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Analytics Fuel the Business of Enforcement

The value of analytics is often discussed in connection with improving business but it has also been used to improve fraud enforcement and prevention as well. The Centers for Medicare and Medicaid Services (CMS) announced this month that its Fraud Prevention System (FPS), an "advanced analytics system," has uncovered $820 million in inappropriate payments. The FPS was established in the Small Business Jobs Act of 2010 to use "predictive modeling and other analytics technologies to find and avoid payment of improper Medicare claims." Using analytics in much the same way credit card companies do, the system finds "troublesome billing patterns and outlier claims." CMS indicated in a press release that it intends to use the system not just to identify and prosecute fraud but also to ferret out potential payment issues that are not necessarily the result of illegal intentions but could be "better served by education or data transparency interventions."

"We are proving that in a modern health care system you can both fight fraud and avoid creating hassles for the vast majority of physicians who simply want to get paid for services rendered. The key is data," Acting CMS Administrator Andy Slavitt said in a press release. Referring to the system's identification in 2014 of $454 million in improper payments, Slavitt declared: "Very few investments have a 10:1 return on taxpayer money."

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Happy 50th Birthday Medicare and Medicaid!

This month, Medicare and Medicaid celebrate the big 5-0 on July 30. On that date in 1965, President Lyndon B. Johnson signed legislation establishing those federal health insurance programs. The anniversary has caused many to look back at the founding of the programs as well as the challenges ahead. "Today, Medicare and Medicaid are creating a health care system that is better, smarter, and healthier – setting standards for how care is delivered. As we take a moment to reflect on the past five decades, we must also look to the future and explore ways to strengthen and improve health care for future generations," said Andy Slavitt, acting administrator of the Centers for Medicare and Medicaid Services, in a statement.

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CMS explained that the analytics help spot potentially improper billing patterns and use information about past billing practices to find fraud. These "predictive models" helped CMS identify questionable payments to a podiatrist and an ambulance provider, for example. CMS Deputy Administrator and Director of the Center for Program Integrity Dr. Shantanu Agrawal emphasized the system's ability to facilitate a more proactive approach to fighting fraud: "The third year results of the Fraud Prevention System demonstrate our commitment to high-yield prevention activities, and our progress in moving beyond the 'pay and chase' model."

The OIG calculated a $2.84 return on investment for each dollar spent.

The Department of Health and Human Services Office of Inspector General was charged with certifying the savings achieved under the system and determining the return on investment. An OIG report released this month reviewed whether HHS properly reported savings from the use of analytics and whether use of the FPS should be continued, expanded or changed. That report indicates the system yielded more than $133 million in adjusted actual and projected savings for Medicare—$85 million from FPS-initiated administrative actions and $47 million from administrative actions in which an FPS lead "contributed to the existing investigation." Adjusted saving is the amount of identified savings that can actually be achieved. Administrative actions include payment suspension, referral to law enforcement, overpayment recovery, prepayment edits, automatic denials or rejections and even revocation of Medicare billing privileges. The OIG calculated a $2.84 return on investment for each dollar spent.

The OIG's 2015 report on the third year of the system's operation concluded that use of FPS does "enhance[] and should continue to enhance its efforts to prevent fraud, waste and abuse in the Medicare Fee-for-Service program" and it achieved a positive return on investment. However, the report indicates that HHS didn't find it "cost-effective and feasible, at this time" to expand use of predictive analytics in all 50 states "because of policy differences among programs," information technology readiness, resources, and data availability. The OIG also recommended that Medicare contractors be better informed about how to attribute FPS savings and document the impact of FPS leads on administrative actions.

Takeaway: New technologies and use of data benefit not only medical treatment and decisionmaking but detection and prevention of improper billing as well. G2

Another BLS Sentencing for Referral Payments

Yet another physician has been sentenced in connection with the Biodiagnostic Laboratory Services (BLS) case, yielding one of the longer sentences in the matter. Previously, we have reported up to two- and three- year sentences but July 8, a New Jersey physician was sentenced to over five years in prison for his role in an alleged fraud scheme. Frank Santangelo, of Boonton, New Jersey had pleaded guilty to Travel Act violations, money laundering and failing to file tax returns. In addition to prison, he also received three years supervised release and a $6,250 fine and $1.8 million forfeiture pursuant to his plea agreement.

The Department of Justice (DOJ) press release was notably more detailed with regard to this sentencing, describing some of the evidence used against Santangelo. The DOJ highlighted text messages used to implicate Santangelo, explaining that the physician had "acknowledged the authenticity" of texts between Santangelo and David Nicoll that referred to test orders. Nicoll was president and part owner of BLS and has also been charged in the case. One such cited message noted the testing was "90 percent legit." The DOJ also said the text messages referenced referral agreements and payments made under those agreements.

The government alleged Santangelo received over $1.8 million in bribes in exchange for referrals and BLS gained over $6 million in Medicare and private insurance payments relating to the referrals. As reported previously, the government also alleged sham lease and service agreements were used to facilitate payments.

"Santangelo's arrest and sentencing send the message the FBI and its law enforcement partners will continue to zealously investigate these fraud and abuse schemes, which divert critical resources from our already overburdened health care system and contribute exponentially to the rising cost of health care," said Special Agent in Charge Richard M. Frankel of the FBI's Newark office, in the press release announcing the sentencing. So far, 38 people including 26 physicians, have pleaded guilty in connection with the BLS investigation. The DOJ reports it has recovered over $11.5 million in forfeiture through these prosecutions.

Takeaway: Individual physicians continue to face significant consequences for receiving payments linked to laboratory referrals.

CMS Offers Physicians and Providers Help Prepping for ICD-10

With the transition to ICD-10 looming, the Centers for Medicare and Medicaid Services (CMS) and the American Medical Association issued a joint press release highlighting various educational resources for providers to help them prepare for the new codes for medical diagnoses and inpatient hospital procedures.

"As we work to modernize our nation's health care infrastructure, the coming implementation of ICD-10 will set the stage for better identification of illness and earlier warning signs of epidemics, such as Ebola or flu pandemics," said CMS Acting Administrator Andy Slavitt, in a press release. CMS also explained in its release that the ICD-10 codes are a much-needed update for diagnosis codes that are over 35 years old and ICD-10 should improve emergency response to "disease outbreaks and adverse drug events, as well as support innovative payment models that drive quality of care."

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>
> — Andy Slavitt, acting CMS Administrator

Among the resources CMS has provided to help physicians adjust to ICD-10:

- "Road to 10" – a web-based resource for small physician practices that includes a quick start guide, an interactive case study tool that quizzes providers on coding specific clinical scenarios—with new scenarios added weekly, specialty-specific tools, webcasts, videos and assistance in building an action plan for the transition.

- Training videos.
- Frequently Asked Questions that indicates there will be some flexibility to account for errors in coding under the new ICD-10 system.

CMS also plans to establish an ICD-10 Ombudsman to assist providers in the transition as well as a communication and collaboration center to monitor implementation. The agency promised guidance explaining how to submit issues and concerns to the Ombudsman.

A valid ICD-10 code will be required on all claims starting on October 1, 2015.

Pathologists and laboratories may gain some comfort from the news that CMS will offer a bit of a grace period while the industry adjusts to the new codes. The Frequently Asked Questions address coding errors and potential claim denials stating that "for 12 months after ICD-10 implementation, Medicare review contractors will not deny physician or other practitioner claims billed under the Part B physician fee schedule through either automated medical review or complex medical record review based solely on the specificity of the ICD-10 diagnosis code as long as the physician/practitioner used a valid code from the right family. However, a valid ICD-10 code will be required on all claims starting on October 1, 2015." (Emphasis omitted)

For 2015 program year quality reporting, physicians and other professionals won't be subject to penalties "related to the additional specificity of the ICD-10 diagnosis code" if an ICD-10 from the "correct family of codes" is used. No penalties will be imposed if "CMS experiences difficulty calculating the quality scores for PQRS, VBM, or MU due to the transition to ICD-10 codes" and CMS won't deny requests for informal review "based on 2015 quality measures if it is found that the EP submitted the requisite number/type of measures and appropriate domains on the specified number/percentage of patients, and the EP's only error(s) is/are related to the specificity of the ICD-10 diagnosis code (as long as the physician/EP used a code from the correct family of codes)."

AMA President Steven J. Stack praised CMS for its response to provider concerns that "inadvertent coding errors or system glitches during the transition to ICD-10 may result in audits, claims denials, and penalties under various Medicare reporting programs" and committed to working with CMS to help ease the transition to ICD-10.

Note too that CMS has provided a MLN Connect Video titled "Coding for ICD-10-CM: More of the Basics," highlighted in a recent MLN Matters article regarding CLIA Waived tests. The video includes presentations from American Health Information Management Association and American Hospital Association representatives and offers an introduction to ICD-10 coding and its unique characteristics as well as a comparison to ICD-9 coding.

Takeaway: Although adjusting to ICD-10 will create challenges, CMS is attempting to offer guidance and assistance to providers as they transition to the new coding system. G2

CMS Releases New CLIA-Waived Tests, Billing Codes

CMS notified contractors of new CLIA-waived tests effective July 1, 2015. There are 7 newly waived complexity tests, the latest approved by the FDA. The tests, listed in the table below, all require the QW modifier be attached to the CPT code for recognition as a waived test.

The following table provides a listing of the new CLIA-waived tests with their CPT Code, effective date and description.

CPT CODE	EFFECTIVE DATE	DESCRIPTION
83036QW	Sept. 23, 2014	Alere Technologies AS, Alere Afinion AS101 Analyzer
G0434QW	Nov. 13, 2014	Native Diagnostics International DrugSmart Dip Multi-Panel Drug Screen Dip Card with OPI 2000 Tests
G0434QW	Dec. 1, 2014	Chemton Biotech, Inc. Chemtrue Multi-Panel DOA Dip Card Tests
G0434QW	Dec. 1, 2014	Chemton Biotech, Inc. Chemtrue Multi-Panel DOA Dip Card with OPI 2000 Tests
87880QW	Dec. 17, 2014	Quidel Sofia Strep A+FIA (throat swab only)
G0434QW	Dec. 29, 2014	Clarity Diagnostics Multi-Panel Drug Screen Dip Card Tests
G0434QW	Dec. 29, 2014	Clarity Diagnostics Multi-Panel Drug Screen Dip Card with OPI 2000 Tests

That same transmittal notes that CPT Code 82055 was replaced by G6040QW. Therefore code G6040QW has been assigned to the following tests:

- Alere Toxicology Services, iScreen Saliva Alcohol Test Strip
- Alfa Scientific Designs Inc. Oral-View Saliva Alcohol Test Strip
- American Screening Corporation, Reveal Saliva Alcohol Test Strip
- Acon Laboratories Inc. Mission Saliva Alcohol Test Strip
- Chematics Inc. Alco-Screen Saliva Alcohol Test
- Chematics Inc. Alco-Screen 02 Saliva Alcohol Test
- CLIAwaived Inc. Rapid Saliva Alcohol Test
- Express Diagnostics International, Incorporated Saliva Alcohol Test
- Germaine Laboratories AimStrip Alcohol Saliva
- Jant Pharmacal Corporation Accustrip Saliva Alcohol Test Strip
- OraSure Technologies Q.E.D. A-150 Saliva Alcohol Test
- OraSure Technologies Q.E.D. A-350 Saliva Alcohol Test
- STC Diagnostics Q.E.D. A150 Saliva Alcohol Test
- STC Diagnostics Q.E.D. A350 Saliva Alcohol Test
- Teco Diagnostics Saliva Alcohol Test.

The CMS Transmittal announcing the latest FDA approved waived tests is Transmittal 3267, Change Request 9164, Pub. 100-04, dated May 22, 2015. The Transmittal and a complete list of CLIA waived devices is available on the CMS website in the Regulations & Guidance Tab, under Transmittals. Note that Contractors won't look for claims affected but are required adjust claims that are brought to their attention.

Hurdle for Whistleblowers Simplified in 9th Circuit

A new court ruling clarifies who can bring a whistleblower or *qui tam* action. The 9th Circuit revisited a decades old interpretation of a rule that barred whistleblower actions based on publicly disclosed allegations unless the person bringing the action was the original source of the information. Federal law defines an original source as someone with "direct and independent knowledge" of the facts and who "voluntarily provided the information to the Government before filing" the whistleblower action.

The case involved claims brought by two different employees relating to misuse of the KX modifier in billing for a wound healing device. The first whistleblower alleged the provider billed using the KX modifier without meeting the requirements for using that modifier. The second whistleblower also alleged the KX modifier was used when criteria weren't met and that the provider failed to get Detailed Written Orders before delivering the device and beginning treatment. These claims were initially denied because the court determined that the information on which the claims were based had already been publicly disclosed and the whistleblowers weren't the original source of the information.

Previously, the 9th circuit had interpreted the rule to require three criteria be satisfied to find a whistleblower plaintiff is an original source: 1) direct and independent knowledge of the relevant information; 2) voluntary submission of the information to the government before filing a whistleblower claim; and 3) having a "hand in the public disclosure" of the information. The 9th circuit reviewed that old interpretation and decided that it was contrary to the language in the False Claims Act. Noting that other circuit courts didn't impose the "hand in public disclosure" requirement, the 9th Circuit declared it would give that requirement "a respectful burial."

The court also addressed a "first-to-file" rule that prevents piggybacking of whistleblower claims.

Therefore, the court ruled there are only two requirements for the original source exception to the rule barring whistleblower actions that are based on information in the public domain: 1) a plaintiff must have direct and independent knowledge of that information and 2) the plaintiff must have voluntarily provided the information to the government before bringing the whistleblower claim. "He need not have played any role in making the disclosure public."

The new interpretation follows a U.S. Supreme Court ruling that said the law's reference to "information on which the allegations are based" refers to the information on which the whistleblower claims are based, not the publicly disclosed information that gives rise to the public disclosure bar.

The court also addressed a "first-to-file" rule that prevents piggybacking of whistleblower claims. Only the first whistleblower to file can bring and profit from a *qui tam* or whistleblower action. No one else can file a whistleblower claim based on the same facts. In this case, while all the claims related to the KX modifier usage, the second whistleblower also had claims that related to violations of a different Medicare requirement—the need for Detailed Written Orders before delivery of the device and beginning treatment. The court agreed that those claims were not made in the first whistleblower's complaint so the second whistleblower could bring those specific claims separately without violating the first-to-file rule.

Takeaway: Whistleblowers in the 9th Circuit will have an easier time meeting the original source rule and bringing their qui tam claims to court.

White House Releases Precision Medicine Privacy Principles

While promoting a personalized approach to medicine, which involves more sharing of data, the Obama administration isn't neglecting the need to protect privacy of health information. The White House released July 8 Proposed Privacy and Trust Principles as part of the Precision Medicine Initiative. These principles provide guidance on access to, sharing and use of data as well as data quality, integrity and security. "The principles articulate a set of core values and responsible strategies for engendering public trust and maximizing the possible benefits of a large national research cohort, while minimizing the risks inherent in large-scale data collection, analysis, and sharing," according to the proposed guidance.

Their efforts yielded 10 fundamental assumptions about the Precision Medicine Initiative, data sharing and privacy.

The principles were developed by a working group spearheaded by the Department of Health and Human Services Office for Civil Rights (which enforces HIPAA's privacy and security rules), the National Institutes of Health and the White House Office of Science and Technology Policy. The group consulted experts and reviewed bioethics literature and biobank and research privacy policies. Their efforts yielded 10 fundamental assumptions about the Precision Medicine Initiative, data sharing and privacy. Those fundamentals include recognition that those who contribute their data to precision medicine related research will come from different backgrounds and have different "preferences and risk tolerances with respect to privacy" and that the sources of data contributed will be numerous and varied. The document also addresses reciprocal access for patients who contribute data to the initiative.

The guidance calls for centralized management of communication with participants, and governance that involves participation from all stakeholders and holds users of the PMI data accountable for maintaining privacy and appropriate use of data. It also recognizes that research under the PMI can involve risks and benefits not just for individual patients but families and communities as well and cautions against social stigmatization based on data collected. Addressing transparency, the guidance recommends participants be informed about data usage at "the point of initial engagement and periodically thereafter" and be "clearly and conspicuously" informed about "how, when, and what information and specimens will be collected and stored; generally how their data will be used, accessed, and shared"; the efforts to protect their data, and ability to withdraw from participation. It also suggests researchers should have to publish their research findings "regardless of the outcomes, as a condition of data use." The principles also discuss access, use and sharing of data, protection against unauthorized re-identification of participants, and disclosure in civil, criminal and other legal proceedings. Finally, state-of-the-art security measures that are easily implemented and periodically tested were recommended.

The group also suggested a similar set of principles be developed for data security and be periodically updated to "keep pace with an ever-advancing technological environment." Public comments are due by August 7, 2015.

Takeaway: While precision medicine calls for sharing of data, privacy and security of data remains paramount. G2

Happy 50th Birthday Medicare and Medicaid!, *Continued from bottom of p.1*

Various organizations have highlighted the auspicious occasion, establishing websites commemorating the programs' history, publishing commentary, holding events recognizing the milestone, and promoting continuation and expansion of the federal benefits. For example, the Brookings Institution and USC Schaeffer Center issued a series of five Working Papers in June commenting on Medicare and future reforms, changes in Medicare spending and beneficiary demographics, trends relevant to the aging population, market competition, and alternative payment models. The Working Papers coincided with a June conference hosted by USC Schaeffer and Brookings titled "Strengthening Medicare for 2030."

The Centers for Medicare and Medicaid Services report that there are currently 55 million Americans benefitting from Medicare and that "in any given month" over 70 million benefit from Medicaid.

The *New England Journal of Medicine* published a two-part series earlier this year anticipating the 50th anniversary by looking back at the history of the Medicare program and discussing its future. The first part of that series notes that Medicare actually arose out of efforts to provide universal health insurance, which met with political resistance and were scaled back to coverage for those over 65. The second part of the series focuses on the challenges facing Medicare—including increased spending; coverage gaps; and fragmentation of Medicare with parts A, B, and D and Medicare Advantage—and potential solutions such as value-based purchasing, blended and bundled payment methodologies, global payments, accountable care organizations, and additional reforms.

The Centers for Medicare and Medicaid Services report that there are currently 55 million Americans benefitting from Medicare and that "in any given month" over 70 million benefit from Medicaid. The Official U.S. Government site for Medicare, www.Medicare.gov, devotes a page to the anniversary, is collecting stories from the public about the impact of these programs on individuals and families, and a press release promises regional and national events in late July to commemorate the event.

Pennsylvania's medical associations released a series of comments from various leaders in the state's health care industry on the impact of Medicare, including the following by Karen Rizzo, M.D., president of the Pennsylvania Medical Society, which aptly sums up many of the comments made about Medicare in honor of its 50th anniversary: "Medicare may not be perfect, but it does a good job of helping millions of older Americans access the care they need. Before Medicare, the financial burden of health care was significant for many of our elderly. They sometimes chose to go without care as they didn't want the costs to create a hardship for their families. Medicare gave them and their families peace of mind, and today continues to play a vital role in the health of those who qualify."

Takeaway: Medicare and Medicaid celebrate 50 years of health insurance coverage as legislators and advocates discuss ways to ensure its survival for decades to come. G2

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