Report on
MEDICARE COMPLIANCE

Volume 25, Number 23 • June 20, 2016

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

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OIG Adopts New CIA Model That Favors Risk Assessment; Goal Is Better Self-Policing

Corporate integrity agreements (CIAs) have gotten an overhaul from the HHS Office of Inspector General, which will now put more weight on risk assessments, a top OIG attorney tells *RMC*. One goal is for providers to be more effective at self-policing when their CIAs, which are part of fraud settlements, come to an end.

"We are coming out with a new CIA model agreement," says Susan Gillin, deputy chief of the Administrative and Civil Remedies Branch. It will favor the "second half of the list" of the seven elements of an effective compliance program, such as auditing and monitoring, after years of focusing on the elements at the top of the list, which include designating a compliance officer/compliance committee, developing a code of conduct and other policies and procedures, and training and educating employees. "We think the industry has caught up with that," Gillin says. "We are now turning our focus to internal auditing processes — to risk assessments and IRO [independent review organization] reviews that target risk. Hopefully they will be more useful for providers and the OIG."

CIAs are compliance measures imposed by OIG in certain fraud settlements as an alternative to exclusion from Medicare and other federal health care programs.

Gillin says the new CIA model has been rolled out internally, and the first one went out the week of June 13 to a health care organization. "The implication for providers is it should be a more meaningful assessment of their compliance practices and better training for how to self-police and catch issues within their own programs before the government comes in and catches issues," she says. "After the CIA ends, providers will be better at catching their own issues."

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Door Is Open to More FCA Cases With High Court Ruling on Implied Certification

In a highly anticipated decision, the U.S. Supreme Court paved the way for more False Claims Act lawsuits that are based on regulatory violations. The high court's June 16 ruling in *Universal Health Services v. United States ex rel. Escobar* supports the theory of implied certification as a basis for a false claims case, which means the mere submission of a claim for payment carries with it the assurance that providers have complied with all conditions of payment, even if they haven't expressly certified compliance. But false claims cases won't necessarily be easy to make under the standard set forth in the Supreme Court decision.

According to the nation's highest court, liability can attach "when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement."

continued

Washington, D.C., attorney Jesse Witten says he can't decide "whether to celebrate or mourn this decision." *The reason:* while the Supreme Court accepted the implied certification theory, it also held that for a claim to be false, the falsity must be "material," and the judges adopted a stringent test for materiality. The "materiality" part of the decision will help lawyers defend some of their cases, while the court's failure to reject the implied certification theory will hurt other defenses, says Witten, who is with Drinker Biddle.

The unanimous decision came down in an appeal of a ruling from the U.S. Court of Appeals for the First Circuit, which held that Universal Health Services had violated Massachusetts Medicaid regulations on licensing and certification of mental health workers that "clearly impose conditions of payment" even though the conditions were not expressly stated. Julio Escobar had sued Universal Health Services under the False Claims Act over treatment his teenage daughter, Yarushka, received at Arbour Counseling Services, a satellite mental health facility in Lawrence, Mass., owned by a subsidiary of Universal Health Services. "In May 2009, Yarushka had an adverse reaction to a medication that a purported doctor at Arbour prescribed after diagnosing her with bipolar disorder. Her condition worsened; she suffered a seizure that required hospitalization. In October 2009, she suffered another seizure and died. She was 17 years old," the decision states. It turned out that "of the five professionals who had treated Yarushka, only one was properly licensed."

Arbour billed Mass. Medicaid using payment codes that identified the therapy and counseling services provided. "By using payment and other codes that conveyed [information about the services and the staff qualifications to perform such services] without disclosing Arbour's many violations of basic staff and licensing requirements for mental health facilities, Universal Health's claims constituted misrepresentations," the court said. Any reasonable person, it explained, would assume that persons providing treatment at a mental health facility were qualified to perform these services.

In its decision, the Supreme Court set out two mandatory conditions under which the implied certification theory can be a basis for liability:

(1) "The claim does not merely request payment, but also makes specific representations about the goods or services provided"; and

(2) The defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths."

The U.S. courts of appeal for various circuits, which have been divided on the application of the theory, often analyze false claims cases on the basis of whether the underlying statute or regulation is a "condition of payment" or a "condition of participation." Most circuit courts have ruled that, if the underlying statute or regulation is a "condition of participation," no false claims liability attaches. Only if the court finds that the statute or regulation is a condition of payment may the False Claims Act case go forward.

'Condition of Payment' Restriction Was Rejected

But the Supreme Court rejected the "condition of payment" restriction. "We first hold that, at least in certain circumstances, the implied false certification theory can be a basis for liability. Specifically, liability can attach when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement. In these circumstances, liability may attach if the omission renders those representations misleading," the ruling states. "We further hold that False Claims Act liability for failing to disclose violations of legal requirements does not turn upon whether those

Report on Medicare Compliance (ISSN: 1094-3307) is published 45 times a year by Atlantic Information Services, Inc., 1100 17th Street, NW, Suite 300, Washington, D.C. 20036, 202-775-9008, www.AISHealth.com.

Managing Editor, Nina Youngstrom; Contributing Editor, Francie Fernald; Executive Editor, Jill Brown; Publisher, Richard Biehl; Marketing Director, Donna Lawton; Fulfillment Manager, Tracey Filar Atwood; Production Editor, Carrie Epps.

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requirements were expressly designated as conditions of payment. But we also conclude that not every undisclosed violation of an express condition of payment automatically triggers liability. Whether a provision is labeled a condition of payment is relevant to but not dispositive of the materiality inquiry.... What matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision."

FCA's Materiality Rule Is 'Rigorous, Demanding'

The Supreme Court characterizes the materiality requirement of the False Claims Act as "rigorous" and "demanding." The act defines "material" as "having a natural tendency to influence, or be capable or influencing, the payment or receipt of money or property (31 U.S.C. §3729(b)(4))....A misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act. A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance."

The Supreme Court rejected an expansive reading of the False Claims Act that said any statutory, regulatory, or contractual violation is material if the party knows that the government would be entitled to refuse payment if it knew of the violations. When evaluating materiality under the False Claims Act, the court said, "the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material."

Because the First Circuit had applied a different interpretation of the FCA requirements, the Supreme Court remanded the case back to the First Circuit to determine whether Escobar had sufficiently pleaded a FCA violation based on the high court's guidelines.

The Supreme Court's opinion, written by Justice Clarence Thomas, was an exercise of "common sense," Witten says. "It did not get hung up on all the False Claims Act jargon and legalistic formulas that the lower courts had adopted over the years. From that standpoint, I think it is welcome even though it does not answer all the questions or provide any black and white lines to follow." According to the high court, if the government regularly pays claims even though it knows some requirements have been violated, that is "very strong evidence that those requirements are not material." As a result, Witten says "we can expect now to see a great deal of discovery regarding government payment practices in the context of particular regulatory violations."

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Telehealth Modifier Use Is a Risk As Medicare Spending Grows

Medicare is spending more on telehealth services every year and opportunities may grow exponentially if pending legislation is enacted. For now, Medicare coverage of telehealth services is somewhat limited and there are compliance risks around use of the telehealth modifier, but attorneys are optimistic about changes on the horizon, between the legislative measures, a CMS demonstration program in Alaska and Hawaii and openings for telehealth in advanced payment models, such as Medicare's Comprehensive Care for Joint Replacement model.

CMS spent 25% more on telehealth services in 2015 than it did the year before, says Tampa attorney Nathaniel Lacktman, with Foley & Lardner LLP (see box, p. 4). Medicare paid $17,601,996 for telehealth services last year on 271,877 claims, up from $13,934,430 for telehealth services on 214,346 claims in 2014. The increase in total payments is a result of more providers using telehealth in fee-for-service Medicare — not an increase in reimbursement, Lacktman notes.

More services are covered now. "The list of CPT codes that providers can use to bill is continuing to

increase," says Washington, D.C., attorney Jacob Harper, with Morgan Lewis. But it's been a slow climb, with an emphasis on behavioral management and training, where clinicians typically don't have to put their hands on patients, he says. "CMS is trying to balance the consumer desire for telehealth services and the increased access that it brings with its responsibility to ensure beneficiaries are well treated and not subject to wasteful or less effective services," Harper says. For 2016, there are 37 services covered, including emergency department or initial inpatient telehealth consultations, office or other outpatient visits, subsequent hospital care services, individual psychotherapy, pharmacologic management, smoking cessation, face-to-face behavioral counseling for obesity, and individual and group diabetes self-management training services.

CMS may get a push from Congress, where a number of telehealth bills are pending that would broaden Medicare coverage. For example, the Creating Opportunities Now for Necessary and Effective Health Care Technologies (CONNECT) for Health Act, introduced in February, would phase in Medicare coverage of many telehealth and remote monitoring services. And on June 7, Reps. Michael Burgess, M.D. (R-Texas) and Doris Matsui (D-Calif.) introduced the Expanding Capacity for Health Outcomes (ECHO) Act, which would use telehealth, such as videoconferencing, to bring more academic specialty care education to local health systems.

Right now, CMS circumscribes coverage in ways beyond CPT codes. "For Medicare to cover a telehealth visit, it typically must be provided in a rural area," Harper says. These areas include counties outside of Metropolitan Statistical Areas (MSAs) or in health professional shortage areas either outside of an MSA or in a rural census tract. Telehealth services have to be delivered in an "originating site," such as hospitals, physician practices and other approved locations; skyping from home doesn't cut it (see Medicare Benefit Policy Manual, Ch. 15, Sec. 270, and the Medicare Claims Processing Manual, Ch. 12, Sec. 190).

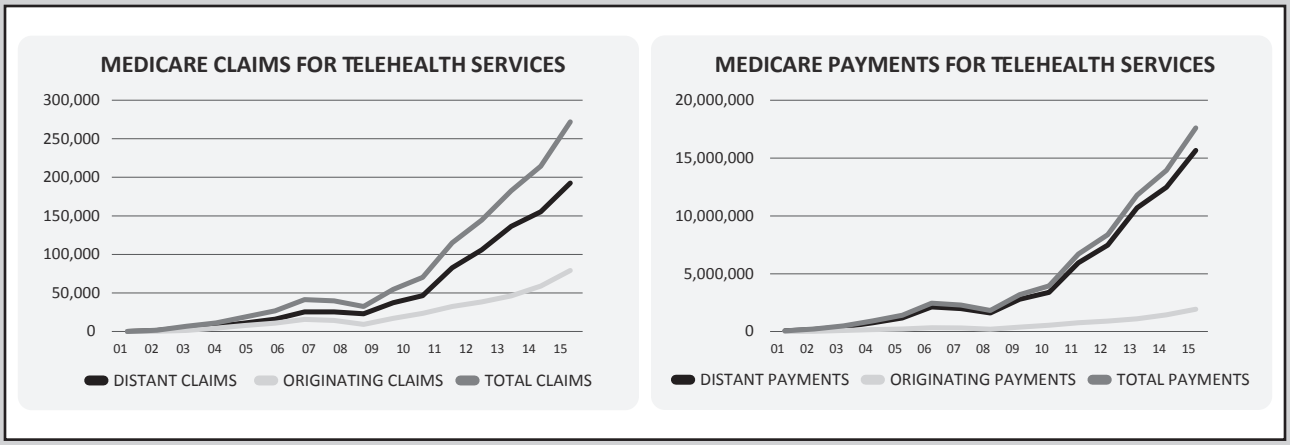
Providers Must Use Face-to-Face Systems

Hospitals and other originating sites bill Medicare with code Q3014 and receive $20 to $25 for hosting the patients, Harper says. The telehealth services are delivered by distant site providers, who bill the CPT codes. CMS specifies the types of providers permitted to bill for telehealth services (e.g., physicians, nurse practitioners and physician assistants).The list excludes certain practitioners, such as physical therapists. "It's in the Social Security Act and CMS doesn't have the authority to contravene that," Lacktman notes. Distant-site providers bill the Medicare administrative contractor in their jurisdictions "and receive the corresponding reimbursement rate," regardless of where patients live, Harper notes. For instance, a New York-based provider furnishing services to a patient in Kansas via telehealth would bill the New York MAC, not the Kansas MAC, and receive the New York, not the Kansas, geographically adjusted reimbursement rate.

Providers also must use face-to-face, interactive audio and video telecommunications systems that en-

Growth in Medicare Spending on Telehealth Services, 2001–2015

Medicare spending on telehealth services has grown steadily over the years, as mapped out in the charts below developed by Foley & Lardner LLP. Contact attorney Nathaniel Lacktman in the Tampa office at NLacktman@foley.com.



able real-time communication between the distant-site provider and the patient at the originating site, according to CMS.

Medicare does, however, cover services that use asynchronous "store and forward" technologies when conducted under a federal demonstration program in Alaska and Hawaii, says Washington, D.C., attorney Anthony Choe, with Morgan Lewis. This technology allows medical information (e.g., diagnostic imaging or photographs) to be saved and made available for review by a physician at a later time, he says. "Commercial and other third-party coverage for this technology has expanded in recent years, but Medicare coverage remains limited," Choe says.

Telehealth services have some unique compliance risks, including the potential misuse of the GT modifier. When providers deliver telehealth services, they must append the GT modifier to CPT codes, Lacktman says. "That designates they are providing services via telemedicine," he notes. But things can go awry. If providers deliver services by telehealth but fail to append the GT modifier, there's no way for the MAC to distinguish between conventional and telehealth services. "To avoid denials, they must append the GT modifier," Lacktman says. Also, billing for telehealth services provided in an urban area with the GT modifier would mislead Medicare. "If it's an urban area, it's an incorrect certification," he explains.

Or perhaps the patients are at home and the distant-site provider knows Medicare doesn't cover telehealth unless the services are provided at an originating site. Again, the provider could pull one over on the MAC by

New CMS Data on Improper Payments Identified by RACs

CMS has posted the results of the recovery audit contractors' (RACs) overpayment and underpayment findings for the second quarter of fiscal year 2016. Visit http://tinyurl.com/js7fh76.

Medicare Fee for Service National Recovery Audit Program (January 1, 2016 – March 31, 2016)

OVERPAYMENTS COLLECTED	UNDERPAYMENTS RETURNED	TOTAL QUARTER CORRECTIONS	FY TO DATE CORRECTIONS
Region A: Performant	$9.24	$3.52	$12.76
Region B: CGI	$6.08	$1.42	$7.5
Region C: Cotiviti	$43.21	$15.92	$59.13
Region D: HDI	$67.54	$16.66	$84.2
Nationwide Totals	**$126.07**	**$37.52**	**$163.59**

Note: Figures rounded to nearest tenth; Nationwide figures rounded based on actual collections. Figures provided in millions. All correction data current through March 31, 2016.

TOP ISSUE PER REGION
Based on collected amounts from January 1, 2016 through March 31, 2016

Region A:	**Global Surgery: Pre- and Post-Operative Visits** (automated review) Identification of overpayments associated to minor and major surgical services. 1) E/M services (as specifically defined in the IOM) billed the day prior to a major (90-day) surgical service without mod-ifiers 57 or 25. 2) E/M services (as specifically defined in the IOM) billed the day of a major (90-day) or minor (0- or 10-day) surgical service billed without modifier 25 or 57. 3) E/M services (as specifi-cally defined in the IOM) billed 10 days following a 10-day minor surgical service or 90 days follow-ing a 90-day major surgical service and billed without modifier 24 (unrelated visit in post op period) or when modifiers 53, 54, 76, 78, Q0, and/or Q1 are appended to the surgical procedure.
Region B:	**Outpatient Therapy Claims above $3,700 Threshold - Skilled Nursing Facility** (complex review) Targeted post-payment review of outpatient therapy claims paid in 2014 that reached the $3,700 threshold for PT and SLP services combined and/or $3,700 for OT services. When one or more lines of a claim have reached a therapy threshold, all lines of therapy services on that claim are subject to review.
Region C:	**Outpatient Therapy Claims above $3,700 Threshold - Outpatient Hospital** (complex review) CMS determines an annual per beneficiary therapy cap amount for each calendar year. Exceptions to the therapy cap are allowed for reasonable and necessary therapy services. Per beneficiary, ser-vices above $3,700 for PT and SLP services combined and/or $3,700 for OT services are subject to manual medical review.
Region D:	**MS-DRG Validation of Major Diagnostic Category (MDC) 04** (complex review) MS-DRG Validation requires that diagnostic and procedural information and the discharge status of the beneficiary, as coded and reported by the hospital on its claim, matches both the attending phy-sician description and the information contained in the beneficiary's medical record. Reviewers will validate principal diagnosis, secondary diagnosis, and procedures affecting or po-tentially affecting MS-DRGs 163, 164, 165, 166, 167, 168,175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187,188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208

skipping the GT modifier. But that's a dangerous game to play. "I wouldn't recommend it," Lacktman says. He emphasizes that the use of the GT modifier means providers are certifying they meet the coverage requirements for telehealth services, including use of originating and distant-site providers, appropriate technology and approved providers, and that they limit billing to covered CPT codes.

Looking ahead, more Medicare doors will open for telehealth in advanced payment models, including the Medicare Shared Savings Program, the Comprehensive Care for Joint Replacement (CJR) model and Next Generation Accountable Care Organizations, Lacktman says. For example, the CJR model, which took effect April 1 *(RMC 3/7/16, p. 4)*, waives some core telehealth coverage requirements. "Under CJR, CMS will allow a beneficiary in a CJR episode in any geographic area to receive services via telehealth. CMS also will allow a home or place of residence to be an originating site for beneficiaries in a CJR episode," according to *MLN Matters* MM9533. "This will allow payment of claims for telehealth services delivered to beneficiaries at eligible originating sites or at their residence, regardless of the geographic location of the beneficiary." But to get the waiver, CMS said certain conditions must be met (e.g., telehealth can't substitute for in-person home health visits for patients in a home health episode of care).

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CMS Transmittals and *Federal Register* Regulations
June 10 – June 16

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

- Billing of Vaccine Services on Hospice Claims (R), Trans. 3540CP, CR 9052 (June 10; eff. Oct. 1; impl. Oct. 3, 2016)
- JW Modifier: Drug Amount Discarded/Not Administered to Any Patient (R), Trans. 3538CP, CR 9603 (June 9, 2016; eff. Jan. 1; impl. , Jan. 3, 2017)
- Corrections to Chapter 1 (R), Trans. 3537CP, CR 9623 (June 8; eff./impl. June 8, 2016)
- New Physician Specialty Code for Dentist (R), Trans. 3544CP, CR 9355 (June 15, 2016; eff. Jan. 1, 2017 (MACs), July 1, 2017 (MCS); impl. Jan. 3, 2017 (MACs), July 5, 2017 (MCS)

Pub. 100-06, Medicare Financial Management

- New Physician Specialty Code for Dentist (R), Trans. 268FM, CR 9355 (June 15, 2016; eff. Jan. 1, 2017 (MACs), July 1, 2017 (MCS); impl. Jan. 3, 2017 (MACs), July 5, 2017 (MCS)

Pub. 100-07, State Operations Manual

- Revisions to Chapter 2, Trans. 154SOMA (June 10; eff./impl. June 10, 2016)
- Revisions to Chapter 5, Trans. 155SOMA (June 10; eff./impl. June 10, 2016)
- Revisions to Appendix P – Survey Protocol for Long Term Care Facilities, Trans. 156SOMA (June 10; eff./impl. June 10, 2016)
- Revisions to Appendix PP – Guidance to Surveyors for Long Term Care Facilities, Trans. 157SOMA (June 10; eff./impl. June 10, 2016)

Federal Register Regulations

Final Rule

- Medicare Shared Savings Program; Accountable Care Organizations — Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations, 81 Fed. Reg. 37949 (June 10, 2016)

Proposed Rule

- Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care, 81 Fed. Reg. 39447 (June 16, 2016)

Drug Sales Reps Are Indicted for Alleged Sham Speaker Fees to MDs

A salesman and a district manager for a pharmaceutical company were charged with violating the anti-kickback law in connection with payments to physicians for participating in a speaker's bureau, the U.S. Attorney's Office for the Southern District of New York said on June 9. Former District Manager Jonathan Roper and former Specialty Sales Professional Fernando Serrano allegedly arranged the speaking fees to induce physicians to prescribe a spray version of the opioid Fentanyl, which is used for breakthrough pain in cancer patients.

The inducement alleged in the case is consistent with "the rhetoric about coming after individuals" from the HHS Office of Inspector General and the Department of Justice articulated in the Yates memo *(RMC 9/14/15, p. 1)*, says Denver attorney Jeffrey Fitzgerald, with Polsinelli.

What's more surprising is how much an FBI affidavit that's cited in the criminal complaint relies on the district manager's emails to his sales team, he says. "The Department of Justice must think this is scandalous activity, but I think sales managers write emails like this every day in other industries," Fitzgerald says. "This is what sales managers do: they write pump-you-up emails and try to make sales. It makes the application of the anti-kickback statute questionable. Is it the right tool to regulate sales behavior? Telling your sales team to sell doesn't seem like criminal behavior."

Roper was initially a specialty sales professional for the pharmaceutical company that sold the sublingual Fentanyl spray, according to the complaint, which includes a statement from FBI Agent Bruce Wayne. The

pharmaceutical company had compliance policies forbidding the types of behavior that Roper and Serrano are accused of. Its 2013 code of conduct prohibits employees from giving health care professionals items unless they serve an educational purpose. Modest meals are allowed if provided at a location "conducive to discussing educational information," the complaint said, but employees were forbidden to offer items of value to influence referrals. The pharmaceutical company is not identified in the complaint, and the U.S. attorney's office declined to identify it because it's not facing civil or criminal liability. However, *The New York Times* says the company is Insys Therapeutics.

The FBI agent stated that the pharmaceutical company had developed speaker programs as a marketing tool. These are paid peer-to-peer education sessions, which require health care professionals to use slide decks developed by the pharmaceutical company. The pharmaceutical company said selection of health care professionals "is not to be used as an inducement to prescribe," according to the FBI agent.

Speaker Agreements Were the Focus

But that's not how things played out, the complaint against Roper alleged. It focuses on speaker agreements with two physicians. They called for "Doctor 1" to receive $3,000 for every in-person speaker program he completed, and "Doctor 2" to get $2,200. But they were allegedly "sham speaker programs" — and Roper was the "designated" specialty sales professional for the two physicians.

For example, Doctor 1 was scheduled to be the speaker at a program at a Manhattan restaurant but never showed up. Instead, Roper had dinner with some of his friends and his then-supervisor, who is a cooperating witness in the case. Some of the attendees were not legitimate participants, so Roper allegedly had to forge sign-in sheets to make it look like enough health care professionals attended, according to the complaint.

Roper was promoted to district manager in fall 2013. He attended a number of speaker programs arranged by specialty sales professionals that allegedly "involved no education regarding the Fentanyl spray and no slide presentation," the complaint said, and told his specialty sales professionals "to expect and demand" that doctors chosen as speakers prescribe large amounts of Fentanyl in return.

Roper's exhortations about physicians' prescriptions continued in emails to his specialty sales professionals. In a February 2014 email, he wrote: "One week until [National Sales Meeting], and I need everyone on this team to work their relationships. Ask each of your top prescribers to do whatever they can to make you look like an absolute superstar for the next week….This is what reps work all year for, do not be hesitant in asking your docs to give you the business in which you are owed, deserve, and will help in making you shine at [the National Sales Meeting]....All the breakfasts, lunches, dinners and [Speaker Programs] and top customer service to go along with helping provide your docs pts with the best [Rapid-Onset Opioid] product in its class for treating BTCP [breakthrough cancer pain]. This has to be reciprocated to you for all your hard work!"

Roper, like other district managers, got bonuses based "in large part on the sales results" of their specialty sales professionals, according to the complaint. For example, he received an $80,000 bonus in the fourth quarter of 2013. He was promoted to regional director at the end of 2015.

The complaint against Serrano has similar allegations. "Many of the speaker presentations that Serrano directly organized…were predominantly social gatherings at high-end restaurants that involved no education and no slide presentation," the complaint alleged. Serrano was Doctor 1's designated specialty sales professional at the time he was one of the top prescribers of spray Fentanyl, with Medicare alone paying $1.2 million for his prescriptions in 2014. That year, the pharmaceutical company paid Doctor 1 speaker fees of $147,245, the complaint said.

Fitzgerald says part of the government's theory in this case appears to be that the pharmaceutical company put pressure on its sales people and that the government thinks that financial incentives "lead people to do bad things," he says. But "that theory is highly questionable because people get paid incentives all the time. None of this is proven."

Contact Fitzgerald at JFitzgerald@polsinelli.com. ✧

OIG Rolls Out New CIA Model

continued from p. 1

Tony Maida, former deputy chief of the OIG's Administrative and Civil Remedies Branch, says OIG's logic holds. "We should expect OIG to adjust CIAs to reflect their view that everyone should have a basic compliance program," says Maida, with McDermott, Will & Emery in New York City. "If everyone has the seven basic elements, then the OIG does not need to see things like a code of conduct or to approve the entity's training program. Those things are important, but OIG wants CIAs to take a deeper dive into the operation of the program. Simplifying some of the more technical aspects of the agreement, such as training 100% of your employees within 90 days or reporting changes in locations, should be beneficial." But the CIA still will have significant

obligations. "You likely can't avoid hiring an IRO, but hope springs eternal that OIG may move in that direction someday," Maida notes. "For providers who have a robust internal audit program, why not have the option to say, 'we have this internal audit system and it works really well. Why do we need to hire an IRO?'"

Greg Radinsky, vice president and chief corporate compliance officer at Northwell Health in Great Neck, N.Y., figures that some of the fundamental components of compliance programs, such as documentation of training and policies and procedures, "probably weren't giving OIG insight into the true risk areas. They won't tell you about the detailed risks that providers might have in the future. You can only do that through comprehensive risk assessments or a true audit process." But the core requirements of compliance programs are very important, "and I would still think OIG would require some certification" that those elements are alive and well, Radinsky says.

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NEWS BRIEFS

◆ **Sea View Health Care Services, Inc., a for-profit home health agency (HHA) on the island of St. Thomas in the U.S. Virgin Islands, was overpaid $184,000 over two years, according to the first Medicare compliance review of an HHA.** OIG said Sea View did not comply with Medicare billing requirements for 122 of the 253 home health claims it reviewed. Some beneficiaries did not meet Medicare's definition of "homebound"; some beneficiaries didn't require skilled services; some services lacked documentation from the certifying physician or the plan of care was missing; and some services had an inaccurate health insurance prospective payment system code. OIG recommends Sea View repay the money and improve its internal controls. Sea View's administrator, Kim Jerome, described the actions it has taken to improve compliance, and noted it has had a compliance program for 14 years. However, Jerome said Sea View is the only Medicare-certified home health agency on St. Croix, and OIG's proposed repayment "may unwantedly have the devastating effect of leaving our population without the valuable services we currently provide." The HHA suggested it instead use the overpayment to improve billing and documentation. In response, OIG said CMS will decide the "amount to be refunded and will work with the Agency on making arrangements for repayment." Visit http://go.usa.gov/chBAT.

◆ **The owner of Alpha Diagnostics Services Inc., in Owings Mill, Md., was sentenced to 10 years in prison in connection with a radiology scheme that resulted in the deaths of two patients, the U.S. Attorney's Office for the District of Maryland said on June 15.** Rafael Chikvashvili, of Baltimore, was convicted after a trial in February of health care fraud and wire fraud conspiracy *(RMC 2/22/16, p. 8)*. Alpha Diagnostics was a portable diagnostics provider that mostly performed X-rays, although it also did ultrasound tests and cardiologic examinations. According to the U.S. attorney's office, interpretations of radiology, ultrasound and cardiologic tests were not performed by physicians. Chikvashvili told his nonphysician employees to interpret the tests instead and "Alpha Diagnostics personnel subsequently submitted false claims to Medicare for these images and fraudulent physician reports," the U.S. attorney's office said. Visit http://tinyurl.com/jrgyunf.

◆ **Its new report on provider-based space has reinforced the HHS Office of Inspector General's belief that CMS should stop paying hospitals more for services performed in provider-based space.** OIG examined CMS's oversight to ensure only provider-based facilities that comply with Medicare requirements receive enhanced payments. *The findings:* Half of all hospitals own provider-based space, yet CMS doesn't check them all for compliance with Medicare requirements and not all provider-based facilities voluntarily attest to their compliance. "CMS is taking steps to improve its oversight of provider-based facilities; however, vulnerabilities identified in this review continue to limit its ability to ensure that all provider-based facilities bill appropriately," OIG said. "CMS also has not provided OIG with evidence that services in provider-based facilities deliver benefits that justify the additional costs to Medicare and its beneficiaries. Therefore, we continue to support previous OIG and MedPAC recommendations to either eliminate the provider-based designation or equalize payment for the same physician services provided in different settings — actions that go beyond those required by the Bipartisan Budget Act of 2015," which put an end to new off-campus provider based space after Nov. 2, 2015 *(RMC 11/23/15, p. 1)*. View the report at http://go.usa.gov/chep4.

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