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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QIO Reviews of Short Stays to Start Jan. 1; Auditors Eye ED vs. Admission Records

Quality improvement organizations (QIOs) will begin medical reviews of short inpatient stays under the two-midnight rule on Jan. 1, a CMS official says. Hospitals were expecting QIOs to take the audit reins from Medicare administrative contractors (MACs) in October, but QIOs are still getting everyone up to speed. When it's time, QIOs will review a sample of paid claims and educate hospitals on short inpatient days, which include zero-day stays, one-day stays "and those instances when a beneficiary started to receive hospital care and wound up being admitted," the CMS official says, such as patients who started in the emergency room or observation and were later admitted as inpatients.

"To insure operational success and to minimize provider disruptions, QIOs are incrementally increasing their review activities to be fully operational with regard to these reviews by Jan. 1, 2016," CMS tells *RMC*. "Beginning Jan. 1, 2016, QIOs will conduct medical review of short hospital stay claims under the two-midnight policy standard adopted with the final rule."

CMS announced the shift to the QIOs in the outpatient prospective payment system (OPPS) regulation proposed on July 8 *(RMC 7/13/15, p. 1)*. There won't be any more probe and educate reviews by MACs or routine patient-status audits by recovery

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Hospital Settles FCA Allegations Over Surgery; Feds: MD Scared Patients Into OR

This time, patients were the whistleblowers in a false claims lawsuit, and it has led to both a settlement with an Ohio hospital that billed Medicare and Medicaid for allegedly medically unnecessary spine procedures and to criminal charges against the surgeon who performed them.

West Chester Hospital in Cincinnati and its parent company, UC Health, agreed to pay $4.1 million to settle the false claims allegations, the Department of Justice (DOJ) and U.S. Attorney's Office for the Southern District of Ohio said Oct. 9. The surgeon embroiled in the case, Abubakar Atiq Durrani, was indicted by a grand jury in 2013 for health care fraud and was arrested, but after his arraignment, he went on the lam and is apparently still a fugitive, DOJ says.

Durrani allegedly duped patients into spine surgeries they didn't need, leaving them damaged and in pain, according to the false claims complaint and indictment. He allegedly told some cervical spine patients their head "would fall off" in a car accident "because there was almost nothing attaching the head to the patient's body," the indictment contends.

Medical necessity continues to be a priority for DOJ as it investigates more civil and criminal cases in tandem, with an eye on patient harm. "This really underscores what the government indicates will be a priority of law enforcement: parallel proceed-

ings," says former federal prosecutor Brian McEvoy, an attorney with Polsinelli in Atlanta. In September 2014, Assistant Attorney General Leslie Caldwell said that all False Claims Act lawsuits filed by whistleblowers will be immediately reviewed by prosecutors in the criminal division in addition to the usual review by lawyers in the civil division *(RMC 9/22/14, p. 1)*. Future civil or criminal cases against hospitals also may mean criminal charges for executives in light of a DOJ policy change. Last month, in the so-called Yates memo, DOJ said it won't settle civil and criminal corporate fraud cases unless corporations cough up names of "culpable" individuals, who will be held accountable *(RMC 9/14/15, p. 1)*. They won't be easy cases to make, McEvoy says, but "I think they will be able to try. It is a scary proposition for health care executives nationwide who, in many instances, will be presumed to have had criminal knowledge they may not have."

In this case, only the corporation settled allegations, which West Chester Hospital and UC Health denied in the settlement. The surgeries were performed between May 27, 2009, and April 25, 2013; West Chester Hospital yanked Durrani's privileges in March 2013.

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The false claims lawsuit was filed by some of Durrani's patients — Ralph David Scott, Cory Wright, Rebecca Applegate and others — who underwent spine surgery. They alleged Durrani performed spine surgery using a drug that was not FDA approved for the type of surgery he performed, and that the surgeon and West Chester Hospital billed Medicare for the surgeries even though they were not covered or reasonably necessary.

According to the complaint, the surgeon implanted spinal rods, screws and cages during spine surgery and used a drug called BMP-2, which is marketed by Medtronic under the name Infuse. BMP-2 was not FDA approved for cervical and thoracic spine surgeries, the complaint says. Its use was FDA approved only "for a limited procedure, performed on a limited area of the spine, using specific components," the complaint says.

There are problems with using the drug off-label, alleged the complaint. Infuse "frequently causes excessive or uncontrolled…bone growth on or around the spinal cord," the complaint alleged, which can compress the nerves. If that happens, patients may suffer from pain, spasms, cramps and paralysis.

The whistleblowers also allege Durrani and the hospital "falsely marketed Medtronic pedicle screw hardware to" two of them as safe for their cervical spine procedures.

Patients Allegedly Misled About Surgery

For example, Durrani performed procedures on Scott at West Chester Hospital using Medtronic hardware and BMP-2 in January and September 2010. The second procedure was an anterior cervical fusion, which involved implanting a cervical pedicle screw at the patient's C6-C7 vertebrae. Use of pedicle screws in the cervical spine is not FDA approved except when the patient suffers extreme trauma or needs end-of-life pain control, which was not relevant here, the complaint said. The surgeon and hospital were paid for the procedure, even though it was medically unnecessary, the complaint alleged.

Durrani is innocent until proven guilty. But the allegations in the indictment paint a picture of the surgeon as sort of a con man. "Durrani would persuade the patient that surgery was the only option, when in fact the patient did not need surgery," the indictment alleged. The surgeon described the patients' medical situations as "urgent," telling them "falsely" they were at risk of "grave injuries without the surgery." Radiology reports were not read at all or were disregarded, even though he ordered them, according to the indictment. "Durrani would provide his own exaggerated and dire reading of the patient's imaging that was inconsistent with or plainly contradicted by the report written from the radiologist."

Also, operative notes and treatment records allegedly had false statements about diagnoses, procedures and instruments used to perform the procedures. "Many of the patients treated by Durrani for back and neck pain were left in a worse position due [to] the unnecessary surgeries he performed," the indictment alleged.

For example, Durrani diagnosed "patient 3" with rotational instability at the C1-C2 level, performed a posterior spinal fusion with instrumentation and documented it in operative notes and medical records. But imaging and medical records revealed that the patient didn't have instability and didn't require surgery, the indictment alleged. The surgery resulted in "serious bodily injury to patient 3" while lining Durrani's pockets, according to the indictment.

Durrani, who allegedly performed medically unnecessary procedures on patients in Kentucky and Ohio, was charged with five counts of health care fraud and five counts of making false statements in health care matters, the U.S. Attorney's Office said.

Screening Is Suggested 'at Every Portal'

The false claims settlement and the indictment are the latest in a series of cases challenging the medical necessity of procedures. In June, Michigan neurosurgeon Aria Sabit pleaded guilty to health fraud for performing medically unnecessary spinal fusions *(RMC 6/1/15, p. 1)*. Several hospitals have settled false claims cases in connection with medically unnecessary stent surgeries *(RMC 8/4/14, p. 1)*, and hundreds of hospitals are on the cusp of resolving false claims allegations of billing for medically unnecessary cardiac defibrillator implants *(RMC 10/5/15, p. 1)*.

"The medical necessity of procedures is even more difficult for a hospital to evaluate than physician decisions regarding hospital admissions, and those are not easy," says San Francisco attorney Judy Waltz, with Foley & Lardner LLP. Unlike many commercial payers, Medicare doesn't preauthorize procedures, so there is no process for evaluating the recommendation of surgery before agreeing to pay for it. "Hospitals clearly don't want to discourage referrals to their hospitals or make it too much of a hassle to be admitted for a lucrative procedure by a physician who probably specializes in these procedures," she says. "Hospitals can't insist on a second opinion before they admit patients for surgery," although they can make some moves to protect themselves, such as pre-op testing for MRSA so they aren't penalized for hospital-acquired conditions.

It takes screening procedures "at every portal of entry" to guard against medically unnecessary procedures and admissions, says Elizabeth Lamkin, CEO of PACE Healthcare Consulting. For example, when patients present to the hospital for tests or procedures, a care manager or registrar nurse should ensure the diagnosis is considered medically necessary or determine if procedures are on the inpatient-only list. Even with safeguards, hospitals may trip up on procedures. "Surgery and radiology are sort of the donut hole that gets missed," she says. Audits of surgery departments often find there is no history and physical in the medical records. "We talk about the environment of familiarity," Lamkin says. "Surgeons have relationships with the departments, which don't understand it's their job to make sure patients don't get put into the OR without all the screening in place. They think if there's an order, they're good." But an order isn't enough; patients have to be screened for appropriate utilization and medical necessity, she notes.

For example, the cardiac catheterization lab may not ask for a diagnosis when cardiologists schedule patients for elective cardiac caths. "They may schedule without the appropriate screening triggers, and this is where the cardiologist gets into trouble," Lamkin says. Auditors are denying claims for unnecessary or undocumented cardiac caths. "Hospitals need to have a system where a care manager or someone else looks at the diagnosis to make sure it's appropriate for the cath," she says. On the back end, the cath lab's cardiac committee, which oversees the medical staff, should monitor physician compliance with American College of Cardiology guidelines, such as the percent of normal caths, Lamkin says. If a physician falls outside any of the metrics, find out why. "It's another check and balance," she says.

Compliance Is 'a Protection'

Physician advisers believe they can prevent medically unnecessary services on the front end, "but if they don't know about it, they can't stop it," Lamkin says. It's effective to combine a front-end process with a physician adviser leading the utilization function, educating physicians and building their trust. "You don't want to alienate doctors, but you have to be truthful and hold them to a regulatory standard that protects them," she says. "Make sure physicians know the government is out there with well-funded [auditors and enforcers]," and compliance "is a protection the hospital is offering."

A gag order was issued in the Durrani case, so attorneys for the whistleblowers and hospital could not comment, said Eric Deters, an attorney for the whistleblowers. UC Health did not respond to a request for comment.

Contact McEvoy at BMcEvoy@Polsinelli.com, Waltz at jwaltz@foley.com and Lamkin at elizabeth.lamkin@pacehcc.com. View the DOJ press release at http://tinyurl.com/ok8cjsq. ✧

Checklist to Keep Track of Corporate Integrity Agreement Requirements

Organizational skills have helped Misty Bridwell, chief compliance officer at One Step Diagnostic, survive her first year on the job, which includes overseeing the Houston company's corporate integrity agreement (CIA) (see story, p. 5). This is a master list of all CIA obligations, which she uses as a reference to ensure they are all completed. It's unique to One Step Diagnostic but could be adapted to other CIAs, which have many of the same requirements. Bridwell keeps paper copies of everything — including physician agreements and fair-market analyses — in a binder so it's all at her fingertips in addition to the electronic versions. "Everything is accessible, clear and easy to read" for the independent review organization, she notes. Contact Bridwell at mbridwell@onestepdiagnostic.com.

Task	Complete
Identify Covered Persons	
CCO Job Description/CCO Appointment	
CCO Report Template for Reports to CEO, Director of Physician Relations	
Compliance Committee Charter	
Compliance Committee Membership	
Minutes Template for Compliance Committee	
Monitoring & Oversight Protocols for Certifying Employees	
Code of Conduct	
Policies & Procedures	
P&P - Reporting Requirements & Mechanism and Non-Retaliation	
P&P - Obligation to Report Sanctions; Screening	
P&P - Compliance Training & Certification	
P&P - Personal Service Arrangements with Physician	
P&P - Anti-Kickback & Stark Requirements	
P&P - Gifts & Gratuities & Non-Monetary Compensation	
P&P - Overpayments from Government Programs	
P&P - Compliance Program Investigation & Reportable Events Procedures	
P&P - CIA Records Retention	
Code of Conduct & P&P Distribution Procedures	
Employee Compliance Performance Evaluations	
Training Plan	
Training Materials - General Training	
Training Materials - Arrangements Training	
Develop Arrangements Database	
Remuneration Tracking - Personal Services & Other AP Payments	
Remuneration Tracking - NMC	
Time Sheet/Activity Log Tracking	
Monitoring Systems - Arrangements	
Arrangements Review & Approval Process	
CCO Arrangements Systems Review Process	
Response Systems - Arrangements	
New Contract Language for Physicians - Training & Certification	
IRO - Compliance Program Review Engagement	
IRO - Arrangements Engagement	
Disclosure Program - Hotline	
Disclosure Program - Promotion (Posters, etc.)	
Disclosure Log	
Annual Report	

In Baptism by Fire, New CCO Learns The Job While Overseeing CIA

One Step Diagnostic didn't have a compliance program when it drafted employee Misty Bridwell — then in a marketing position — to be the chief compliance officer (CCO) last year and put her in charge of its new corporate integrity agreement (CIA). It has been compliance baptism by fire for Bridwell, who spent much of her career up to that point in marketing and administrative positions.

"I didn't know the role existed, so when they proposed it to me, I did Google searches," she recalls. She had to start from scratch, with the HHS Office of Inspector General (OIG) looking over her shoulder. But starting from scratch turned out to be a relative concept. "Compliance is its own little world, and once you get in it, you realize you don't have to reinvent the wheel," she says.

The CIA was imposed when One Step Diagnostic, a Houston-based chain of diagnostic testing facilities, in October 2014 agreed to pay $1.2 million to settle false claims allegations that it violated the Stark law by paying physicians for referrals through "sham consulting and medical director agreements," according to the U.S. Attorney's Office for the Southern District of Texas.

Bridwell assumed she was just taking on CIA oversight, which is formidable enough. "I thought, 'OK, I will monitor these things in the CIA, make sure it's flowing smoothly, ensure the organization is in compliance,'" she says (see box, p. 4). But of course, being the compliance officer requires more than that. While she calls the CIA her "bible," Bridwell says the company has developed additional policies and procedures and is building a culture of compliance "and doing things necessary to have a compliance program. It's a busy job. You never know what your day will be like."

Supported by the Board

There have been ups and downs this past year and valuable lessons learned.

"One big thing was resources," Bridwell says. "The board assumed [the compliance officer] can do it all." But compliance obviously involves a lot of tasks, including exclusion screening, and she sought to fund them and bring the compliance program to life. "Not so much now, because they see [compliance] as a benefit," she says. Bridwell also had to learn the art of dealing with the board. "There were growing pains," she says. Board members didn't always understand her approaches to the compliance program and developing the corporate culture. They have gotten better, though, at talking things through. "Instead of dictating what we are doing, it's more strategic. We come up with a solution together," she says. "Having a great board that supports me has added to the success of our compliance program."

At one point, Bridwell was thrown a curveball when a member of the compliance committee questioned her ability to perform the job — even though she says she had been handpicked by the CEO of One Step Diagnostic and approved by its outside law firm. "That was extremely challenging," she said. "Based on how well the compliance plan was running, I didn't expect someone to say the things that were said or feel the way they felt or for me to be perceived as the bad guy. When the changes started, I was the face of the changes, so I took the brunt of everything." Two weeks later, the committee member who had questioned her apologized. The stress of it was somewhat mitigated when the chief operating officer defended Bridwell at the meeting and reiterated the support she had from many quarters. But Bridwell was still frustrated by the fact that the person had criticized her performance on areas that don't fall under her jurisdiction. "Some people think human resources is compliance," she says. "We have been working hard to distinguish the two. If I get approached with a question like, 'when do my health benefits kick in?' I say, 'you need to call HR.'"

Another lesson was learning to make use of all the resources out there. She relies on the Health Care Compliance Association and got certified as a compliance officer. Also, the first consulting firm that One Step Diagnostic hired wasn't a good fit professionally or personally, but things turned around when she found Susan Walberg of Kohler HealthCare Consulting. As a new compliance professional, Bridwell said she needed to slow down and have the reasons "why we were doing this and how this works" explained to her.

The main thrust of the CIA is "focus arrangements" — preventing and detecting improper physician relationships. Bridwell sometimes ran into resistance to implementing policies and procedures in areas that did not pertain to physician arrangements. She would be asked how it was relevant. "It was an evolution," she says. "It took us a year to where we are all on the same page on

how the compliance program will work." Now the company has an audit and overpayment refund program.

One Step Diagnostic has gone from having no compliance program to Bridwell's goal of omnipresence. There is the usual — training and a hotline — but also smaller gestures, such as compliance questions on the intranet (i.e., where can you find the code of conduct?) and $5 Starbucks cards for the first employee to answer correctly through email. She communicates with the board almost daily.

"I make sure compliance is in everyone's face all the time so they understand who we are and what we stand for," she says.

A CIA was an abrupt way to learn about compliance. "I never knew someone — an IRO [i.e., independent review organization] — would come in and ask a ton of questions about what I do and how I do it. There is no rock unturned with a CIA. You have to be constantly ready for a change or some new concerns," Bridwell says. "In the beginning, the sky is falling, and then [you're] able to fall back and say, 'this is the issue, and this is how we address it.'"

So far, the IRO has reviewed all the reports Bridwell prepared for the CIA and has had no findings, which means "it all looks good." One Step Diagnostic will submit its first annual report to OIG in November.

For more information, contact Bridwell at mbridwell@onestepdiagnostic.com. ✧

CMS Transmittals and *Federal Register* Regulations

Oct. 9 - Oct. 15

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

- 2016 Annual Update for the Health Professional Shortage Area Bonus Payments, Trans. 3370CP, CR 9342 (Oct. 9; eff. Jan. 1; impl. Jan. 4, 2016)

Pub. 100-06, Medicare Financial Management

- Notice of New Interest Rate for Medicare Overpayments and Underpayments - 1st Qtr Notification for FY 2016, Trans. 255FM, CR 9437 (Oct. 13; eff./impl. Oct. 20, 2015)

Pub. 100-07, State Operations Manual

- Revisions and Deletion to Chapter 9 Exhibits, Trans. 148SOMA, (Oct. 9; eff./impl. Oct. 9, 2015)
- State Operations Manual for All Types of Providers and Suppliers Subject to Certification, Trans. 149SOMA, (Oct. 9; eff./impl. Oct. 9, 2015)

Federal Register Regulations

- None published

OMHA Expands Mediation to Clear Appeals; Part A Claims Are Next

Hoping to reduce the backlog of appeals, the Office of Medicare Hearings and Appeals (OMHA) is expanding and "streamlining" its pilot program for alternative dispute resolution, an official said at an Oct. 15 teleconference.

OMHA wrapped up Phase I of the pilot, known as settlement conference facilitation, and moved into Phase II on Oct. 1. So far, it's limited to Medicare Part B claims, but Phase III, which will be rolled out next year, will welcome some Part A claims, said Cherise Neville, a senior attorney in the Office of the Chief Judge.

During settlement conference facilitation, appellants (i.e., providers and suppliers) and CMS try to compromise on a percentage of payment for disputed claims with the help of an OMHA-trained facilitator. "The facilitator uses mediation principles to work toward an agreeable solution," Neville said. The facilitator doesn't make decisions about the merits of a claim or serve as a factfinder. But if CMS and the appellant can hammer out a deal and sign an agreement drafted by the facilitator, everyone can skip a hearing before an administrative law judge (ALJ), and the Medicare administrative contractor can write a check, she said.

Phase I Has Been 'Very Successful'

Phase I of the settlement conference facilitation pilot has been "very successful," Neville said, with "over 2,400 appeals resolved."

There are a number of eligibility requirements for Phase II. For example, appellants can't appeal individual claims worth more than $100,000, and the request for a hearing — while still unscheduled — must have been filed by Sept. 30, 2015.

Neville described the process for Phase II of settlement conference facilitation. To get the ball rolling, appellants submit an "expression of interest" form to OMHA. "Don't include any information on appeals pending with the expression of interest," she said. OMHA then runs a report on pending appeals for that appellant and sends it to CMS. If CMS wants to participate, OMHA updates the appellant and sends a preliminary spreadsheet of the claims eligible for settlement conference facilitation. Appellants then have 15 days to request a settlement conference facilitation "package," which includes the spreadsheet. Appellants have to fill in certain data elements on the spreadsheet and return it to OMHA.

"We understand the amount of information requested may appear to be overwhelming," Neville said, but most of it can be found on the remittance advice, and "most appellants in Phase I have been able to provide it."

CMS or appellants can quit the process at any time, she noted. If they quit, appellants go back in line for an ALJ hearing at the same spot they had before considering mediation. If it's all aboard, CMS, the appellant and the facilitator have conference-call mediation and come to some agreement on the disputed claim.

Payment is negotiated by the parties, but it is based on a percentage formula. For prepayment denials, "the percentage agreed to by CMS is a percentage of the Medicare approved amount less the applicable deductible and/or co-insurance," she said. For postpayment denials, "the percentage agreed to by CMS is the percentage by which CMS will reduce the overpayments at issue."

Visit OMHA at www.hhs.gov/omha. ✧

QIO Reviews Pushed to Jan. 1

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audit contractors (RACs). Instead, every year QIOs will audit 50 medical records from larger hospitals and 20 from smaller hospitals, and refer only repeat offenders to RACs *(RMC 8/24/15, p. 5)*. That means hospitals with "persistent noncompliance with the Part A policy," including a high denial rate, disregard for the two-midnight rule and repeated submission of noncompliant claims after educational intervention. CMS has not yet defined what will push providers over the edge into "persistent noncompliance" but eventually will get there.

When QIOs conduct patient-status reviews under the two-midnight rule, they will request medical records and give hospitals 30 days to produce them. CMS notes that "the documentation that the hospitals have to submit to the QIOs is isolated to the requested medical record."

Although the QIOs won't start reviews until January, they apparently will be looking at claims submitted during the period from October to December, says Ronald Hirsch, M.D., vice president of regulations and education at Accretive Physician Advisory Services. Hospitals should be "as vigilant as ever" and not assume they can wait to see if CMS finalizes proposed changes to the two-midnight rule. In the 2016 OPPS proposal, CMS would allow physicians to admit patients for less than two midnights, but not routinely, if they documented why inpatient admission was medically necessary, such as risk of adverse outcomes. Otherwise, CMS left the two-midnight rule intact *(RMC 7/13/15, p. 1)*.

The fact that QIOs are looking at a relatively small number of medical records only twice a year is a relief for hospitals, "but we don't want them to get a false sense of security for short-stay admissions," says Nancy Perilstein, a senior manager with Deloitte & Touche in Philadelphia. QIOs will expect improvement, or hospitals will wind up back in the RAC's lap, she notes. And other auditors, such as the HHS Office of Inspector General and zone program integrity contractors, are eyeballing admissions.

When they audit short stays, QIOs will exclude claims for patients who died, transferred, left against medical advice or had procedures on the inpatient-only list, Perilstein says. Their education for hospitals that submitted claims deemed medically unnecessary in terms of crossing two midnights will be claim-specific. "That is a huge improvement," she says. CMS allows for Part A payment when patients are discharged before two midnights — often they recover unexpectedly *(RMC 3/16/15, p. 5)* — as long as documentation supports the expectation. "It's the same old story: Documentation will be the key to getting it right," she says.

When reviewing inpatient admissions, Medicare auditors tend to look for discrepancies between emergency department medical records and the attending physician's documentation, Perilstein says. If the ED physician stated there was clinical improvement, it's hard for the attending physician to make a convincing case for a two-midnight expectation. "The first place the contractors go is the emergency department record. It often tells a different story," with the ED doctor writing the patient is stable and then the attending physician admitting him, Perilstein says. "CMS is wondering, 'if the patient is so stable, why are they being admitted to inpatient?' They focus on how the treatment went in the ED." She says hospitals should look closely at how treatment progressed in the ED because maybe observation is the right place for the patient. If not, then documentation should spell out why. Did the chest pain patient's father die of a heart attack at age 40? Is the physician concerned the patient is at risk of dying if he's discharged? Is the patient an asthmatic who has been ventilated in the past? Sometimes patients require the higher patient-nurse ratio of a step-down unit. If it's warranted, document it.

Expect Audits of Syncope, Chest Pain

It's not crystal clear which MS-DRGs will be the focus of QIO reviews, but Perilstein figures they will be the usual short-stay suspects, including syncope, chest pain, cardiac procedures, gastrointestinal disorders and DRGs that represent symptoms instead of diagnoses (e.g., urinary tract infection, dehydration) — "all the low-hanging fruit." Hospitals without low-hanging fruit "are in great shape." Everybody else should audit all or a sample of their one-day stays, she recommends.

CMS reconfigured its QIO program last year. As of Aug. 1, 2014, the QIOs were split into two types: "beneficiary family centered care QIOs" (BFCC-QIOs) and "quality innovation network QIOs" (QIN-QIOs). BFCCs,

which are now in charge of two-midnight reviews, also hear beneficiary appeals of hospital discharges and conduct reviews of higher-weighted MS-DRGs; reviews of hospital readmissions; EMTALA reviews; and focused reviews, which include concerns identified during beneficiary appeals or trends flagged during case reviews. Two companies, Livanta and KEPRO, perform all BFCC-QIO tasks, with KEPRO operating in 33 states and Livanta in 17 states.

Contact Perilstein at nperilstein@deloitte.com. ✧

NEWS BRIEFS

◆ **For now, hospitals can't obtain discounts under the 340B program on orphan drugs used for nonorphan purposes,** according to a federal court decision. The U.S. District Court for the District of Columbia on Oct. 15 vacated interpretive guidance issued by HHS's Health Resources and Services Administration (HRSA), which oversees the 340B drug-discount program (14-1685 (RC)). The court decision was years in the making. When the Affordable Care Act invited more types of entities (e.g., rural and cancer hospitals) to participate in the 340B program, it said they were not allowed to purchase orphan drugs — which are drugs developed to treat rare medical conditions — at the 340B discounted price. However, HRSA in July 2013 issued a final rule (78 Fed. Reg. 44016) clarifying that the exclusion was limited to the indication for which the drug received its orphan designation. That meant covered entities got 340B discounts on orphan drugs if they used them for other conditions. In September 2013, the Pharmaceutical Research and Manufacturers of America filed suit against HRSA to block the implementation of the rule, and on May 23, 2014, the U.S. District Court for the District of Columbia agreed with PhRMA's contention that HHS lacked the statutory authority to issue the regulation. HHS then filed a motion for summary judgment. Meanwhile, the industry is busy evaluating the recently released proposed "omnibus guidance" for the 340B program *(RMC 9/7/15, p. 1; 8/31/15, p. 1)*. View the court decision at http://tinyurl.com/oha4uwk.

◆ **In its fiscal year 2014 report to Congress on the recovery audit contractor (RAC) program, posted Oct. 15, CMS said $2.39 billion of overpayments were collected, and $173.1 million of underpayments repaid to providers.** CMS also addressed efforts to improve the RAC program. All RACs participate in the Electronic Submission of Medical Documentation (esMD) program, and they reported greater provider use in FY 2014. Also, the next round of five-year RAC contracts, which will be going out to bid soon, will include improvements, including giving providers 30 days to request a discussion about an improper payment finding before sending the claim to be adjusted by the Medicare administrative contractor, CMS said. The report to Congress also included CMS's plan to wait to pay RACs their contingency fee until the second level of appeal is exhausted, but that change in payment terms is at the heart of the successful challenge to the new RAC contracts, which forced CMS to re-issue its "request for quotes" *(RMC 3/16/15, p. 1)*. Visit http://tinyurl.com/olkv63w.

◆ **Altru Hospital in Grand Forks, N.D., was overpaid $66,000,** according to a Medicare compliance review (A-07-15-05070) posted Oct. 15. The HHS Office of Inspector General audited 253 outpatient and inpatient claims submitted by the 265-bed hospital in 2012 and 2013 and found mistakes on 12 claims. They included unbillable services related to teeth removal, billing for the incorrect number of units, failing to report manufacturer credits for one replaced medical device and inadequate documentation to support DRG codes. In the hospital's response, Teresa Moe, director of reimbursement at Altru Hospital, said it had refunded the overpayments and improved internal controls. "Altru staff is committed to a culture which upholds a behavioral and ethical model of the highest standards," she wrote. Visit http://go.usa.gov/3Jtux.

◆ **A Tennessee physician was charged with health fraud in connection with his podiatric services to nursing home residents,** the U.S. Attorney's Office for the Middle District of Tennessee said Oct. 9. Podiatrist John J. Cauthon of Murfreesboro was indicted on seven counts of health fraud. Cauthon was contracted to provide podiatric services at nursing homes throughout Tennessee. From May 2015 to August 2015, he allegedly billed Medicare, TennCare and BlueCross BlueShield of Tennessee for nail avulsions that he didn't perform, according to the indictment, the U.S. attorney's office said. Nail avulsions are a procedure to treat ingrown toenails. Visit http://tinyurl.com/njpyfd9.

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