CMS Sends Message That Stark Liability Is Limited to Four Years With Self-Disclosure

Hospitals may escape Stark penalties for claims that are more than four years old if they apply to the CMS self-referral disclosure protocol (SRDP), as long as there’s no fraud. CMS recently indicated that providers in the SRDP can’t be held responsible for Stark violations on claims beyond the Medicare re-opening period, according to Bob Wade, who is with Krieg DeVault in Mishawaka, Ind. Older claims probably couldn’t be hit with a false claims lawsuit because they are closed, unless there was proof the hospital knew they were fraudulent at the time of submission, he says.

“Stark liability does not exist forever. If you are outside the four-year reopening period, you probably have no liability to CMS,” Wade says.

Wade got the good news when CMS responded to several of his hospital-clients’ applications to the self-referral disclosure protocol. CMS turned them down, but only because the hospitals didn’t have liability under the Stark law because the claims were deemed too old. In letters to Wade, CMS explained that it “uses the time frame established under the reopening regulations at 42 C.F.R. 405.980(b) as a guide to determine the time frame of the SRDP. As such, the time frame of the SRDP is limited to four years from the date that the disclosing party submits the disclosure to the SRDP, unless reliable evidence of fraud or similar fault exists….Because all of the noncompliance disclosed by [reporting entity] occurred outside of the four-year time frame under the SRDP, CMS is removing [reporting entity] from the SRDP.”

continued on p. 7

60-Day Refund Mandate Tops Major Risks For ’15; Stark, Short Stays Also Rate Highly

The Medicare 60-day refund rule is playing out in ways large and small that make it an overarching risk area for 2015. As the new year approaches, hospitals and other providers should brace for more False Claims Act cases that invoke the requirement that providers return Medicare and Medicaid overpayments 60 days after they are identified, and they might see a final CMS regulation nailing down the details of this watershed mandate from the Affordable Care Act.

Other big risk areas — some of which are inextricably linked to the 60-day refund requirement — include compensation under the Stark law, provider-based status, short hospital stays, the 340B drug-discount program and meaningful use audits, according to attorneys interviewed by RMC.

The 60-day refund mandate has bedeviled providers for years because “there is a lot of ambiguity in establishing when the clock starts ticking,” says Boston attorney Larry Vernaglia, who is with Foley & Lardner LLP. CMS’s February 2012 proposed regulation on the mandate said when providers learn about a potential overpayment, they are obliged to make a “reasonable inquiry” to figure out whether an overpayment...
exists. "If the reasonable inquiry reveals an overpayment, the provider then has 60 days to report and return the overpayment," CMS said (RMC 2/20/12, p. 1).

Exactly what "reasonable inquiry" means is fuzzy and the regulation is still not final, Vernaglia says. But that hasn’t stopped the Department of Justice and whistleblowers from seizing on the 60-day refund mandate for “reverse” false claims cases. Their premise is it’s a violation of the False Claims Act to knowingly hold onto Medicaid money that you’re not entitled to. In one case that is out from under seal, the U.S. Attorney’s Office for the Southern District of New York and the state attorney general alleged that Continuum Health Partners, Inc., which at the time of the alleged misconduct was the parent company of Beth Israel Medical Center and St. Luke’s-Roosevelt Hospital Center, allegedly kept almost $1 million of Medicaid managed care overpayments caused by a software glitch for many months after learning about them (RMC 7/21/14, p. 1).

“While the New York case may be the one to watch right now, there are a number of other cases in the pipeline where a 60-day rule violation is among the challenged activities,” Vernaglia says.

Negotiations with prosecutors on a variety of matters may take surprising turns because of the 60-day refund mandate, he says. In one state false claims case, a prosecutor insisted the provider return overpayments in the middle of working out a settlement. The message seems to be that “even when you are cooperating with the government, you need to have an eye on the duty to make refunds. That’s a tricky perspective,” says Vernaglia, who didn’t think the prosecutor was playing games. “We are all in uncharted waters,” he says. “Everyone’s learning the ropes as they go.”

The level of disclosure required is also unclear. The Medicare administrative contractor (MAC) refund form is adequate at least until there’s a final CMS rule, Vernaglia says, although “I’m not sure everyone agrees with that.” Some people think a cover letter elaborating on the overpayment is also necessary to satisfy any concerns the U.S. attorney might raise. “The government doesn’t always speak with one voice,” he says. “That’s a big problem.”

And providers should be aware that some state Medicaid programs don’t want providers to send checks with their overpayment revelation, Vernaglia says. The policy in some states is to evaluate the disclosure and, if they agree with it, providers send the money. “That doesn’t strictly comply with the statutory mandate that you report and refund in 60 days, but my view is, you haven’t knowingly withheld payment if you are strictly complying with Medicaid policy and are willing and attempting to make the repayment, but the state won’t accept it.”

Vernaglia also urges hospitals to be on the lookout for employees who may send “emails with provocative language saying they found potential overpayments” to lay the groundwork for a whistleblower lawsuit. If you get these emails, “immediately start your inquiry to see if there’s anything to the allegations these people are raising,” he says. “Don’t ignore them. They could portend a future qui tam case.”

Ten More Risk Areas for 2015

Here are other top risk areas compliance officers should focus on, not necessarily in order of importance:

◆ Physician compensation under the Stark self-referral law: Next year, more hospitals will direct more internal resources to vetting financial resources to ensure they have documentation of fair-market value, says attorney Bob Wade, who is with Krieg DeVault in Mishawaka, Ind. For example, Halifax Health in Daytona Beach, Fla., has established a physician arrangement review committee (PARC). Every financial relationship with a referring physician must get the committee’s approval. Every member of the committee, which is comprised of
hospital executives, has veto power, says Wade, who is the “compliance expert” to the board of Halifax required by its corporate integrity agreement, which is part of the hospital’s $85 million settlement of a Stark-based false claims settlement (RMC 3/10/14, p. 1). “There was one financial arrangement that went back to the PARC five times because they wanted more information,” he says. “The deal didn’t change, but the documentation supporting it got more robust.”

After the Halifax settlement and the jury verdict against Tuomey Healthcare (RMC 5/13/13, p. 1), more providers applied to the CMS self-referral disclosure protocol, and “it will get further slammed next year,” Wade says. “Tuomey and Halifax stand for the proposition if you self-report, you will cut off potential whistleblowers and any settlement you reach will be substantially less than if you are in litigation,” he says.

When hospitals fall out of compliance, it’s often because contracts expire but the payments to physicians continue, says Minneapolis attorney David Glaser, who is with Fredrikson & Byron. He recommends hospitals and clinics make sure all contracts have an “auto-renew” feature. “The agreement is written in a way that it continues indefinitely until it’s actively terminated by one party or another,” he says. That only works if the terms don’t change (e.g., more or less money, more or less square footage). Any time the terms change, it’s essential to modify the written agreement, Glaser notes.

Noncompliance with Stark is also tied to the 60-day refund mandate and gives the Department of Justice and whistleblowers more grist for the mill, says Washington, D.C., attorney Troy Barsky, former director of the CMS Division of Technical Payment Policy. “There is great focus by providers and suppliers to make sure they are compliant and, if they are not, to determine whether they need to disclose potential overpayments to CMS under the self-referral disclosure protocol,” says Barsky, who is with Crowell & Moring. Stark analysis increasingly will take new directions as hospitals and physicians integrate and some start insurance networks, he says. Although hospitals and physicians have fraud and abuse waivers to protect them inside the Medicare Shared Savings Program, that’s not the case outside. “The two worlds are colliding,” which muddies the analysis of financial relationships under the anti-kickback and Stark laws, he says. For example, hospitals and physician groups starting their own managed care plans are entering into new, complex financial relationships that will need to fit within various Stark exceptions and anti-kickback safe harbors that they have not needed to employ before, Barsky says. “It makes a lot of hospitals think twice about how they might want to integrate if the Department of Justice or whistleblowers will say they entered into a relation-
ship that violated the Stark law,” he says. “These new relationships and business ventures are possible under the fraud and abuse laws, but they raise interesting questions that must be addressed.”

Provider-based status: Pressure is building on provider-based status because it yields more reimbursement for hospitals compared to freestanding clinics that perform the same services. What appears to be the first false claims settlement over the alleged misrepresentation of provider-based status came down in October when Our Lady of Lourdes Memorial Hospital in Binghamton, N.Y., self-disclosed to the HHS Office of Inspector General that it billed Medicare for services provided at its off-campus mobile hyperbaric oxygen facility, which was operated by Mobile Hyperbaric Centers LLC. The services were provided to the hospital “under arrangements” and allegedly the facility did not qualify for provider-based status, which led to the Department of Justice stepping in and the hospital paying $3.373 million (RMC 10/20/14, p. 1). “If it stands for the proposition that any failed provider-based arrangement inherently results in an overpayment or something that must be reported to OIG, that’s a problem, because the provider-based rules are complicated, subjective and lack regulatory clarity,” Vernaglia says. “If providers filed an attestation and received written approval from CMS, that’s the gold standard. For providers who don’t have that or got it but their structure changed, my view is they should look at their provider-based entity to make sure they are compliant.” If not, how serious is the problem? Does it rise to the level of a payment violation? Maybe the provider-based entity is 37 miles from the hospital, when it’s required to be located within a 35-mile radius, or it failed to hand out special beneficiary co-insurance forms. Or perhaps medical and financial records are not integrated with the hospital.

“Will people fall on their swords unnecessarily because of this case?” Vernaglia wonders. “I don’t think you should go to OIG for minor errors; minor errors could be raised to the Medicare administrative contractor.” Meanwhile, as an apparent step toward reducing the payment differential between provider-based entities and freestanding clinics, CMS will now require hospitals and physicians to report on claim forms when services are performed in provider-based entities. Hospitals will have to use a new modifier and physicians a new point-of-service code, according to the 2015 outpatient prospective payment system regulation and Medicare physician fee schedule, respectively (RMC 11/10/14, p. 1). And OIG’s 2015 Work Plan again targets provider-based status.

Inpatient level of care: As the two-midnight rule is institutionalized, hospitals continue to enter into big-dollar settlements for billing outpatient cases as inpatient stays under the pre-Oct. 1, 2013, admission criteria. On April 1, MACs will again be free to audit short stays outside the confines of the probe-and-educate program and RACs will eventually join them when CMS awards the next round of contracts or possibly under the current contracts. Meanwhile, there are rumblings in Congress to replace the acute-care hospital payment system and/or implement a short-stay payment (RMC 11/24/14, p. 8) to calm the patient-status pressure cooker. “I don’t think the problem goes away until they harmonize the level of care determination process and harmonize reimbursement for inpatient and observation,” Vernaglia says. Meanwhile, state Medicaid fraud control units are examining short-stay cases on the heels of all the OIG’s Medicare compliance reviews that have identified errors in this area, he says. Some states have Medicare-like inpatient vs. outpatient rules, but not all. “We are also contemplating that

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✔ A Guide to Complying With Stark Physician Self-Referral Rules, a comprehensive looseleaf (plus quarterly updates) with practical summaries of the federal rules and separate analyses for hospitals, physician groups and other stakeholders.

✔ Conducting Internal Investigations in Health Care Organizations, a practical guide on how to resolve allegations of wrongdoing. Written by former HHS IG Richard Kusserow, the book also contains more than 30 adaptable policy and form templates (in print and on an accompanying CD).

✔ Vendor Relations in Health Care: Compliance Policies and Procedures for Hospitals, Health Systems and Other Providers, written by veteran hospital compliance officer Nickie Braxton. The book contains an overview of the laws, government interest and general climate surrounding vendor relations, with examples of effective approaches for addressing the risks these relationships present.

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commercial payers will be looking at the same issues,” Vernaglia says.

**Cardiac stents:** Medically unnecessary insertion of cardiac stents will continue to be hot. It has already been the proximate cause of false claims settlements with hospitals and jail time for a few physicians, Glaser says. “I can’t count on one hand the number of cases I am working on involving cardiac stents,” he says (RMC 8/4/14, p. 1; 11/14/11, p. 8). “It’s a very big risk.” Although it appears the Department of Justice focuses on cases “where someone is really up to no good, there will be allegations [all over the map] and they will look,” Glaser says.

**Physician-owned distributorships (PODs):** If the government gets the decision it wants in its False Claims Act case against Reliance Medical Systems, a spinal implant company, and two Reliance distributorships (RMC 9/15/14, p. 1), it could take on other PODs it thinks are abusive, Vernaglia says. The feds also went after some physicians in the POD case and have since arrested one of them — Aria Sabit — on unrelated health fraud charges (RMC 12/8/14, p. 1). PODs sell medical devices to hospitals and ambulatory surgical centers, where they are often implanted by the surgeons who own the PODs. OIG issued a special fraud alert in April 2013 calling PODs “inherently suspect” and listing fraud-and-abuse red flags. Some hospitals refuse to buy devices from them, but sometimes that’s easier said than done. With all the heat, PODs may not advertise themselves as physician owned, and hospitals may lack the legal resources to analyze them under the fraud alert, Vernaglia says. “Presumably the distributorship had lawyers do their analysis and they can send it to the hospital,” he says. When it comes to so-called “physician-preference devices,” hospitals may be forced to choose between buying from PODs or buying from a big-name manufacturer at a much higher price, he says.

**Meaningful use audits:** They will continue in earnest as 2015 dawns, since Medicare has paid hospitals and physicians $16 billion to adopt interoperable electronic health record technology and Medicaid has paid $8 billion, says Los Angeles attorney Rick Rifenbark, who is with Foley & Lardner LLP. Inquiring minds at OIG also have questions about incentive payments for meaningful use of EHRs. According to its 2015 Work Plan, OIG will “review Medicare incentive payment data from 2011 to identify payments to providers that should not have received incentive payments (e.g., those not meeting selected meaningful use criteria). We will also assess CMS’s plans to oversee incentive payments for the duration of the program and corrective actions taken regarding erroneous incentive payments.”

**Discounted drugs under the 340B program:** In April, the HHS Health Resources and Services Administration (HRSA) plans to propose a regulation on civil monetary penalties for safety-net providers that knowingly violate the 340B statute and for pharmaceutical manufacturers that knowingly overcharge for their drugs. HRSA will follow up in September with a proposed rule on administrative dispute resolution between providers and drug manufacturers under the 340B program, which requires drugmakers to discount outpatient drugs purchased by certain entities that serve the nation’s most vulnerable patients (e.g., disproportionate share hospitals, cancer hospitals and critical access hospitals). There also will be guidance in other areas sometime this year, but not the highly anticipated “mega-reg,” which was supposed to end confusion around the definition of “eligible patients” and compliance requirements for contract pharmacies, among other things (RMC 11/24/14, p. 1). When hospitals and other covered entities are noncompliant with 340B rules, HRSA’s Office of Pharmacy Affairs now posts the audit results, potential sanctions and corrective action plans on its website, says Los Angeles attorney Elizabeth Elson, who is with Foley & Lardner LLP. That arms manufacturers with the data they need to audit hospitals and potentially recoup the difference between the 340B discounted price and the retail price. The dynamic is strange — it’s a government program, but the manufacturers’ money is at stake, she says. That may not always be the case, as OIG is exploring how much Medicare could cut Part B spending if it shared in savings on drugs purchased under 340B, which now has 10,000 participating covered entities, according to the 2015 Work Plan. “I think 2015 will be an interesting year for the program,” Elson says.

**Criminal review of all civil false claims allegations:** Prosecutors from the Department of Justice’s criminal division will now review all civil cases filed under the False Claims Act by whistleblowers. Announced in September (RMC 9/22/14, p. 1), this formal review is a bit ominous considering the convergence of “really complicated cases in the world of managed care, Stark and other payment issues” and relators’ counsel who increasingly see their cases through even when DOJ declines to intervene, Vernaglia says. “You need to continue to be vigilant to make sure you have strong compliance programs to make sure you deal with whistleblowers in appropriate ways,” both in terms of preventing and detecting fraud and abuse and avoiding claims of retaliation and employment discrimination.

**Billing Incident-to a physician’s services/shared visits:** Practices are running afoul of the requirements, and Glaser expects more scrutiny. Providers are still making rookie mistakes with direct supervision, which means physicians must be onsite, and with the hospital version of incident to, which is known as shared services or split

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visits but requires both the nonphysician practitioner and the physician to see the patient on the same day. A subtler compliance issue is the requirement that the care must be for the same course of treatment. “Some people shorthand that to mean if there is a new problem, the doctor has to see the patient. The Medicare manual doesn’t say that. It never talks about new problems. It refers to ‘the course of treatment,’” Glaser says. What is “a course of treatment”? CMS never says explicitly. “The conventional wisdom is anytime that it’s a new problem, patients have to see a doctor. But that’s not consistent with the way the manual is worded. You can make the argument that if someone has cancer and develops an infection, it is a new problem but still the course of treatment,” he says. Physicians still have to see patients frequently enough to say they are involved in treatment. “However you interpret the language, it’s clear you can’t have new patients seeing someone other than the physician and bill the service incident to. Similarly, the physician must be periodically involved in the care,” Glaser says.

**Medicare 855 enrollment forms**: Errors in the enrollment or revalidation process can lead to revocation of Medicare billing privileges, and CMS this month expanded its authority for revoking privileges and cracked down on corrective action plans (RMC 12/8/14, p. 1). “We’ll be watching CMS execute the authorities given them under the Affordable Care Act,” Vernaglia says.

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**CMS: New -59 Modifiers Are Optional Until New Guidance Is Released**

Modifier -59 — the most popular modifier — will be replaced by four new modifiers on Jan. 1, but hospitals and physicians don’t have to use them until CMS has more to say on the subject.

“To allow for a gradual transition, CMS and its MACs will not require the use of the new modifiers without publishing guidance about specific circumstances in which the modifiers will be expected,” a spokesman tells RMC.

CMS in August announced it was replacing modifier -59, effective Jan. 1, with more defined subsets of the modifier, according to Change Request 8863 and a companion MLN Matters article (MM8863). The purpose of the new modifiers is to minimize the potential for overpayments.

Modifier -59 is appended to a CPT code when providers perform a separate and distinct procedural service on the patient on the same day as another procedural service that is not an evaluation and management service. It allows providers to bypass National Correct Coding Initiative edits that normally block a separate payment, which means the modifier can provide for more reimbursement. “It is also associated with considerable abuse and high levels of manual audit activity, leading to reviews, appeals and even civil fraud and abuse cases,” the MLN Matters article states. “CMS believes that more precise coding options coupled with increased education and selective editing is needed to reduce the errors associated with this overpayment.”

The potential delay is an interesting development, but unless CMS puts it in writing, providers have to follow the published instructions, says Stephen Gillis, director of compliance coding, billing and audit at Partners HealthCare in Boston. In other words, he thinks hospitals and physicians should implement the new modifiers on Jan. 1, as CMS stated in the change request. “Otherwise, there could be claim rejections,” Gillis says.

The four new modifiers are:

- **XE**: Separate Encounter (a service that is distinct because it occurred during a separate encounter).
- **XS**: Separate Structure (a service that is distinct because it was performed on a different organ/structure).
- **XP**: Separate Practitioner (a service that is distinct because it was performed by a different practitioner).
- **XU**: Unusual Non-Overlapping Service (the use of a service that is distinct because it does not overlap usual components of the main service).

CMS notes that, consistent with AMA guidelines for CPT coding, modifier -59 or the four new modifiers should be used only “if there is not a more specific modifier than the X modifier.”

The four modifiers are a great data mining opportunity for Medicare, Gillis says. He assumes CMS and its auditors will use the data the modifiers generate to zero in on providers who are improperly charging Medicare for two procedures. While XE and XP are unlikely candidates for errors — “it’s pretty clear” if there are two separate encounters or practitioners — XS and XU are another story, he says. Suppose a physician uses XS to report two separate procedures on different parts of the shoulder or colon. “The physician says ‘I did two different procedures and I am considering this two separate structures,’” Gillis says. “Or it could be two different layers of the skin,” even though the coding guidelines consider it one location. “If I were a MAC or RAC, I’d be excited to have this additional data.”
Although it’s early, Gillis thinks clinicians will be trained on the use of modifiers XS and XU, while coders will be trained on XP and XE. Depending on where procedures are performed — physician offices vs. the hospital — clinicians may assign modifiers XS and XU, with coders vetting them. Coders will assign the other two.

However and whenever the four new modifiers shake out, their use will require more thinking by coders and clinicians, Gillis says. “Questions coders ask will be more pointed and they will be more vigilant. They have to back up the modifier with specific detail because it is more auditable,” he says. “Auditors will say ‘you said this is a separate anatomic site. We say this doesn’t make sense because you would not report two procedures on the shoulder.’”

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Stark Pain Stops at Four Years
continued from p. 1

That means the hospitals are off the hook, even though they feared at some point they were out of compliance with Stark. It’s moot, CMS is saying, because the potentially tainted claims are too far outside the reopening period.

“Using the reopening period to cut off Stark law liability is a powerful weapon providers have so that Stark liability is not endless,” Wade says.

Re-opening allows Medicare contractors and providers to adjust claims before they’re a done deal. According to Chapter 34 of the Medicare Claims Processing Manual, “a contractor may reopen and revise its initial determination or redetermination on its own motion” within one year for any reason and within four years “for good cause” (e.g., new and material evidence has come to light). The manual also states that providers can ask contractors to reopen claims along the same lines. There’s no time limit in cases of fraud or clerical errors.

Two years ago, CMS laid the groundwork for a limit on liability. In an answer to a frequently asked question about the SRDP, CMS said that providers using the SRDP had to report only four years of payments stemming from noncompliant physician relationships, even if they were out of sorts with Stark for a longer period of time (RMC 5/7/12, p. 1). “A disclosing party will satisfy section IV.B.2.c of the SRDP by disclosing the total amount of remuneration received by a physician as a result of the disclosed actual or potential violation based upon the time frame established for reopening determinations at 42 C.F.R. § 405.980(b),” according to the FAQ. That conformed the “look-back” period to the Medicare claims reopening period.

But that only meant they had to self-report for that period of time. That didn’t mean they were off the repayment hook. Now CMS appears to have gone further, with liability beyond the four-year reopening period no longer a concern for providers that disclose actual or potential violations to the SRDP, Wade says.

Even though the False Claims Act has a six-year statute of limitations, potentially giving the Department of Justice a two-year window to pursue noncompliant claims, Wade says its hands may be tied because the claims are closed. DOJ has a leg to stand on only if it argues the hospital knew at the time the claims were filed that they represented services referred by a physician with whom the hospital had a financial relationship that violated the Stark law, Wade says. “It’s a high degree of proof,” he says. “You’d have to show there is some email or board minutes to prove there was fraud indicating that the hospital knew that the financial relationship was not Stark compliant at the time the claims were filed.”

Less Auditing May Be Necessary

The government also can’t use a theory of reverse false claims, which means the hospital knowingly retained undeserved Medicare payments in violation of the False Claims Act, if the claims are beyond the four-year reopening period, Wade contends. “You cannot be accused of inappropriately keeping reimbursement from referrals from Stark-tainted physicians because the claims are closed and neither the provider nor CMS can reopen such claims,” he says.

There’s a practical lesson in CMS “rejecting” Wade’s clients because all their claims were beyond the four-year reopening period. As organizations do audits, he doesn’t recommend they look at claims that are older than four years because there’s no point. “Those claims are closed,” Wade says. “If someone says ‘we believe the Stark violation ended two years ago but lasted three years,’” he advises only auditing for two years, starting two years earlier — between year two and year four. “It reduces internal audit expenses and defines the period they should be auditing,” Wade says. He has been in situations where hospitals say they have to audit over a six-year period because of the False Claims Act. “I say, ‘if it’s purely a Stark law infraction, don’t do that. Only go back four years.’”

However, Wade cautions hospitals not to drag their feet on applying to the SRDP so more of their tainted claims fall outside the reopening period, which is the only period subject to Medicare repayment. “That would be disingenuous,” he says, and could open up hospitals to government allegations of intentional acts, circumvention of the Stark law and perhaps a false claims lawsuit.

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NEWS BRIEFS

♦ “Fundamental reform of the RAC process” is essential to unplug the Medicare appeals machinery, the American Hospital Association said in a Dec. 4 letter to the Office of Medicare Hearings and Appeals. Other solutions, such as the new Kansas City OMHA office, additional administrative law judges and pilot programs, are only “a temporary fix,” AHA said. While OMHA has no “direct control” over the RACs, AHA urged OMHA to share data with CMS and Congress to show how RAC denials gum up the ALJ works. The AHA letter also urged immediate RAC reforms. Because their contingency fees prompt RACs to “issue inappropriate denials with impunity,” some countermeasures should be adopted. “If RACs were assessed a financial penalty for making inappropriate denials, it would lessen these strong financial incentives and promote more appropriate and accurate assessments by the RACs,” AHA said. They also should base medical-necessity denials of inpatient admission only on the documentation available to providers at the time the admission decision is made to avoid the “hindsight is 20/20” problem. AHA wrote to OMHA in response to its request for fresh ideas for expediting Medicare appeals and reducing the backlog (RMC 11/10/14, p. 7).

♦ Spending on compliance rose in 2014 but not quite as impressively as in 2013, according to the results of a new survey on the economy, compliance and ethics conducted by the Health Care Compliance Association and the Society of Corporate Compliance and Ethics. Of the compliance officials who responded to the survey, 35% reported an increase in spending on compliance and ethics programs and 14% reported a decrease. That’s a change from 2013, when it was 38% vs. 12%. But growth in staffing was impressive in 2014, at 36%. And things are looking up for 2015, with 46% of respondents believing spending will rise, although the prediction dropped to 39% for the health care industry. And health care compliance officers expect only a 20% increase in staffing next year, according to the survey, which was announced Dec. 11. Compliance officers’ belief that management sees compliance programs as a “very or somewhat positive asset” dropped from 60% of respondents in 2013 to 55% in 2014, with a corresponding increase in the perception that management saw compliance as a “hindrance” rising from 12% to 18%. View the survey at http://tinyurl.com/lpw6xpp.

♦ OtisMed Corp. and its former Chief Executive Officer Charlie Chi pleaded guilty to charges related to the distribution of FDA-rejected knee replacement surgery cutting guides, the Department of Justice said Dec. 8. OtisMed, which pleaded guilty to distributing, with the intent to defraud and mislead, adulterated medical devices in interstate commerce in violation of the Food, Drug, and Cosmetic Act agreed to pay more than $80 million to resolve criminal and civil liability in the case, DOJ said. Chi pleaded guilty to introducing adulterated medical devices in interstate commerce. Visit http://tinyurl.com/pehbgtm.

♦ The HHS Office of Inspector General issued its semiannual report to Congress on Dec. 10. The report summarizes the office’s achievements during the second half of fiscal year 2014, which ended Sept. 30, OIG says. According to the report, during all of FY 2014, OIG’s oversight and investigations are expected to recover $4.9 billion. Of that, $834.7 million is attributable to audits and $4.1 billion to investigations, “which includes about $1.1 billion in areas such as States’ shares of Medicaid restitution.” OIG also figures there are $15.7 billion in estimated savings thanks to legislative, regulatory, or administrative actions stemming from its recommendations. Those calculations usually come from third parties, such as the Congressional Budget Office. The report also states that OIG excluded 4,017 individuals and entities from federal health care programs in FY 2014 and reported 971 criminal actions. “There were 533 civil and administrative cases, including false claims and unjust-enrichment lawsuits filed in Federal district court and civil monetary penalties administrative matters, which included both OIG-initiated actions and provider self-disclosures,” OIG said. About 80% of its work relates to Medicare and Medicaid. Read the report at http://go.usa.gov/F4vV.

♦ Ear Nose and Throat Associates of Corpus Christi, LLC, agreed to pay $200,630 to resolve allegations it violated the civil monetary penalty law, the HHS Office of Inspector General said on Dec. 3. OIG alleges that for three years the otolaryngology practice submitted claims to Medicare and Texas Medicaid for hearing assessment services provided by unqualified technicians. Visit http://tinyurl.com/3bnymfs.

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