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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Managing Editor
Nina Youngstrom
nyoungstrom@aishealth.com

Contributing Editor
Francie Fernald

Executive Editor
Jill Brown

With ACO Fraud and Abuse Waivers, There's Some Leeway but No Room for 'Subterfuge'

Federal prosecutor Andrew Bobb probably wouldn't lose any sleep over an accountable care organization (ACO) giving Fitbits to patients. But the fitness tracker would have to further the ACO's goals of improving efficiency and quality of care, and the information gathered by the Fitbit must be communicated to the ACO hospital or physician — part of a "holistic" approach to its use — or the ACO could run afoul of CMS's waiver from civil monetary penalties for beneficiary inducements.

"There are no bright lines" about what's acceptable under the ACO beneficiary inducement waiver, Bobb, an assistant U.S. attorney in the Southern District of Texas, said Oct. 24 at the Health Care Compliance Association's Healthcare Enforcement Compliance Institute. "But make sure it's improving outcomes, you're monitoring it, patients are using it and it's providing information to improve the care of patients — and it's not subterfuge to get around the fraud and abuse laws."

The beneficiary inducement and four other waivers give providers a shot at navigating ACOs, which were authorized by Sec. 3022 of the Affordable Care Act, without stumbling over the fraud and abuse laws. Under the Medicare Shared Savings Program (MSSP), ACO "participants," such as hospitals and physician groups, are expected to coordinate patient care with the goal of achieving better outcomes and reducing costs. Medicare pays ACOs, which must be separate companies, on a fee-for-service basis, with shared savings payments if quality and cost-reduction goals are achieved. They must appoint a compliance officer who doesn't double as legal counsel but reports directly to the governing body.

Possibly most pressing from a compliance perspective are the fraud and abuse waivers because they're generally important to ACO survival. In the fee-for-service

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DOJ: Data Analytics Are Giving Enforcers an Edge in Identifying Billing Outliers

Advanced data analysis is allowing federal investigators to identify questionable billing much faster and make connections between what sometimes is a "spider web" of providers that may be perpetuating other violations.

"Data isn't everything, but in terms of getting leads, data is fantastic and unique," said Andrew Weissmann, chief of the fraud section in the Department of Justice (DOJ) criminal division, Oct. 25 at the Health Care Compliance Association's Healthcare Enforcement Compliance Institute. Providers should be using the same kinds of techniques to improve their auditing and monitoring.

"HHS and DOJ have gotten better at how we use data," he said. DOJ hired a compliance consultant and both agencies "have Ph.D.s on staff to mine data to find links and leads. We can take data and make it incredibly granular, breaking it down by state and city." The data is at the fingertips of federal prosecutors in the 93 U.S. attorneys'

offices around the country, through the computers on their desks, and their mothership — the main DOJ office in Washington, D.C. — offers training on how to capitalize on its potential to identify fraud, waste and abuse.

High-Risk Docs Are Targeted

The government mines physician records in real time and retrospectively. Data are used to target high-risk physicians, who face greater scrutiny, Weissman said. "High-risk physicians are conservatively identified by outlier detection methods at both the national and state levels," he says. For example, four of the top 10 high-risk physicians are in the southern district of Texas. Other areas with a concentration of high-risk physicians include parts of California and Florida, based on data from November 2013 to October 2015. He emphasized, however, that physicians may be outliers on a metric for legitimate reasons. "Some doctors will be in the 99th percentile and it doesn't mean it's fraud. This is a question of looking for leads. It is a number of metrics," such as how much was billed to Medicare Part B, how many home health services were ordered or how many patients were "churned," which refers to how long patients were seen by one physician before being referred to another physician and then another physician.

Weissman walked through the case of a Houston primary-care physician — "Dr. A" — who was an outlier. That was based on the number of services billed, ordered or certified compared to other primary care physicians. "First we looked nationally. How did the doctor fare against national statistics?" The results jumped off the page. In eight metrics, the physician was in the 99.5th percentile and in 11 metrics he was in the 95th percentile, Weissman said. In Texas, the physician was at the 99.5th percentile in seven metrics (see box, p. 3).

"One thing we noticed is we see Dr. A billed $67.7 million in total Part B payments," he said. "That's a particularly high figure." On top of that realization, the data seemed to be taking investigators and prosecutors down other promising paths. Of the $67.7 million of Part B payments, 97% was related to orders to 119 home health agencies. "Your antenna starts to go up," Weissman said.

As it turned out, Dr. A accounted for more than 50% of patients at 62 of the home health agencies. The question then became, "how financially dependent are the home health agencies on the business brought by Dr. A?" For five of the home health agencies, more than 90% of the patients were referred by Dr. A. "You see where this is going," Weissman said. "You start with Dr. A and it's a spider web" leading to other entities that benefit from the services he provides or orders, raising questions about potential violations of the anti-kickback law and perhaps prompting prosecutors to look for cooperating witnesses and talk to beneficiaries who were treated by Dr. A and/or the home health agencies. In fact, Weissman said, "the spider web expands." He said that 95% of the home health agencies that Dr. A referred patients to get a lot of their business from similar high-risk physicians. "Seven of the home health agencies of the 119 rely on high-risk physicians to provide 99% of their patients. Do we have more leads to follow?"

Data Make Investigations 'Smarter'

And that "is how you use data" to make fraud and abuse investigations "smarter" and more effective, allowing the government to get a bigger bang for its buck, Weissman said. Health care organizations can leverage data the same way to identify potential problems. "We are aware of the enormous pressure on compliance," he said. When the Department of Justice is conducting investigations, prosecutors will ask about the compliance officers, and "they should have resources and tools," he said. That includes data analytics, which may detect aberrations in various areas. For example, he said, Tenet Healthcare Corp.'s $513 million criminal and civil settlement over kickbacks that four of its hospitals paid for

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patient referrals from a maternity clinic *(RMC 10/7/16, p. 1)* raises questions about its use of data. "A good compliance program would have readily integrated with the procurement process," Weissman contended. "They would have seen contracts that violated the rules." Effective use of data analytics would pick up on problems, such as substitute invoices that did not comport with paper processes.

"We are hoping [compliance officers] can go back and say, 'if you don't pay attention to it now, you will have to pay attention later,'" Weissman said. "We are trying to endorse your role and empower compliance professionals." DOJ welcomes feedback if the health care industry thinks things should be done differently. One suggestion DOJ received: ask senior leaders about their compliance backgrounds when reviewing compliance programs, which is par for the course in an investigation. "It was duly noted," he said. "We now ask about the compliance backgrounds of the board of directors." ✧

Medical Group Settles Case Over Copay Waivers, Low-Level Codes

A medical group in New York state has settled a false claims lawsuit over copay waivers and misuse of low-level CPT codes, two areas that seem to be dogging providers.

Hudson Valley Hematology-Oncology Associates, which operates six clinics, agreed to pay $5.31 million to settle Medicare and Medicaid false claims allegations, the U.S. Attorney's Office for the Southern District of New York said Oct. 21. Hudson Valley also entered into a five-year corporate integrity agreement with the HHS Office of Inspector General over the misconduct, which spanned 2010 to 2015.

The routine waiver of Medicare cost-sharing amounts potentially implicates the anti-kickback statute and the civil monetary penalty (CMP) law forbidding inducements to beneficiaries. Hudson Valley also billed for

Using Analytics to Identify Billing Outliers

Andrew Weissman, chief of the fraud section in the criminal division at the Department of Justice, explained how DOJ uses data analysis to track down leads at the Oct. 25 Healthcare Enforcement Compliance Institute, which was sponsored by the Health Care Compliance Association. Here are two examples based on real cases.

Data Analytics can focus an Investigation and discover other "high-risk" providers		
Metric	**Commentary**	**Follow-Up**
Dr. A billed for $67.7M in total **Medicare Part B*** payments.	For physicians generally, especially primary care, this figure is high. Dr. A's billing correlated with a pattern of not providing care.	Is there a particular code or service Dr. A for billing for the most? Would the reimbursement level account for the billing?
$65.6M (97%) of total Part B payments were for home health orders to 119 **Home Health Agencies** (HHAs).	Clear outlier. In a deeper analysis, Dr. A is an outlier for HHA services in 4+ metrics nationally and in Texas.	Can we detect a relationship between Dr. A and the HHAs? Is there a suspicious pattern?
At 62 of the 119 HHAs, Dr. A accounts for over 50% of the HHA's patients.	Financially, these HHAs are very dependent on Dr. A. In fact, at 5 of the HHAs, over 90% of the patients are referred by Dr. A.	How financially dependent are these HHAs on business brought to them by Dr. A? Alert investigators to look for kickbacks.
Just from Dr. A's referrals, the 119 HHAs received $55M in payments.	In fact, Dr. A accounts for over 75% of total HHA payments at 8 separate HHAs.	Is there anything characteristic among these 119 HHAs?
95% of the HHAs Dr. A referred to get the majority of their patients from "high-risk" physicians like Dr. A.	The spider web expands. Particularly worrisome are the 7 HHAs relying on high-risk physicians to provide 99%+ of their patients.	What other "high-risk" physicians are referring to these HHAs? Are these physicians colleagues with Dr. A?
Data Analytics builds stronger cases by combining multiple databases		
Metric	**Commentary**	**Follow-Up**
79.9% of Dr. B's **Medicare Part D**** patients were prescribed a **Controlled Substance**.†	National outlier comparison shows Dr. B's controlled substance metric is significantly above the national 99.5th percentile (52.8%).	Do Dr. B's patients seem to be drug-seeking? Are they only receiving prescriptions for controlled substances?
33.9% of Part D patients were ONLY prescribed Controlled Substances. Most prescriptions were for **hydrocodone and oxycodone**.‡	Many of these patients may show drug-seeking behavior and seek care from multiple physicians in different locations.	Where are patients coming from? Since patients switch often, analysts must utilize realtime databases.
Dr. B patients are not just from Michigan. He is writing prescriptions for patients from Ohio, Kentucky, and Indiana.	Patient recruiters may be involved. The form of payment for these prescriptions needs to be determined.	How much Medicare Part D billing is attributable to Dr. B's Controlled Substances prescriptions? Could patients be paying in cash?

***Medicare Part B:** This medical insurance helps cover physicians' services and outpatient care. It also covers some medical services not covered in Part A, such as services of physical and occupational therapists and some home health care.

****Medicare Part D:** This Medicare prescription drug benefit subsidizes the costs of prescription drugs and prescription drug insurance premiums for Medicare beneficiaries.

†**Controlled Substance:** A prescription drug or chemical whose manufacture, possession, or use is regulated by a government (Title 21 C.F.R. §§ 1308.11-1308.15). These medications are categorized by the Drug Enforcement Administration (DEA) as a Schedule II-V Controlled Substances.
‡ Hydrocodone (e.g. Vicodin) and Oxycodone (e.g. Percocet) are both Schedule II Controlled Substances.

low-level services that were already included in payment for other procedures, such as infusions. "With a little lack of oversight, this is something that could happen to any practice in the country," says Washington, D.C., attorney Jake Harper, with Morgan Lewis.

The false claims lawsuit was set in motion by a former Hudson Valley employee, Lucille Abrahamsen, who was an accounts receivable representative responsible for coding and charge entry. She became a whistleblower and the U.S. Attorney's office later intervened in the case and filed a complaint in intervention.

Copay waivers trouble the government because they inflate the amount Medicare pays for services. As the HHS Office of Inspector General said in a 1994 fraud alert, "if a supplier claims that its charge for a piece of equipment is $100, but routinely waives the copayment, the actual charge is $80. Medicare should be paying 80 percent of $80 (or $64), rather than 80 percent of $100 (or $80). As a result of the supplier's misrepresentation, the Medicare program is paying $16 more than it should for this item."

Providers are permitted to occasionally waive copays when they document the patient's financial hardship, but it shouldn't be the norm. According to the complaint, "Hudson Valley routinely waived copayments, without making an individualized determination of financial hardship or exhausting reasonable collection efforts." Patients were given a pass because they had high balances, said they couldn't pay or were frequent patients. "Hudson Valley often waived the copayment associated with it even if the patient did not request a waiver. Hudson Valley would note the automatic waiver in its billing systems by indicating '99212 courtesy write off,'" the complaint said. These reasons didn't pass muster, and there was no documentation to support them.

"It is such a black and white area, and it has been since the 1994 OIG fraud alert," says Ed Gaines, chief compliance officer for Zotec Partners' Emergency Medicine Division in Greensboro, N.C. There's no waiving copays and deductibles routinely for government payers and it should be done on a case-by-case basis when patients have established financial need, he says. While there's "tremendous pressure on practices to ease the burden on patients — aside from government payers, they are now the largest payer in health care, with average out-of-pocket costs of $1,060 per patient, according to the Kaiser Family Foundation" — copay waivers will get practices in hot water, Gaines says. They have been dominant in other cases. The Institute of Cardiovascular Excellence in Ocala, Fla., was accused in a false claims lawsuit of waiving copays and performing medically unnecessary procedures *(RMC 1/12/15, p. 5)*, and on June 30, 2016, agreed to settle the case for $2 million. Its owner, cardiologist Asad Qamar, accepted a three-year exclusion from federal health care programs. In an unrelated case, the HHS Office of Inspector General alleged that Seton Family of Hospitals in Texas, doing business as Seton Shoal Creek Hospital, violated the CMP laws that prohibit the submission of false claims and copay waivers. Seton agreed to pay $2.474 million *(RMC 5/11/15, p. 5)*.

"Commercial health plans have also been active in litigation challenging physician groups and hospitals that routinely waive patient cost-sharing when these providers go out of network and do so in an attempt to maintain their patient and referral network base," Gaines says.

Providers Need Proof Patients Can't Pay

Absent an individualized determination of financial hardship, providers should attempt to collect copays, no matter how small or how precarious the patient's finances, Harper says. When providers decide to waive copays for certain financially needy patients, they must document this in advance. "This settlement makes it clear that providers can't rely on the patient's representation," he says. "They need documented proof of inability to pay before waiving the copay." And copay waivers can't be advertised, Harper notes. If patients are not eligible for waivers, they should be subject to the usual collection practices. And remember to treat commercial, Medicare, Medicaid and TRICARE patients the same. Even if hospitals and physicians feel like it's not worth their while to pursue patients for $5 copays, they have no choice, Harper said. "Otherwise they could be accused of violating the anti-kickback law, civil monetary penalty for beneficiary inducements and insurance fraud laws."

The other allegation against Hudson Valley was its billing for lower level codes — 99211 and 99212 — when the services associated with the codes were not medically necessary, performed or documented or otherwise didn't comply with Medicare rules, according to the complaint.

Providers use CPT 99211 when a patient's problems are "minimal," the complaint states. "Code 99211 is the only E/M code that explicitly states that it 'may not require the presence of a physician or other qualified healthcare professional.' Code 99211 is typically used to bill for services provided exclusively by nurses." More effort is required to bill 99212. Typically, the physician spends about 10 minutes face to face with the patient and/or family. It requires "two of three key components: (1) a problem-focused history; (2) a problem-focused ex-

amination; and (3) a straightforward medical decision," according to the complaint.

Because Hudson Valley provides infusions, injections and chemotherapy, the CPT codes for those treatments have been bundled, and they bill the relevant procedure codes. "E/M code 99211 cannot also be billed," the complaint contends. To bill for a higher-level E/M code, Hudson Valley would have to provide "a significant, separately identifiable E/M service that is above and beyond the usual pre- and post-operative work of the procedure."

But that's not what happened, the complaint said. It is, however, what the medical group billed Medicare for.

The way the complaint explains it, Hudson Valley had two schedules: the M.D. schedule and the R.N. schedule. If they were on the latter schedule, patients received their B12 injections, blood withdrawals or chemotherapy. Even though the patients on the R.N. schedule didn't see physicians, the progress notes in their charts were signed by one of the Hudson Valley physicians. "For those charts, the doctor would falsely certify that he or she had participated in the evaluation and management of the patients on the R.N. schedule," according to the complaint. Then Hudson Valley would bill Medicare or Medicaid extra for an E/M service "based upon the false certifications by the Hudson Valley doctors."

Low-Level Codes Are Sleeper Risk

For example, "patient C" received infusions three times in September 2012 related to her hernia. There's no documentation indicating other services, the complaint says. "The patient's chart, however, falsely certifies for each of those dates that a physician spent at least ten minutes 'in evaluation and management of the patient,' and contains the physician's signature. For these procedures Hudson Valley submitted claims to Medicare for CPT code 99212, in addition to the CPT codes relating to venipuncture and infusion, although no separate evaluation and management service was necessary, nor is there evidence that any such service was actually provided to the patient, apart from the doctor's false certification," according to the complaint.

Improper billing for low-level codes may be a surprising risk area for many practices. "Providers shouldn't skimp on the compliance efforts they put into those codes, thinking the ramifications of getting them wrong don't seem as threatening," Harper says. Under the False Claims Act, even codes that generate minimal reimbursement "can quickly add up to astronomical liability," he notes. Low-level coding recently led to a $1.4 million settlement with a New Hampshire hospital *(RMC 10/17/16, p. 3)*.

In the settlement, Hudson Valley admitted to the misconduct alleged in the complaint. Harper is concerned about the implications of more providers admitting to conduct in settlements. It makes them more vulnerable in related litigation, including malpractice lawsuits and future actions by enforcers, he says. "If a defendant doesn't have a clear admission of liability in an underlying case, it makes it more difficult for a party in related litigation, such as a criminal matter or private civil matter, to use the defendant's settlement against them."

Contact Harper at jacob.harper@morganlewis.com and Gaines at egaines@ZotecPartners.com. ✧

Some Hospitals Say QIOs Approve Cases That Should Be Denied

Some physician advisers are worried the short-stay audit pendulum has swung too far the other way, with the quality improvement organizations (QIOs) approving claims for inpatient admissions that should be denied. While it's always nice for hospitals to get paid, they learn nothing about the way QIOs apply the two-midnight rule when they get favorable determinations in dubious cases, since there is no discussion unless claims are denied.

"My concern is, if the QIOs are really soft, people will lower their guard," says the physician adviser at one northeastern hospital, who asked not to be identified.

Last year, CMS handed short-stay hospital reviews to the QIOs, Livanta and KEPRO, with recovery audit contractors (RACs) on standby to review hospitals that are repeat offenders *(RMC 11/9/15, p. 1)*. But CMS had to call a time-out to educate the QIOs and ensure they apply the two-midnight rule accurately and consistently *(RMC 5/16/16, p. 7)*. The reviews resumed in mid-September after a four-month "pause" *(RMC 9/19/16, p. 4)*.

Now concerns have emerged that the QIOs are taking it too easy on hospitals, which creates its own set of problems.

"If a hospital uses the QIO determination as an authoritative interpretation of the rules, they may tend to be more liberal with admitting patients as inpatients and then have a rude awakening when there's a stricter interpretation from RACs, the comprehensive error rate testing contractor or the HHS Office of Inspector General," says Ronald Hirsch, M.D., vice president of education and regulations at Accretive Physician Advisory Services.

At the physician adviser's hospital, the QIO approved all 10 short-stay admissions that were reviewed. He thought two of them should have been denied. In one case, a 78-year-old man presented with dizziness and was placed in observation. "He was here for two midnights, but it didn't look like he needed to be here," the physician adviser says. At discharge, he was given Cipro

for a urinary tract infection. The inpatient admission order was signed after the discharge order. "He stayed a second night, but converted to inpatient inappropriately," the physician adviser says. "Timely authentication of the admission order prior to discharge is a condition of payment. That alone should have resulted in a denial of this claim," Hirsch adds.

The QIO excluded the second case because it was a spine surgery on the inpatient-only list. "However, when our compliance people investigated, they found that the CPT codes that were used for the procedure were 22551 and 22552, and neither of these are on the 2016 inpatient-only list," the physician adviser says. Because the patient left the hospital on the second day after staying overnight as part of routine recovery, and didn't suffer any complications, "it looked pretty clear to me that inpatient was not the correct level of care."

He's going to continue to educate physicians as if the cases were denied because "these are not appropriate [admissions]."

QIOs Leave Hospitals Guessing

Another physician adviser was surprised when the QIO approved all 24 short stays at his hospital. "We thought they were being a little too lenient," he says.

Seventeen of the patients had "associated midnights in observation or the emergency room or the referring hospital," he says. The other seven patients didn't cross two midnights for various reasons. They recovered faster than expected, for example, or left against medical advice, both reasons that don't get in the way of Part A payment as long as there's supporting documentation. But he says, in some cases, the hospital couldn't produce the documentation. For example, there was a patient admitted as an inpatient with transient ischemic attack who was discharged before two midnights after improving faster than expected, but there wasn't supporting documentation. The same thing happened in a case of uncontrolled hypertension where the patient was discharged because of a faster-than-expected recovery, which wasn't reflected in the documentation.

And still, the QIO gave the short stays the green light. "I'm happy when cases are approved, but on a different level, it would be nice to have one denial to have a little discussion [with the QIO]," the physician adviser says. "Because now we are guessing." He wonders if the favorable audit findings stem from the QIOs overcompensating for their earlier denials, which caused CMS to temporarily suspend the reviews. If that's the case, "will the pendulum swing back to some place in the middle?"

Notwithstanding the QIO's findings, the physician adviser says he will stay the course with education on the two-midnight rule. For example, "we still want documentation the patient improved sooner than anticipated or is refusing care," he says.

Pam Applegate, senior program manager at Livanta, tells *RMC* that the QIO "is following the required process as defined in the new CMS guidelines that were distributed during the pause in reviews. CMS spent a significant amount of time retraining staff to their new process and has also performed accuracy review audits on our cases and has indicated full agreement with the decisions."

Meanwhile, education continues on the two-midnight rule *(RMC 9/19/16, p. 1)*.

Contact Hirsch at rhirsch@accretivehealth.com. ✧

Waivers Clear ACO Obstacles

continued from p. 1

world, hospitals court disaster under the Stark and anti-kickback laws if they give money, goods or services to referring physicians or patients. But the incentives are different in ACOs, and Stark compliance can hinder the collaboration that's necessary for ACO implementation, attorneys say.

"It boils down to incentives to increase coordination between hospitals, doctors and other facilities, and increased coordination can be a problem if compensation is based on the volume or value of referrals," said Nashville attorney J.D. Thomas at the HCCA conference. "You need to be careful how you increase coordination with physicians." That's why CMS and the HHS Office of Inspector General in November 2011 established the five fraud and abuse waivers for ACO participants, and on Oct. 29, 2015, issued a rule finalizing them *(RMC 11/3/14, p. 1)*. Other Medicare pay-for-performance programs, such as the Comprehensive Care for Joint Replacement model, have their own fraud and abuse waivers *(RMC 12/7/15, p. 1)*, and they will be front and center as CMS moves toward its goal of having half of fee-for-service payments made through alternative payment models by 2018.

Here are the five ACO waivers and some compliance implications:

(1) ACO pre-participation waiver: Hospitals may pay start-up costs on behalf of physicians if they're reasonably related to the purpose of the MSSP. As long as hospitals meet certain conditions, they are protected from the Stark and anti-kickback statutes and the civil monetary law that imposes fines for gainsharing (i.e., hospital payments to physicians for efficiency or quality improvement). "The governing board must have a good-faith intent to develop the ACO," Bobb said. "It's not to be used as a mechanism to get around the fraud and abuse laws."

(2) ACO participation waiver: This waiver is similar to the pre-participation waiver, but it extends protection for operating costs past the go-live date of the ACO. The governing board has to determine that the arrangement is related to the purpose of the MSSP. "We give deference to governing boards, but if the board establishes policies and procedures to get it up and running, we like to see it implemented," Bobb said. "We will look beyond the minutes — at everything done and actually implemented — and we will look at the infrastructure."

(3) Shared savings distribution waiver: This waiver protects shared-savings payments and distributions among ACO participants and providers from the Stark and anti-kickback statutes and gainsharing CMP.

(4) Stark compliance law waiver: Under this waiver, hospital-physician relationships that implicate the Stark law but fall into a Stark exception don't have to worry about the anti-kickback statute or gainsharing CMP. There's protection for arrangements among or between ACO participants if they're reasonably related to the MSSP's purpose. That would not include, for example, the following examples: Paying a specialist $500 for every referral he or she generated; paying a skilled nursing facility staffer $100 for every patient brought to the ACO hospital; physicians paying the ACO hospital in return for ACO-related referrals; and the ACO compensating referring physicians for serving as medical directors even though no services are performed. "It's common sense, but you'd be surprised by how many organizations do things like this," Bobb said. "Exercise good judgment and don't go down roads like these."

Medical Directorships Need Attention

ACOs have to tread very carefully here, said Thomas, who is with Waller Lansden. "If you have medical directorships in fee for service where they have not been doing time sheets, it's not the worst thing in the world. Maybe you can undo it and fix the problem," he said. "But in this world with waivers, it's a much harder egg to put back together. It's much harder to say, 'the medical director showed up every week at the same time but didn't document it.'"

Bobb emphasized that prosecutions won't hinge on one bad move. "We are looking at the ACO as a whole, and not basing prosecutions on one evaluation" of a medical directorship that's questionable, he said.

However, a single incriminating email, for example, may tip the scales, Thomas said. "It could be dispositive," he noted. "It could cause [prosecutors] to take a case they otherwise would not take. It depends on what the email says. If you have all medical director agreements except one or all documents but you can't find public notification, then it becomes a sliding scale and they will look at the totality of circumstances." CMS requires ACO participants to inform Medicare beneficiaries that they participate in the MSSP.

Bobb suggested walling off the compensation side of the ACO from the management side so "the people setting up and managing ACOs are not the people establishing compensation. If you set up a Chinese wall, that's a good step toward not being looked at by [the government]." While separation is ideal, it's easier said than done, Thomas noted, because "every ACO is different. We live in an imperfect world and a lot of times people wear more than one hat."

(5) Patient incentive waiver: Incentives offered by ACOs to beneficiaries to encourage preventive care and compliance with treatment regimens are protected from the CMP law that prohibits inducements to beneficiaries to sway them to pick a particular provider or supplier. The items or services given to patients must advance clinical goals (e.g., adherence to treatment regimens, management of a chronic disease). "You can't give them theatre tickets," Stephen Page, vice president and

CMS Transmittals and *Federal Register* Regulations
Oct. 21 – Oct. 27

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Transmittals

(R) indicates a replacement transmittal.

Pub. 100-04, Medicare Claims Processing Manual

- Correcting Editing for Condition Code 54 and Updating Remittance Advice Messages on Home Health Claims, Trans. 3630CP, CR 9826 (Oct. 27; eff. April 1; impl. April 3, 2017)
- Denial of Home Health Payments When Required Patient Assessment Is Not Received, Trans. 3629CP, CR 9585 (Oct. 26; eff. April 1; impl. April 3, 2017)
- Changes to the Laboratory National Coverage Determination Edit Software for January 2017 (R), Trans. 3628CP, CR 9806 (Oct. 21; eff. Oct. 1, 2016; impl. Jan. 3, 2017)
- Fiscal Year 2017 Inpatient Prospective Payment System and Long Term Care Hospital PPS Changes (R), Trans. 3626CP, CR 9723 (Oct. 19; eff. Oct. 1; impl. Oct. 3, 2016)

Pub. 100-10, Quality Improvement Organization Manual

- Quality of Care Review, Trans. 28QIO (Oct. 21; eff./impl. Oct. 21, 2016)
- QIO Manual Chapter 3, "Memoranda of Agreement for Case Review," Trans. 29QIO (Oct. 21; eff./impl. Oct. 21, 2016)

Federal Register Regulations

Notice

- Medicaid Program; Final FY 2014 and Preliminary FY 2016 Disproportionate Share Hospital Allotments, and Final FY 2014 and Preliminary FY 2016 Institutions for Mental Diseases Disproportionate Share Hospital Limits, 81 Fed. Reg. 74432 (Oct. 26, 2016)

associate general counsel at RCCH HealthCare Partners, a Nashville-based health system, said at the HCCA conference. "It should be things like blood pressure cuffs." And ACOs need to do more than hand out the cuffs, Bobb emphasized. They have to educate patients on their use and provide a portal so the readings can be communicated to the ACO and put to use in managing the patient's hypertension. What about enhancing cell phones so they can transmit blood pressure readings to the ACO? "That's not something I would worry about as a federal prosecutor," Bobb said. There must be infrastructure — including telehealth tools and metrics for measuring quality and cost — and the items and circumstances around them must be documented, the speakers said.

They also suggested safeguards to prevent ACO fraud and abuse. For example, there should be an audit trail, including documentation of board approvals of ACO activities and modifications/amendments approved by the board.

"You want to be able to show that the waiver requirements have been met," Thomas said. "You have to have all these documents readily available to you." If regulators or enforcers come knocking, it doesn't look good to say, "I'll try to find the minutes of the board meeting" or "we don't have the participation agreement in hand." Not being able to immediately locate supporting documentation for waivers is a red flag. "In the world of waivers, if it quacks like a duck and swims like a duck it may not be a duck because you can't come up with a piece of paper to prove it's a duck."

The importance of documentation in the eyes of prosecutors can't be overstated. "I look at a lot of board minutes and you'd be shocked at how many board members are absent," Bobb said. "If it's not documented, it didn't happen and it doesn't matter what the board members tell us."

Contact Thomas at jd.thomas@wallerlaw.com, Page at stephen.page@regionalcare.net and Bobb at andrew.bobb@usdoj.gov. ✧

NEWS BRIEFS

◆ **Atlanta-area physician Robert E. Windsor is headed to prison for more than three years over his billing for monitoring the nerve and spinal cord activity of patients during surgery when he actually had an unqualified medical assistant deliver the care,** the U.S. Attorney's Office for the Northern District of Georgia said on Oct. 24. Windsor pleaded guilty in March "for filing over $1.1 million in false claims for surgical monitoring services that he did not perform," the U.S. attorney's office said. Windsor had a contract with a Maryland company, American Neuromonitoring Associates, P.C. (ANA), to provide intra-operative monitoring, which involves monitoring a patient's nerve and spinal cord activity during a procedure to minimize possible adverse effects. The physician monitors the surgery online and conveys information to the surgeon. According to the U.S. attorney, for three years Windsor let the medical assistant use his log-in credentials so it appeared the physician was monitoring surgeries. "Windsor submitted monitoring reports falsely stating that he had conducted the monitoring," the U.S. attorney's office said. Visit http://tinyurl.com/h6u2rxr.

◆ **The New York state Office of Medicaid Inspector General (OMIG) on Oct. 26 posted its compliance program review guidance.** The guidance is used by OMIG to review the effectiveness of compliance programs. Visit http://tinyurl.com/jhdozn9.

◆ **Daybreak Partners LLC, a holding company for subsidiaries that operate skilled nursing facilities (SNFs) in Texas, agreed to pay $5.3 million to settle false claims allegations they billed Medicare and Medicaid for substandard nursing services,** the Department of Justice (DOJ) and U.S. Attorney's Office for the Northern District of Texas said on Oct. 24. Daybreak denies the allegations. The SNFs are run as individual limited partnerships owned by Daybreak Venture, LLC and Daybreak Healthcare, Inc. According to allegations in the settlement, from 2006 to 2010, some of the skilled nursing services provided at four SNFs that Daybreak owned "were materially substandard and/or worthless." For certain residents, the SNFs didn't properly administer medications, failed to abide by pressure ulcer and infection control protocols, didn't comply with fall protocols, and had other problems. Daybreak entered into a five-year corporate integrity agreement as part of the settlement. Visit http://tinyurl.com/h8twhpr.

◆ **Best Choice Home Health Care Agency Inc. and its owner, Reginald King, have agreed to pay $1.8 million to settle false claims allegations,** the Department of Justice said on Oct. 25. Best Choice, which is based in Kansas City, Kan., and King allegedly paid kickbacks for the referral of Medicaid patients for home and community-based services, DOJ alleged. Visit http://tinyurl.com/h6fkhyf.

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