

# MEDICARE COMPLIANCE

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

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## Pharma Manager Excluded From Medicare In a Case Showing Risks of Drug Samples

The risks of drug samples came into sharp focus with the Medicare exclusion of a pharmaceutical company district sales manager. Due to potential conflicts of interest and patient safety issues, free drug samples may require greater oversight, experts say. The exclusion also is a reminder that the government has vowed to hold individuals accountable when resolving corporate fraud cases.

Thomas C. Valentine, a former Sanofi sales representative and district sales manager in Orange County, Calif., will not be able to participate in federal health care programs for five years, according to an exclusion agreement with the HHS Office of Inspector General. The exclusion stems from free samples of Hyalgan, an injectable drug for knee pain. Between early 2006 and 2009, Valentine "delivered or supervised the delivery to physicians of samples of Hyalgan...with knowledge that the physicians would bill Federal health programs for the samples," OIG alleged.

The free Hyalgan samples reduced the per-unit price for the physicians, who were reimbursed by federal programs as if they had paid for the drug, OIG alleges. Because there was a reduction in the per-unit price of Hyalgan, physicians increased the spread between their acquisition costs and their reimbursement.

"OIG alleges that the provision of these samples with the knowledge that physicians would bill Federal health care programs for the samples constituted remuneration to induce the physicians to use or continue using Hyalgan instead of a competing product," the exclusion agreement says.

*continued on p. 6*

## Reaping the Rewards of Experience: The DOs and DON'Ts for Filing Claim Appeals

Claims for surgery may be doomed if hospitals don't run them by the relevant national coverage determination or local coverage determination. Hospitals may not want to bother appealing claim denials if the procedures didn't meet the NCD or LCD.

"If you are denied for failure to meet the NCD or LCD, there is no possibility of winning an appeal," says Ronald Hirsch, M.D., vice president of the regulations and accreditation group for Accretive Physician Advisory Services. "NCDs are binding on all Medicare administrative contractors and LCDs can only rarely be overruled." For example, Palmetto GBA, a MAC, has denied claims for inpatient defibrillators and in some cases it was for failure to satisfy the NCD, he says. "To make it more painful, without a properly executed advance beneficiary notice or hospital-issued notice of non-coverage, the hospital is still responsible for the cost of the implanted device, which can approach \$30,000," he adds.

That's one of the lessons that hospitals and their advisers have learned after years of appealing Medicare claim denials by recovery audit contractors and MACs. Here are other DOs and DON'Ts for defending claims from medical-necessity denials.

*continued*

## DOs

◆ **Make sure the hospital understands exactly why a claim was denied and develops an appeal letter that shows how documentation meets Medicare requirements to support payment**, says Larry Hegland, M.D., chief medical officer and system medical director for recovery audit and appeal services at Ministry Saint Clare's Hospital and Ministry Good Samaritan Health Center in Weston, Wis.

◆ **Produce all supporting documentation at every level of appeal**, says Denise Wilson, director of training and education for Denial Research Group AppealMasters in Luthersville, Md. For example, with pulmonary rehabilitation audits, hospitals may send medical records from the latter part of the three-month treatment. But earlier records contain the patient evaluation and physician orders. "If you don't send in the entire three months of medical records, auditors don't get the full picture of why the patient needs pulmonary rehab," she says. This is an important message for total joint replacement because MACs and RACs will deny claims if the documentation fails to show the patient exhausted more conservative treatments, such as medication and physi-

cal therapy, before surgery. That means hospitals have to retrieve patient records from the physician's office.

◆ **Go back to the basics in your appeals**, says attorney Abby Pendleton, with The Health Law Partners in Southfield, Mich. That includes Chapter One, Section 10 of the *Medicare Benefit Policy Manual*. "I don't care if the judge has been through 5,000 of these cases. A lot of time decision makers throughout the appeals process misapply the criteria," she says. For example, RACs, MACs and QICs may assert that an admission wasn't necessary because there were no complications during a procedure. "That's not a standard," Pendleton notes. "If you go back to the basics and keep tying your facts to that language, it is so helpful."

◆ **Use objective data to strengthen your appeal**. Stating opinions without a Medicare manual provision or policy or data makes it easier for Medicare to rule against you, says Richelle Beckman, an attorney with the Forbes Law Group in Overland Park, Kan. "If you say a service is medically necessary and Medicare says it's not, what is your reason for that? Are there studies, evidence and medical experts providing that information?"

◆ **Write appeal letters for lay people**, Hegland says. "Use a respectful, professional tone. Use an active voice (i.e., avoid the passive voice) and spell check your letters."

◆ **Send the entire medical record at every level of appeal**, Wilson says. Use Federal Express or some other shipping method that ensures you have proof of delivery. Several times the MAC or QIC said it didn't receive the appeal, but she had a way to show the package was delivered.

## DON'TS

◆ **Don't assume the only choice is to appeal cases using the formal Medicare appeals process**, Hegland says. "Use the discussion period and peer-to-peer (physician-to-physician) process with the RAC auditor. Although there is great variability in the results achieved with these processes across the country, when they work you avoid a lengthy appeal process," he says.

◆ **Don't assume the RAC denial is correct**. "Address factual errors in your appeal to demonstrate that the auditor has done a poor or cursory review," Hegland says. For example, auditors often say vital signs are normal when they aren't, he says. "They frequently use retrospective review and knowledge of the outcome of the hospital admission to deny a claim when Medicare requires physicians to make status determinations prospectively at the time of admission with limited information."

◆ **Don't accept the RAC's use of InterQual or Milliman criteria as gospel**, Hegland says. "They are guidelines to be used by case managers for initial review and only consider severity of illness and intensity of patient services

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required at the instant in time when the patient is being assessed." The screening tools don't reflect the physician's judgment on potential risks facing patients from co-morbid conditions, for example, or the uncertainty of how they will fare over time.

◆ *Don't assume that the only way to win a RAC appeal is before an administrative law judge* (level three of the Medicare appeals process). "Write your first appeal letter as if it were going to the ALJ. We win the majority of our appeals at level one and two of the appeal process," Hegland says.

◆ *Don't let auditors or appeal tribunals "change the definition of reality,"* says attorney Jessica Gustafson, with The Health Law Partners. Sometimes RACs and MACs mistakenly frame the denial in terms of the service. They deny individual procedures listed on the claim as medically unnecessary for the site of service rather than evaluating the admission itself, she says. "If that were the case, then every hospitalization appropriate for an inpatient setting would have to entail a procedure that's on the inpatient-only list," Gustafson says.

◆ *Don't forget to ensure physicians document their expectation that the patient will stay in the hospital for at least 24 hours and explain why,* Gustafson says. "I know there is no presumption tied to the 24-hour benchmark, but it is a key determination of whether the admission is medically necessary," she says.

◆ *Don't forget to include all new information/evidence by level two of the appeal process.* "An ALJ will not accept new information/evidence," Hegland says.

◆ *Don't use the InterQual inpatient-only list of procedures to defend inpatient surgery claim denials,* Hirsch says. Medicare publishes Addendum E, which lists the procedures that must be performed on an inpatient basis to secure payment. "If the surgery is not on that list, there must be documented reasoning that the surgery be performed as an inpatient, such as the presence of comorbidities, anticipation of a surgery that is more complex than usual or an expected medically necessary recovery period beyond 24 hours," he says.

◆ *Don't use as a primary argument that the inpatient admission was based on the physician's judgment and therefore the claim should get a green light without arguing medical necessity,* Hirsch says. A Medicare Appeals Council ruling in a Sacred Heart Hospital case reiterated a standing 1993 CMS statement that "no presumptive weight should be assigned to the treating physician's medical opinion in determining the medical necessity of inpatient hospital or SNF services under section 1862(a) (1) of the Act. A physician's opinion will be evaluated in the context of the evidence in the complete administrative record."

◆ *Don't focus appeals on all the "normal" results.* "Stay to the point and list the abnormal, the concerns, the risks and keep concise," says Yvonne Focke, principal with Advanced Patient Solutions in Cincinnati.

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## Proving That Beneficiaries Were Told of Appeals May Slow Decisions

At least one administrative law judge is requiring hospitals to produce evidence they informed beneficiaries when they appeal claim denials. The requirement delays the resolution of the case because the ALJ won't schedule a hearing until the hospital proves the beneficiary is in the loop, compliance officials say.

The requirement to send beneficiaries a copy of an ALJ hearing request is nothing new. It debuted in a 2005 interim final regulation and was finalized in 2009, an HHS spokesperson says. "Legally beneficiaries have a right to participate in the ALJ hearing," notes Denise Wilson, director of training and education for Denial Research Group AppealMasters in Luthersville, Md. But the request for proof, which wasn't enforced until recently, is holding up appeals and increasing costs, says Colleen Dailey, clinical coordinator of defense audits at WellSpan Health in York, Pa.

WellSpan received a letter from the Miami-based Office of Medicare Hearings and Appeals saying the appeal paperwork wasn't quite up to snuff. ALJ Jane Van Duzer wrote that WellSpan's request for a hearing on multiple claim denials would not be scheduled until WellSpan submits "written proof" that beneficiaries know about it. "For example, send the ALJ a copy of the documentation you sent to each beneficiary, along with one of the following: a copy of a signed, certified mail receipt; a copy of a signed delivery confirmation ticket; or a statement with the name and address of the beneficiary, along with

### **Conducting Internal Investigations in Health Care Organizations: A Practical Guide on How to Resolve Allegations of Wrongdoing**

by former HHS Inspector General Richard Kusserow

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documentation showing the date you forwarded the copy of the appeal request to the beneficiary," the ALJ wrote.

In response, Dailey, who says beneficiaries are always informed of appeals by WellSpan, has been re-sending the beneficiary letter by certified mail. That increases postage costs because ALJs don't accept appeals electronically (although documentation can be submitted on CDs). "It baffles me," Dailey says. "The beneficiary is not involved with this. They couldn't care less." And notifications may backfire, with the beneficiary or a family member getting upset because they think the appeal means they might get stuck with the hospital bill. Beneficiaries also may be hard to track down because they died or moved to nursing homes during the time that claims were audited, denied and appealed, Dailey says.

Other hospitals have received requests for proof of beneficiary notification, which is mostly coming from the Miami ALJ region, says Steven Greenspan, vice president of regulatory affairs at Executive Health Resources in Newtown Square, Pa. "We have seen judges dismiss cases because they didn't provide proof the beneficiary was sent the [notification]," he says. He thinks the focus on beneficiary notification is motivated by the desire to get through the docket faster. ALJs are swamped with appeals of medical necessity and other claim denials by recovery audit contractors. Requesting more paperwork buys them time to address the hospital's request for a hearing. Some ALJs send hospitals a checklist to indicate what's missing from hospital requests for a hearing,

which could also serve as a way to double-check that your submission is complete (see box, below).

The 2009 final regulation requires a notice of hearing to be sent to all parties to an appeal (see 42 CFR Sec. 405.1020(c)). Hospitals and beneficiaries alike are parties to the initial claim determination and subsequent appeals, the HHS spokesperson says (see 42 CFR Sec. 405.906(a)(1) and (b)(1)). "The appellant must also send a copy of the request for hearing to the other parties," according to the regulation (70 FR 11420).

The HHS spokesperson says the Office of Medicare Hearings and Appeals will base its decision to ask for proof of beneficiary notification partly on whether beneficiaries were copied on appeals to qualified independent contractors (QICs), which is a step below ALJs. The notice of reconsideration in a QIC case must be sent to "all parties at their last known address" unless the overpayment determination involves multiple beneficiaries with no liability, the spokesperson says (see 42 CFR 405.976(a)).

The regulation doesn't dictate a method for demonstrating that beneficiaries were copied on appeals. "We are aware the administrative law judges may give examples of what may evidence delivery of the required copy, but it does not appear they are requiring specific forms of proof (e.g., a certified mail return)," the HHS spokesperson says. "However, we are listening to our appellant community and will explore whether guidance to OHMA staff and appellants is necessary to ensure the

### Using an ALJ Checklist to Improve Appeals

This checklist was attached to an administrative law judge's letter to a hospital requesting more documentation before scheduling a hearing. It could be used by hospitals to double-check that they have included all relevant materials in their appeals.

#### CONTENT REQUIREMENTS FOR THE REQUEST FOR ALJ HEARING

A review of your request for ALJ hearing shows that you did not include the following information:

- the name of the beneficiary whose claim is being appealed;
- the address of the beneficiary whose claim is being appealed;
- the Medicare health insurance claim number of the beneficiary whose claim is being appealed;
- the name and address of the appellant, when the appellant is not the beneficiary;
- the name and address of the designated representatives if any;
- the document control number assigned to the appeal by the QIC, if any;
- the dates of service;
- the reasons the appellant disagrees with the QIC's reconsideration or other determination being appealed;
- a statement of any additional evidence to be submitted and the date it will be submitted.

#### NOTICE REQUIREMENTS FOR THE REQUEST FOR ALJ HEARING

- A review of the record shows that you did not send a copy of the request for hearing to the other parties. There is no evidence in the record that you sent a copy of the request for hearing to each beneficiary.
- You submitted a request for hearing using CMS Form 20034-A/B U3, which instructs an Appellant to send a copy of the request for hearing to the other parties. While you checked the box indicating "Yes," on the form, there is no evidence in the record that you, in fact, sent a copy of the request for hearing to each beneficiary.

regulation is being effectuated as intended and applied consistently across the agency.”

While it’s true that some beneficiaries don’t care about the status of claims filed on their behalf, “others do have an interest,” the HHS spokesperson says. It may affect their pocketbook; hospitals that lose appeals of Part A claim denials have to refund the deductibles to beneficiaries.

If beneficiaries have died in the interim, a copy of the request for a hearing “may be sent to the estate or a person obligated to make payment or entitled to receive payment,” the HHS spokesperson says.

Greenspan finds it interesting that while providers have to notify the beneficiary that they have filed an appeal request, judges are not required to provide notice to the beneficiary that they are going to hold a hearing. “In addition to the administrative burden this would place on the law judges, it appears that a fair number of cases are adjudicated without hearing because of the strength of the documentation alone,” he says. “You can only do that if the paperwork is strong enough.”

### **Auditors Should Start at the Beginning**

Even if documentation supports the claim, auditors may not focus on the patient’s story up until the time of admission, Greenspan says. “We understand that many reviewers start with a review of the discharge summary when this document should actually play no role in the admission decision unless it supports the decision in accord with Chapter 1, Section 10 of the *Medicare Benefit Policy Manual*,” he says. “Reviewers should start their review with the initial triage notes and H&P and then work their way through the course of treatment up until the time of admission.”

And it’s preferable if documentation supports the service provided instead of defending it, Greenspan says. Suppose a 53-year-old male presents at the emergency room with chest pain, pressure in his chest and sweati-ness. “Upon evaluation the physician elicits that this guy is of normal weight (no obesity), regularly plays tennis and cuts the grass, and has no comorbidities that might impact his condition. Here the patient appears to be at low risk, but is of the age where there might be a cardiac issue,” he says. The physician orders a full cardiac work-up and documents “possible angina, could be esophagitis.” No evidence of a cardiac problem emerges from the workup. On the discharge summary, the physician writes “extensive cardiac workup despite low risk and low index of suspicion.”

Contact Dailey at [cdailey2@wellspan.org](mailto:cdailey2@wellspan.org), Greenspan at [sgreenspan@ehrdocs.com](mailto:sgreenspan@ehrdocs.com) and Wilson at [dwilson@appealmasters.com](mailto:dwilson@appealmasters.com). ✧

## **OIG Opinion Says GPO Proposal Raises the Specter of Kickbacks**

A group purchasing organization’s proposal to give its members equity in the GPO’s parent company in exchange for locking in their business got bad news from the HHS Office of Inspector General. In an advisory opinion posted July 23, OIG said the arrangement could violate the anti-kickback law and invite sanctions.

The opinion was requested by a publicly traded company that owns the GPO, most of whose members are health systems. The GPO negotiates discounts for its members with vendors, which pay the GPO administrative fees of 0.25% to 3%. Administrative fees are shared with the members.

The publicly traded company wants to offer current and future GPO members an equity interest in exchange for agreeing to a five- to seven-year contract and a pledge not to reduce the volume of purchases through the GPO. Members also would forego part of the administrative fees.

OIG analyzed the arrangement under the anti-kickback law and said in its opinion: “Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated.” Two safe harbors — for GPOs and discounts — potentially provide immunity from prosecution under the anti-kickback law. But OIG says the equity interest is a type of remuneration that doesn’t meet any safe harbors. When that happens, OIG evaluates them on a case-by-case basis. And OIG sounded some alarms bells. “Under the proposed arrangement, the Requestor would ask members to forego a portion of those distributions in exchange for shares of stock in the publicly traded parent of the GPO. Unlike a discount, the remuneration under the Proposed Arrangement would have no potential to benefit payors, including Federal health care programs,” the opinion states.

### **The Risks of Fraud and Abuse Would Increase**

Other aspects of the deal increase the risk of fraud and abuse, OIG says. Members who get an equity interest must extend their contracts by five to seven years even if the GPO doesn’t get them the best prices. And GPO members are not allowed to reduce the volume of their purchases. As a result, OIG thinks the proposal would let the GPO’s owner give remuneration “to GPO members to reward past referrals and to induce them to continue purchasing items...at equal or higher volume as in the past through the GPO, for an extended period of time.”

Any time a transaction doesn’t enjoy safe harbor protection, providers should shore up their anti-fraud

measures, says attorney Bob Wade, with Krieg Devault in Mishawaka, Ind. "You have to snuggle as closely to the safe harbor as possible," he says. "Identify components you are not meeting and build in safeguards to limit fraud and abuse and prevent an increase in Medicare costs."

Contact Wade at [rwade@kdlegal.com](mailto:rwade@kdlegal.com). ✧

## Drug Samples Can Be Risky

*continued from p. 1*

Last year, Sanofi settled a false claims lawsuit with the Department of Justice over Hyalgan samples.

In coming after Valentine, OIG exercised its "affirmative" exclusion authority because the exclusion was not derivative or mandatory, OIG spokeswoman Janna Raudenbush says. That means OIG must convince an HHS administrative law judge of its merits instead of just dropping the exclusion bomb. Valentine, however, settled the case before that was necessary and did not admit wrongdoing. His attorney, Kate Corrigan, says Valentine was never properly trained on samples. "This thing blindsided him," says Corrigan, with Corrigan & Welbourn in Newport Beach, Calif. Valentine apparently is the only individual to face an administrative or enforcement action in connection with the Sanofi case. "He is the only guy who goes down on this. It seems to be categorically unfair," she says.

Under the terms of the exclusion settlement, no federal health programs will pay Valentine for goods or services, including administrative and management services, furnished, ordered, or prescribed by Valentine. The ban on payment also applies to all "other individuals and entities (including, for example, anyone who employs or contracts with Valentine, and any hospital or other provider where Valentine provides services)."

Some physician groups and hospitals restrict the use of free drug samples, which raise conflict-of-interest, safety and billing issues. "Samples continue to be a tough issue and we take a hard line on it," says Gary Wimsett, director of the conflict-of-interest program at the University of Florida College of Medicine in Gainesville, which is part of UF Health. "Like many institutions, we took a look at how sampling was happening because it is one of the pharmaceutical industry's prime marketing tools. We struggled with it because there are some patient advocates here who are doctors serving vulnerable populations and they were adamant that we provide the samples. The patients have economic hardships, so there are real reasons to have samples."

But there are so many risks associated with drug samples that the faculty practice plan decided to more or less ban them, Wimsett says. However, physicians can request permission to dispense free samples if they have a compelling reason. They make their case to a patient safety committee, which considers the medical necessity of handing out samples. "There is a healthy debate about whether the drug is something that needs to be provided as a sample," Wimsett says.

The use of drug samples in hospitals is complex, says the head of a hospital's pharmacy policies, who prefers to not be identified. In addition to conflicts of interests and compliance with state laws, hospitals face the challenge of monitoring the safety and quality of drugs that are outside the traditional supply chain. "If samples are given to individual physicians and they aren't dispensed by the pharmacy, that can lead to problems with drug interactions, therapeutic duplication, and allergic reactions with patients who are more critically ill," the pharmacist says. Hospitals also have to worry about proper labeling and secure storage of drug samples and ensure they haven't expired. There are also risks around so-called "lookalike" drugs. If two drugs have similar names or

### Policy on Drug Samples

Here is an excerpt from the University of Florida College of Medicine in Gainesville's conflict-of-interest policy that pertains to drug samples handed out by pharmaceutical sales representatives. Contact Gary Wimsett, director of the conflict of interest program there, at [gwimsett@ufl.edu](mailto:gwimsett@ufl.edu)

#### Pharmaceutical Samples and Educational Materials

*Pharmaceutical Samples.* Generally, College of Medicine (COM) personnel may not accept pharmaceutical samples unless those samples are forwarded to the pharmacy service identified by the applicable conflict-of-interest committee (CIC). The pharmacy will distribute such samples through a voucher system. However, if a COM faculty physician believes the use of the voucher system rather than direct provision of samples to patients would jeopardize a vulnerable population of patients, or would otherwise adversely impact the appropriate and timely delivery of healthcare, the physician may request a waiver of this requirement from the entity identified by the applicable CIC for this purpose. A physician requesting a waiver must show a clear and convincing benefit and provide safeguards for the appropriate distribution and control of samples when the waiver is granted. Samples shall not be accepted for personal use by any COM personnel.

sound alike, “you don’t want to store them on the same shelf. You want to separate them somehow.”

Hospitals should have policies and procedures governing samples, including who gives and receives them and how to account for them, says San Francisco attorney Judy Waltz, with Foley & Lardner LLP. Billing also can trip up hospitals. Samples are less of an issue on the Part A side because drugs are bundled into prospective payments. But under Part B, CMS says that if physicians charge for drugs, they should bill them as a supply under the Part B incident-to provisions. According to *MLN Matters* SE0441, incident-to services include non-self-administrable drugs and other biologicals.

### Free Samples Require Many Safeguards

OIG also draws a distinction between dispensing free samples and billing for them. In its “Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse,” OIG says that “Many drug and biologic companies provide physicians with free samples that the physicians may give to patients free of charge. It is legal to give these samples to your patients for free, but it is illegal to sell the samples....If you choose to accept samples, you will need reliable systems in place to safely store the samples and ensure that samples are not commingled with your commercial stock.”

OIG’s focus on samples is manifested in the corporate integrity agreements with pharmaceutical manufacturers that require them to have policies and procedures on samples, Waltz says. “OIG considers this a pretty high risk area,” she contends. However, drug samples are not reportable under the Physician Payments Sunshine Act. The new law requires drug and medical device manufacturers to report their physician payments to CMS, which will make the reports available online by Sept. 30, 2014 (*RMC* 2/11/13, p. 4). Drug samples may be exempt because lawmakers view them as a patient benefit more than a physician perk, Waltz says. But free drug samples are gifts to physicians, the hospital pharmacist says. Prescribers benefit in various ways. Patients are grateful for the free meds, which helps cement their loyalty to the physician. And “a fairly high percentage of samples get diverted,” he says. Physicians or employees may take them home for personal use or sales reps may dump a competitor’s product if they are not supervised.

Some medical centers flat-out forbid the dispensing of drug samples. The hospital pharmacist prefers a moderate approach. If physicians want to dispense them, they have to abide by all of the rules and regulations on samples. Most don’t because it’s a hassle, he says.

The pushback on drug samples has had a ripple effect, Wimsett says. Pharmaceutical manufacturers now offer other perks, such as coupons and vouchers that

reduce the cost of the drugs for patients, but not insurers. And sales reps are less likely to request time with physicians who work at entities that frown on samples.

The exclusion agreement with Valentine is another sign the government is holding more individuals accountable when their organizations are accused of fraud. OIG excluded three senior executives from the drugmaker Purdue Frederick Company, a move that was upheld by the U.S. Court of Appeals for the District of Columbia Circuit in July 2012. However, the judges ordered a lower court to reconsider the length of the 12-year exclusions, which were based on the executives’ misdemeanor convictions under the “responsible corporate officer doctrine” (*RMC* 8/6/12, p. 1).

For more information, contact Wimsett at gwimsett@ufl.edu, Waltz at jwaltz@foley.com and Corrigan at kate@cw-lawcorp.com. ✧

## CMS Transmittals and Federal Register Regulations July 19 — July 25

Live links to the following documents are included on *RMC*’s subscriber-only Web page at [www.AISHealth.com](http://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

- Type of Service Corrections 2013 (R), Trans. 2744CP, CR 8392 (July 24; eff. Jan. 1; impl. Oct. 7, 2013)
- New Waived Tests (R), Trans. 2745CP, CR 8301 (July 24; eff. Oct. 1; impl. Oct. 7, 2013)

#### Pub. 100-07, State Operations Manual

- Federally Qualified Health Center (FQHC) Medicare Participation, Trans. 85SOMA (July 19; 2013)
- Revisions to State Operations Manual (SOM) Chapter 5, Trans. 86SOMA (July 19; 2013)
- Revised Appendix A, Interpretive Guidelines for Hospitals, Condition of Participation: Discharge Planning, Trans. 87SOMA (July 19; 2013)

#### Pub. 100-08, Medicare Program Integrity Manual

- Chapter 6 Medical Review Guidelines 6.5.4-6.5.7 Update, Trans. 475PI, CR 8379 (July 19; eff./impl. Aug. 19, 2013)

### Federal Register Regulations

#### Proposed Rules

- Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals, 78 Fed. Reg. 43533 (July 19, 2013)
- Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014, 78 Fed. Reg. 43281 (July 19, 2013)

## NEWS BRIEFS

◆ **Park Avenue Medical Associates and Park Avenue Medical Associates, P.C. (PAMA) of New York settled a false claims lawsuit for \$1 million**, the U.S. Attorney for the Southern District of New York said July 18. The lawsuit was originally filed by a whistleblower, and the government intervened on March 5. The government alleged that PAMA provided psychotherapy to patients with severe dementia who could not benefit from the care and billed for duplicative psychiatric evaluations and services that “lacked any documentation whatsoever.” In an interesting twist, the whistleblower was Zachary Wolfson, which is the last name of PAMA’s medical director. According to the *New York Post*, Wolfson is the son of the medical director. Visit <http://tinyurl.com/l56nkg1>.

◆ **CMS notified providers and contractors that the overpayments identified for incarcerated beneficiaries and the demand notices sent to providers may not be correct** (*RMC 7/22/13, p. 3*). According to its announcement, “CMS is working to quickly identify claims that resulted in our recent recovery actions and take steps, as appropriate, to correct any inappropriate overpayment recoveries.” Until the problem is resolved, CMS says that providers and suppliers should not encourage beneficiaries to work to have their records updated and should not fax information to the regional CMS office. Updates on CMS’s progress will be posted on the All Fee-for-Service Providers website. Visit <http://tinyurl.com/n2l4cyh>.

◆ **Hernando-Pasco Hospice, Inc. (HPH Hospice) of Florida has agreed to pay \$1 million to settle allegations that it submitted false Medicare and Medicaid claims between 2005 and 2010**. A whistleblower lawsuit filed by two former employees alleged that the provider “caused staff to admit ineligible patients in order to meet targets imposed by management, adopted procedures to delay and discourage staff from discharging patients who were not appropriate for hospice services, instructed staff to make false or misleading statements in patients’ medical records to make them appear eligible when they were not, and failed to implement an adequate compliance program that might have corrected these problems,” according to a July 22 press release from the U.S. Attorney for the Middle District of Florida. Visit <http://tinyurl.com/m84byek>.

◆ **CMS’s Medicare Learning Network has released a special edition article explaining how physicians can opt out of Medicare altogether or opt out and elect to order and refer services**. SE1311 identifies which physicians and nonphysician practitioners may opt out and explains the affidavit these providers must submit. Visit <http://tinyurl.com/mgnt3ul>.

◆ **The HHS Office of Inspector General has released its annual report on the performance of Senior Medicare Patrol projects**. These projects, which are under the auspices of HHS’s Administration on Aging, fund organizations to recruit and train retired professionals and senior citizens to recognize and report instances or patterns of health care fraud. In 2012, the 54 projects had 5,137 active volunteers, a 9% decrease from 2011, who conducted 113,457 one-on-one counseling sessions and 14,748 group education sessions, a 71% and 33% increase from 2011, respectively. In 2012, expected Medicare and Medicaid funds recovered attributable to the projects were \$6 million. Visit <http://go.usa.gov/jBTH>.

◆ **Two companion bills are pending in the House and Senate that would require CMS to allow general supervision, rather than direct supervision, for many outpatient therapy services**. The bills would have CMS appoint an advisory board to create an exceptions process and would “hold harmless” hospitals and critical access hospitals for any actions regarding direct supervision since 2001. Visit <http://thomas.loc.gov/home/thomas.php> for the status of H.R. 2801 and S. 1143.

◆ **Researchers at the University of Wisconsin Hospital in Madison concluded that CMS should re-evaluate many aspects of its policy on observation and its reimbursement**. The study, published online on July 8 in *JAMA Internal Medicine*, looked at the clinical use and financial impact of observation at the academic medical center’s hospital. *The conclusions*: observation status for hospitalized patients differed markedly from CMS’s definition of “observation,” which specifies “a well-defined set of specific, clinically appropriate services,” usually lasting fewer than 24 hours, and in “only rare and exceptional cases” more than 48 hours. The researchers identified more than 1,000 different diagnoses for observation patients; and lengths of stay frequently were more than 24 hours and often more than 48 hours. Visit <http://tinyurl.com/m5manhd>.

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