Report on
MEDICARE COMPLIANCE

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

Contents

OIG Finalizes New Exclusion Powers; Enrollment Lies, Omissions Are Risks

The HHS Office of Inspector General now has a stronger hand in excluding providers and suppliers from federal health programs, according to a final regulation announced Jan. 11. That extends to kicking providers out of federal health care programs for false statements and omissions on their enrollment applications or certifying services without backing them up. But OIG backed off plans to let the clock tick indefinitely on exclusions in fraud cases and opened the door to fast-track reinstatements to federal health care programs after exclusions are over.

The final regulation implements exclusion provisions from the Affordable Care Act, other statutes and its own authority. It flexes its muscle for both mandatory exclusions and permissive exclusions. With mandatory exclusions, OIG is required to bar providers from Medicare and other federal health care programs for at least five years for certain offenses, such as health-care related criminal convictions. There is discretion with permissive exclusions, which may be imposed for excessive charges or unnecessary services claims; certain criminal convictions, even if they're not health care-related; kickback and Stark violations; license revocation/suspension; and failure to reveal certain information.

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HIPAA Audits of BAs Are Unpredictable; Hospitals May Need to Vet Vendors Better

A Minnesota insurance agent who is a business associate (BA) to health plans seemed an improbable candidate for a HIPAA audit by the HHS Office for Civil Rights (OCR) because she is a one-woman show. But that assumption went out the window last month when the insurance agent made the hit list of the first-ever OCR audits of BAs, and it has been eye-opening.

"OCR was asking for things that don't apply to her," says the insurance agent's attorney, Richelle Marting, with the Forbes Law Group in Overland Park, Kan. "She doesn't write policies and procedures for herself." That is changing in light of the audit, but it has been frustrating because OCR's documentation demands were onerous and sometimes inexplicable, Marting says. The insurance agent isn't worried about breaches, but whether there will be a fine for lack of compliance with HIPAA rules on conducting a security risk assessment and other requirements is another story.

BAs and some covered entities (CEs) are just starting to get the message they are on the hook for HIPAA compliance, says Brian Selfridge, a partner at Meditology Services. "BAs had a free pass and have not invested in HIPAA compliance programs and security controls they need to put in place. Having OCR teeth is sending all the right signals to the market that covered entities and business associates need to figure out whether they have processes in place." Selfridge says 40% of breaches are associated with a third-party firm, according to a May 2016 Ponemon report, but "there isn't enough

HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

Managing Editor
Nina Youngstrom
Nina.Youngstrom@hcca-info.org

vetting of third-party security beyond signing a business associate agreement or having vendors complete a basic security questionnaire." That will have to change now that "the federal government is tuning in," he says. "From a risk management perspective, we can't continue to shift this amount of data outside the proverbial four walls without validating it will meet the regulatory obligations and protect that information from breach." The hospital compliance team may lack the "bandwidth" to review dozens or hundreds of BAs, which is understandable, but it creates risk. "If the hospital wants to buy specialized cardiology software, that deal may go through regardless of the results of a security review that indicates security deficiencies," he says. "They take shortcuts."

And the shortcuts may be exposed in the BA audits, which are part of Phase Two of OCR's HIPAA audits. Phase One audits focused exclusively on CEs, and Phase Two covers both CEs and BAs. Selfridge says most of the audits of covered entities were conducted in the fall, but the BA audits recently got under way. Audits of a CE or BA examine compliance with either the security rule, the privacy rule or breach notification — not all three, he says. The CE or BA loads the information to a portal — in a security rule audit, for example, that means policies and procedures for access controls, technical security management and patching — and then OCR disappears to evaluate the information. If a serious compliance issue surfaces, OCR may conduct a compliance review to further investigate the CE or BA. Ultimately, this could lead to a fine and corrective action plan.

The implications of the BA audit of the insurance agent — one of two to cross Marting's desk on the same December day — were staggering. "She was in a panic, not knowing what the purpose of the audit was," Marting says. "Was she targeted? Would she be penalized? Could her business be shut down?"

The OCR documentation request didn't seem to shed much light on what auditors wanted. For example, OCR said: "consistent with 164.316(b)(2))ii)-(iii), upload documentation from the previous calendar year demonstrating that documentation related to the implementation of this implementation specification is available to the persons responsible for implementing this implementation specification and that such documentation is periodically reviewed and, if needed, updated."

Marting figured it out, but she said the OCR request wasn't a model of clarity. OCR also requested documentation of breach notification and security incident reports the insurance agent had sent to covered entity-clients, as required by the business associate agreement. "I don't know if that's suggestive of OCR wanting to verify that CEs are reporting breaches that have been found," Marting says. In any case, the insurance agent had nothing to report.

Risk Analysis Was the Achilles Heel

The overarching problem, however, was that the insurance agent hadn't memorialized her practices in formal policies and procedures, Marting says. The Achilles heel — as is the case with many HIPAA and meaningful use audits — was the security risk analysis. "OCR wants the actual security risk analysis that shows controls, risk areas and what additional actions may need to be taken to reduce your risks," she says.

Under the gun of OCR's demands, the documentation began moving forward, Marting says. For example, they documented her standard operating procedure in areas like computer passwords. "We walked through questions we normally ask during the risk assessment and wrote them down and our response to OCR was that, even though this agency hadn't written this down before, here is what she is aware of and currently doing," Marting says.

There's no word yet from OCR. "I don't think there will be monetary fines, but she will now put in place policies and procedures for herself," Marting says.

If BAs receive OCR audit demand letters and their HIPAA compliance programs aren't up to snuff, there's not a lot they can do except "try to stop the bleeding,"

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Selfridge says. They have to show "they are getting on this now. We saw the same with the covered entity audits." In situations like these, OCR tends to "give you a fine that hurts, but doesn't put you out of business," Selfridge says. The message will be clear, however: build your HIPAA compliance program immediately. "It's all hands on deck."

Selfridge says the language of audit requests may be "tricky to interpret," but "conceptually, it's not a mystery what OCR wants." There should be evidence that CEs and BAs have a risk management process in place (including routine risk assessments), a security and privacy officer, policies, compliance-officer training and "implementation of the plan was made available for those responsible for implementing it in a timely fashion," he says.

What's unclear is how much to show and tell. "Where the anxiety is, auditors don't like to be overloaded with data," Selfridge says. "You don't want to appear to be bamboozling them. You want to provide enough information to answer the question and explain the documentation. The art form is trying to make an auditor satisfied you are doing the right thing without doing so much that their head spins."

Contact Marting at rmarting@forbeslawgroup.com and Selfridge at brian.selfridge@meditologyservices.com. Read the Ponemon report at http://tinyurl.com/zceb286. ✧

Employee Grumbling Led Morehouse To Revamp Compliance Training

When it was time for routine compliance training at Morehouse School of Medicine in Atlanta, some employees went to Compliance Training Coordinator Francesqua Chapman to ask why they had to sit through it. How would training be different this time around? How was it relevant to their job duties?

"The questions got us thinking long and hard about compliance training," Chapman said. It was boring and impersonal. "As a result of cookie-cutter training, we missed a prime opportunity to integrate training with the core values and overall mission" of Morehouse School of Medicine, a freestanding medical school with a faculty practice plan affiliated with Grady Hospital.

The soul searching set in motion an overhaul of the compliance training program. "We sought to make compliance training more than just a requirement," Chapman explained. "Instead of saying 'complete compliance training or there would be consequences,' we created meaningful messages that said 'do the right thing.' We made a huge pivot. It led to a snowball effect that transformed compliance training from rigid to exciting."

She now uses two techniques — "perceptual arousal" and "inquiry arousal" — that engage employees in learning and give them the "illusion of choice" about how training is delivered. Morehouse also uses a custom-

Checklist to Prepare for HIPAA Audits

Here's a way to evaluate where your organization is on the HIPAA compliance continuum as the HHS Office for Civil Rights continues its second round of audits. It was developed by Brian Selfridge, a partner at Meditology Services. Contact him at brian.selfridge@meditologyservices.com.

OCR Audit Readiness Scorecard		
Audit Preparedness	✔ Identify single point of contact for OCR ✔ Identify single point of contact for document ✔ Assemble requested evidence	❑ Adequate ❑ Requires Attention
Policy and Procedure Documentation	✔ Verify policies are signed and dated ✔ Verify documents reference the corporate entity and apply to all subsidiaries ✔ Remove references to documents that have not been implemented	❑ Adequate ❑ Requires Attention
Risk Assessment and Risk Management	✔ Verify the latest risk assessment includes likelihood (i.e., threats, vulnerabilities), impact, and controls	❑ Adequate ❑ Requires Attention
Access Control (Process and Evidence)	✔ Verify risk remediation strategy / corrective action plan lists all unremediated risks and demonstrates progress from year to year ✔ Document the process for approving access and for terminations ✔ Document the annual review process, especially for systems with a high number of contractor and temporary users ✔ Document how access controls meet minimum necessary requirements	❑ Adequate ❑ Requires Attention
Business Associates	✔ Create a list of business associates ✔ Verify business associate agreements are in place and all business associates are using the latest version	❑ Adequate ❑ Requires Attention
Device and Media	✔ Create an inventory of mobile devices ✔ Verify portable media uses encryption ✔ Verify security controls in place for mobile devices	❑ Adequate ❑ Requires Attention

ized learning management system and has taken steps to reduce the "stigma" of training.

"Without effective compliance training, our efforts miss the mark in improving performance," Chapman said. If it's dull and doesn't inspire change, she said, training "is costly, damaging, ineffective and wasteful."

Considering the money that organizations sink into it and the time employees spend in it, training should work. According to the American Society for Training and Development (ASTD), organizations spent $164.2 billion on formal employee training in 2013. And employees train more than ever, ASTD said in a 2015 report, with the number of hours rising from 31.5 in 2013 to 53.8 in 2014. "Think of the hundreds of hours that employees endure [in training] in a lifetime," Chapman said at a Jan. 11 webinar sponsored by the Health Care Compliance Association.

The problem is they don't always get much out of it. "When learners find training unimportant, attention is lost and they find a means to escape," she said. "They use the time allotted to do something more meaningful to them"— checking emails, updating their status on social media, shopping online and even taking screen shots of content and pasting them into a Word document so they can answer the quiz questions at the end.

"No attention means no learning," she noted.

To turn training into something employees find "engaging and effective," start by ending "the checkbox movement." Training should be "personal, relevant, timely and actionable." This was accomplished in various ways, and Morehouse got ideas from its employees. "Before the end of every year, we get feedback about what worked and didn't," she says. "The secret ingredient to retune compliance training is to zone in on what they find motivating and memorable." Morehouse learned that employees varied in the ways they benefited from the compliance-training experience. Some preferred instructor-led training and others valued the online experience.

Provide Trainees With 'Illusion of Choice'

As a result, Morehouse added the "illusion of choice," she said. That's when "you take training requirements and add flexible components that are highly visible to the audience. We sought to generate more options to change the landscape of learning for the better." Employees are offered three ways to complete the training requirement by the deadline:

(1) Live training at two different times;

(2) Online training; or

(3) Departmental training, "where we give them the opportunity to invite us to their department meetings."

Employees are also much more responsive when there's a "hook" to compliance training. "It's a great way to make training relatable and specific to your community. She described two techniques that tailor training to the audience and inspire it to take action:

(1) Perceptual arousal is about creating a twist on a topic that "may be regular," she said. "The intention is to raise eyebrows and get people thinking." This includes using "provocative stories, startling facts and statistics and celebrity gossip" to stimulate conversation and problem solving around compliance issues. "Go for the unexpected." For example, in 2014, Carolina Panthers quarterback Cam Newton's surgery was revealed by a caller to a radio show, who said he learned it from his spouse, reportedly a nurse at the hospital where Newton had the surgery. "It's an example of what can go wrong when a spouse talks a little too much," Chapman said. Examples of settlements also have an impact, so she shows employees how much money hospitals and other providers have paid to settle potential HIPAA violations, such as stolen laptops with unencrypted protected health information (e.g., Massachusetts Eye and Ear Infirmary and Massachusetts Eye and Ear Associates settled for $1.5 million with the HHS Office for Civil Rights).

(2) Inquiry arousal refers to inciting curiosity about what they thought they knew. This pushes employees to question what they know and use their skills to solve problems. Chapman suggested "creating a series of cliffhangers," and Morehouse uses the vehicle of a fictional employee, Maria, and builds a story line around her. Maria is designed as "an everyday employee" who people can relate to, and she is used in code of conduct training. What would employees do when faced with her challenges? There are thought-provoking scenarios presented with humor to absorb employees, and "we incorporate twists and turns," Chapman said. For example, there's a discrepancy in Maria's expense report but she has a deadline for handing it in and there's a policy against working overtime. Her co-worker encourages Maria to turn in the expense report, saying someone else will fix it. "We asked the audience what the right thing to do was," Chapman said. What would happen if she went down various paths of submitting the expense report on time with an error vs. fixing it but breaking overtime rules? "Then we add another part to the story and show them what happens," Chapman said. Maybe it's a major report or a grant is involved and requires approval up the chain of command. "Those scenarios are real life scenarios," added Chief Compliance Officer Desiree Ramirez. "We want to draw out the concern and talk it over."

It's effective in training to draw on mistakes in your own organization "and add the right elements to forge a connection with your audience," Chapman said. "Look

deep and trigger emotions with your community." She said they should "ooze with empathy and humanity and have a dash of humor. Create controversy and portray the consequences. Compelling stories are more likely to be successful and get people to act."

Another element of effective training is "breaking the stigma," Ramirez said. "People feel training is a bureaucracy, like we put a burden on them," she said. "We changed the message. Instead of seeing it as a burden, it's an honor and a duty. You are the eyes and ears. You are a community member and you want what's best for Morehouse School of Medicine."

In the wake of all the changes, Morehouse employees finished compliance training much faster, Ramirez said. The completion rate used to be 100% in four to five months, but now it's 100% in one month.

Contact Chapman at fchapman@msm.edu. ✧

CMS Guidance: Provider-Based Departments May Shape Exception

As if it were an election with a write-in candidate, hospitals have the opportunity to propose when their provider-based departments (PBDs) qualify for the relocation exception to the ban on billing under the outpatient prospective payment system, according to CMS's subregulatory guidance posted on Jan. 9. The agency created the relocation exception for "extraordinary circumstances" in the 2017 OPPS regulation.

"They have left it open," says Washington, D.C., attorney Andy Ruskin, with Morgan Lewis. That doesn't mean the exception will be expansive, but it gives hospitals an opening to seek a relocation exception beyond the natural disasters and other limited reasons cited in the preamble to the regulation, which implemented the law that cracked down on OPPS billing by new off-campus provider-based space.

CMS also issued subregulatory guidance on the mid-build exception to the OPPS billing ban that appeared in the 21st Century Cures Act *(RMC 1/9/17, p. 1; 12/5/16, p. 3).*

Elimination of OPPS Billing Was the Trigger

The relocation guidance stems from the change that rocked the hospital world: the elimination of OPPS billing by off-campus provider-based space established after Nov. 2, 2015, as decreed by Sec. 603 of the Bipartisan Budget Act of 2015 *(RMC 11/2/15, p. 1)*. It set in motion all sorts of changes, including a new billing system for services that provider-based departments add after Nov. 2, 2015, unless they're grandfathered, or "excepted," to use CMS terminology, according to the final regulation *(RMC 11/7/16, p. 1)*

Even though a site may be grandfathered under Section 603, that status isn't necessarily permanent, Ruskin explains. CMS stated that provider-based departments would lose their status if they moved. But a door was nudged open in the final rule with an exceptions process that's limited to "extraordinary circumstances outside a hospital's control," according to the regulation. Provider-based space would be "excepted" despite relocation if it's caused by "natural disasters, significant seismic building code requirements, or significant public health and public safety issues." Exactly what that means will be decided on a case-by-case basis by CMS regional offices. But the ball is sort of in the hospital's court, according to the subregulatory guidance.

Future Requests Must Be Made Within 30 Days

Hospitals must request a relocation exception within 30 days after the extraordinary circumstance happens for relocations that occur on Jan. 1, 2017, or after. Sites that have already relocated must file their request by January 31. There's no limited list of choices. In a form at the end of the guidance, CMS asks hospitals to "Provide a detailed explanation of the rare and unusual circumstance that necessitated (or will necessitate) relocation of the existing PBD. Include in the explanation factual details, such as the date the event occurred and resulting damages to the building, details about the ability to continue to furnish services in the building, as well as any relevant laws, regulations or other reasons that necessitated (or will necessitate) the move (may submit as separate attached document)."

The fact that hospitals can fill in the blanks gives them a chance to shape CMS's and the regional offices' response to their requests for the exception and for future guidance — and they will need more guidance, Ruskin says. "It's up to providers to say 'we think this is extraordinary because of X,'" he says. "Any provider submitting this is getting in on the ground floor of the making of a policy."

In a separate document, CMS issued subregulatory guidance on the mid-build exception to Sec. 603 in the 21st Century Cures Act (H.R. 6), which allows OPPS billing by off-campus provider-based departments that had a binding written agreement for construction on or before Nov. 2, 2015, and jump through other hoops. The hospital CEO or COO has to submit a letter to CMS stating that the provider-based department meets the definition of "mid-build"; the hospital must file an attestation of compliance with provider-based status within 60 days of the bill becoming law (it was signed by President Obama on Dec. 13); and the site must be added as a new location on the 855 enrollment form, Ruskin says.

The guidance mostly parrots the statute, he says. "It's very frustrating." What hospitals need to know is how to define "actual construction," Ruskin says. "A lot of providers are leasing. Is that 'actual construction' or 'mid-build'? Leasing means you are incurring financial obligations and you may not be able to get out of that lease. You may have to tear down the walls. Why does mid-build have to mean pouring cement and erecting steel beams? I think this is open to question." The problem, however, is Congress in other laws has been explicit, using the term "actual construction," and that doesn't bode well for the mid-build exception. But CMS should say so one way or the other. "They have to issue more guidance. What it's done so far is just an FYI," Ruskin says.

The guidance also reiterates that provider-based departments must now append modifier PN to HCPCS codes for "nonexcepted" items and services. That refers to services that can't be billed at the full OPPS rate because they were added at off-campus provider-based departments on or after Nov. 2, 2015.

Visit Ruskin at aruskin@morganlewis.com. View the extraordinary circumstances guidance at http://tinyurl.com/j45cl55 and the mid-build exception guidance at http://tinyurl.com/hzcxfub. ✧

Mich. Neurosurgeon Sentenced To 20 Years in Spine Surgery Case

Detroit-area neurosurgeon Aria Sabit is heading to prison for 20 years after being convicted in connection with medically unnecessary spinal fusion surgeries in a case that also raised questions about physician-owned distributorships (PODs). Sabit, who pleaded guilty in 2015 to four counts of health care fraud, one count of conspiracy to commit health care fraud and one count of unlawful distribution of a controlled substance *(RMC 6/1/15, p. 1)*, was sentenced to 235 months for his part in a $2.8 million fraud scheme, the Department of Justice said Jan. 9. The surgeries allegedly "caused serious bodily harm to patients" and ripped off Medicare, Medicaid and various private insurers, according to DOJ.

Sabit, who ran the Michigan Brain and Spine Physicians Group, billed for spinal fusions that patients didn't need or that were performed without the medical device that is the backbone of the procedure.

Sabit's plea agreement contends the ball got rolling on this "conspiracy" to perform medically unnecessary surgery when he was seduced by POD incentives. PODs sell medical devices to hospitals and ambulatory surgical centers, where they are often implanted by the surgeons who own the PODs, a situation the HHS Office of Inspector General called "inherently suspect" in a 2013 special fraud alert *(RMC 4/8/13, p. 3)*. In fact, Sabit is embroiled in the first false claims lawsuit against a POD, which DOJ filed in 2014 against Reliance Medical Systems, a spinal implant company, as well as two Reliance PODs — Apex Medical Technologies and Kronos Spinal Technologies — and their owners. The lawsuit alleges they paid physicians, including Sabit, to induce them to use Reliance spinal implants in their surgeries *(RMC 9/15/14, p. 1)*. The false claims lawsuit is still pending, DOJ says.

When the POD arrangement began, Sabit practiced in California, but he ran into trouble with the state medical board, which alleged he performed unnecessary spinal procedures, according to the false claims lawsuit. Around March 2011, Sabit moved to Detroit and obtained temporary hospital privileges at Detroit Medical Center, Doctor's Hospital of Michigan and McLaren Lapeer Regional Medical Center. Sabit implanted Reliance devices in patients there until spring 2012. He was arrested in November 2014 *(RMC 12/8/14, p. 1)*.

The plea agreement describes how Sabit "derived significant profits" by persuading patients to have spinal fusion with instrumentation, which he didn't perform as documented in the medical records. Here are some examples and how they connect to the POD, according to the plea agreement:

◆ ***In a surgery at Doctor's Hospital of Michigan in Pontiac in February 2012, Sabit wrote in an operative report that he performed a spinal fusion with instrumentation at L4, L5 and S1 levels and used Zimmer transfacet screws.*** But subsequent diagnostic imaging showed this wasn't true. Even though Sabit didn't put screws in the patient or perform a posterolateral fusion, he billed Medicaid for $26,067.

◆ ***In a surgery at Detroit Medical Center in April 2012, Sabit's operative report said the patient had spinal fusion with instrumentation at levels L4, L5 and S1, using transfacet screws.*** Instead, Sabit implanted a cortical bone dowel, which is made of tissue, but he billed Medicaid $28,604 for the fusion with screws.

◆ ***In a surgery at Doctor's Hospital in March 2012, Sabit documented he performed a spinal fusion with instrumentation at L4-L5 and placed two transfacet screws.*** Subsequent imaging of the patient's spinal column showed there were no screws in the spinal column and that Sabit never performed a posterolateral fusion. He charged Blue Cross Blue Shield of Michigan $20,383 for the procedure.

The plea agreement then alleges the connection to Sabit's relationship with Apex. Every spine surgery he performed using Apex devices "was predicated on illegal kickback payments" he received from co-conspirators, the plea agreement alleges. "Moreover, incentivized by this illegal kickback arrangement and his involvement

in the conspiracy, [Sabit] performed medically unnecessary surgeries that caused serious bodily injury to at least some of his patients."

Eventually, he reduced his use of Apex devices, and the Michigan hospitals slowed or stopped paying for them. Apex and Sabit parted ways in August 2012.

Visit http://tinyurl.com/zy3m62j. ✧

OIG Issues New Exclusion Rules

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Perhaps the most worrisome part of the enhanced exclusion authority is OIG's power to boot people out of federal health care programs for misinformation — false statements, omissions or misrepresentations of a material fact — on an enrollment form or other bid or contract to participate as a provider or supplier (e.g., Medicare, Medicare Advantage, Part D), says San Francisco attorney Judy Waltz, with Foley & Lardner LLP. "OIG says it's not its intention to pursue exclusion based on inadvertent errors and minor oversights. However, I'm sure there will be some disputes between OIG and providers and suppliers as to what is a material fact omission or misrepresentation or even a false statement, and an inadvertent error or minor oversight," she says. "This increases the risks to providers and suppliers in not making their enrollment applications a very high priority. It's a daily risk to people."

OIG remarked in the rule that one purpose of this new exclusion authority is to "deter entities and individuals from misstating or falsifying information on enrollment applications, and incentivize providers to create safeguards to prevent fraud, waste, and abuse."

On a more encouraging note for providers, OIG included a provision for early reinstatement to federal health care programs for providers excluded over licensing. Providers often think they're automatically back in Medicare after exclusions expire, but that's not the case. They have to reapply and their future as providers in good standing depends on whether the government thinks their value to federal health care programs outweighs any risk they pose. In the final rule, OIG said it will consider early reinstatement based on securing a license in a different state (rather than the state that took the licensing action), except when exclusion stems from license revocation or suspension for patient abuse or neglect. "This can be helpful if the excluded entity provides a service that is difficult to come by otherwise, or when the excluded entity decides it doesn't want to seek reinstatement in the original state," Waltz says.

Here are some of the other developments in the final regulation:

◆ ***OIG ditched plans to free itself from deadlines for excluding providers for fraud, kickbacks and other "prohibited activities,"*** an idea floated in the proposed regulation *(RMC 2/16/15, p. 4)*. For example, it didn't want to be hamstrung by any statute of limitations, such as the six years under the False Claims Act. That would have meant OIG had the option to exclude providers long after they settled false claims cases. But OIG changed its tune in the final rule. "As a result of the comments we received, OIG has decided not to finalize the rule as proposed and to instead codify a ten-year limitations period."

◆ ***OIG can now exclude providers for obstruction of an investigation or an audit*** (e.g., meaningful use, zone program integrity contractor, comprehensive error rate testing program). "The permissive nature of the exclusion authority at section 1128(b)(2) of the Act allows OIG to exercise discretion and analyze the facts and circumstances of each relevant conviction before using the authority," the regulation stated. It looks like this extends to the survey and certification process, Waltz says. As the preamble states, "the Medicare survey and certification process is implemented for the purpose of inspecting facilities for compliance with Medicare health and safety standards. Where Government entities or contractors conduct an official inspection for the purpose of verifying compliance with Government program standards, we believe the term 'audit' would include such actions for purposes of the exclusion authority." Waltz says this raises the stakes for providers. But they would have to be convicted of obstructing the audit or investigation first, and that's not that common, she notes.

◆ ***OIG can exclude "any individual or entity furnishing, ordering, referring for furnishing, or certifying the need***

CMS Transmittals and *Federal Register* Regulations
Jan. 6 — Jan. 12

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. 100-20, One-Time Notification

- Modifications to the National Coordination of Benefits Agreement (COBA) Crossover Process, Trans. 1770, CR 9681 (Jan. 6, 2017, eff. April 1)

Federal Register

Proposed Regulation

- Medicare Program: Establishment of Special Payment Provisions and Requirements for Qualified Practitioners and Qualified Suppliers of Prosthetics and Custom Fabricated Orthotics, 82 Fed. Reg. 3678 (Jan. 12, 2017)

for items and services for which payment may be made under Medicare or Medicaid that fails to provide certain payment information to the Secretary." That means the exclusion axe can fall on providers over items or services they don't directly provide.

Waltz finds it interesting the way OIG describes exclusions as "prospective remedial actions to protect Federal health care programs and their beneficiaries from untrustworthy individuals and entities," as the preamble states. In the eyes of the OIG, exclusions are not punitive, she says. "This approach is important to understanding OIG's application of exclusions. They are taking actions that they consider remedial, and what's necessary to protect the federal health care programs going forward. So the provider's conduct dictates what's necessary to protect the program — and the length of the exclusion, while it considers aggravating and mitigating factors, is not designed to 'punish' the offender but what is considered necessary to protect the program."

Contact Waltz at jwaltz@foley.com. View the regulation at http://go.usa.gov/x9Ugu. ✧

NEWS BRIEFS

◆ **Family Care Visiting Nurse and Home Care Agency and its owners have agreed to pay $5.25 million to settle state and federal false claims allegations,** the U.S. attorney's office for the District of Connecticut and the state attorney general said Jan. 12. Family Care VNA and owners David A. Krett and Rita C. Krett allegedly billed Medicaid with HCPCS code S9123 (services rendered by a registered nurse) even though a registered nurse hadn't performed a 60-day assessment and/or the documentation didn't live up to Medicaid standards from Jan. 1, 2009, to April 30, 2016, according to the settlement. Family Care VNA also allegedly billed Medicaid for patients who were or may have been dually eligible for Medicare and Medicaid, although eligibility requirements for claims submission weren't satisfied, the settlement says. Family VNA, David Krett and Rita Krett did not admit liability in the settlement. Visit http://tinyurl.com/hu3j5hc.

◆ **NorthShore University HealthSystem was overpaid $4.1 million over two years, according to a Medicare compliance review.** OIG audited a stratified random sample of 190 claims submitted by NorthShore, a 789-bed acute care teaching health system in the Evanston, Ill., area. The findings: 97 had errors, which resulted in a $624,638 overpayment for the audit period (2013 and 2014). "On the basis of our sample results, we estimated that the Hospitals received overpayments of at least $4,110,073 for the audit period," OIG contended. The health system mostly disagreed with OIG's findings. The majority of the overpayment, OIG said, stems from mistakes that NorthShore made when billing Part A for acute inpatient rehabilitation services. The health system also incorrectly reported observation time when it was part of another Part B service, including postoperative monitoring or standard recovery care, or billed observation when patients stayed in the hospital after treatment was completed or lacked timely orders in the medical records, according to OIG. There was a smattering of other errors as well, such as failure to report a manufacturer credit for a replaced medical device. In the health system's written response, Chief Compliance Officer Harry Jones noted how seriously it takes compliance. But he disagreed "with the reasonableness of the overall extrapolation as well as the statistical validity of the overall Point Estimate." He noted that OIG doesn't take into account the partial payments the health system would receive if inpatient rehab patients were billed at a lower level of care because this isn't a question of medical necessity. "The only controversy is whether payment should have been provided under Part A or Part B," Jones stated. Visit http://go.usa.gov/x9n87.

◆ **Shire Pharmaceuticals LLC and other subsidiaries of Shire plc will fork over $350 million to resolve federal and state false claims allegations that Shire and a company it acquired in 2011, Advanced BioHealing, used kickbacks and other "unlawful methods"** to persuade clinics and physicians to use or overuse its product, Dermagraft, which is a skin substitute used to treat diabetic foot ulcers, the Department of Justice said Jan. 11. "The settlement resolves allegations that Dermagraft salespersons unlawfully induced clinics and physicians with lavish dinners, drinks, entertainment and travel; medical equipment and supplies; unwarranted payments for purported speaking engagements and bogus case studies; and cash, credits and rebates, to induce the use of Dermagraft," according to DOJ. This settlement is the largest kickback-related False Claims Act recovery. DOJ said Shire sold the assets related to Dermagraft in early 2014. Visit http://tinyurl.com/zv3auet.