Report on
Medicare Compliance

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Weekly News and Compliance Strategies on CMS/OIG Regulations, Enforcement Actions and Audits

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Outlook 2016

From Government to Board Members, Expect More Compliance Accountability

Seismic activity in the compliance and enforcement world last year will start to be felt in 2016, and some of it may rock health care organizations hard. They will start to feel the effects of the reorganization of CMS's Center for Program Integrity (CPI), the Department of Justice's pursuit of culpable individuals in corporate fraud cases, the increase of whistleblower lawsuits that proceed without DOJ and new or revised regulations (see story, below). These and other developments are raising the stakes for accountability, as the government, boards and others seek assurance there is adequate oversight of compliance with laws and regulations, compliance experts say.

Accountability takes on new meaning this year, maybe in ways beyond what people think. It's increasingly apparent that CMS's compliance-program requirements for Medicare Advantage plans and drug plans extend to their first tier, downstream and related entities (FDRs), such as hospitals and physicians, says Mark Pastin, president of the Council of Ethical Organizations in Alexandria, Va. "It's basically a pass-down requirement to providers," he says. "This is the way CMS has essentially realized the promise that was made years back [in the Affordable Care Act] that providers would

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Outlook 2016

Risk Areas: Watch Out for Watchman Device, Whistleblowers and Stark Twist

Short hospital stays and physician contracts are two of the compliance risk areas that rattle health care organizations the most, but there are up and comers that will attract attention as the new year unfolds. They also face new compliance challenges from looming regulations on several fronts, including discharge planning and the 60-day rule. However, evaluating risks may get easier because compliance officers have better tools at their disposal, experts say.

As health care organizations develop their compliance audit plans, they will increasingly benefit from data analytics and electronic health records, says Kimberly Zeoli, a partner in Deloitte & Touche in Boston. "We are in an information-rich environment," she says. When compliance and audit departments look at where their risks are, they can use internal claims data to detect higher-than-average use of a service, product or code and to track billing trends over time, she says. There are also external sources, including the Program for Evaluating Payment Patterns Electronic Report (PEPPER).

Where are the risks for 2016? The winner for the sleeper risk in the billing/medical necessity arena may be the Watchman device. Ronald Hirsch, M.D., vice president of regulations and education at Accretive Physician Advisory Services, sees the potential for the Watchman to become embroiled in the same kind of DOJ enforcement initiative as hospital billing for implantable cardiac defibrillators (ICDs). There were 70 settle-

ments with 457 hospitals for $250 million over allegations they charged Medicare for procedures that did not comply with Medicare's national coverage determination for ICDs *(RMC 11/2/15, p. 8; 10/5/15, p. 1)*. Since the FDA approved the Watchman in April 2015, Hirsch says physicians "have been clamoring to begin using that device as an alternative to long-term anti-coagulation drugs." CMS on Nov. 10 proposed a decision memo suggesting adoption with evidence development status for the device, although most commercial payers consider it investigational.

"Until CMS publishes the final decision memo and a registry is established and hospitals are able to enroll in the registry, any placements of a Watchman in a Medicare patient will be noncovered, and insurance coverage will be on a case-by-case basis," says Hirsch. There is another echo of the ICD experience: Criteria in the proposed decision memo are stricter than the criteria from professional societies, so there may be cases where the physician believes the patient will benefit, but the device isn't covered, he says. Considering the device will probably cost around $10,000 on top of the cost of the procedure, "if hospitals are not cognizant of the rules, in a few years we could see a repeat of the DOJ ICD settlement with high-volume hospitals owing millions of dollars," he says.

In terms of other risk areas, compliance officers are thinking about physician financial relationships, telehealth, privacy/security, DRG validation and the two-midnight rule, to name a few.

Physician contracts will continue to pose a significant risk to hospitals — and there are ominous signs on the horizon of where Stark law enforcement will go. Attorney Bob Wade, with Krieg DeVault in Mishawaka, Ind., sees two interlocking trends. First, "people need to be concerned about fair-market-value issues and making sure they document in every physician financial arrangement that it's fair-market," he says. The risk is greater because of the number of Stark-based false claims settlements in 2015, including the $115 million settlement inked with Adventist Healthcare *(RMC 9/28/15, p. 1)*. Second, "people need to be concerned about the structure of financial relationships with referring physicians. Structure is really important to make sure compensation does not take into account the volume or value of the referrals from employed or [independent-contractor] doctors." Even if compensation is fair-market value, hospitals are at risk under the Stark law if the structure (e.g., a bonus pool) is called into question, Wade says. That's what happened in the false claims case against Halifax Health, which settled for $85 million *(RMC 3/10/14, p. 1)*.

Coverage for Telehealth Varies

Telehealth services are also attracting a lot of interest. Compliance officers have to consider the regulatory implications of telehealth in terms of coverage (Medicare vs. Medicaid vs. commercial) and the privacy and security of the devices at both ends of the telehealth service, says former federal prosecutor Robert Trusiak *(RMC 6/29/15, p. 3)*. For example, Medicare reimburses telehealth services when the originating site — which refers to the patient's location — is in a Health Professional Shortage Area or a county outside of a Metropolitan Statistical Area, and it has to be a medical facility, not the patient's home. Medicare also requires telehealth services to "mimic normal face-to-face interactions between patients and their health care providers," he says. There's no widely used telehealth coverage standard for private payers, says Trusiak, a principal at Health Care Compliance Support in Buffalo, N.Y. Some pay for a variety of services while others haven't devised comprehensive coverage policies, which means reimbursement could require prior approval. State Medicaid policies also vary.

The new exception to the two-midnight rule continues to confound hospitals, says Sara Kay Wheeler, with King & Spalding. According to the final outpatient prospective payment system (OPPS) rule, which took effect

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Jan. 1, hospitals may receive Part A payment for admissions that don't satisfy the two-midnight benchmark if the medical necessity is supported by documentation as determined by medical reviews *(RMC 11/9/15, p. 1)*. "The concern is the exception may swallow the two-midnight rule," Wheeler says. "Some providers think they will only use it in defense of a denial."

On the regulatory front, compliance officers anticipate the release of several potential game-changers. One is the final regulation on the 60-day Medicare overpayment refund rule (see box, below). The final rule must be released by mid-February, four years after CMS published the proposed rule, or CMS will have to scrap the proposed rule, says Washington, D.C., attorney Andy Ruskin, with Morgan Lewis. "Medicare law says you have to finalize within three years," he says; when that deadline was imminent, CMS gave itself an extension.

Another is the final "omnibus guidance" on the 340B drug discount program, which was proposed Aug. 31 *(RMC 9/7/15, p. 1; 8/31/15, p. 1)*. In the proposed guidance, the HHS Health Resources and Services Administration (HRSA), which oversees the 340B program, narrowed the definition of "eligible patient," clarified the definition of "covered outpatient drugs," and addressed program eligibility and termination.

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Counting Down the Days to the Final 60-Day Refund Rule

CMS has to finalize its regulation on the 60-day Medicare overpayment refund rule (Parts A and B), which was proposed in February 2012, next month, or scrap it and start over (or not). Here are highlights of the rule from the law firm of King & Spalding. Contact Sara Kay Wheeler at skwheeler@kslaw.com.

60-DAY OVERPAYMENT REPORTING AND REFUNDING RULE:

The Moving Overpayment "Identification" Standard

Affordable Care Act (ACA) Requirements: Reporting and Refunding *Identified* Overpayments

- A healthcare organization must report and return an overpayment received from Medicare or Medicaid within 60 days after the date when the overpayment is "identified," or by the date the corresponding cost report is due, whichever is later. See 42 U.S.C. § 1320a-7k(d)(2).
- Potential FCA liability for the improper retention of overpayments.

Overpayment "Identification" Standard – *Moving Target*

LAW/REGULATIONS

AFFORDABLE CARE ACT (MARCH 2010)

- "Identified" is ***not*** defined in the ACA.

CMS MEDICARE PARTS A/B PROPOSED RULE (FEBRUARY 2012)

- CMS proposes that a person has identified an overpayment ***"if the person has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment."*** (77 Fed. Reg. 9182)

CMS MEDICARE PARTS C/D PROPOSED RULE (JANUARY 2014)

- In its proposed form, the Parts C and D rule (issued in January 2014) proposed that a person identified an overpayment if the person had actual knowledge of the existence of the overpayment or ***acted in reckless disregard or deliberate ignorance of the overpayment.*** (79 Fed. Reg. 1997)

CMS MEDICARE PARTS C/D FINAL RULE (MAY 2014)

- However, in the May 2014 final rule for Parts C and D, CMS defined identification of an overpayment as when the MA organization or Part D Sponsor "has determined, or ***should have determined through the exercise of reasonable diligence***" that it received an overpayment. (79 Fed. Reg. 29923-24)

CMS MEDICARE PARTS A/B FINAL RULE (PENDING)

- CMS recently sent the Medicare Parts A and B Overpayment Final Rule to the Office of Management and Budget. It is anticipated that the Final Rule will be issued soon.

COURT DECISION

- The Southern District of New York held that a provider "identifies" an overpayment when it is ***"put on notice that a certain claim may have been overpaid."*** (*United States v. Healthfirst, Inc.*, No. 11 Civ. 2325 (ER), 2015 WL 4619686 (S.D.N.Y. Aug. 3, 2015))

Hospitals will soon find some of their reimbursement at the mercy of big overlapping regulatory decisions of CMS and HRSA, Ruskin says. CMS has the job of interpreting Sec. 603 of the two-year spending bill signed into law by President Obama on Nov. 2. Sec. 603 said goodbye to new off-campus provider-based space, although hospitals were given a few exceptions *(RMC 11/23/15, p. 1; 11/2/15, p. 1)*. Hospitals will take a hit because of the legislation, both in terms of losing the Medicare reimbursement advantages of provider-based space and because of 340B implications, Ruskin says. Drugs furnished under the 340B program are limited to provider-based space, he notes. However, the impact of Sec. 603 won't be clear until CMS fleshes out the sparse statutory language.

"CMS can either interpret it narrowly or interpret it broadly," he says. "If they interpret it broadly, that may force HRSA's hand to decide either to continue its approach of categorically relying on CMS provider-based determinations or creating a whole new set of criteria as to where 340B drugs can be dispensed." Amending 42 CFR Part 419 — the OPPS rules — allows CMS to "implement what Congress did in a narrow way that ties closely to the statute," says Ruskin. However, if CMS implements Sec. 603 by amending 42 CFR Sec. 413.65 — which is the provider-based rule — "there could be a cascading effect," he says. It could upset bad debt payments and disproportionate share hospital uncompensated care payments, among others. And if the interpretation changes the way hospitals report their sites on their cost reports, HRSA may have to change its rules to ensure hospital outpatient clinics (i.e., "child" sites) are still eligible for 340B drugs, or HRSA "will have to acquiesce to there being fewer child sites that qualify for 340B drugs."

Another regulation that will be finalized this year raises the stakes for hospital discharge planning with six

Top Error Rates for Inpatient Hospital Services

CMS in December released data on improper payments across service types for 2015. The data are gathered annually by the comprehensive error rate testing (CERT) contractor and appear in appendices to the Medicare fee-for-service improper payments report. The chart below, which shows one slice of the data, reveals high error rates for chest pain and transient ischemia DRGs. View the CERT report at http://tinyurl.com/jyrr28h.

Top 20 Service Types with Highest Improper Payments: Part A Hospital IPPS

Part A Hospital IPPS Services (MS-DRGs)	Projected Improper Payments	Improper Payment Rate	95% Confidence Interval	Type of Error					Percent of Overall Improper Payment
				No Doc	Insufficient Doc	Medical Necessity	Incorrect Coding	Other	
Major Joint Replacement Or Reattachment Of Lower Extremity (469, 470)	$359,081,955	5.5%	3.4% -7.7%	0.0%	88.6%	4.0%	7.4%	0.0%	0.8%
Psychoses (885)	$351,305,555	8.4%	5.0% -11.7%	0.0%	36.2%	54.3%	0.2%	9.4%	0.8%
Esophagitis, Gastroent & Misc Digest Disorders (391, 392)	$277,403,789	20.4%	15.8% -24.9%	0.0%	6.0%	86.5%	5.0%	2.5%	0.6%
Kidney & Urinary Tract Infections (689, 690)	$240,676,138	19.1%	11.6% -26.5%	0.0%	0.0%	99.8%	0.2%	0.0%	0.6%
Heart Failure & Shock (291, 292, 293)	$220,376,467	5.9%	3.8% -7.9%	0.0%	19.2%	57.4%	23.4%	0.0%	0.5%
Circulatory Disorders Except Ami, W Card Cath (286, 287)	$214,473,263	15.5%	10.5% -20.4%	0.0%	2.1%	94.1%	3.8%	0.0%	0.5%
Perc Cardiovasc Proc W Drug-Eluting Stent (246, 247)	$212,567,324	11.2%	6.3% -16.0%	0.0%	5.5%	93.0%	1.5%	0.0%	0.5%
Misc Disorders of Nutrition, metabolism, fluids/ Electrolytes (640, 641)	$207,068,070	17.2%	2.7% -31.8%	0.0%	0.0%	98.6%	1.4%	0.0%	0.5%
Renal Failure (682, 683, 684)	$179,363,686	7.8%	5.1% -10.5%	0.0%	6.7%	64.7%	28.6%	0.0%	0.4%
Permanent Cardiac Pacemaker Implant (242, 243, 244)	$166,848,914	13.0%	10.8% -15.2%	0.0%	3.8%	95.0%	0.7%	0.6%	0.4%

new standards, among other changes. CMS proposed the rule in November, partly to "modernize" discharge planning and partly to implement the mandates in the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 *(RMC 11/2/15, p. 5)*. "It's going to generate a lot of additional expense in organizations and potentially cause some issues between case managers and nursing," says Valerie Rinkle, president of Valorize Consulting. The reason: Nurses do a lot of outpatient and straightforward inpatient discharge planning, while case managers handle more complex inpatient discharge planning, she says. "If CMS dictates all the elements of discharge planning and includes large groups of outpatients who will require the same level of formal discharge planning, it may become too time consuming for nursing to do it, and both case management and nursing are often understaffed," Rinkle explains. Hopefully CMS will heed comments from hospitals on the burdens of the proposed rule, she says.

Rinkle sees some other billing and payment challenges on the horizon. CMS will have to focus more on the risk-adjustment model it uses in risk-based contracts (i.e., Medicare Advantage) and Medicaid. "CMS has acknowledged it doesn't properly account for all the risk factors and explain socioeconomic factors that lead to higher costs," she says. ICD-10 has diagnoses that represent the reasons that patients might use a lot of services — such as homelessness (Z59.0) and no assistance at home for care (Z74.2) — but use of the codes is not required by CMS or coding guidelines, Rinkle says. "It's important to capture the information consistently across all patients so you can begin to explain socioeconomic information and target it with some of the new value-based methodologies," she says. Also, CMS has been expanding the number of modifiers it requires on claim forms, but it's not clear that all four modifier places in the transaction data sets are read by the Medicare transaction system or which modifier goes first, Rinkle says. For example, in 2016, health care organizations that bill for CT modifiers that don't comply with National Electrical Manufacturers Association standards for radiation safety face a 5% payment cut. But where should that modifier be placed vis-à-vis the new place-of-service modifier for off-campus departments? "This is unresolved," she says.

Value-based purchasing, hospital acquired conditions and other quality and safety initiatives will be front

Top Error Rates for Inpatient Hospital Services (continued)

Top 20 Service Types with Highest Improper Payments: Part A Hospital IPPS (continued)

Part A Hospital IPPS Services (MS-DRGs)	Projected Improper Payments	Improper Payment Rate	95% Confidence Interval	Type of Error					Percent of Overall Improper Payment
				No Doc	Insufficient Doc	Medical Necessity	Incorrect Coding	Other	
Back & Neck Proc Exc Spinal Fusion (490, 491)	$148,972,369	34.6%	29.7% -39.4%	0.0%	10.7%	79.2%	10.1%	0.0%	0.3%
Chronic Obstructive Pulmonary Disease (190, 191, 192)	$145,741,664	7.5%	4.3% -10.7%	0.0%	15.6%	58.4%	26.1%	0.0%	0.3%
Transient Ischemia (069)	$142,995,056	44.9%	32.4% -57.3%	0.0%	6.6%	92.9%	0.5%	0.0%	0.3%
Chest Pain (313)	$136,772,894	45.9%	37.6% -54.1%	0.0%	2.2%	96.8%	1.0%	0.0%	0.3%
Syncope & Collapse (312)	$132,102,045	28.0%	14.8% -41.2%	0.0%	22.0%	71.8%	6.2%	0.0%	0.3%
Cardiac Defibrillator Implant W/O Cardiac Cath (226, 227)	$125,093,281	25.6%	22.6% -28.6%	0.0%	6.3%	90.9%	2.2%	0.6%	0.3%
Cardiac Arrhythmia & Conduction Disorders (308, 309, 310)	$119,854,973	9.5%	5.6% -13.4%	0.0%	5.9%	68.7%	25.4%	0.0%	0.3%
Degenerative Nervous System Disorders (056, 057)	$117,968,633	19.8%	8.9% -30.6%	0.0%	3.6%	96.4%	0.0%	0.0%	0.3%
Red Blood Cell Disorders (811, 812)	$111,832,432	14.2%	7.1% -21.3%	0.0%	0.0%	85.3%	14.7%	0.0%	0.3%
Medical Back Problems (551, 552)	$108,692,863	21.2%	15.6% - 26.7%	0.0%	4.1%	92.6%	0.6%	2.7%	0.3%
All Type of Services (Incl. Codes Not Listed)	$8,333,107,590	7.4%	6.8% - 8.1%	0.0%	14.7%	68.6%	15.7%	1.0%	19.2%

IPPS = inpatient prospective payment system

and center this year, Zeoli says. "It's an area of growing importance in reimbursement," she notes. There are several items on the 2016 OIG Work Plan about quality, including a new evaluation of "CMS validation of hospital-submitted quality reporting data." Zeoli says it's time for compliance officers to look at the integrity of their data in the quality arena. And it's time to start planning for the new alternative payment model for physicians adopted by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, adds Kelly Sauders, a partner with Deloitte & Touche. The law, which killed the "doc fix," is welcome news financially, she says, "but as always, compliance officers need to understand the requirements and what triggers incentives."

Enrollment issues and payment suspensions loom large for 2016, says San Francisco attorney Judy Waltz, with Foley & Lardner LLP. CMS is using the enrollment process more aggressively to keep bad apples out of Medicare, and while CMS and Medicaid agencies haven't been trumpeting their payment suspensions "and the numbers have been relatively small, they are showing up in a variety of situations, including state and federal investigations," she says. "I think we'll be seeing more of them" *(RMC 12/14/15, p. 1)*.

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CMS Transmittals and *Federal Register* Regulations
Jan. 1 – Jan. 7

Live links to the following documents are included on *RMC*'s subscriber-only Web page at www.AISHealth.com. Please click on "CMS Transmittals and Regulations" in the right column.

Transmittals

(R) indicates a replacement transmittal.

Pub. 100-02, Medicare Benefit Policy Manual

- Rural Health Clinic and Federally Qualified Health Center — Medicare Benefit Policy Manual Update, Trans. 217BP, CR 9442 (Dec. 31; eff./impl. Feb. 1, 2016)

Pub. 100-03, National Coverage Determinations

- National Coverage Determination for Screening for Colorectal Cancer Using Cologuard — A Multitarget Stool DNA Test (R), Trans. 188NCD, CR 9115 (Dec. 30; eff. Oct. 9, 2014; impl. Jan. 4, 2016)

Pub. 100-04, Medicare Claims Processing Manual

- 2016 Durable Medical Equipment Prosthetics, Orthotics, and Supplies Healthcare Common Procedure Coding System Code Jurisdiction List, Trans. 3432CP, CR 9481 (Dec. 31; eff. Jan. 1; impl. Feb. 1, 2016)
- Clinical Laboratory Fee Schedule — Medicare Travel Allowance Fees for Collection of Specimens, Trans. 3433CP, CR 9485 (Dec. 31; eff. Jan. 1; impl. Feb. 1, 2016)
- Reorganization of Chapter 9, Trans. 3434CP, CR 9397 (Dec. 31; eff./impl. March 31, 2016)
- Clarification on Patient's Reason for Visit Necessary to Capture HIPAA Compliant Fields, Trans. 3435CP, CR 9450 (Dec. 31; eff. July 1, 2015; impl. March 31, 2016)
- National Coverage Determination for Screening for Colorectal Cancer Using Cologuard — A Multitarget Stool DNA Test (R), Trans. 3436CP, CR 9115 (Dec. 30; eff. Oct. 9, 2014; impl. Jan. 4, 2016)
- Fiscal Year 2016 Inpatient Prospective Payment System and Long Term Care Hospital PPS Changes (R), Trans. 3431CP, CR 9253 (Dec. 29; eff. Oct. 1; impl. Oct. 5, 2015)

Federal Register Regulations

- None published.

Stakes Raised for Accountability

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have to have a compliance program, and CMS would do enabling regulations to tell them what that meant. They never came, but this is basically it." Medicare Advantage (Part C) and drug plans (Part D) are demanding attestations from providers that their compliance programs are effective, Pastin says.

Atlanta attorney Sara Kay Wheeler also says Part C and D plans are starting to pursue "exacting attestations from FDRs," and that will increase as they face scrutiny from recovery audit contractors (RACs). CMS issued a draft statement of work and request for information in December for RAC audits of Medicare Advantage plans. "You often find that managed care organizations say their ability to be accurate is in part dependent on the accuracy of the information the participants in the network provide to them," says Wheeler, with King & Spalding. "That creates a ripple effect on providers, and it's already playing out with the downstream contractors."

The FDRs will be asked to put in writing they have completed compliance training, have disseminated the code of conduct, have established a reporting mechanism, have a process for returning overpayments, protect offshore protected health information and have implemented other compliance functions, she says.

That's not the only pressure point for attestations, says Wheeler. Corporate integrity agreements that are often part of fraud settlements now require annual certifications from top managers that their departments are in compliance with relevant laws and regulations *(RMC 8/31/15, p. 1)*. "The list has gotten longer of who is expected to certify," she says. "It's pretty huge because anytime you are making a certification, it could be argued that you're certifying for the purpose of payment, and there are a lot of ways it could go sideways as far as the False

Claims Act. Providers should have a documentation trail of how they reached a comfort level to be able to give certification or attestation. You can't just say, 'CFO, are you good with this?'"

There's another angle on attestations. In light of the so-called Yates memo, which will start to change the way DOJ handles cases in the coming year, attestations can help protect senior executives from prosecution, Pastin says. Per the Yates memo, which revised the Principles of Corporate Prosecution, corporations won't be able to settle fraud cases unless they divulge the names of the people involved, and "culpable individuals" stand a good chance of facing civil or criminal enforcement actions *(RMC 9/14/15, p. 1)*. "Because of the Yates memo, which is very scary stuff for senior executives, they are going to want to have their direct reports sign and attest to them there are no compliance problems," he says. For example, the CEO will want written reassurance that the information on the cost report is true and accurate to the best of the CFO's knowledge. "If you are going to sign in blood, you will want your direct reports to sign in blood," Pastin contends.

RACs Move in CMS Shuffle

There are also changes on the horizon from CMS, which recently redesigned its CPI, says Ted Doolittle, former deputy director. Acting CMS Administrator Andy Slavitt "is very interested in program integrity," he says. CPI, which is headed by Shantanu Agrawal, M.D., has grown from 230 full-time employees to 500 in the space of a few years. Some of the increase stems from moving the RAC program to CPI from the Office of Financial Management in the fall, says Doolittle, who is now a project director for CGI Federal in Baltimore. "Bringing the RACs in goes toward an enhanced concept of what program integrity encompasses," he says. "CPI maybe at first was just the fraud part, and now they are more into abuse and perhaps waste also."

The purpose of the CPI reorganization was largely to align Medicare and Medicaid anti-fraud initiatives, Doolittle says. It will culminate in the selection of the first unified program integrity contractor (UPIC) this year. UPICs will eventually replace zone program integrity contractors and Medicaid integrity contractors. For years, CMS has tried to get better access to Medicaid data to improve auditing. While it still has a way to go, "you will see UPICs coming online, and the CPI reorganization will start to have an impact," he says. Providers will begin experiencing joint Medicare and Medicaid audits and enforcement actions that used to be handled separately. "CMS is consolidating its gains in a good way," says Doolittle. "I see them poised for the next chapter."

2016 also will be the year that providers feel more heat from the HHS Office of Inspector General's (OIG) new "litigation team," which was formed in mid-2015 to focus solely on civil monetary penalty (CMP) and exclusion cases *(RMC 7/27/15, p. 1)*. "Providers were coasting on the thought their behavior wouldn't attract the attention of DOJ or there weren't enough dollars [at stake], and the purpose of the team was to institute enforcement actions that were being lost in the shuffle, but it's still culpable behavior," says Washington, D.C., attorney Linda Baumann, with Arent Fox. She expects the team to focus on physicians in allegedly illegal contracts with hospitals. OIG spokesman Don White tells *RMC* that in fiscal year 2015, it settled 110 CMP cases for total recoveries of $70.77 million. So far in FY 2016 — Oct. 1, 2015 to Dec. 23, 2015 — OIG has settled 41 CMP cases for a total of $36.74 million.

Medicare audits will look a little different this year, as reviews of short hospital stays shift to quality improvement organizations (QIOs). RACs will conduct patient-status reviews only when hospitals are persistently noncompliant, which CMS defined as "including, but not limited to: having high denial rates and consistently failing to adhere to the Two Midnight rule (including repeatedly submitting inappropriate inpatient claims for stays that do not span one midnight), or failing to improve their performance after QIO educational intervention," according to a Dec. 31 posting.

But hospitals shouldn't let their guard down in 2016, says former federal prosecutor Robert Trusiak. "Don't think for a moment a neutered RAC process means hospitals can no longer be vigilant about their zero- to one-day stays," he says. "That vacuum will be filled by whistleblowers, who are going to provide evidence of inpatient mischief that will give rise to zero- to one-day stays. Make sure you are still monitoring them." The staying power of the kyphoplasty enforcement initiative, which originated with a whistleblower, is proof that whistleblowers and the False Claims Act are "the golden goose that keeps on giving," says Trusiak, a principal at Health Care Compliance Support in Buffalo, N.Y. A total of 130 hospitals have settled allegations they performed the spine surgery on an inpatient basis when it should have been performed on an outpatient basis; the first batch of settlements came down in 2009 and the most recent in December *(RMC 12/21/15, p. 7)*.

continued

In fact, Trusiak says, "your greatest risk as an institutional provider is working in your shop right now." DOJ recently reported $3.5 billion in False Claims Act recoveries and settlements for fiscal year 2015, which was half a billion dollars less than in FY 2014, but the amount recovered in cases where whistleblowers proceeded alone exceeded the amount recovered in cases where DOJ intervened, he says. That's eye opening; when Trusiak was a federal prosecutor, "it was a rule that if the government declined a *qui tam* [case], it went away," he says. "The presumption was the case lacked merit." Cases no longer die because DOJ turns up its nose because it lacks resources or doesn't believe in them.

For this and other reasons, compliance officers should develop a relationship with the assistant U.S. attorney (AUSA) handling health fraud cases in their district, Trusiak advises. Invite the AUSA to meet with the board to hear about enforcement priorities and what the organization needs to do to be more compliant, he says. "It won't put some kind of target on your back." It will, however, build rapport and "gives you the opportunity to ensure a fair result when a bad thing happens."

There's a silver lining here, says Fort Lauderdale, Fla., attorney Gabriel Imperato, with Broad and Cassel. Health care organizations are "more interested in perfecting their compliance practices," he says, and "more resources are being devoted to compliance, and board and management are much more educated and sensitized to the need for effective compliance." That trend will continue as the industry watches the effect of the Yates memo on enforcement matters, Imperato says. "It is a stay-tuned kind of thing, but we are starting to see the repercussions. I have already experienced, in cases, investigative activities by DOJ focusing on individuals who may have been involved in compliance issues. It requires individuals to have their own counsel, and in settlements DOJ will not be giving releases for individuals absent extraordinary circumstances. That puts individuals more at risk, and they will respond to that risk differently. It changes the landscape a little."

The Yates memo is one reason boards are taking a more active role this year in compliance oversight, but they were already on their way, partly because of OIG's guidance on compliance oversight by boards, published in April 2015 *(RMC 4/17/15, p. 1)*. "I am seeing a greater attention to the role of boards in compliance meltdowns and compliance planning," says Boston attorney Larry Vernaglia, with Foley & Lardner.

In the wake of the false claims cases against Halifax Health and Tuomey Healthcare System, it's clear the government expects boards to do more than passively receive reports on the number of hotline calls received by the compliance department, Pastin says. "Boards are really trying to figure out what they are supposed to do to provide oversight to the compliance program," he notes.

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NEWS BRIEFS

◆ **An Illinois physician was sentenced to two years in prison on Jan. 7 after pleading guilty in September to health fraud for certifying patients for home health services that were not medically necessary,** the U.S. Attorney's Office for the Northern District of Illinois said *(RMC 7/14/15, p. 8)*. Arthur Davida, M.D., an employee and part-owner of Home Care Physicians Inc., got referrals from home health agencies, which asked him to certify patients as homebound. He allegedly knew at least 20% of the patients were not homebound, but he certified them anyway out of fear he'd lose the referrals, the U.S. attorney's office said. Visit http://tinyurl.com/hgwt3s8.

◆ **Englewood Hospital and Medical Center in New Jersey was overpaid $115,000 for outpatient cardiac and pulmonary rehabilitation services in 2012 and 2013,** according to an audit by the HHS Office of Inspector General (A-02-14-01013). OIG audited 100 Medicare Part B claims and concluded 46 had errors. The hospital disagreed with some of OIG's findings. Visit http://go.usa.gov/ck8YZ.

◆ **Nebraska Methodist Hospital in Omaha was overpaid $111,000 in 2012 and 2013,** according to a Medicare compliance review (A-07-15-05073). OIG audited 138 claims and found errors on 19 of them. The inpatient errors included inadequately documented diagnosis codes and inpatient stays that should have been billed as outpatient or observation services. Outpatient errors were for manufacturer credits for recalled devices not passed on to Medicare. In its response, the hospital said it refunded the overpayments and improved some internal controls, noting it has had a compliance program for 20 years. Visit http://go.usa.gov/ck8ru.

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