Clinical Compliance Officers Complement Traditional Approaches to Compliance

When NHS Human Services saw the way the enforcement winds were blowing, it created the novel position of “clinical compliance officer.” After all, the number of false claims cases based on medically unnecessary care are on the rise, CMS is linking payments to patient outcomes and the HHS Office of Inspector General’s corporate integrity agreements and guidance for board members emphasize quality of care. So it seemed like a smart move for the compliance officer to have a clinical alter ego to audit many of the same risk areas from a different frame of reference.

“We were trying to create a seamless partnership because I think down the road, quality is the next compliance,” says John Ciavardone, chief compliance officer for NHS, a Philadelphia-based behavioral health company that operates in seven states.

Apparently, Ciavardone was a little ahead of his time. For budget, organizational and cultural reasons, the clinical compliance officer — psychologist Debra Burock, Ph.D. — was moved out of the compliance office at the corporate headquarters and back into the quality improvement department in the field. Her title is now regional director of program evaluation and practice development, but to some extent, that’s
just semantics because Burock is carrying out most of the same clinical-compliance functions. She is the yin to Ciavardone’s yang, auditing the clinical aspects of a risk area while Ciavardone audits the regulatory aspects — with the support of management and the help of their respective teams.

“What I do is clinical compliance. It just falls into a different part of the organization,” says Burock, a certified compliance officer. They are just in a different part of the organizational chart, which makes sense for quality of care because it means closer proximity to clients and to the NHS employees delivering care.

For example, oversight of treatment plans is important from both regulatory and compliance perspectives, which overlap. The pressure to get it right across-the-board is intensifying as payers and their auditors are scouring documentation for deficiencies. Ciavardone reviews treatment plans with a more traditional compliance eye. Have they been completed? Do they have proper signatures? Is the time frame accurate? “We always had a monitoring plan, but it was more compliance-oriented,” he says.

Burock went through an intense process to add a quality filter. Do treatment plans have all the necessary elements? Are they up to snuff? “We audit monthly to ensure that treatment plans are written in a way to meet quality standards. Is it concrete, observable and measurable in terms of its goals and objectives?” For example, quality of care might be suspect if a clinician set a goal that stated “individual will decrease anxiety” because it’s not measurable or concrete. “How do we know what’s ‘less anxiety?’ How much does the person have now, and how will I know when it’s lessened? That is a quality disconnect and payers would have a problem if the referral is for depression but the treatment plan focuses on anger,” Burock says.

She also worked with a team of managers to design a treatment-plan template that prompts clinicians to insert required information. It’s particularly helpful with less experienced clinicians, Ciavardone says. The clinical-compliance oversight is a real boon, he says. “You could have a treatment plan that meet regulatory requirements, but does it do a good job of addressing the needs of the person receiving services? I felt no one in my department could look at that. What she has done is create indicators to say whether or not something is meeting quality standards.”

Next Step: Monitoring for Value

The treatment plan is a perfect example of the compliance/quality nexus because the regulation requiring it was designed to ensure quality of care, Burock says. “Over time, it [became apparent] it was a good start, but not enough,” she says. “We realized what went into the treatment plan was very important.” So compliance with the regulation’s list of DOs and DON’Ts became intertwined with the evolution of what NHS calls PQI — performance and quality improvement. They are two sides of the same coin, she says. And the more that health care organizations experience adverse consequences from payers and licensing bodies, “the more they will focus on what is actually in the documentation,” she says.

“That’s how you get into measuring quality. People are sometimes stuck at that basic level of monitoring what’s in there — is it in accordance with the regulations?” But the next level is to determine whether the documentation reflects value and quality, she says. “Organizations will see there are consequences if they don’t have integrated compliance and quality,” Burock says.

Ciavardone sees the future of compliance propelled by a shift in the risks that organizations face. “There is going to be a change in thinking for compliance officers,” he says. But having a clinical compliance officer in his department didn’t work out because there was not enough buy-in, the compliance staff was resistant and the HQ location wasn’t productive, he says. “I did not realize
how much of a change this would be for people. It was a disconnect. It could have been really disastrous, but it worked out very well.” One reason is that a senior executive was very supportive of clinical compliance. “It came out better than we planned,” he says.

In addition to auditing and monitoring, Burock oversees incident management and peer review, all of which ties into quality improvement. “I have been partnering with her team,” says Ciavardone, completing the circle back around to compliance. “There is a lot to it.”

Contact Ciavardone at jciavardone@nhsOnline.org and Burock at DBurock@nhsOnline.org.

**OIG Calls PODs ‘Inherently Suspect’; Vetting Process Is Recommended**

The HHS Office of Inspector General didn’t mince words in its special fraud alert on physician-owned distributorships (PODs) issued March 26. It warned that certain attributes of PODs increase the risk of fraud and abuse and may jeopardize patient safety.

“We believe that PODs are inherently suspect under the anti-kickback statute,” OIG said.

PODs sell medical devices to hospitals and ambulatory surgery centers (ASCs), where they are often implanted by the surgeons who own the PODs. They have come under fire from the Senate Finance Committee’s minority staff, led by Orrin Hatch (R-Utah), and Democratic chairman Max Baucus (D-Mont.), who are concerned that PODs may be used by hospitals to reward surgeons for referrals, invite overutilization and possibly lead to medically unnecessary procedures. In June 2011, the lawmakers asked OIG to investigate PODs and recommend strategies for regulating them (RMC 6/20/11, p. 1), and OIG has been questioning hospitals on their use of PODs (RMC 10/29/12, p. 1).

And now here are the results. “OIG doesn’t like PODs and wants them to go away,” says Denver attorney Jeffrey Fitzgerald, with Polsinelli Shughart. In light of this, compliance officers should develop a process for vetting potential distributors and proving their value, regardless of whether a physician has an ownership stake, he says. It’s also a good idea to monitor POD payments to physicians. That will be easier soon because PODs generally have reporting obligations under the Physician Payment Sunshine Act (RMC 2/11/13, p. 4), says Los Angeles attorney Brad Tully, with Hooper, Lundy & Bookman.

In the fraud alert, OIG described “suspect characteristics” of PODs. They include:

- The size of the POD investment offered to a physician varies with the volume or value of devices used by the physician.
- Physician-owners of a POD make their patient referrals to hospitals and ambulatory surgery centers contingent on their buying the POD’s devices “through coercion or promises by stating or implying they will perform surgeries or refer patients elsewhere if a hospital or an ASC does not purchase devices from the POD, by promising or implying they will move surgeries to the hospital or ASC if it purchases devices from the POD, or by requiring a hospital or an ASC to enter into an exclusive purchase arrangement with the POD.”
- The PODs don’t make distributions in proportion to ownership interest, or physician-owners pay different prices for their ownership interests based on volume or value of devices used by doctors.

Macon, Ga., attorney Alan Rumph sees a sliver of a silver lining in the fraud alert. “It gives a good roadmap of issues to avoid to support the claim that your POD is not abusive,” he says. Most of the risk factors cited by the OIG “are easily avoidable.” For example, distributions or investment offerings obviously should not vary with the volume or value of referrals.

**Not Good News for PODs and Providers**

Other than that, this is not good news for PODs or the hospitals and ASCs that do business with them, says Rumph, with Smith Hawkins. “With the fraud alert, there is an increasing risk of whistleblowers” filing cases if the government doesn’t go it alone, he says.

Substantively, lawyers didn’t see a lot that was new in the fraud alert in terms of anti-kickback analysis. “The law is pretty well settled with respect to physician investments in health care businesses,” Tully says. And the features that OIG considers suspicious “are not necessarily features of PODs,” Tully says. “Nevertheless, the OIG used highly charged language at places in the fraud alert that appear likely to feed continued controversy in this area.”

OIG’s hard line is unmistakable and it’s drawn around hospitals and ASCs as much as PODs, Fitzgerald says. “Because the anti-kickback statute ascribes criminal liability to parties on both sides of an impermissible ‘kickback’ transaction, hospitals and ASCs that enter into arrangements with PODs also may be at risk under the statute. In evaluating these arrangements, OIG will consider whether one purpose underlying a hospital’s or an ASC’s decision to purchase devices from a POD is to maintain or secure referrals from the POD’s physician-owners,” the fraud alerts asserts.

Compliance officers should help their purchasing departments implement a process to vet prospective...
distributors, Fitzgerald says. “If hospitals are going to purchase from PODs, they should have a process to clearly document the non-referral benefits of purchasing from that distributor, such as better pricing, greater access to certain devices or improved customer service,” he says. “Hospitals should have the same expectations and demands for all distributors, whether owned by a physician or not.”

Contact Fitzgerald at jfitzgerald@polsinelli.com, Rumph at alan@shhrlaw.com and Tully at wtully@health-law.com. View the fraud alert at http://go.usa.gov/2fAk.

Outpatient Therapy Is a New Target Of RAC Prepayment Reviews

Physical, speech and occupational therapy performed in hospital outpatient departments and other outpatient settings will now face prepayment reviews, CMS said March 22. When outpatient rehab exceeds the annual per-beneficiary threshold of $3,700, it will be subject to prepayment or postpayment reviews.

CMS limits physical and speech therapy combined to $3,700 per beneficiary and/or $3,700 for occupational therapy, but “exceptions to the therapy cap are allowed for reasonable and necessary therapy services,” according to its website.

There will be prepayment reviews in 11 states — Florida, California, Michigan, Texas, New York, Louisiana, Illinois, Pennsylvania, Ohio, North Carolina and Missouri — and postpayment reviews in the other 39. However, claims above the threshold will automatically trigger a RAC review. Initially, CMS says, Medicare administrative contractors (MACs) will do prepayment reviews on claims above the $3,700 threshold with dates of service from January 1, 2013, to March 31, 2013, and they have 10 days to complete the reviews. On April 1, 2013, RACs will take over the rehab reviews. CMS’s previous approach to manual medical review of claims above the threshold, the preapproval process, is no longer available.

“If you are not in the 11 prepayment states, your $3,700 therapy threshold will be paid by your MAC, which will simultaneously send you a notice for you to send your claims for postpayment review,” says Nancy Beckley, president of Nancy Beckley & Associates in Milwaukee. But RACs will perform the postpayment reviews.

A CMS official told RMC that prepayment reviews will be expanded to other Part B services. RACs already have prepayment reviews of eight MS-DRGs that are under way, including syncope and transient ischemia (RMC 2/4/13, p. 1).

Beckley says the new prepayment and postpayment reviews raise troubling questions. Is there a discussion period with the RAC for therapists who face claims denials for services above the threshold? Other providers have the right to persuade RACs to reverse claims denials, but therapists do not.

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als before starting a formal appeal process. Then there is the threat of beneficiary liability. “When faced with the uncertainty of liability, the beneficiary may elect not to have therapy,” she says. What are their risks here? And there is concern about the lack of a cap on medical-records requests that comes with 100% medical review.

Contact Beckley at nancy@nancybeckley.com. 

**Intermountain Healthcare Settles Stark Case Over 209 MD Deals**

After self-disclosing potential Stark violations to the government, Intermountain Health Care Inc. agreed to pay $25.5 million to settle false claims allegations, the Department of Justice said April 3. The case centers on allegations that Utah’s largest health system violated Stark in both mundane and substantive ways, in 209 physician arrangements.

According to the settlement, Intermountain disclosed in 2009 that it submitted claims to Medicare between 2000 and 2009 that were allegedly unlawful in various ways:

- Intermountain’s medical group subsidiary compensated certain employed physicians using a bonus formula that may have improperly taken into account the volume or value of the physicians’ patient referrals to Intermountain, the settlement alleged.

- Intermountain rented office space to some physicians at Cassia Regional Medical Center in Barley, Idaho and Sevier Valley Medical in Richfield, Utah, without written leases and/or “where there may have been fair market value issues.”

- Other compensation and financial relationships between Intermountain and certain physicians were not memorialized in executed agreements for their duration, the settlement alleges.

Intermountain, which did not admit liability in the settlement, identified Stark problems during “its regular review processes,” Chief Medical Officer Brent Wallace, M.D., said in a statement. “Intermountain’s management recognized that potential penalties could be significant, but at no time was there ever any consideration given to not self-disclosing the issues.” He emphasized the alleged violations were primarily technical, focusing, for example, on the “lack of proper paperwork involving leases of physician offices and service agreements,” Wallace noted. However, he added, “Intermountain should have monitored this situation more closely. We are embarrassed that these issues occurred and regret that our controls at the time were inadequate to properly monitor these matters.”

The self-disclosure is remarkable in terms of the number of physicians involved, the mix of technical and substantive violations, the nine-year look-back period of Intermountain’s self-audit, and the settlement amount,
Rebilling Procedures Cause Concern  

continued from p. 1  

At the open-door forum, Dave Danek, health insurance specialist in the CMS Division of Appeals Policy, described the three categories for rebilling Part B services after Medicare auditors deny Part A claims or hospitals lose their medical-necessity appeals. Surprisingly, he said the clock on the rebilling deadline starts when hospitals get remittance notices, not demand letters, from Medicare auditors. The three categories are:

1. **Rebilling after claim denials**: Since March 13, Danek said that hospitals have been able to rebill Part A denials without filing an appeal as long as the timing is right. “If you have a remittance notice with a denial after November 8, 2012, that is eligible for rebilling under the ruling,” he said.

2. **Pending appeals, with no decision yet**: Hospitals can withdraw their Part A appeals and rebill Part B instead. But they must first obtain dismissal orders from the administrative tribunal where their appeal is pending (e.g., the administrative law judge, qualified independent contractor). Directions for requesting withdrawals are on the Office of Medicare Hearings and Appeals website, he said (www.hhs.gov/omha). CMS probably won’t require hospitals to attach the dismissal order to the Part B claim, he noted.

3. **Post-appeal denials**: When administrative law judges (ALJs) or other administrative tribunals turn down hospital Part A medical-necessity appeals, rebilling Part B is still an option.

The deadline for rebilling under all three categories is 180 days, which is a departure from the 120 days that hospitals have to file the first appeal of a Medicare claim denial. “It is 180 days from the date of receipt of the last date of adjudication — the appeal decision, the dismissal order or the claims denial,” he said. But “one of the caveats in terms of rebilling or submitting Part B claims is that the timeframe to appeal must not have expired as of the date of the ruling” — which is where the 120 days comes into play.

What drives hospitals a little crazy is the reference point for claim denials. Danek said the clock starts when hospitals get the remittance advice. But that’s contrary to standard operating procedure, compliance officials say. Recovery audit contractors routinely tell hospitals that demand letters trigger the appeals process. Demand letters contain RAC overpayment findings, but are sent to hospitals and other providers by Medicare administrative contractors.

In response to frustration expressed by hospitals, Danek reiterated the pivotal role of remittance notices. “It has to be this way, he said, because Medicare won’t register a Part A claim denial until the remittance advice is sent out.

Ann Marshall, technical adviser in the CMS Hospital and Ambulatory Policy Group, explained at the open-door forum that the location where beneficiaries receive services does not drive the split between Part B inpatient and Part B outpatient claims. “The time for the order is the demarcation,” she said. Suppose a patient was admitted to the hospital through the emergency department (ED) and the Part A claim was denied as medically unnecessary. To recover costs under Part B, the hospital can rebill for the ED visit before admission (Part B outpatient) and submit a second Part B claim for services provided after the admission (Part B inpatient). “Anything furnished prior to the inpatient order goes on the 131 [Type of bill] for outpatient claims and services,” Marshall said. Anything furnished after is billed as 121 TOB.

**Hospitals Face Procedural ‘Nightmare’**

Trout doubts that configuration will pan out. “My billers tell me they won’t be able to get the ED claim through. No matter what we do, we can never get two claims paid on the same day under the same Tax ID,” she says. “One claim will reject and [Medicare] will always reject the claim with the higher payment. So we will get paid for the ED service, but then the Part B inpatient claims will deny as a claim overlap.” The bottom line is that while CMS says hospitals can bill both types of claims, “I don’t believe it will functionally work.”

Trout thinks the rebilling procedure invites errors. Part B claims must include a condition code, treatment authorization code, 837I prior authorization code, and the denied inpatient claim number with its the last adju-
April 8, 2013 Report on Medicare Compliance

Citation date. “Administratively, it’s a nightmare,” she maintains.

CMS will publish billing instructions imminently, and has already issued both a Medicare transmittal (1203) and MLN Matters article (MM8185) on Part A to Part B rebilling.

The discussion about deadlines and remittance advices rattled hospitals. Colleen Dailey, clinical coordinator of defense audits at WellSpan, says, “RACs have always been based on the premise of the demand letter, so why all of a sudden is it a remittance advice?” This will require hospitals to reprogram their tracking software to ensure they rebill Part B claims in a timely manner, pre- and post-appeal.

Some key questions about rebilling remain unanswered. For one thing, it’s unclear what happens to claims denials when the proposed rule is finalized, says Royal Oak, Mich., attorney Drew Wachler. Does the rule, with its more liberal appeals timeframe, still apply to claims that were denied before the regulation takes effect even though they haven’t been rebilled yet? Or is the effective date of the regulation a game-changer for all claims still in the appeals process? “CMS indicated…it would not apply to claims subject to the ruling, but only to denials after the date that final rule is effective.”

In light of the ruling, Wachler says, hospitals can no longer seek Part B payment (e.g., observation services) in their Part A appeals. Hospitals should also ensure they notify beneficiaries when they appeal Part A denials.

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Contact Marshall at ann.marshall@cms.hhs.gov, Danek at david.danek@cms.hhs.gov, Trout at wtrout@wellspan.org, Dailey at cdailey2@wellspan.org, Wachler at awachler@wachler.com and Glaser at dglaser@fredlaw.com. View the transmittal at http://tinyurl.com/bmdsjo2. ✦

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### New Medicare Compliance Review Findings

The HHS Office of Inspector General contends that North Shore Medical Center in Massachusetts was overpaid $816,000 in multiple risk areas identified during a comprehensive audit (see brief, p. 8).

#### Risk Areas Reviewed and Billing Errors

<table>
<thead>
<tr>
<th>Risk Area</th>
<th>Selected Claims</th>
<th>Value of Selected Claims</th>
<th>Claims With Overpayments</th>
<th>Value of Overpayments</th>
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SOURCE: HHS Office of Inspector General

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NEWS BRIEFS

♦ The HHS Office of Inspector General wants North Shore Medical Center in Massachusetts to repay almost 30% of the payments it received in 2009 and 2010 on 316 inpatient and outpatient claims, for a total of $816,000, according to a Medicare compliance review posted on March 20, 2013 (see table, p. 7). Inpatient admissions for patients that should have been treated as outpatients accounted for $635,716 of the overpayment to North Shore, which includes two acute-care hospitals. According to OIG, these errors occurred primarily because the hospital did not have adequate controls to prevent the incorrect billing and lacked the understanding of the Medicare billing requirements for the 11 risk areas with errors. The hospital generally agreed with the OIG findings. It also told OIG that it had strengthened its internal controls of inpatient short stays by training physicians and residents on level-of-care determinations and that its hospitalist service had hired an in-house physician manager to review cases. Visit http://tinyurl.com/bvbq52y to view the report (A-01-12-00506).

♦ OIG has posted its latest podcast featuring Jeannette Gaughan, senior auditor for the Office of Audit Services in Boston, interviewing Kim Rapoza, an audit manager in her office. The focus of the podcast is the OIG’s Medicare compliance reviews. Rapoza explains how risk areas are determined and key actions hospitals and their compliance officers can take based on these reviews. Rapoza said that OIG has completed reviews of 79 hospitals across the country and recovered about $34 million and is actively working with another 25 hospitals. Visit http://tinyurl.com/d7bmt9s for the podcast.

♦ Of the 325 claims Norwalk Hospital of Connecticut submitted to Medicare in 2010 for inpatient rehabilitation services, OIG audited 100 and concluded that 98 of them did not meet Medicare documentation requirements, according to report (A-01-11-00531). OIG’s audit objective was to see whether hospitals were complying with revised documentation requirements for rehab hospitals that took effect in 2010. The report maintains that the hospital, which operates a 25-bed inpatient rehabilitation facility, did not have medical records with sufficient documentation to support four required elements for inpatient rehab admission. The noncompliant claims resulted in an overpayment of $2,738,379. OIG recommended that Norwalk refund the money and identify any subsequent noncompliant IRF claims. It also suggested the hospital work with CMS to review the remaining 225 claims paid in 2010 for possible overpayments of $5,236,378. The hospital strongly disagreed with the recommendations regarding the overpayments “and reserves all rights in the event that CMS accepts the OIG’s proposed recommendations.” It maintained that the audit methodology was flawed because auditors used a “documentation checklist” and that documentation was not necessarily the exclusive means of assessing medical necessity. Visit http://tinyurl.com/d99dpb7 for the full report.

♦ The Sixth Circuit Court of Appeals on April 2 overturned an $11 million fine levied against MedQuest Associates for alleged False Claims Act violations. The court found that MedQuest’s use of physician supervisors not approved by the Medicare administrative contractor and the failure to properly enroll as an independent diagnostic testing facility were violations of the conditions of participation, not the conditions of payment. “The regulatory scheme does not support FCA liability for failure to comply with the supervising-physician regulations, and failure to satisfy the enrollment regulations...do not trigger the hefty fines and penalties created by the FCA.” Visit http://tinyurl.com/c9rhwy.

♦ Temple University in Philadelphia has agreed to pay $100,000 to settle allegations that it over-billed for neurology services. According to a press release from the U.S. Attorney for the Eastern District of Pennsylvania, “Upon review of the documentation underlying these claims, Temple University agreed that the coding was not accurate.” Visit http://tinyurl.com/cdzyav2 for the press release.

♦ Three republican senators on the Senate Finance Committee have asked HHS Secretary Kathleen Sebelius to explain why CMS is not using all the tools provided to it in the Affordable Care Act to combat fraud and abuse. Senators Orrin Hatch (R-Utah), Chuck Grassley (R-Iowa) and Tom Coburn (R-Okl.) focused on CMS’s authority to impose a temporary enrollment moratorium on new Medicare types of providers and suppliers or in areas of the country the agency determines have a significant potential for fraud, waste and abuse. In a letter, the senators list areas that in their view deserve the moratorium. Visit http://tinyurl.com/c9wal5u.
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