Dedicated Observation Units Gain Ground Amid Concerns Over Compliance, Revenue

More hospitals are opening dedicated observation units to improve efficiency and quality of care, prevent claim denials and increase revenue. The numbers are growing as more Medicare and commercial-payer patients are treated in observation every year.

Between one-third and half of hospitals now have observation units of some kind, said Hussain Marandi, M.D., vice president of physician services for BayCare Health System in Florida, at a webinar sponsored by the Appeal Academy, American College of Physician Advisers and PACE Healthcare Consulting on June 3. There are a lot of forces moving them in this direction. The number of Medicare patients who were treated in observation rose by 88% — to 1.8 million — in 2012, up from 828,353 in 2006, he said. Observation stays that last longer than 48 hours rose from 1% to 11% during that period. This was partly a response to the proliferation of Medicare auditors, who often deny claims for inpatient admissions based on the site of service. In turn, CMS, worried about over-reliance on observation and its effect on the finances of patients, who pay 20% of outpatient services, implemented the two-midnight rule. The intention of the two-midnight rule is to push physicians and hospitals to decide whether patients need hospital care at all based on medical necessity, and then to admit them as inpatients only if they are expected to stay two midnights (or for inpatient-only procedures). CMS anticipates this will generate more revenue for hospitals because some observation patients cross the second midnight, but it may not turn out that way.

continued on p. 6

Risks Grow for Hospitals That Pay MDs Generously Though Practices Lose Money

Hospitals often pay physicians generously after acquiring their practices even when they lose money, a dynamic that puts hospitals in the path of a fraud and abuse freight train, experts say. Hospitals take the losses in stride despite big-dollar false claims cases that focus on the disconnect between compensation and losses.

“They all have gotten comfortable with the idea that practices lose money, and they don’t focus on why they lose money, and they don’t think it’s a risk,” says Timothy Smith, senior managing director of Ankura Consulting Group in Dallas. “Do we have a ticking time bomb? The red flags are out there.” If there isn’t a documented justification for the money drain, such as treating an underserved population, the compensation may not be commercially reasonable as required by the Stark law. Even more perilous is a quid pro quo. “If there is direct evidence of payment for referrals, then that is a kickback, and no amount of lawyering will avoid multimillion dollar liability,” says former federal prosecutor Robert Trusiak, who is now a principal at Compliance Experts, LLC, in Buffalo, N.Y.

When physicians’ compensation is out of whack with the net earnings their practices generate, hospitals figure it must be OK because they relied on physician
compensation surveys, Smith says. But salary surveys are giving people a false sense of security, he says. Using survey data is only one approach to valuing compensation, and it doesn’t usually account for other economic factors, such as reimbursement differences from one market to another and the universe of other valuation methods (e.g., market and cost). Inextricably linked to this is the fact that hospitals focus their Stark compliance far more on fair-market value than commercial reasonableness, Smith and Trusiak say. If compensation seems kosher according to survey data, hospitals may set aside the fact that the practice loses money post-acquisition.

“The feds are focused on this, but the marketplace is not,” Smith says.

The divorce of losses from compensation arose recently in the Department of Justice’s false claims case against Citizens Medical Center in Texas, which paid $21.75 million to resolve Stark allegations that it gave bonuses to emergency room physicians for their patient referrals to a cardiac unit and overpaid employed cardiologists (RMC 4/27/15, p. 1). While the case was ongoing, Judge Gregg Costa of the U.S. District Court for the Southern District of Texas denied a motion to dismiss, saying, “the Court notes Relators’ allegations that the cardiologists’ income more than doubled after they joined Citizens, even while their own practices were costing Citizens between $400,000 and $1,000,000 per year in net losses. Even if the cardiologists were making less than the national median salary for their profession, the allegations that they began making substantially more money once they were employed by Citizens is sufficient to allow an inference that they were receiving improper remuneration. This inference is particularly strong given that it would make little apparent economic sense for Citizens to employ the cardiologists at a loss unless it were doing so for some ulterior motive — a motive Relators identify as a desire to induce referrals.”

Three Reasons Hospitals Lose Money

Smith notes many market participants were surprised by this ruling, since paying physicians at the median has been considered low risk in the industry from a compliance perspective.

He suggests hospitals pay more attention to the reasons physician practices lose money and connect the dots to commercial reasonableness. Here are three reasons why hospitals lose money on their physician practices:

(1) Indifference to maximizing performance and operations at the practice level: “Hospitals don’t always run practices with an eye for their profitability or just breaking even by operating them efficiently,” he says. “They’re running thinking more about the larger continuum of care in their integrated delivery systems. Practices often are just small potatoes in the larger menu of services.”

(2) Conversion of in-office ancillaries to hospital outpatient services: The compensation that many specialists receive is based partly on the net profits they generate from ancillary services, such as EKGs, echocardiograms, MRIs and the administration of chemotherapy drugs, Smith says. But after employing physicians, hospitals often shift the ancillaries to hospital outpatient departments, where they can charge Medicare more for them as provider-based services. “Net earnings from ancillaries are baked into the physicians’ compensation in the marketplace, including survey data, but when hospitals acquire them and convert the ancillaries to the outpatient departments, it puts the revenue, expense and profits onto the hospital books, which is appropriate,” Smith says. That means a loss on the practice side and leaves hospitals having to justify these losses as commercially reasonable.

(3) Use of survey data to set compensation without considering other economic and environmental factors: Smith says this is a recipe for overpaying or underpaying physicians. Since the current wave of practice acquisitions and employment of the physicians kicked into high
gear over the past decade, there has been a shift toward survey-based compensation. Hospitals use surveys from professional associations, such as the Medical Group Management Association (MGMA) and the American Medical Group Association, and from executive compensation consulting firms to identify fair-market valuation ranges for every specialty. This is a trend partly fueled by Phase II of the Stark II regulations, which recommended survey use in valuations, although CMS dropped the language from Phase III of Stark II, and partly a function of their simplicity, he points out. Typically, surveys report compensation data by specialty in different percentiles (e.g., 25th, 50th, 75th) and other metrics, such as work relative value units (wRVUs), which measure physician productivity. If a physician produces at the 75th percentile of wRVUs, the conventional wisdom is that paying the physician at the 75th percentile of compensation for the specialty is fair-market value. But that method ignores other factors, Smith says. The cost of medicine, like real estate, is based on location. Medicare payments are adjusted for geographic variations, and commercial payer rates vary widely depending on market dynamics among payers, providers and employers.

Industry Is Obsessed With Median Rate

Another piece of conventional wisdom is that physicians should make at least the median rate, a position the government’s expert took in the Stark-based False Claims Act cases against Halifax Health in Florida (RMC 3/10/14, p. 1) and Tuomey Healthcare System in South Carolina (RMC 10/7/13, p. 1), Smith says. Suppose a cardiologist historically earned $42 per wRVU, and the survey median for the cardiologist’s subspecialty is $55. Assuming the cardiologist’s revenue is $100 per wRVU and his overhead is $55 per wRVU, the hospital will lose $10 per wRVU if it pays him the median. “By definition, half the markets in the country can’t sustain the median rate,” Smith says.

Even though it’s risky in terms of commercial reasonableness, surveys are treated like the gold standard, he says. That’s partly because CMS and the HHS Office of Inspector General (OIG) are perceived as favoring surveys, Smith says. Regulators have conveyed that valuation in health care should be different from other industries because of the referral relationship between parties (e.g., hospitals and physicians). As a result, determining fair-market value under the Stark and anti-kickback laws may depart from standard appraisal methodology, he contends, citing a 1992 letter written by then-OIG Chief Counsel D. McCarty Thornton to the IRS (69 FR 16107) and commentary in the Stark II regulations (66 FR 16107, 72 FR 51015). Sometimes that means hospitals pay physicians more than the independent local marketplace would pay. In fact, Trusiak says, “the limitations of fair-market value and no commercial reasonableness become especially fatal when there is direct evidence of wrongdoing.” If the government can prove a physician referred patients to hospitals A and B until a certain point in time and then only to hospital B after it entered into a generous compensation arrangement with the physician, survey data won’t insulate hospital B, he says.

With so much scrutiny of physician arrangements and big-dollar settlements in the Stark and kickback arena, hospitals that are serious about compliance must use a more comprehensive economic analysis for their compensation, Smith says. For example, the IRS just unveiled a practice aid for determining reasonable compensation or the fair-market value of services. It calls for consideration and use of all three approaches to value (income, cost and market), he says. For an income approach, the so-called independent investor test is used, he says. It bases fair-market-value compensation on revenue minus costs, comprehensively defined. Smith also encourages hospitals to identify what causes losses to their physician practices. Is it poor payer mix? A lot of charity care? “Document it and tie it back to the facts and circumstances of the practice by calculating the actual dollar impact of the charity care,” he says. Hospitals also should operate practices more efficiently. “Bring some cost discipline to the practices,” he says. “Don’t simply rely on a general claim of providing charity care.”

And Stark compliance belongs on every hospital’s annual audit list, Trusiak says. That requires continual reviews of the commercial reasonableness of physician arrangements. “Just because they’re commercially reasonable at one point in time doesn’t mean they’re commercially reasonable at another point in time,” he says. Market factors may change. For example, if local market conditions required inflated on-call coverage compensation at a historical point in time, hospitals should critically reassess the market conditions before renewing the physician’s contract to ensure continued commercial reasonableness of the contract price, Trusiak says. Or if deficient quality measures prompted the hospital to increase the time a medical director spent on quality improvement, then every year the hospital should determine

A Guide to Complying With Stark Physician Self-Referral Rules

The industry’s #1 resource for avoiding potentially enormous fines and penalties
(looseleaf/CD combo with quarterly updates)

Go to the “Marketplace” at www.AISHealth.com and click on “Books.”
whether it needs to continue the enhanced oversight. “Set it and forget it creates risk,” he says. “Always assess the status quo with a new set of eyes, or the government will be that new set of eyes.”

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**Senate Committee OKs Medicare Appeal and Audit Reforms Bill**

There may be some hope for breaking the Medicare appeals logjam now that the Senate Finance Committee approved a bipartisan bill with fairly significant changes to the process.

The Audit & Appeal Fairness, Integrity, and Reforms in Medicare (AFIRM) Act of 2015, which was approved on a voice vote June 3, covers a lot of ground. It would provide more funding for the Office of Medicare Hearings and Appeals (OMHA), establish a new category of quasi-judges called “Medicare magistrates” and create a Medicare ombudsman for provider and supplier appeals. Recovery audit contractors wouldn’t be able to do patient-status reviews more than six months after the date of service, and providers with a low denial rate in a particular type of claim would be free from audits of those claims for one year assuming there’s no evidence of fraud and abuse.

If the bill is enacted by the full Congress and signed into law by President Obama, hospitals and other providers should see some movement in appeals that can take months or years to get resolved. OMHA says there’s a 20-to-24 week delay in entering new requests in its case processing system, and “the average processing time for appeals decided in fiscal year 2015 is 603.8 days.”

It’s a good first step, says attorney Andrew Wachler, with Wachler & Associates in Royal Oak, Mich. “It may reduce the backlog,” adds Mic Sager, compliance officer for Olympic Medical Center in Port Angeles, Wash. But the bill “changes the red tape” rather than reducing it.

Here are highlights of the bill, according to the “Chairman’s Mark,” because a draft of the bill is not yet available:

◆ **Provide more money**: OMHA would get an additional $125 million in funding in FY 2016, and the HHS Departmental Appeals Board (DAB) would get $2 million more for conducting reviews, hearings and appeals. That’s on top of their usual funding, which is $87.4 million in FY 2015 for OMHA.

◆ **Increase the “amount in controversy”**: Administrative law judges (ALJs) only hear appeals of denials of claims worth $150 or more, although denials for similar claims involving the same patient or “common issues of law” can be lumped together to cross that threshold. The bill would increase the “amount in controversy” required to get before an ALJ to $1,460, which brings it in line with the amount required for a claim in federal district court. However, claim denials worth less have a new avenue of appeal (see next item).

◆ **Create “Medicare magistrates” inside OMHA**: They would be lawyers with the power to rule on appeals of claim denials that fall between $150 and $1,459. Medicare magistrates would have to be knowledgeable about Medicare laws, regulations, policies and procedures.

◆ **Improve oversight of auditors and HHS administrative judges (e.g., qualified independent contractors (QICs), ALJs)**: This includes developing a strategy to identify claim errors that hit Medicare the hardest or pose the greatest threat to quality of care, devise methods to prevent duplicative review, identify local and national coverage determinations that need updating, ensure providers get discussion periods after postpayment reviews, and coordinate with OMHA and the DAB to ensure the changes mandated in the bill are carried out.

◆ **Establish the right to start over when there’s new evidence**: QICs, Medicare magistrates, ALJs and the DAB would be required to return an appeal to the Medicare administrative contractor (MAC) if the appellant introduces new evidence. There are exceptions to the “remand process,” however.

◆ **Use statistical sampling and extrapolation in appeals**: If the provider is OK with it, MACs, QICs, Medicare magistrates and ALJs would be able to consolidate similar appeals, rule on a sample of them and extrapolate the findings to the rest of them. OMHA already has a pilot project for sampling and extrapolation (RMC 7/28/14, p. 3).

◆ **Refer fraud cases**: CMS, the HHS Office of Inspector General and the Department of Justice would set up a process for OMHA and the DAB to refer “credible suspicion of fraudulent activity” to CMS or law enforcement.

◆ **Train**: OMHA would be required to train ALJs and Medicare magistrates annually on Medicare policies.

Sager says he isn’t thrilled by the additional bureaucracy (e.g., Medicare magistrates). And he thinks increasing the financial eligibility for ALJ reviews will hurt physician practices because they rarely submit claims that will cross the threshold. But “I like that they are proposing grouping claims with similar issues for adjudication,” he says. “We have a form letter for a couple issues and must submit for each individual claim. We win all those appeals.”

Wachler welcomes parts of the bill, including its creation of an alternative dispute resolution process and the opportunity to settle volumes of claims through
When Referrals and Marriage Don’t Mix: MD, Pharmacy Settle Case

In a pure TRICARE case, a compounding pharmacy agreed to pay $3.775 million to settle false claims allegations that it billed for prescriptions written by a physician who is married to an executive at the pharmacy, the U.S. Attorney’s Office for the Middle District of Florida said June 1.

MediMix Specialty Pharmacy LLC in Jacksonville allegedly billed TRICARE for compounded drugs that were not reimbursable from Jan. 1, 2009, to Dec. 31, 2014, according to the settlement. The prescriptions were written by Ankit Desai, M.D., who is married to a MediMix senior vice president, the settlement said. The U.S. attorney’s office notes that Desai is a party to the settlement.

The United States contends these prescriptions resulted in improper referrals and were not appropriately reimbursable,” the settlement says. Desai sent hundreds of prescriptions to the compounding pharmacy and was its top referring physician, the U.S. attorney’s office contends. Neither MediMix nor Desai admits liability in the settlement.

The allegations play like a violation of the Stark law, but Stark doesn’t apply to TRICARE. “Recognizing this problem, we asserted that the claims submitted by Dr. Desai were tainted by an improper financial arrangement that was designed to defraud TRICARE,” says Amy Filjones, a spokeswoman for the U.S. attorney’s office. “In support of this position, we relied on 32 CFR Sec. 199.9, which prescribes certain ‘administrative remedies for fraud, abuse and conflict of interest’” in TRICARE. The regulation defines “fraud” as “[a]rrangements by providers with employees, independent contractors, suppliers, or others which appear to be designed primarily to overcharge the [TRICARE program] through various means used to divert or conceal improper or unnecessary costs or profits.”

The conduct at the heart of the case came to the attention of the U.S. attorney’s office through mining of reimbursement data. In mining these data, “MediMix was identified as a top biller of compounding pain prescriptions,” a U.S. attorney press release notes.

TRICARE is another vehicle for false claims cases, and this settlement may spark more interest among whistleblowers, says attorney Alan Rumph, with Baker Donelson in Atlanta, Ga. They may be able to make arguments using the TRICARE regulations that they can’t with the Stark law, which has explicit exceptions, he says. For example, under Stark, an entity providing designated health services can have a financial relationship with the spouse of a referring physician as long as it’s not an

statistical sampling and extrapolation. It will speed things along, he says. But there are some things in the bill that aren’t helpful, Wachler says. “Remanding an ALJ hearing back to the MAC for introduction of new evidence seems to delay the process,” he says.

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**CMS Transmittals and Federal Register Regulations**

**May 29 – June 4**

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. 100-04, Medicare Claims Processing Manual**

- July Quarterly Update for 2015 Durable Medical Equipment, Prosthetics, Orthotics and Supplies Fee Schedule (R), Trans. 3277CP, CR 9177 (May 29; eff. Jan. 1; July 1; impl. July 6, 2015)

**Pub. 100-07, State Operations Manual**

- Revisions to Appendix C — Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Trans. 1405OMA (May 29; eff./impl. May 29, 2015)

**Federal Register Regulations**

**Final Rule**

- Principles of Reasonable Cost Reimbursement; Payment for End-Stage Renal Disease Services; Optional Prospectively Determined Payment Rates for Skilled Nursing Facilities: Correction, 80 Fed. Reg. 31485 (June 3, 2015)

**Proposed Rule**

- Medicaid and Children’s Health Insurance Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; Proposed Rules, 80 Fed. Reg. 31097 (June 1, 2015)
investment interest and as long as the compensation relationship satisfies an exception (e.g., it’s fair-market value), Rumph says. In contrast, the TRICARE regulations are more open-ended.

“Section 199.9 is pretty broad and captures all kinds of provider fraud involving the TRICARE program,” notes Washington, D.C., attorney Donna Lee Yesner, with Morgan Lewis.

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**Observation Units Are Growing**

Marandi said a study at the University of Wisconsin School of Medicine and Public Health “contradicted” some of CMS’s assumptions about the impact of the two-midnight rule. In the 2014 inpatient prospective payment system regulation debuting the two-midnight rule, CMS said it figured the net effect would be 360,000 more observation cases and 400,000 more inpatient admissions, and used that to explain a 0.29% payment decrease. To evaluate the accuracy of that calculation, researchers applied the two-midnight rule retrospectively to inpatient and observation cases at University of Wisconsin Hospital and Clinics from Jan. 1, 2012, to Feb. 28, 2013. The findings: 7.4% more inpatient cases would have been reclassified as observation if the two-midnight rule were in effect at the time, Marandi said.

The study also found that whether patients are admitted or placed in observation depends on the time they presented at the hospital and the day of the week, Marandi said. “Patients admitted after 4:00 p.m. were admitted as inpatients 31% of the time. Patients who arrived before 8:00 a.m. were admitted as inpatients only 13.6% of the time,” he said. If they came on weekdays, they were less likely to be admitted — 22.6% compared with 26.5% of patients who came on weekends.

MACs Review Patient Status

Because the volume of observation stays continues to increase and the volume of inpatient admissions continues to decrease, hospitals need “efficient delivery methods” that reduce costs, improve “throughput,” provide high-quality care and promote compliance, Marandi said. Patient status remains a fixation of auditors. Under probe-and-educate reviews, Medicare administrative contractors (MACs) determine whether hospitals are complying with the two-midnight rule, and when recovery audit contractors (RACs) are back in the patient-status business, they will also focus on whether admitted patients — including those discharged earlier than expected — should have received outpatient or observation services instead.

Observation units are one solution to the regulatory, quality, revenue and patient-satisfaction challenges facing hospitals, Marandi said. They can ease overcrowding in emergency rooms, improve patient satisfaction by getting patients in beds faster and reduce readmissions and their associated Medicare penalties. Units also reduce liability by “closing the disposition donut hole,” Marandi said.

Patients are typically treated in observation for chest pain; abdominal/gastrointestinal conditions; asthma/bronchitis; dehydration; congestive heart failure; syncope; head injuries/headaches/migraines; seizures; and transient ischemic attacks. But observation is not appropriate for many other situations. Don’t let the units turn into a “dumping ground,” he said. “It becomes one if you let it.” He listed the following “non-qualifier diagnoses for observation services”:

- **Routine preparation for surgery**
- **Diagnostic tests**
- **Recovery from a diagnostic procedure**
- **Outpatient therapy/procedures**
- **Normal post-procedure recovery**
- **Convenience or custodial stays**
**Stays longer than 48 hours**

**Hold for placement in an extended care facility**

When they open observation units, hospitals have to decide whether to dedicate space and staff to observation or distribute observation beds throughout. With the dedicated model, “everyone involved belongs in that unit and is solely responsible for the outcomes in that unit,” Marandi said. It’s been amply demonstrated that the distributed model leads to longer hospital stays. A 2010 study found that average length of stay in a dedicated observation unit was 17.5 hours compared with 22.3 hours nationally for observation patients.

Before hospitals open observation units, they have to answer four questions and re-evaluate the answers annually, Marandi said:

1. **Where will the observation unit be located?** In the ED? Next to it? Will it be virtual (i.e., dispersed)?
2. **How big will it be?** That depends on its goals, the hospital’s census and the size of the ED.
3. **How many beds will be in the observation unit?** (Ninety percent have more than 16 beds; hospitals have an average of five observation beds per 30,000 to 50,000 ED visits annually.)
4. **Who will staff the observation unit?** Hospitalists and/or ED physicians? Physician extenders (i.e., physician assistants and nurse practitioners)? Staffing should be one physician per 3,000 patients, and the recommended patient-to-nurse ratio is five to one, although four to one is preferred, he said.

To succeed, he said observation units also must have protocol-driven care, and policies and procedures that are reviewed annually. “You don’t want to take every patient into observation,” he said. “The more algorithms and standardization of care you provide,” the better.

To evaluate the performance of their observation units, Marandi said hospitals should track and evaluate their volume and occupancy rate; length of stay in hours; percent of patients requiring hospitalization or discharged home (with a discharge-home goal of 80% or more); protocol and guideline compliance; direct and indirect net revenue; costs (variable, total and severity/diagnosis adjusted); and patient/provider satisfaction. The observation length of stay should be under 18 hours, and the inpatient admission rate from observation should be 15% to 40%.

Sometimes observation units fail. The reasons include a lack of strong leadership and failure of the administration to follow through with revenue after units are built, Marandi said. There have to be enough resources for staffing and equipment. If patients need an MRI or a consult, it shouldn’t take 24 hours.

“Ancillary services and diagnostics can be a real killer for dedicated and distributed models,” said Elizabeth Lamkin, CEO of PACE Healthcare Consulting in Bluffton, S.C., at the webinar. Observation time may drag on if the patient is placed there on a Sunday, but the services aren’t available until Monday. If 30% of the patients receiving a certain ancillary service are observation patients, consider establishing treatment protocols. “You don’t need to do a shotgun approach,” she said. “Know which ancillaries you will need, and keep space open on the schedule. Have some staff who can react quickly to observation patients.”

Building a “sustainable unit” also requires meaningful systems of utilization management (UM) that measure and report results (see box, p. 6). Lamkin said. “Utilization committees are one of the few committees that CMS mandates,” and they are in a unique position because they bring together physicians and hospital administrators. “Make it something physicians want to participate in,” she said. Use scorecards because “physicians love data. They are scientists.” RAC results and billing compliance reports should be presented to the UM committee. “CMS expects the committee to deal with outliers,” she noted.

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**NEWS BRIEFS**

**Loma Linda University Medical Center in Loma Linda, Calif., was overpaid $671,000 for calendar years 2011 and 2012,** according to a Medicare compliance review (A-09-13-02056) posted June 2. The HHS Office of Inspector General (OIG) reviewed 214 claims and found errors on 76 of them. On the outpatient side, the hospital billed the wrong number of units for surgeries and injectable drugs, billed for intensity-modulated radiation therapy that was already included in IMRT planning services on the same claim, billed for noncovered dental services and didn’t report manufacturer credits for replaced medical devices, OIG contends. On the inpatient side, the hospital submitted claims for admissions that should have been billed as outpatient or observation services and used incorrect MS-DRG codes. In a letter to OIG, Loma Linda CEO Kerry Heinrich said the hospital disagreed with 53 of OIG’s findings, all
related to inpatient claims. He described its multistep process for reviewing the medical necessity of admissions and asserted the right to appeal 39 of the claims denied by OIG. “Loma Linda University Medical Center takes compliance with Medicare program billing requirements seriously,” Heinrich wrote. Visit http://go.usa.gov/3XpsW.

◆ A False Claims Act (FCA) lawsuit against the pharmaceutical company Allergan, Inc., filed in the Eastern District of Pennsylvania in 2009, will go forward. The whistleblowers alleged that the company violated the anti-kickback statute by remunerating physicians in return for writing prescriptions for its products. Judge Michael Kearny rejected all of Allergan’s arguments in its motion to dismiss and found that the whistleblowers had met all the elements for an FCA claim. Of importance, it rejected Allergan’s argument that the pharmacists filling the physicians’ prescriptions, not the company, had filed the claims at issue. Case law, the court said, does not “effectively immunize from FCA liability pharmaceutical companies who rely on unknowing pharmacists to seek reimbursement — where Allergan allegedly caused false claims to be submitted to the United States rather than physicians or Allergan itself.” Allergan also had argued that business consulting services and expert billing advice it provided physicians did not constitute remuneration and were protected by the First Amendment. But the judge ruled that “it is Allergan’s conduct in providing ‘illegal remuneration’ to physicians and optometrists and not its speech that is at issue.” U.S. ex rel. Nevyas et al, v. Allergan, Inc., No. 2:09-cv-00432 (E.D. Penn., May 26, 2015).

◆ OIG cleared the way for more financial arrangements in two separate advisory opinions posted on June 4. In opinion 15-06, OIG said it won’t impose civil money penalties on a charitable entity’s plan to set up a program to give financial assistance to patients who have cost-sharing obligations for prescription drugs or devices, health insurance premiums or incidental expenses (e.g., travel expenses, ongoing testing) in connection with the treatment of chronic diseases. Although there’s kickback potential if there’s an intent to induce or reward referrals, OIG said it won’t pursue sanctions on this arrangement. In opinion 15-07, OIG gave the fraud-and-abuse green light to a proposal by a company that makes instruments used in percutaneous image-guided lumbar decompression (PILD), which is a minimally invasive procedure involving direct decompression of the lumbar spine in patients with lumbar spinal stenosis. Medicare doesn’t cover PILD for lumbar spinal stenosis except in certain circumstances (i.e., a clinical study). In consultation with CMS, the instrument manufacturer developed a clinical study to assess the effectiveness of PILD using its system vs. a sham procedure. The instrument manufacturer will cover patient copayments and also will pay the costs of the PILD procedure for patients in the control group who are “deemed a failure and elect to have the procedure at the primary endpoint” or who leave the study within a year to have another intervention. View 15-06 at http://go.usa.gov/3Um9. View 15-07 at http://go.usa.gov/3Um3.

◆ OIG on June 1 posted its semiannual report to Congress for the six months that ended March 31. It says it anticipates more than $1.8 billion in recoveries from audits and investigations. It also reported 486 criminal actions and 326 civil actions, including false claims cases and unjust-enrichment lawsuits. Visit http://go.usa.gov/3XN7.

◆ Medicaid pays millions of dollars for claims billed in the names of deceased beneficiaries, according to a new report (GAO-15-313) from the Government Accountability Office. GAO looked at Medicaid beneficiary and provider data in four states — Arizona, Florida, Michigan and New Jersey — for 2011 (the most recent year it had full data). The four states accounted for 13% of Medicaid payments that year. “The identities of about 200 deceased beneficiaries received about $9.6 million in Medicaid benefits subsequent to the beneficiary’s death,” GAO said. Also, about 50 providers billed Medicaid even though they were excluded from the program for various reasons (e.g., patient abuse or neglect, fraud). Since 2011, CMS has improved the integrity of the enrollment process and beneficiary eligibility verification, but there’s room for improvement, GAO said. For example, CMS doesn’t require states to review Medicaid beneficiary files for dead people more often than yearly and doesn’t make them use the Social Security Administration Death Master File in conjunction with state-reported death data. Read the report at http://www.gao.gov/products/GAO-15-313.
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