared savings: 11	Number of ACOs earning performance payments: 92
Total amount of shared savings earned by participants: $82 million	Total amount of shared savings earned by participants: > $341 million
Number of ACOs owing shared losses: 3	Number of ACOs owing losses: 0
Total amount of shared losses owed: $9 million	Amount of losses owed: $0.00

Source: Centers for Medicare & Medicaid Services

OIG Says Most COOP Health Plans Are Underperforming

The communes and the co-ops of the 1960s are now mostly a distant memory. And it could soon be that way for many of the COOP health plans mandated by the Affordable Care Act (ACA) and currently offering coverage in many states.

The Office of the Inspector General (OIG), has concluded that many of the consumer-oriented and operated plans have fallen far short of their projected financial performance. In a recent report, it surveyed the finances of 23 COOPS that have been operating throughout the United States. They were established under the ACA with the intent of creating non-profit competitors in regions of the country where larger commercial health plans tend to predominate. The Centers for Medicare & Medicaid Services have granted COOPs $2.4 billion in short-term and long-term loans to get them operating. "Loans were to be awarded only to entities that demonstrated a high probability of becoming financially viable," the OIG said in its report.

> *"Most of the (COOPs) we reviewed had not met their initial program enrollment and profitability projections as of December 31, 2014."*
>
> — OIG Report

The COOPs, like other commercial health insurers, cover basic laboratory and pathology services at negotiated rates.

One COOP in Iowa and Nebraska, CoOportunity Health, was taken over by state regulators late last year and is currently in the process of being liquidated. It had reported losses through the third quarter of last year of nearly $40 million—the highest of any COOP. Altogether, the plan had about 120,000 covered lives, all of whom will have their coverage terminated at the end of August if they did not switch health plans. Another COOP, the Louisiana Health Cooperative, announced that it would exit the market at the end of this year.

COOPs have struggled with enrollment, which nationwide have reached less than 600,000, a fraction of the 8 million Americans who enrolled in coverage through state health insurance exchanges last year, according to the ratings agency A.M. Best. It issued a report earlier this year expressing concern that some of the COOPs were at risk of becoming financially impaired—a sentiment echoed in the more recent OIG report.

"Most of the (COOPs) we reviewed had not met their initial program enrollment and profitability projections as of December 31, 2014 ... specifically, member enrollment for 13 of the 23 CO-OPs that provided health insurance in 2014 was considerably lower than the COOPs' initial annual projections, and 21 of the 23 co-ops had incurred net losses as of December 31, 2014," the OIG said in its report. It noted that some COOPs suffered as a result of the technical issues connected with the launch of the healthcare.gov exchange. Others also had issues obtaining licenses to actually sell insurance—in one case, a COOP received its license just days before the open enrollment period, and therefore could not offer its plan on the state health insurance exchange.

Patrick Kelly, a senior auditor with the OIG, said in a podcast that half of the CO-OPs had less than 50 percent of their projected enrollment, while five of them had less than 10 percent of their projected enrollment.

The nine COOPs that exceeded their enrollment projections did so primarily because they offered competitive premiums, according to the OIG.

The OIG recommended that the CMS place underperforming COOPs under enhanced oversight and establish corrective action plans; work with state regulators to identify COOPS that are underperforming and provide assistance; and provide specific guidelines to determine when a COOP is no longer financially viable.

Some COOP plans have also decided to take greater initiative in building their enrollment, announcing plans to lower rates and offer coverage to individuals outside of the state insurance exchanges.

Takeaway: It has been a rocky financial start to most of the nation's consumer-oriented and operated health plans. G2

Coordinated Care Projects Continuing to Blossom Nationwide

The U.S. healthcare system is continuing to take the leap into value-based care wholesale, with large medical groups, big payers and even entire states recently entering into initiatives.

> *"Through this landmark partnership, we'll make it possible for independent physicians to participate in value based care in a meaningful way."*
>
> — Opella Ernest, M.D., Chief Medical Officer, Blue Cross Blue Shield

Such efforts mean more sharing of medical records and laboratory tests among more providers, placing greater pressure on the sector to provide more accurate results. In Illinois, Chicago's largest independent practice, DuPage Medical Group, is teaming with Blue Cross and Blue Shield of Illinois to create BCBSIL Practice Advance, which is expected to provide more coordinated care in order to improve quality and cut costs. Officials also noted that the collaborative will make it easier for independent doctors to switch over to a value-based model of care.

"Through this landmark partnership, we'll make it possible for independent physicians to participate in value based care in a meaningful way," said Opella Ernest, M.D., Blue Cross Blue Shield's chief medical officer, in a statement.

Meanwhile, in Rhode Island, the entire state is teaming with the Centers for Medicare & Medicaid Services (CMS) to provide more coordinated care to the state's dual-eligible population, those Medicare enrollees who also are eligible for Medicaid. Such a population typically requires far more care than enrollees in either just the Medicare or Medicaid program. The initiative is an extension of the state's Rhody Health Options, its capitated Medicaid managed care program. The demonstration project is expected to enroll as many as 30,000 lives, officials said.

In Ohio, five of the Buckeye State's largest independent physician practices—Community Health Care, Northern Ohio Medical Specialists, Pioneer Physicians Network, Premier Physicians and Unity Health Network—have joined forces to create the Ohio Independent Collaborative (OIC). The OIC will offer enrollees more coordinated care at a lower cost and higher quality. It will serve more than 450,000 patients throughout much of the state.

"The (OIC) creates a high-quality new care option in the marketplace for patients, insurance providers and hospitals, allowing our members to develop strategic partnerships that, on their own, they would not be able to develop," said Tony Paras, M.D., of Premier Physicians, in a statement.

Takeaway: A variety of coordinated care projects are continuing to be launched across the United States. G2

AHRQ Funding Cuts Threaten Evidenced-Based Testing Advances, *Continued from bottom of p.1*

services research provides those answers," wrote Friends of AHRQ, a coalition of advocates from 250 organizations, in a letter to Congress, on behalf of the agency. The $465 million from defunding AHRQ would be reallocated to the National Institutes of Health (NIH) for disease-specific projects, such as Alzheimer's research ($300 million in new funds), $100 million for NIH's contribution to a federal antibiotic resistance initiative, and $200 million for President Barack Obama's Precision Medicine Initiative. (The budget for the Patient-Centered Outcomes Research Institute (PCORI), which was created by Congress under the Affordable Care Act for comparative effectiveness research, was also slashed by $100 million by the House.)

While creating significant alarm throughout the field of health services, the FY 2016 cuts to AHRQ are not final and will be reconciled by the House and Senate during fall conference negotiations. Evidenced-based medicine has become a partisan issue, as its funding is in part tied to 2009 stimulus legislation and the Affordable Care Act. Furthermore, evidenced-based findings are often seen as a threat to the revenue stream of some health industry stakeholders. But AHRQ critics also argue that the agency's work duplicates efforts of other groups, including the NIH and PCORI.

"PCORI is focused on funding comparative effectiveness research, trying to figure out whether in practice treatment A works better than treatment B," says AHRQ Director Richard Kronick, Ph.D., in an August interview with *JAMA*. "We complement PCORI's focus ... [as] we continue to fund research into how physicians and hospitals can quickly put PCORI's discoveries into practice."

Supporters say, however, that unlike other agencies working on new medical discoveries, AHRQ research centers on cost, quality, and safety of care delivery. While defunding AHRQ would wreak havoc in medical research, experts say the agency is needed to ensure investments in new technologies are effectively used throughout the health care system. The challenge, even AHRQ supporters admit, is that while the agency's work is for the public good, the nature of its work makes it difficult to generate public enthusiasm or dominate headlines, as it lacks the pizazz of Ebola vaccines and emerging cancer treatments.

"Our nation spends more than $3 trillion annually on health care ... [but research] tells us too many patients receive sub-optimal, unsafe, and even harmful care. We can do better, and health services research tells us how," says Lisa Simpson, CEO of AcademyHealth, a national organization representing the field of health services research. "Investments in discovery and development will fall short if we don't have research on how best to deliver them to the right patients, at the right time, and in the right setting."

AHRQ had asked for $479 million with stated priorities for FY 2016 to include: improve health care quality and safety, increase accessibility and affordability, and improve health care efficiency and cost transparency.

"The appropriated budget of the agency is about 1/100th of 1 percent of national health spending," said Kronick in the *JAMA* interview. "The return on investment from this 1/100th of 1 percent is very large, as evidenced by recent reports on quality of care and patient safety."

Takeaway: AHRQ research efforts face threat of elimination despite its role in assessing effectiveness and value of health care delivery. G2

FTC Issues Guidance on Unfair Competition Enforcement

While experts have not proclaimed it an overwhelmingly helpful resource, the Federal Trade Commission (FTC) released a *Statement of Enforcement Principles Regarding "Unfair Methods of Competition" Under Section 5 of the FTC Act* (Statement). The Statement issued earlier this month sets forth three principles addressing how the FTC enforces Section 5 of the FTC Act prohibiting unfair competition. The FTC explains that Section 5 takes FTC's enforcement reach beyond violations of the Sherman and Clayton Acts to encompass activities "that contravene the *spirit* of the antitrust laws and those that, if allowed to mature or complete, *could* violate the Sherman or Clayton Act." (Emphasis added).

The Sherman and Clayton Acts are antitrust laws that prohibit activity that restrains trade and address potential for such restraint posed by monopolies, exclusive contracts, mergers and acquisitions and certain contracting arrangements. The FTC notes that Congress left it to the commission, "an expert administrative body," to interpret and apply Section 5 on a "case-by-case basis" so that enforcement could "evolve with changing markets and business practices." The Statement expresses three principles that will guide FTC enforcement of the unfair competition prohibition in Section 5:

- A public policy supporting protection of consumer welfare.
- A rule of reason analysis that considers whether the activity will "cause, or [be] likely to cause, harm to competition or the competitive process, taking into account any associated cognizable efficiencies and business justifications."
- A violation is "less likely" to be found if the Sherman or Clayton Act "is sufficient to address the competitive harm."

In an address last month at the Competition Law Center, George Washington University Law School, FTC Chairwoman Edith Ramirez called the issuance of the principles a "milestone" and confirmed her preference for a "case-by-case" approach to enforcement rather than specifically enumerating "precisely what conduct is prohibited." It would be "nearly impossible to describe in advance all of the conduct that may threaten competition or the competitive process in our dynamic economy," she explained.

While the FTC asserted that the principles "are ones on which there is broad consensus," Commissioner Maureen K. Ohlhausen issued a dissenting statement objecting to the issuance of "*this* policy statement in *this* manner"—claiming it is "too abbreviated in substance and process" and "provides more questions than answers, undermining its value as guidance." (Emphasis in original) Ohlhausen also criticized the lack of public input from stakeholders and the lack of reference to prior court decisions regarding unfair competition cases or examples of "either lawful or unlawful conduct to provide practical guidance" on how the law will be enforced.

Takeaway: The Federal Trade Commission has made a policy statement on unfair competition but the brevity and generality of the statement has stakeholders and industry experts questioning its value.

Federal Appeals Decision Addresses Unfair Competition Lawsuit Between Ameritox and Millenium

As we went to press, the Eleventh Circuit Court of Appeals ruled that a federal court didn't really have jurisdiction to hear state law claims of unfair competition in a lawsuit that led to a jury award against Millenium Health exceeding $12 million. The appeals court said that Ameritox's allegations really raised state law claims when it argued that point-of-care testing (POCT) cups Millenium supplied to referring physicians for free violated *state* unfair competition laws because those practices violated *federal* Stark and AKS law. The court didn't decide whether Millenium's provision of the POCT cups for free violated the Stark law or AKS or other state law or whether violations of the Stark and AKS should support claims of unfair competition under state law. We'll address this court decision in more detail in the next issue of *National Intelligence Report*.

Shift to Gene Panels to Assess Hereditary Cancer Risk Forges Ahead Despite Reimbursement Hurdles and Concerns About Clinical Utility

A virtually unlimited number of genes tied to hereditary cancer risk can be simultaneously assessed in commercially available tests given both advances in technology and the Supreme Court's two-year old ruling overturning gene patents. By screening multiple genes in parallel, research has shown that diagnostic yields are on the rise and time to results are down, with the added benefit of not adding much incremental cost for delivery of additional information.

As a result of all of these factors, there has been a noticeable uptick in clinical adoption of multigene panels to assess hereditary cancer risk. Yet, despite research heralding the effectiveness of these multigene panels' appearing in the literature, some clinicians are asking whether adoption is occurring prematurely, before there is a good understanding of the consequences of panel-based testing on clinical management of the patient and other potentially affected relatives.

Given the questions over the clinical utility of test results, it is no surprise that insurers often balk at paying for panel-based. ... Yet, industry watchers are hopeful that momentum is gaining for reimbursing these multigene panels.

"Many cancer genetics experts have again urged caution, characterizing the use of multigene testing in the clinical setting as premature. Yet thousands of women and their physicians are ignoring this advice, ordering a wide selection of multiplex tests daily," writes Elizabeth Swisher, M.D., from University of Washington, Seattle in an editorial in *JAMA Oncology* on Aug. 13. "The train has left the station and is unlikely to return. It is therefore critical that we assess the clinical utility of such testing."

While some appreciate the potential future importance of collection of more genetic data (as it can be reanalyzed as genetic understanding evolves), others view mega-panels that include low- to moderate-risk genes mutations as actually complicating clinical decision-making, since the clinical actionability of these results is less defined. Given the questions over the clinical utility of test results, it is no surprise that insurers often balk at paying for panel-based tests. While the industry is well aware of the need to generate evidence of clinical utility, there remains scant evidence as to the cost effectiveness of panel-based testing.

Insurers, including the Centers for Medicare and Medicaid Services (CMS), are not yet convinced of the benefit of paying for panel-based testing, according to a research note published May 28 by senior research analyst William Quirk at Piper Jaffray & Co. CMS published preliminary gap fill rates for sequencing-based panels well below current reimbursement levels calculated using stacking of Current Procedural Terminology (CPT) codes. Of the 21 next-generation sequencing-related CPT codes, which were designed to improve transparency in reimbursement, only four were priced using preliminary gap fill payment. Of the four priced tests, targeted sequencing panels (of five to 50 genes) were priced by only a single Medicare administrative contractor. Quirk called the pricing for the panel "surprising." Quirk cites industry sources saying that there is "little reimbursement traction from private payers" as well, with most tests billed under the new codes denied payment.

Yet, industry watchers are hopeful that momentum is gaining for reimbursing these multigene panels. In mid-August a multi-stakeholder group convened by the Center for Medical Technology Policy (CMTP, Baltimore, Md.) recommended coverage for sequencing panels of 5-50 genomes if they include a subset of constituent genes that

are considered to be standard-of-care and medically necessary for the patient. The groups says such reimbursement is necessary to advance personalized medicine for cancer. CMTP focuses on comparative effectiveness and patient-centered outcomes research. The group, which included sequencing testing and technology companies, medical professional societies, patient advocacy groups, and leading health plans, also recommended that payers rely on the College of American Pathologists accreditation program and proficiency testing to assure the analytic validity of sequencing tests, as well as a proposal for payers to cover larger, even more comprehensive panels with preauthorization under circumstances of "extenuating medical need." Additionally, the group's recommendations call for proposals to incentivize laboratory and clinician sharing of data, to promote patient participation in clinical trials and registries.

Takeaway: Despite reimbursement hurdles and the need to study the effect panel-based testing has on clinical care, panel-based testing for heritable cancer risk will continue to gain momentum. G2

Laboratory Data and Interoperability to be Focus of FDA Workshop

Recognizing that laboratory tests "influence between 70 to 80 percent of clinical decisions," the U.S. Food and Drug Administration (FDA) , Centers for Disease Control and Prevention (CDC) and the National Library of Medicine (of the National Institutes of Health) are holding a public workshop Sept. 28, 2015, to improve ease of sharing laboratory data. The agencies seek public input on "promoting semantic interoperability of laboratory data between in vitro diagnostic devices and database systems." Also at issue are the standards for reporting laboratory data and models for interoperability.

The full-day workshop will include discussion regarding use of Logical Observation Identifiers Names and Codes (LOINC), uniform Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT), Unified Code for Units of Measure (UCUM), Unique Device Identifier (UDI) codes, Structured Product Labeling (SPL) and Electronically Exchanging Directory of Services (eDOS). The FDA indicated a discussion paper with more detailed discussion of the workshop's subject matter will be released online before the workshop.

Brief presentations to establish parameters for the discussion will be followed by interactive panel discussions and opportunity for public comment. A streaming webcast of the workshop will also be available. Space for live and web attendance is limited. Attendance is free and first-come, first-serve but attendees must register by Sept. 18. Written and electronic public comments on the issues are also welcomed and are due by Oct. 26, 2015. More information can be found at the FDA website or the Notice published in the Aug. 3, 2015 Federal Register. G2

National Intelligence Report (ISSN 2332-1466) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320. Phone: 1-888-729-2315 • Fax: 1-855-649-1623. Web site: www.G2Intelligence.com.

Kelly A. Briganti, JD, Editorial Director, Kelly@plainlanguagemedia.com; Barbara Manning Grimm, Managing Editor; Lori Solomon, Contributing Writer; Ron Shinkman, Contributing Writer; Stephanie Murg, Managing Director; Kim Punter, Director of Conferences & Events; Randy Cochran, Corporate Licensing Manager; Michael Sherman, Director of Marketing; Jim Pearmain, General Manager; Pete Stowe, Managing Partner; Mark T. Ziebarth, Publisher.

Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 1-888-729-2315.